



Immunization Manual

INTRODUCTORY LETTER

Vaccines are one of the greatest achievements in Public Health and have saved countless lives over the centuries. With the advancement of medical science more and more diseases are being prevented through vaccines. As a result what use to be a relatively simple process of providing immunizations in health care provider's offices has become more complex. Proper storage and handling, increasingly complex immunization schedules and increasing financial burdens have made immunizing patients in provider's offices a challenge.

Immunize Kansas Kids—a coalition that supports innovative, collaborative and sustainable methods to increase age-appropriate immunization for young Kansas children (age 0-5)—saw that there was a need for Kansas-specific immunization information. IKK hired me as a consultant for creating an immunization manual due to my experience in the field and first-hand knowledge of what healthcare providers need to provide immunizations. The purpose of this manual is to give health care providers a resource to meet the challenges of immunizing in office. We have tried to coalesce the large amount of information available, and present it in a concise and easy-to-read manual. The main target audience are the busy providers and their staff who administer immunizations in their practice setting. We hope that it may be of use to other individuals or organizations who are also involved with vaccines.

The manual is divided into ten chapters that we feel cover all aspects of providing immunizations; each chapter is identified by a tab for easy navigating. The chapters include descriptions of vaccines, proper administration, schedules, recording and documentation, parent information, adverse effects, storage and handling, billing, and discussing immunizations with parents.

The manual is the product of the Kansas Chapter of the American Academy of Pediatrics and Immunize Kansas Kids but it could not have been written without the funding provided by the Kansas Health Foundation, Wichita, Kansas. The Kansas Health Foundation is a philanthropic organization whose mission is to improve the health of all Kansans.

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IKK: www.immunizekansaskids.org

Introduction

THE IMPORTANCE OF VACCINES

According to the Center for Disease Control, the number one public health achievement in the twentieth century has been vaccinations. In the last century, we have seen dramatic decreases of 99-100% in smallpox, diphtheria, measles, polio, rubella, and varicella. Vaccines have had significant impact in decreasing meningitis due to *Hemophilus influenzae* and pertussis. It has been estimated that vaccines prevent 3 million deaths in children annually worldwide. That vaccines are successful cannot be questioned.

There is still a need for health care providers to remain vigilant and make high immunizations rates a priority. With the exception of small pox, the organisms that cause vaccine-preventable diseases are still in existence in the US and other parts of the world. In some ways, however, the success of vaccines has provided a false sense of security among the public. With the near eradication of many of these terrible diseases, the public and many providers haven't seen first-hand the effects of these diseases. Who could forget a child presenting in shock with H. Flu meningitis or an infant die in the throes of pertussis? We are seeing a growing trend among the public and even a few health care providers that question the need for vaccines.

It is a challenge for providers to convince an increasingly skeptical public that high immunization rates must continue to be a priority. More and more of the time spent during preventative care visits is being spent discussing vaccines. In addition as new vaccines are developed and the amount of vaccine related research continues to expand dramatically, providers struggle to keep updated. This may seem a daunting task to providers who are already being asked to do more with less time.

Over the years as new vaccines are developed and become available the task of administering vaccines has become more involved. Schedules which used to involve relatively few vaccines are now more complex. Proper storage of thousands of dollars worth of vaccines takes on a new priority.

This manual, which is being funded by a grant from Immunize Kansas Kids and the Kansas Health Institute, is an attempt to help providers deal with the ever changing immunization milieu. It is written by health care providers in practices that are providing immunizations to their patients. The purpose of this manual is to provide a coalescence of the large amount of information available, and present it in a concise and easy to read source for the busy provider. We will also provide resources for users who want to look at topics more in depth.

Materials that can be reproduced for office usage or as handouts are available at the end of each chapter. These are available on the CD provided with each manual to allow easy accessibility.

IMMUNIZE KANSAS KIDS

Historically, Kansas has had some of the highest immunization rates in the country, but in 2004 Kansas immunization rates for two year olds had slipped dramatically and the state was rated 44th in the country. In an effort to improve our rates then Governor Kathleen Sebelius established the Kansas Blue Ribbon Panel on Immunizations. This broad group of stakeholders was given the task of making recommendations to get Kansas back to the top. One of the recommendations from the Panel was the establishment of a group that would work in the future to look at the issues concerning immunizations in the state. From this was developed the Immunize Kansas Kids project. The Immunize Kansas Kids project is a unique partnership among the Kansas Department of Health and Environment, the Kansas Health Institute and dozens of stakeholder organizations. The goal is simple: to protect every Kansas child from vaccine preventable diseases!

For more information please visit: www.immunizekansaskids.org



Impact of Vaccines in the 20th & 21st Centuries

Comparison of 20th Century Annual Morbidity & Current Morbidity

Disease	20 th Century Annual Morbidity*	2010 Reported Cases [†]	% Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Pertussis	200,752	21,291	89%
Tetanus	580	8	99%
Polio (paralytic)	16,316	0	100%
Measles	530,217	61	>99%
Mumps	162,344	2,528	98%
Rubella	47,745	6	>99%
CRS	152	0	100%
<i>Haemophilus influenzae</i> (<5 years of age)	20,000 (est.)	270 (16 serotype b and 254 unknown serotype)	99%

Sources:

* JAMA. 2007;298(18):2155-2163

† CDC. *MMWR* January 7, 2011;59(52);1704-1716. (Provisional *MMWR* week 52 data)

Comparison of Pre-Vaccine Era Estimated Annual Morbidity with Current Estimate

Disease	Pre-Vaccine Era Annual Estimate	2008 Estimate	% Decrease
Hepatitis A	117,333*	11,049	91%
Hepatitis B (acute)	66,232*	11,269	83%
Pneumococcus (invasive)			
All ages	63,067*	44,000 [†]	30%
<5 years of age	16,069*	4,167 [¶]	74%
Rotavirus (hospitalizations <5 years of age)	62,500 [§]	7,500 [‡]	88%
Varicella	4,085,120*	449,363	89%

Sources:

* JAMA. 2007;298(18):2155-2163

† CDC. Active Bacterial Core surveillance Report; *S. pneumoniae* 2008. (www.cdc.gov/abcs/survreports/spnew08.pdf)

¶ 2008 Active Bacterial Core surveillance

§ CDC. *MMWR*. February 6, 2009 / 58(RR02); 1-25

‡ New Vaccine Surveillance Network

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Immunization Schedules

Receipt of immunizations in a timely fashion is a key element in the success of providing a community with protection against vaccine preventable diseases. In order to accomplish this goal, a standardized immunization schedule is important. In the United States this task is performed by the Advisory Committee on Immunization Practices (ACIP). Established under the Public Health Service Act, ACIP is a group of medical and public health experts that develops recommendations on how to use vaccines to control vaccine preventable diseases in the United States. Chosen by the Secretary of the U.S. Department of Health and Human Services (DHHS), the ACIP consists of 15 experts in the fields of vaccines, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and preventive medicine. Voting members are responsible for making vaccine recommendations. These recommendations are re-evaluated at least yearly. We have included the schedule in a graph form that is color coded to help simplify it.

Despite our efforts to have patients receive immunizations in a timely fashion for various reasons, some patients fall behind. ACIP also has schedules for catching patients up. This very important schedule is included in the attachments.

Both of these schedules have extensive footnotes which are useful when interpreting the schedules.

In addition to these schedules, Kansas also has requirements for school and child care entry. The requirements for school and child care entry are developed annually by the Kansas Immunization Advisory Committee (KIAC) under the Department of Health and Environment. This group of stakeholders meets each year, usually in January, to make adjustments for the upcoming year.

The KIAC takes into account the ACIP recommendations when determining these requirements. One of the sources of confusion for the public, and some providers is that ACIP makes “recommendations”, while the State has “requirements”. It is important to remember that **the state does not make schedules for giving immunizations it simply supports the ACIP and CDC schedules.** KDHE only makes decisions on which vaccines are required for school and child care entry. There are many factors that are considered in making these requirements, including the difficulty providers may incur while trying to implement new recommendations from the CDC/ACIP.

Despite the fact that the State doesn’t make immunization schedules, we have included the school and child care entry requirements here because this is most likely where providers will think to look for them.

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.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16–18 yrs
Hepatitis B ¹ (HepB)	< 1 st dose →	< 2 nd dose →			< 3 rd dose →											
Rotavirus ¹ (RV)			< 1 st dose →	< 2 nd dose →	See footnote 2											
RV-1 (2-dose series); RV-5 (3-dose series)			< 1 st dose →	< 2 nd dose →				< 4 th dose →								
Diphtheria, tetanus, & acellular pertussis ³ (DTaP; < 7 yrs)			< 1 st dose →	< 2 nd dose →	< 3 rd dose →									< 5 th dose →		
Tetanus, diphtheria, & acellular pertussis ⁴ (Tdap; ≥ 7 yrs)														(Tdap)		
<i>Haemophilus influenzae</i> type b ⁵ (Hib)			< 1 st dose →	< 2 nd dose →	See footnote 5			< 3 rd or 4 th dose, see footnote 5 →								
Pneumococcal conjugate ^{6a,c} (PCV13)			< 1 st dose →	< 2 nd dose →	< 3 rd dose →			< 4 th dose →								
Pneumococcal polysaccharide ^{6b,c} (PPSV23)																
Inactivated Poliovirus (IPV) (< 18 years)			< 1 st dose →	< 2 nd dose →	< 3 rd dose →							< 4 th dose →				
Influenza ⁸ (IV; LAIV) 2 doses for some: see footnote 8					Annual vaccination (IV only)							Annual vaccination (IV or LAIV)				
Measles, mumps, rubella ⁹ (MMR)							< 1 st dose →					< 2 nd dose →				
Varicella ¹⁰ (VAR)							< 1 st dose →					< 2 nd dose →				
Hepatitis A ¹¹ (HepA)																
Human papillomavirus ¹² (HPV2; females only; HPV4; males and females)																
Meningococcal ¹³ (HibMenCY ≥ 6 weeks; MCV4-D ≥ 9 mos; MCV4-CRM ≥ 2 yrs)					see footnote 13											

Range of recommended ages for all children
Range of recommended ages for catch-up immunization
Range of recommended ages for certain high-risk groups
Range of recommended ages during which catch-up is encouraged and for certain high-risk groups
Not routinely recommended

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 through 15 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.

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

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>.

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
<i>Haemophilus influenzae</i> 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 on pages 4–5 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 through 15 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/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.

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

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.

SCHOOL IMMUNIZATION REQUIREMENTS FOR THE 2013-2014 SCHOOL YEAR

Immunization requirements and recommendations for the 2013-2014 school year are based on the Advisory Committee on Immunization Practices (ACIP) recommendations and the consensus of the Governor's Child Health Advisory Committee Immunization Workgroup.

K.A.R. 28-1-20 defines immunizations required for any individual who attends school or early childhood programs operated by a school. http://www.kdheks.gov/immunize/download/KS_Imm_Regs_for_School_and_Childcare.pdf

- **Diphtheria, Tetanus, Pertussis (DTaP):** Five doses required. Four doses acceptable if dose 4 is given on or after the 4th birthday. A single dose of **Tdap** is required at Grades 7-12 if no previous history of Tdap vaccination regardless of interval since the last Td.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm>
- **Poliomyelitis (IPV/OPV):** Four doses required. Three doses acceptable. One dose required after age 4 regardless of the number of previous doses, with a 6 month minimum interval from the previous dose.
- **Measles, Mumps, Rubella:** two doses required.
- **Hepatitis B:** three doses required through grade 12.
- **Varicella (chickenpox):** two doses required for grades K-4 and 7-9; one dose required for grades 5-6 and 10-12 unless history of varicella disease documented by a licensed physician.
Two doses are currently *recommended* by the ACIP for all ages.
- **Haemophilus influenzae type b (Hib):** four doses required for children less than 5 yrs of age in early childhood programs. Total doses needed for series completion is dependent on the type of vaccine and the age of the child when doses given.
- **Pneumococcal conjugate (PCV):** four doses required for children less than 5 yrs of age in early childhood programs. Total doses needed dependent on the age of the child when doses given.
- **Hepatitis A:** two doses required for children less than 5 years of age. The first dose is given at 12 to 18 months of age, with a 6 month interval between the first and second dose.

Detailed school immunization requirements by age group are listed on the 02/01/13 version of the Kansas Certificate of Immunization (KCI). http://www.kdheks.gov/immunize/download/KCI_Form.pdf

In addition to the immunizations required for school entry listed above, the 2013 ACIP recommendations also include the following for school children:

- **Meningococcal (MCV4):** one dose *recommended* at 11 years with a booster dose at 16 yrs of age; not required for school entry. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm?s_cid=mm6003a3_e%0d%0a
- **Human Papillomavirus (HPV):** three doses *recommended* for males and females at 11 years of age; not required for school entry.
- **Influenza:** yearly vaccination *recommended* for all ages \geq 6 months of age; not required for school entry.

The Recommended ACIP with minimum intervals can be found at: <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.
The minimum age and interval must be met for any vaccine dose to be considered valid.

Efforts by schools have been central to the success of public health efforts in eliminating vaccine preventable diseases and protecting their students and families. Thank you for your dedication.



IMMUNIZATION REQUIREMENTS FOR LICENSED CHILD CARE FACILITIES AND EARLY CHILDHOOD PROGRAMS OPERATED BY SCHOOLS 2013-14 School Year

Immunization requirements and recommendations for the 2013-2014 school year are based on the Advisory Committee on Immunization Practices (ACIP) recommendations. The current immunization schedules, including catch up schedules, may be found at <http://www.kdheks.gov/immunize/schedule.htm>.

K.A.R. 28-1-20 defines immunizations required for children attending child care facilities licensed by KDHE or early childhood programs operated by schools. The complete regulation is available at http://www.kdheks.gov/immunize/download/KS_Imm_Regs_for_School_and_Childcare.pdf.

- **Diphtheria, Tetanus, Pertussis (DTaP):** five doses required. Doses given at 2 months, 4 months, 6 months, 15-18 months (4th dose may be given at 12 months provided at least 6 months after dose 3) and 5 years of age. Four doses acceptable if dose 4 given on or after the 4th birthday and 6 months after 3rd dose. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm>
- **Poliomyelitis (IPV/OPV):** four doses required. Doses given at 2 months, 4 months, 6-18 months and 4-5 years of age. One dose is required after age 4, with a 6 month minimum interval from previous dose.
- **Measles, Mumps, Rubella:** two doses required. Doses given between 12-15 months and 4-5 years of age.
- **Hepatitis B:** three doses required. Doses given at birth, 2 months, and 6-18 months of age.
- **Varicella (chickenpox):** two doses required unless history of varicella disease documented by a licensed physician. Doses given at 12-15 months and 4-6 years of age.
- **Haemophilus influenzae type b (Hib):** four doses required for children less than 5 years of age. Doses given at 2 months, 4 months, 6 months and 12-15 months of age. Total doses needed for series completion is dependent on the type of vaccine and the age of the child when doses given.
- **Pneumococcal conjugate (PCV):** four doses required for children less than 5 years of age. Doses given at 2 months, 4 months, 6 months, and 12-15 months of age. Total doses needed dependent on the age of the child when doses given.
- **Hepatitis A:** two doses required for children less than 5 years of age. The first dose is given at 12 to 18 months of age, with a 6 month interval between the first and second doses.

In addition to the immunizations required for children attending child care facilities licensed by KDHE and early childhood programs operated by schools, the 2013 ACIP recommendations include the following additional immunizations:

- **Rotavirus:** three doses *recommended* for < 8 months of age; not required.
- **Influenza:** yearly vaccination *recommended* for all ages \geq 6 months of age; not required.

The complete Recommended ACIP with the minimum interval schedules can be found at:

<http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>

The minimum age and interval must be met for any vaccine dose to be considered valid.

Efforts by child care providers and schools have been central to the success of public health efforts in eliminating vaccine preventable diseases. Thank you for this success.

KANSAS CERTIFICATE OF IMMUNIZATIONS (KCI)

This record is part of the student's permanent record and shall be transferred from one school to another as defined in Section 72-5209 (d) of the Kansas School Immunization Law (amended 1994.)

Student Name: _____ Address: _____
 Parent or Guardian Name: _____
 Phone: _____
 Birthdate (MM/DD/YYYY): _____ SEX: [] MALE [] FEMALE Race: _____ Ethnicity: _____ County: _____

VACCINE	RECORD THE MONTH, DAY, AND YEAR THAT EACH DOSE OF VACCINE WAS RECEIVED						
	1st	2nd	3rd	4th	5th	6th	7th
DTaP/DT/Td/Tdap (Diphtheria, Tetanus, Pertussis) Required for school entry. Single Tdap required for grades 7-12. State Type	DT DTap Td Tdap	DT DTap Td Tdap	DT DTap Td Tdap	DT DTap Td Tdap	DT DTap Td Tdap	DT DTap Td Tdap	DT DTap Td Tdap
Polio Required for school entry.							
HEP B (Hepatitis B) Required for school entry.							
Varicella (Chickenpox) Required for school entry. 2 doses grades K-4 & 7-9. One dose Grades 5-6 and 10-12 for school year 2013-2014.			Hx of Disease: _____ Physician Signature: _____				Date of Illness: _____ If additional doses are added, please initial the dose and sign below:
MMR (Measles, Mumps, and Rubella combined) Required for school entry.		MMR Me/Wu/Ru	MMR Me/Wu/Ru				
Influenza (Flu) Recommended annually for ages 6mo and older. Not required for school entry.							
H1B (Haemophilus Influenzae Type B) Required < 5 years of age for preschool or child care operated by a school.							
PCV (Pneumococcal Conjugate) Required < 5 years of age for preschool or child care operated by a school.							
HEP A (Hepatitis A) Required < 5 years of age for preschool or child care operated by a school.							
MCV4 (Meningococcal) Initial dose recommended at 11-12 years of age and booster dose recommended after 16 years of age. Not required for school entry.							
HPV (Human Papillomavirus) Recommended for males and females at 11-12 years of age. Not required for school entry.							
Rotavirus Recommended < 8 mo. Not required for school entry.							

DOCUMENTATION

KCI MAY ONLY BE SIGNED BY A PHYSICIAN (MD/DO), HEALTH DEPT., OR SCHOOL.
 I certify I reviewed this student's vaccination record and transcribed it accurately.
 Agency Name: _____
 Authorized Representative: _____
 Address: _____
 Date: _____
 The record presented was
 Kansas Immunization Record
 Other Immunization Record (Specify) _____

LEGAL ALTERNATIVES TO VACCINATION REQUIREMENTS "KSA 72-5209"

1. "Annual written statement signed by a licensed physician (Medical Doctor/M.D. or Doctor of Osteopathy/D.O.) stating the physical condition of the child to be such that the tests or inoculations would seriously endanger the life or health of the child." Medical exemption shall be validated annually by physician completion of KCI Form B and attachment to the KCI.
 2. "Written statement signed by one parent or guardian that the child is an adherent of a religious denomination whose religious teachings are opposed to such tests or inoculations."

I give my consent for information contained on this form to be released to the Kansas Immunization Program for the purpose of assessment and reporting.

Parent/Legal Guardian's Signature _____ Date _____

KANSAS IMMUNIZATION PROGRAM
 1000 SW Jackson, Suite 075, Topeka, KS 66612-1274
 PHONE 785-296-5591 FAX 785-296-6510
 WEB SITE www.kdheks.gov/immunize

Rev. 02/01/2013

As per Kansas Statute 72-5209, all children upon entry to school must be appropriately vaccinated. In each column below, vaccines are required for all ages listed in that column.

Ages 0-4		Ages 5-6		Ages 7 and Older	
Recommended Schedule	DTaP: 5 Doses	DTaP: 5 Doses	DTaP/Tdt:	DTaP: 5 Doses	DTaP/Tdt:
Birth	HEP B	a) 4 week minimum interval between first 3 doses; 6 month interval between dose 3 and dose 4.	3 doses if no history of any DTaP doses (a-b)	a) 4 week minimum interval between dose 1 and dose 2; first dose must be Tdap	
2 Months	DTaP/DT POLIO HEP B HIB PCV ROTAVIRUS	b) 4 doses acceptable if dose 4 given on or after the 4th birthday. c) If dose 4 administered before 4th birthday, 5th dose must be given at 4-6 years of age.		b) 6 months between dose 2 and 3 c) Single dose of Tdap for an incomplete primary DTaP series d) Single dose of Tdap required for <u>Grades 7-12</u>	
4 Months	DTaP/DT POLIO HIB PCV ROTAVIRUS	POLIO - Grade K-2 a) 4 week minimum interval between first 3 doses; 6 month interval required between dose 3 and dose 4; one dose after 4th birthday b) 3 doses acceptable if 4 weeks between dose 1 and 2; 6 months between dose 2 and 3; one dose after 4th birthday	POLIO Grades 3-12 <u>Polio - All IPV or OPV Schedule: 4 doses</u> a) 4 week minimum interval between doses, regardless of age given. <u>Polio - All IPV or OPV Schedule: 3 doses</u> a) 4 week minimum interval between each dose, with 1 dose given on or after the 4th birthday.		
6 Months	DTaP/DT POLIO HEP B HIB PCV ROTAVIRUS	POLIO - IPV/OPV Combination Schedule: 4 Doses required a) 4 week minimum interval between first 3 doses; 6 month interval required between dose 3 and dose 4; one dose after 4th birthday b) 3 doses not acceptable with combination schedule Grades K-2, new students and students completing series must have 6 months between last two doses with one dose after 4th birthday.	<u>Polio - IPV/OPV Combination Schedule</u> a) Must be 4 doses with 4 weeks between doses New students and students completing series must have 6 months between last two doses with one dose after 4th birthday.		
12-15 Months	MMR VAR HIB PCV HEP A	MMR: 2 Doses a) First dose on or after the 1st birthday. b) 4 week minimum interval between doses.	MMR: 2 Doses a) First dose on or after the 1st birthday. b) 4 week minimum interval between doses.		
15-18 Months	DTaP/DT	VARICELLA: 2 Doses Grades K-4 for School Year 2013-2014 a) First dose on or after the 1st birthday. b) Second dose must be given at least 28 days after first dose. c) None required if prior varicella disease verified by physician. d) Two doses are <u>recommended</u> for all children.	VARICELLA: 2 Doses Grades 7-9 School Year 2013-2014 1 Dose Grades 5-6 and 10-12 School Year 2013-2014 a) First dose on or after the 1st birthday. b) Second dose must be given at least 28 days after first dose. c) None required if prior varicella disease verified by physician. d) Two doses are <u>recommended</u> for all children.		
18-24 Months	HEP A	HEPATITIS B: 3 Doses a) 4 week minimum interval between dose 1 and dose 2. b) 8 week minimum interval between dose 2 and dose 3. c) 16 week minimum interval between dose 1 and dose 3. Dose 3 must be given after 24 weeks of age.	HEPATITIS B: 3 Doses a) 4 week minimum interval between dose 1 and dose 2. b) 8 week minimum interval between dose 2 and dose 3. c) 16 week minimum interval between dose 1 and dose 3. Dose 3 must be given after 24 weeks of age.		
Recommendations are based on the ACIP recommended schedule.†					

† - The ACIP Schedules may be accessed at: <http://www.cdc.gov/vaccines/recs/schedules>

Vaccine doses given up to 4 days before the minimum interval or age may be considered valid.

With the exception of Hepatitis B vaccine, immunizations given before 6 weeks of age are not considered valid.

Half doses or reduced doses of vaccine are not considered valid.

ACIP - Varicella vaccine minimum interval less than 13 yrs is 3 months; 13 yrs and older is 4 weeks however, a 28 day interval regardless of age may be counted as valid. All doses must be after first birthday.








PARENTS AND/OR GUARDIANS ARE NOT AUTHORIZED TO COMPLETE KCI FORMS.

KCI FORM B - MEDICAL EXEMPTION is located at http://www.kdheks.gov/immunize/imm_manual_pdf/KCI_formB.pdf
BLANK VERSION OF KCI FORM is available at http://www.kdheks.gov/immunize/download/KCI_Form.pdf




A ROSTER WITH THE NAMES OF ALL EXEMPT STUDENTS SHOULD BE MAINTAINED. PARENTS OR GUARDIANS OF EXEMPT CHILDREN SHOULD BE INFORMED THAT THEIR CHILDREN SHALL BE EXCLUDED FROM SCHOOL IN THE EVENT OF AN OUTBREAK OR SUSPECTED CASE OF A VACCINE-PREVENTABLE DISEASE.

Vaccines

Content





-  Vaccine Basics
-  Vaccine Types
-  Substances Found in Vaccines
-  Administration of Vaccines
-  FAQs Concerning Vaccine Administration
-  Contraindications
-  Common Special Considerations

Tables

-  Table 1 - Vaccine List
-  Table 2 - Administering Vaccines
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Vaccines

Figures

-  Check your Vials
-  Immunization Site Map
-  Standing Orders
-  Vaccine Contraindications

Resources / Website Links

CDC PINK BOOK - www.cdc.gov/vaccines/pubs/pinkbook/index.htm

AAP RED BOOK - aapredbook.aappublications.org/

Vaccines

VACCINE BASICS

Active immunity is protection produced by a person's own immune system in the form of antigen induced antibodies and cellular response. When we survive an infection the body develops this immunity and the protection usually lasts for an individual's lifetime.

Vaccines are biological substances that cause the body to develop an immunological response that is similar to the actual infectious disease, but is not a risk to the recipient. They can do this by using all or part of a microorganism or modified portions such as a toxoid which then stimulates the body's immune system. When the entire organism is intact in the vaccine these may be "attenuated," inactivated, or genetically engineered.

The length of the immunity provided by the vaccine varies. It may prove lifelong or of a shorter duration. When lifelong immunity is not developed "booster" immunizations are required. The recipient's response is also variable depending on numerous factors. Because of this a "series" of immunizations separated by a specific duration of time, may be needed in order to attain adequate protection. A good summary of this information can be found in the CDC's PINK BOOK: www.cdc.gov/vaccines/pubs/pinkbook/index.htm.

VACCINE TYPES

Live-attenuated - Vaccines that contain living virus that has been weakened so it doesn't cause serious disease. Examples: MMR, Varicella; contraindicated in individuals with weakened immune systems.

Inactivated - Vaccines that use a killed virus; the virus is killed during the vaccine making process. Example: polio (IPV); may need multiple doses to get appropriate immunity.

Toxoids - Certain bacteria produce toxins that cause disease. Toxoids are weakened toxins that produce an immune response, but don't cause the disease. Example: Tetanus, Diphtheria.

Subunit Vaccines - These vaccines contain parts of a virus or bacteria instead of the entire organism. Because of this subunit, the vaccines tend to cause fewer side effects. Example: Pertussis.

Conjugate - These vaccines protect against bacteria that have an outer polysaccharide coat that disguises the antigens. The conjugate vaccines link the polysaccharides to the antigens allowing the recipient to develop an immune response. Example: Haemophilus Influenzae B.

It is not the purpose of this manual to individually review each vaccine that is available. There are a number of references that this information can be obtained. We recommend the CDC PINK BOOK from the CDC and the AAP RED BOOK - (aapredbook.aappublications.org/) from the American Academy of Pediatrics for more specific information on a specific disease and vaccine. A list of the vaccines made in the U.S. is provided in Table 1 of this manual (see page 28).

SUBSTANCES FOUND IN VACCINES

Active Antigens - Foreign substances; such as viruses, bacteria, or portions of these organisms that elicit the body's immune response.

Conjugating organisms - Proteins linked to the polysaccharides of a bacterial cell wall. These linkages in turn make the vaccine more potent.

Suspending fluid - Fluid vehicles for the vaccine; these fluids may be sterile water, saline, or fluid from tissue cultures used to make the vaccine. When tissue culture fluid is used it may contain proteins and other constituents.

Preservatives - Very small amounts of substances added to vaccines to ensure potency and sterility.

Adjuvants - Small amounts of substances added to vaccines that increase immunogenicity and prolong the stimulating effect.

ADMINISTRATION OF VACCINES

The proper techniques to administer vaccines by injections and other methods is part of the standard training nursing staff receive, and it is not in the scope of this manual to repeat it. Suffice it to say that when administering vaccines these techniques should be followed. We have listed the individual vaccines in a table with administration information (Table 2). In addition, we have included other materials to help nursing staff including a set of standing orders for the office which should be utilized (pg. 36).



ADMINISTRATION OF VACCINES (CONT.)

Immunizing children and infants poses a special set of problems. Children have difficulty comprehending the need for vaccines and are fearful of “shots.” While parents understand the need for vaccines they are understandably concerned about the pain and discomfort the child goes through. This can make for a stressful situation when administering the vaccines. Here are some tips that can make it easier for the child, parents, and staff during the process of administering vaccines to children:

- Display a positive attitude.
- Be honest; don't tell the child it won't be painful, but also don't over emphasize the pain.
- Encourage parents to hold their child. Data shows children do better if the parent holds them during the immunization. Be prepared to instruct parents on the proper way to immobilize the child, however, never force a parent to do this if they truly choose not to.
- Have the child sit up. Again, data shows children experience less anxiety if they are allowed to sit upright.
- Distraction; this can be a way to alleviate some of the anxiety.
- Breastfeeding; allowing a child to breastfeed during the procedure lessens the time of crying.
- Sweet liquids; from our experience with performing painful procedures in children, we know that small amounts of sweetened liquids (Sweet-Ease) prior to administration helps with the pain.
- Consider dual administrators. This can make the time of the procedure less and parents look favorably on this procedure.



FAQs CONCERNING VACCINE ADMINISTRATION

What is the appropriate spacing of vaccines?

Vaccine doses should not be administered at intervals less than the minimum intervals or earlier than the minimum age. Table 3 has these intervals for each vaccine.

What if a vaccine dose is given less than the minimum interval?

ACIP recommends that vaccine doses given up to four days before the minimum interval or age be counted as valid. Doses given five days or more before the minimum age or interval must be repeated. Immunization programs and/or school entry requirements may not accept all doses given earlier than the minimum age or interval.

Does administering vaccines past the recommended interval mean the series must start over?

Because available studies of extended intervals have shown no significant difference in final titer it is not necessary to restart the series or add doses because of an extended interval between doses.

What interval is needed between live vaccines not given simultaneously?

If multiple live vaccines (MMR, MMRV, varicella, zoster, yellow fever, live intranasal influenza vaccine) need to be given and they are not given at the same visit they should be separated by at least four weeks. This interval is intended to reduce or eliminate interference from the first vaccine to the vaccine given later.

Can vaccines be administered to a patient receiving Synagis?

Circulating antibodies to a vaccine's antigen can have an effect on vaccine response. Inactivated vaccines generally are not affected by circulating antibody to the antigen. Live attenuated vaccines may be affected by circulating antibody to the antigen. Palivizumab (Synagis), used for the prevention of respiratory syncytial virus (RSV) infection in infants, and young children, contains antibody directed only at RSV. This product can be given any time before or after administration of MMR, or varicella-containing vaccines.

Are vaccines made by different manufacturers interchangeable?

Vaccines made by different manufacturers may differ slightly in the components, but generally can be considered interchangeable. There are some exceptions though such as some of the Hepatitis B vaccines. Most of the time, it is recommended that if at all possible, vaccines from the same manufacturer be used in the primary series.

CONTRAINDICATIONS

There are very few true permanent contraindications to vaccines. Here is a list of contraindications:

- Severe allergic reaction (anaphylaxis) to a vaccine component (specific vaccine).
- Encephalopathy of unknown cause that occurs within seven days of the pertussis vaccination (Pertussis).
- Primary Immunodeficiency Syndromes- all live vaccines; check with an Infectious Disease expert for specific disorders.
- History of Intussusception (Rotavirus).

CONDITIONS NOT CONTRAINDICATED

The public and many providers share some common misconceptions about vaccine contraindications. The following are NOT contraindications:

- Mild illness; URIs, ear infections, and diarrhea are not reasons to defer immunizations.
- Fever; low grade fevers are also not a cause to postpone vaccinating. There is no set temperature that ACIP has determined to be used to defer immunization. Clinical appearance rather than a temperature reading should be used to guide vaccine administration.
- Antibiotic usage.
- Exposure to an illness.
- Breastfeeding.
- Allergy, not anaphylaxis; if there is an allergy to a vaccine component, such as egg, that is not anaphylactic, this is not a contraindication.

COMMON SPECIAL CONSIDERATIONS

Severe reactions after pertussis vaccine - A child who develops fever of 105 or more, a shock like state, or intractable crying lasting three hours or more within 48 hours of receiving the pertussis vaccine should have future pertussis immunizations deferred until adolescence. The vaccine is not, however, contraindicated if the benefits outweigh the risks.

Preterm and LBW infants - Premature and LBW infants should receive immunizations at the same chronological age and the same dosages as full term infants.

Pregnancy - Theoretically, vaccines could pose a risk to the developing fetus. If a vaccine must be given, delaying until the second or third trimester is recommended. All live vaccines are contraindicated. An exception to this may occur if the exposure is imminent and the disease poses a greater risk to the fetus and mother than does the vaccine. There are two immunizations recommended to be given during pregnancy: Tdap and inactivated Flu Vaccine.

Children in Household with Pregnant Member - As a general rule, children with a pregnant member in the household can receive all the recommended immunizations including MMR and Varicella Vaccines.

Corticosteroid Usage - Children frequently, have recently received, or are in the process of receiving corticosteroids. The route and amount can result in immunosuppression which may be a contraindication for live vaccine administration.

- Topical therapy, local injection, or aerosolized usage of corticosteroids usually do not result in immunosuppression and therefore are not a cause to postpone administration of live attenuated vaccines. If there is clinical or laboratory evidence of immunosuppression then live vaccines should not be given for at least 1 month after discontinuation of corticosteroids.
- Physiological doses of corticosteroids are not a contraindication to receiving live attenuated vaccines.
- Low dose oral steroids defined as < 2mg/kg per day of prednisone, or < 20mg of prednisone per day in patients over 20Kg weight can receive attenuated live vaccines during the course of their steroid treatment.
- High dose oral steroids for < 14 days defined as greater than or equal to 2mg/kg per day or greater than or equal to 20mg/ day in children who weigh more than 20 kg can be given immediately after discontinuation of the steroids.
- High dose oral steroids for greater than 14 days: see above definition. Children should wait at least 1 month after discontinuation of steroids before receiving live attenuated vaccines.

Children in the Household of Immunocompetent Family Members - Children are frequently in a household where immunosuppressed family members reside. As a rule, the current standard vaccines including the live attenuated ones can be given to the child. There are two exceptions, Small Pox and Oral Polio Vaccine, neither of which are currently routinely given in the US. The virus in the MMR is not transmitted. Transmission of the rotavirus and varicella virus from vaccines is exceedingly rare and is thus recommended. No special precautions should be given, however if the vaccine recipient develops a rash after the varicella vaccine the recipient should avoid contact until after the rash has resolved.

Children with Seizures - If a child has a history of seizures or there is family seizure history there is a slightly increased risk of seizures after the administration of DTP (whole cell), MMRV, and when Influenza and PCV13 are given simultaneously. These seizures appear to be febrile seizures and there has not been any evidence of permanent sequelae. The use of DTaP (acellular) has decreased the incidence significantly. It is still the recommendation that until the cause of a recent seizure has been determined pertussis vaccine be deferred. Separate MMR and varicella vaccine can be given at the appropriate schedules. A family history of seizures is not in and of itself a reason to defer immunizations.

For more specific question about these and other special populations, refer to AAP Red Book or CDC Pink Book. We also list a brief table with vaccine precautions and contraindications.

CDC PINK BOOK - www.cdc.gov/vaccines/pubs/pinkbook/index.htm

AAP RED BOOK - aapredbook.aappublications.org/

U.S. Vaccines

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Adenovirus	Adenovirus		Barr Labs Inc.	Live Viral	Oral	Adenovirus Type 4 & Type 7. Two tablets taken together. Approved for military populations 17 through 50 years of age.
Anthrax	BioThrax	AVA	Emergent BioSolutions	Inactivated Bacterial	IM	
	Daptacel	DTaP	sanofi	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
DTaP	Infanrix	DTaP	GlaxoSmithKline	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
	Tripedia	DTaP	sanofi	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
	Generic	DT	sanofi	Inactivated Bacterial Toxoids	IM	Pediatric formulation (through age 6).
DTaP-IPV	Kinrix	DTaP-IPV	GlaxoSmithKline	Inactivated Bacterial & Viral	IM	Licensed for 5 th (DTaP) and 4 th (IPV) booster at 4-6 years.
DTaP-HepB-IPV	Pediarix	DTaP-HepB-IPV	GlaxoSmithKline	Inactivated Bacterial & Viral	IM	Licensed for doses at 2, 4, & 6 months (through 6 years of age). Not licensed for boosters.
DTaP-IPV/Hib	Pentacel	DTaP-IPV/Hib	sanofi	Inactivated Bacterial & Viral	IM	Licensed for 4 doses at 2, 4, 6, and 15-18 months.
<i>Haemophilus influenzae</i> type b (Hib)	PedvaxHIB	Hib	Merck	Inactivated Bacterial	IM	PRP-OMP. Polysaccharide conjugate (mening. protein carrier). 2-dose primary series.
	ActHIB	Hib	sanofi	Inactivated Bacterial	IM	PRP-T. Polysaccharide conjugate (tetanus toxoid carrier). 3-dose primary series.
	Hiberix	Hib	GlaxoSmithKline	Inactivated Bacterial	IM	Polysaccharide conjugate (tetanus toxoid carrier). Booster only.
<i>Haemophilus influenzae</i> type b – hepatitis B	Comvax	Hib-HepB	Merck	Inactivated Bacterial & Viral	IM	Should not be used for hepb birth dose.
Hepatitis A	Havrix	HepA	GlaxoSmithKline	Inactivated Viral	IM	Pediatric (≤ 18) and adult formulations. Pediatric = 720 EL.U., 0.5mL Adult = 1,440 EL.U., 1.0mL Minimum age = 1 year

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Hepatitis A	Vaqta	HepA	Merck	Inactivated Viral	IM	Pediatric (≤ 18) and adult formulations. Pediatric = 25 U. 0.5mL Adult = 50 U. 1.0mL Minimum age = 1 year
Hepatitis B	Engerix-B	HepB	GlaxoSmithKline	Inactivated Viral	IM	Pediatric (≤ 19) and adult formulations. Pediatric formulation not licensed for adults.
	Recombivax HB	HepB	Merck	Inactivated Viral	IM	Pediatric (≤ 19), adult, and dialysis formulations. Two pediatric doses may be substituted for an adult dose.
	Twinrix	HepA+HepB	GlaxoSmithKline	Inactivated Viral	IM	Pediatric dose of HepA + adult dose of HepB. Minimum age = 18 years. 3-dose routine series (4-dose alternate schedule for rapid protection).
Herpes Zoster (Shingles)	Zostavax	ZOS	Merck	Live Attenuated Viral	SC	Licensed for age 50 and older.
Human Papillomavirus (HPV)	Gardasil	HPV4	Merck	Inactivated Viral	IM	Quadrivalent (types 6, 11, 16, 18). Licensed for males and females 9 through 26 years.
	Cervarix	HPV2	GlaxoSmithKline	Inactivated Viral	IM	Bivalent (types 16, 18). Licensed for females 10 through 26 years.
Influenza (Trivalent, types A & B)	Fluarix	TIV	GlaxoSmithKline	Inactivated Viral	IM	Minimum age = 3 years.
	Fluvirin	TIV	Chiron	Inactivated Viral	IM	Purified surface antigen. Minimum age = 4 years.
	Fluzone	TIV	sanofi	Inactivated Viral	IM	Subvirion. Minimum age (multidose vial) = 6 mo. Age range (0.25mL prefilled syringe) = 6 through 35 mo. Minimum age (0.5mL prefilled syringe) = 3 years.
	Fluzone High-Dose	TIV	sanofi	Inactivated Viral	IM	Licensed for age 65 and older.
	Fluzone Intradermal	TIV	sanofi	Inactivated Viral	Intradermal	Age range 18 through 64 years. 0.1 mL dose.
	FluLaval	TIV	GlaxoSmithKline	Inactivated Viral	IM	Minimum age = 18 years.
	Afluria	TIV	CSL	Inactivated Viral	IM	Minimum age = 6 months.
Agriflu	TIV	Novartis	Inactivated Viral	IM	Minimum age 18 years.	
FluMist	LAIV	LAIV	Medimmune	Live Attenuated Viral	Intranasal	Age range = 2 through 49 years.

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Japanese encephalitis	Ixiaro	JE	Novartis	Inactivated Viral	IM	Licensed for age 17 and older. 2-dose series.
	M-M-R II	MMR	Merck	Live Attenuated Viral	SC	Minimum age = 12 months
Measles, Mumps, Rubella	ProQuad	MMRV	Merck	Live Attenuated Viral	SC	Age range = 1 through 12 years.
	Menomune	MPSV4	sanofi	Inactivated Bacterial	SC	Polysaccharide (serogroups A, C, Y, W135). Minimum age = 2 years.
Meningococcal	Menactra	MCV4	sanofi	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 9 months through 55 years.
	Menveo	MCV4	Novartis	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 2 through 55 years.
Pneumococcal	Pneumovax 23	PPSV23	Merck	Inactivated Bacterial	SC or IM	Polysaccharide (contains 23 strains). Minimum age = 2 years.
	Prevnar 13	PCV13	Wyeth	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria protein carrier, contains 13 strains). Age ranges = 6 months through 5 years and 50 years & older.
Polio	Ipol	IPV	sanofi	Inactivated Viral	SC or IM	Trivalent, Types 1, 2, 3
	Imovax Rabies		sanofi	Inactivated Viral	IM	
Rabies	RabAvert		Chiron	Inactivated Viral	IM	
	Rota Teq	RV5	Merck	Live Viral	Oral	Pentavalent. First dose between 6 weeks and 14 weeks 6 days; complete 3-dose series by 8 months 0 days.
Rotavirus	Rotarix	RV1	GlaxoSmithKline	Live Viral	Oral	Monovalent. First dose between 6 weeks and 14 weeks 6 days; complete 2-dose series by 8 months 0 days.
	Decavac	Td	sanofi	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).
Tetanus – (reduced) Diphtheria	Tenivac	Td	sanofi	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).
	(Generic)	Td	Massachusetts Biological Labs	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Tetanus – (reduced) Diphtheria (reduced) Pertussis	Boostrix	Tdap	GlaxoSmithKline	Inactivated Bacterial	IM	Tetanus and diphtheria toxoids & pertussis vaccine. Minimum age = 10 years.
Tetanus – (reduced) Diphtheria (reduced) Pertussis	Adacel	Tdap	sanofi	Inactivated Bacterial	IM	Tetanus and diphtheria toxoids & acellular pertussis vaccine. Age range 11 through 64 years.
Tetanus toxoid	(Generic)	TT	sanofi	Inactivated Bacterial Toxoid	IM	May be used for adults or children.
Typhoid	Typhim Vi		sanofi	Inactivated Bacterial	IM	Polysaccharide
	Vivotif Berna		Berna	Live Attenuated Bacterial	Oral	Ty21a strain.
Varicella	Varivax	VAR	Merck	Live Attenuated Viral	SC	Minimum age = 12 months.
Vaccinia (Smallpox)	ACAM2000		Acambis	Live Attenuated Viral	Percutaneous	
Yellow Fever	YF-Vax	YF	sanofi	Live Attenuated Viral	SC	Minimum age = 9 months.

February, 2012

The abbreviations on this table (Column 3) were standardized jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the *Morbidity and Mortality Weekly Report (MMWR)*, the editor of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the *Pink Book*), ACIP members, and liaison organizations to the ACIP.

These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Policy Notes published in the *MMWR*, the *Pink Book*, and the American Academy of Pediatrics *Red Book*, and in the U.S. immunization schedules for children, adolescents, and adults.

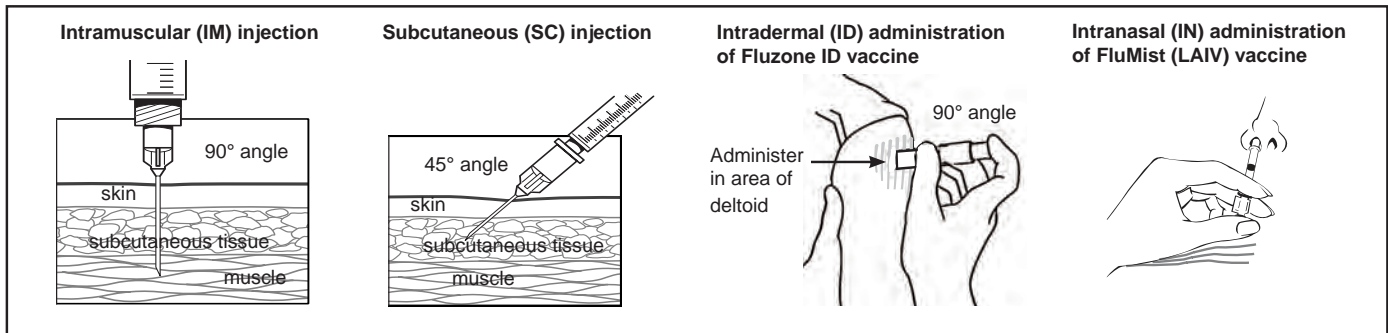
A dash (-) in an abbreviation for a combination vaccine indicates products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution. A slash (/) indicates products that must be mixed or reconstituted by the user.

Administering Vaccines: Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
<i>Haemophilus influenzae</i> type b (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL ≥19 yrs: 1.0 mL	IM
Hepatitis B (HepB) <i>*Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.</i>	<19yrs: 0.5 mL ≥20 yrs: 1.0 mL	IM
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL	Intranasal spray
Influenza, trivalent inactivated (TIV)	6-35 mos: 0.25 mL ≥3 yrs: 0.5 mL	IM
TIV: Fluzone intradermal (18–64 yrs)	0.1 mL	ID
Measles, Mumps, Rubella (MMR)	0.5 mL	SC
Meningococcal – conjugate (MCV)	0.5 mL	IM
Meningococcal – polysaccharide (MPSV)	0.5 mL	SC
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or SC
Polio, inactivated (IPV)	0.5 mL	IM or SC
Rotavirus (RV)	Rotarix: 1.0 mL Rotateq: 2.0 mL	Oral
Varicella (Var)	0.5 mL	SC
Zoster (Zos)	0.65 mL	SC
Combination Vaccines		
DTaP-HepB-IPV (Pediatrix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix) Hib-HepB (Comvax)	0.5 mL	IM
MMRV (ProQuad)	≤12 yrs: 0.5 mL	SC
HepA-HepB (Twinrix)	≥18 yrs: 1.0 mL	IM

Injection Site and Needle Size		
Subcutaneous (SC) injection Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person’s age and body mass.		
Age	Needle Length	Injection Site
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps
Intramuscular (IM) injection Use a 22–25 gauge needle. Choose the injection site and needle length appropriate to the person’s age and body mass.		
Age	Needle Length	Injection Site
Newborns (1 st 28 days)	5/8"*	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 yrs)	1–1¼" 5/8–1"*	Anterolateral thigh muscle or deltoid muscle of arm
Children & teens (3–18 years)	5/8–1"* 1"–1¼"	Deltoid muscle of arm or anterolateral thigh muscle
Adults 19 yrs or older		
Male or female less than 130 lbs	5/8–1"*	Deltoid muscle of arm
Female 130–200 lbs Male 130–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm

*A 5/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle *only* if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.



Please note: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC’s Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well (see www.immunize.org/acip).



Check Your Vials:

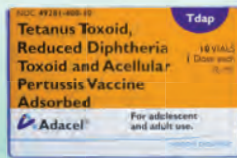
is it
DTaP
or Td?



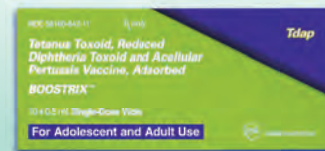
Tdap: Tetanus, Reduced Diphtheria, Acellular Pertussis

Preteens - Adults

ADACEL™ (sanofi pasteur)
Ages 11-64 years



Boostrix® (GlaxoSmithKline)
Ages 10 years and older

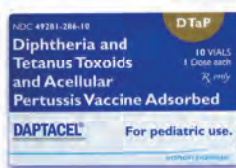


ACIP recommends a dose of Tdap for those over 7 years of age without a complete DTaP series

DTaP: Diphtheria, Tetanus, Acellular Pertussis

Infants - Young Children

DAPTACEL® (sanofi pasteur)
Ages 6 weeks up to 7 years



Infanrix® (GlaxoSmithKline)
Ages 6 weeks up to 7 years



TRIPEDIA® (sanofi pasteur)
Ages 6 weeks up to 7 years



Pediarix® (GlaxoSmithKline)
Ages 6 weeks up to 7 years



Pentacel® (sanofi pasteur)
Ages 6 weeks up to 5 years



Td: Tetanus, Diphtheria

Td (sanofi pasteur)
Ages 7 years and older



Kinrix® (GlaxoSmithKline)
Ages 4 years through 6 years



Age indications for use of products in the VFC program may differ from age indications on this guide or in the package inserts.

Questions: 785-296-5592 or email immreporting@kdheks.gov

For 8 1/2" x 11" copies, enlarge to 155%

Immunization Site Map

Suggested sites for infant immunizations:



RD: _____

RT: _____

LT: _____

LD: _____

LT: _____

RD= Right deltoid (RH) or subcutaneous tissue on upper arm (SC)
 RT= Right vastus lateralis (RH) or subcutaneous tissue on thigh (SC)

LD= Left deltoid (RH) or subcutaneous tissue on upper arm (SC)
 LT= Left vastus lateralis (RH) or subcutaneous tissue on thigh (SC)



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PHN7E (05)

Immunization Site Map

Suggested sites for toddler immunizations:



RD: _____

RT: _____

LT: _____

LD: _____

LT: _____

RD= Right deltoid (RH) or subcutaneous tissue on upper arm (SC)
 RT= Right vastus lateralis (RH) or subcutaneous tissue on thigh (SC)

LD= Left deltoid (RH) or subcutaneous tissue on upper arm (SC)
 LT= Left vastus lateralis (RH) or subcutaneous tissue on thigh (SC)

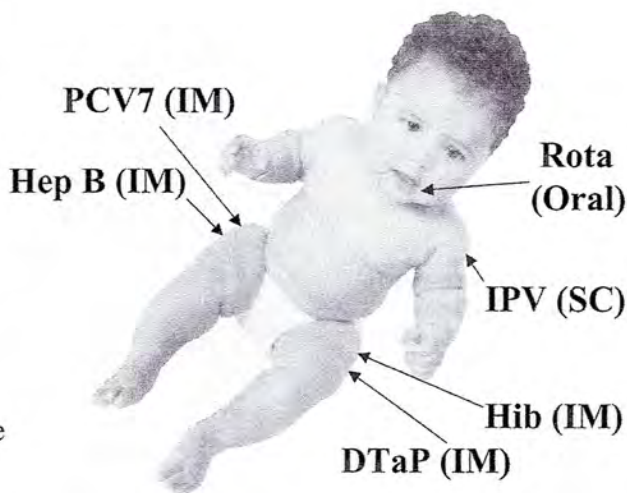


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PHN7E (05)

Giving All the Doses Under 12 Months

- Needle Lengths:
IM=1 inch SC=5/8 inch
- Using combination vaccines will decrease the number of injections
- IM injections are given in the infant's thigh
- SC injections may be given in the arm or thigh
- Separate injection sites by 1-2 inches
- May consider a 5/8" needle for IM injections only in newborns less than 4 wks

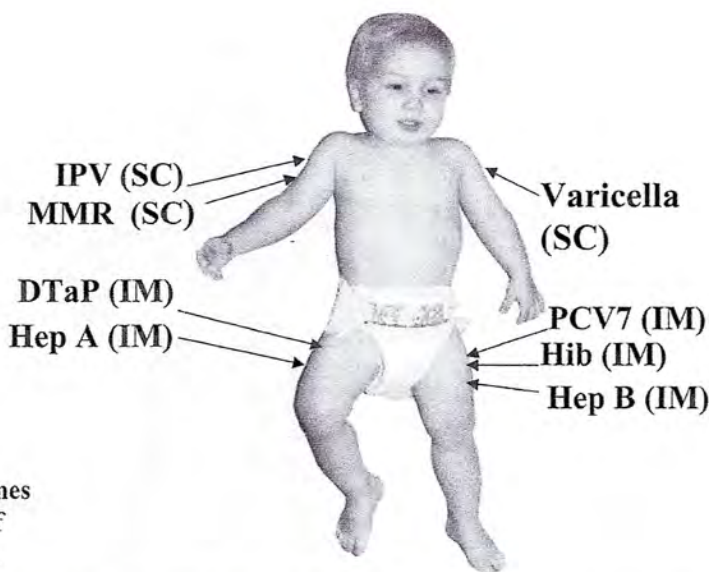


Alliance for Immunization in Michigan 2007 AIM Kit – Childhood Section

December 20, 2006

Giving All the Doses 12 Months and Older

- Needle Lengths
IM=1 to 1.5 inches
SC=5/8 inch
- Separate injection sites by 1-2 inches
- Anterolateral thigh is the **preferred** site for multiple IM injections
- Deltoid (upper arm) is an option for IM in children ≥ 18 mo with adequate muscle mass
- Using **combination vaccines** will decrease the number of injections needed to keep a child up-to-date



Alliance for Immunization in Michigan 2007 AIM Kit – Childhood Section

December 20, 2006

D

Standing Orders for Administering Inactivated Poliovirus Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from poliomyelitis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure

1. Identify infants, children, and teens ages 2 months through 17 years who have not completed a poliomyelitis vaccination series.
2. Screen all patients for contraindications and precautions to inactivated poliovirus vaccine (IPV):
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of IPV or to an IPV vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:**
 - moderate or severe acute illness with or without fever
 - pregnancy
3. Provide all patients (or, in the case of a minor, parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with IPV at ages 2 months, 4 months, 6–18 months, and 4–6 years. Administer 0.5 mL IPV intramuscularly in the vastus lateralis for infants (and toddlers lacking adequate deltoid mass) and in the deltoid muscle (for toddlers and older children). Use a 22–25 g needle. Choose needle length appropriate to the child's age and body mass: infants younger than 12 mos: 1"; 1 through 2 yrs: 1–1¼"; 3 yrs and older: 1–1½". (Note: A ⅝" needle may be used for patients weighing less than 130 lbs [$<60\text{kg}$] for injection in the deltoid muscle only if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.) IPV may also be given subcutaneously (23–25g, ⅝" needle) in the anterolateral fat of the thigh for infants younger than 12 mos and in the posterolateral fat of the upper arm (for older children and teens).
5. For children and teens who have not received IPV at the ages specified in #4, give one dose at the earliest opportunity and then schedule subsequent doses by observing minimum intervals of 4 weeks between doses 1–2 and, if child younger than age 4 years, between doses 2–3. Give a final dose at age 4 years or older, separated by a minimum interval of 6 months from the previous dose. If the child or teen has received a third dose at age 4 years or older, a fourth dose is not necessary.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to IPV to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Technical errors reviewed by the Centers for Disease Control and Prevention, December 2009.

www.immunize.org/catg.d/p3071.pdf • Item #P3071 (12/09)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

Standing Orders for Administering DTaP to Children Younger than Age 7 Years

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate infants and children who meet the criteria below.

Procedure

1. Identify infants and children ages 2 months through 6 years who have not completed a diphtheria, tetanus, and acellular pertussis (DTaP) vaccination series.
2. Screen all patients for contraindications and precautions to DTaP:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of DTaP or to a DTaP component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/exipient-table-2.pdf.
 - a history of encephalopathy (e.g., coma, decreased level of consciousness; prolonged seizures) not attributable to another identifiable cause within 7 days of a previous dose of pertussis-containing vaccine.
 - b. **Precautions:**
 - fever of 105° F (40.5° C) or higher not attributable to another cause within 48 hours of a previous dose of DTaP
 - a hypotensive-hyporesponsive episode within 48 hours of a previous dose of DTaP
 - seizure within 3 days of a previous dose of DTaP
 - persistent, inconsolable crying lasting more than 3 hours that occurred within 48 hours of a dose of DTaP
 - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
 - moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with DTaP at ages 2 months, 4 months, 6 months, 15–18 months, and 4–6 years. Administer 0.5 mL DTaP intramuscularly in the vastus lateralis for infants (and toddlers lacking adequate deltoid mass) and in the deltoid muscle (for toddlers and older children). Use a 22–25g needle. Choose needle length appropriate to the child's age and body mass: infants younger than 12 mos: 1"; 12 mos–6 yrs: 1–1¼".
5. For patients who have not received DTaP at the ages specified in #4, give one dose at the earliest opportunity and then schedule subsequent doses by observing minimum intervals of 4 weeks between the first three doses, and 6 months between the third and fourth dose. If child is age 4–6 years and the fourth dose was given before fourth birthday, give an additional dose at least 6 months after the fourth dose.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to DTaP vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, January 2008.

www.immunize.org/catg.d/p3073.pdf • Item #P3073 (1/08)

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Standing Orders for Administering Influenza Vaccines to Children and Adolescents

Purpose: To reduce morbidity and mortality from influenza by vaccinating all children and adolescents who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and adolescents who meet any of the criteria below.

Procedure:

1. Identify children and adolescents ages 6 months and older who have not completed their influenza vaccination(s) for the current influenza season.
2. Screen all patients for contraindications and precautions to influenza vaccine:
 - a. **Contraindications:** a serious systemic or anaphylactic reaction after ingesting eggs, after receiving a previous dose of influenza vaccine, or to an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV; nasal spray) to people with a history of hypersensitivity to eggs, either anaphylactic or non-anaphylactic; pregnant adolescents; children younger than age 2 yrs; children age 2 through 4 yrs who have experienced wheezing or asthma within the past 12 mos, based on a healthcare provider's statement; or children or adolescents with chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic (e.g., diabetes) disorders; immunosuppression, including that caused by medications or HIV; long-term aspirin therapy (applies to a child or adolescent age 6 mos through 18 yrs).
 - b. **Precautions:** moderate or severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination; for TIV only, allergic reaction to eggs consisting of hives only (observe patient for 30 minutes following vaccination); for LAIV only, close contact with an immunosuppressed person when the person requires protective isolation, receipt of influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours or possibility of use within 14 days after vaccination
3. Provide all patients (or, in the case of a minor, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Administer injectable trivalent inactivated vaccine (TIV) intramuscularly in the vastus lateralis for infants (and toddlers lacking adequate deltoid mass) or in the deltoid muscle (for toddlers, children, and teens). Use a 22–25 g needle. Choose needle length appropriate to the child's age and body mass: infants 6 through 11 mos: 1"; 1 through 2 yrs: 1–1/4"; 3yrs and older: 1–1/2". Give 0.25 mL to children 6–35 mos and 0.5 mL for all others age 3 yrs and older. (Note: A 3/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for injection in the deltoid muscle *only* if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.) Alternatively, healthy children age 2 yrs and older may be given 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position. Children age 6 mos through 8 yrs should receive a second dose 4 wks or more after the first dose if they are receiving influenza vaccine for the first time or if they did not receive at least 1 dose of vaccine in the 2010–2011 vaccination season.
5. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967, VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

www.immunize.org/catg.d/p3074a.pdf • Item #P3074a (8/11)

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Standing Orders for Administering Hepatitis B Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure:

1. Identify infants, children, and teens who have not begun or have not completed a hepatitis B vaccination series.*
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL hepatitis B vaccine intramuscularly in the anterolateral thigh muscle for infants and toddlers (deltoid may be used for toddlers with adequate muscle mass) or in the deltoid muscle of the arm for children ages 3 yrs and older (anterolateral thigh muscle may be used if deltoid is inadequate). Use a 22–25 g needle. Choose needle length appropriate to the child's age and body mass: newborns (first 28 days of life) and premature infants: 5/8"; infants younger than age 12 mos: 1"; toddlers 1–2 yrs: 1–1 1/4" (anterolateral thigh) or 5/8–1" (deltoid muscle); children 3–18 yrs: 5/8–1" (deltoid) or 1–1 1/4" (anterolateral thigh). A 5/8" needle may be used in toddlers and children if inserted in the deltoid muscle at 90° angle to the skin which is stretched flat between thumb and forefinger. It is necessary to give 4 doses of HepB when Comvax or Pediarix vaccines are given after the birth dose. For patients ages 11–15 years, an alternative 2-dose schedule using Recombivax-HB adult formulation vaccine may be used; give 1.0 mL hepatitis B vaccine intramuscularly in the deltoid.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 16 weeks between the first and third doses. The last dose in the infant series should not be given earlier than age 24 weeks. For patients ages 11–15 years on the 2-dose adult formulation Recombivax-HB schedule, give the second dose 4–6 months following the first dose.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

*For persons born in Asia, the Pacific Islands, Africa, or other countries identified as having high rates of HBV infection (see *MMWR* 2005;54 [No. RR-16]:25), ensure that they have also been tested for hepatitis B surface antigen (HBsAg) to find out if they are chronically infected. If test is performed on same visit, give hepatitis B vaccine **after** the blood draw. Do not delay initiating hepatitis B vaccination while waiting for test results. If patient is found to be HBsAg-positive, appropriate medical follow-up should be provided.

This policy and procedure shall remain in effect for all patients of the _____ until
rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Standing Orders for Administering Hepatitis A Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from the hepatitis A virus (HAV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure

1. Identify all children and teens in need of vaccination against hepatitis A based on the following criteria:
 - a. age 12–23 months
 - b. age 2–18 years who live in communities, regions, or states where routine vaccination is recommended (contact your health department for recommendations)
 - c. anticipated travel to a country with intermediate or high endemicity for hepatitis A (i.e., all except Canada, Japan, Australia, New Zealand, and Western Europe)
 - d. anticipated close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days after the arrival of the adoptee in the United States
 - e. a male who has sex with other males
 - f. users of street drugs (injecting and non-injecting)
 - g. diagnosis of chronic liver disease, including hepatitis B and C
 - h. diagnosis of a clotting-factor disorder, such as hemophilia
 - i. an unvaccinated child or teen with recent possible exposure to HAV (e.g., within previous two weeks). (*Note: Children younger than age 12 months should be given IG instead of vaccine.*)
 - j. any other child or teen who wants to be protected from hepatitis A
2. Screen all patients for contraindications and precautions to hepatitis A vaccine:
 - a. **Contraindications:** a history of a serious reaction after a previous dose of hepatitis A vaccine or to a hepatitis A vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:** moderate or severe acute illness with or without fever; pregnancy
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer hepatitis A vaccine intramuscularly as follows: 0.5 mL for patients age 1–18 years and 1.0 mL for patients age 19 years and older. Use a 22–25g needle. Choose needle length appropriate to the child's age and body mass: 1 through 2 yrs: 1–1¼"; 3 yrs and older: 1–1½". (*Note: a 5⁄8" needle may be used for patients who weigh less than 130 lbs [<60kg] for injection in the deltoid muscle, only if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.*)
5. Provide a subsequent dose of hepatitis A vaccine to complete each patient's 2-dose schedule by observing a minimum interval of 6 months between the first and second doses.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, May 2010.

www.immunize.org/catg.d/p3077a.pdf • Item #P3077a (5/10)

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Standing Orders for Administering Td/Tdap to Children Ages 7 Years and Older

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

1. Identify children and teens ages 7 years and older in need of vaccination against diphtheria, tetanus, and pertussis based on the following criteria:
 - a. lack of documentation of at least 4 doses of diphtheria, tetanus, and pertussis vaccine, with at least one of the doses given after the age of 4 years and with the most recent dose given a minimum of 6 months after the preceding dose,
 - b. lack of documentation of at least 3 doses of diphtheria and tetanus vaccine (i.e., DT, Td),
 - c. lack of history of pertussis-containing vaccine given at age 10 years or older, or
 - d. completion of a 3-dose primary series of diphtheria and tetanus toxoid-containing vaccine with receipt of the last dose being 10 years ago or longer.
2. Screen all patients for contraindications and precautions to Td or Tdap:
 - a. **Contraindications:**
 - a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP not attributable to another identifiable cause
 - b. **Precautions:**
 - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
 - history of an arthus-type reaction following a previous dose of tetanus-containing vaccine
 - moderate or severe acute illness with or without fever
 - For Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td (or a one-time dose of Tdap, if indicated) intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Schedule vaccination as follows:
 - a. For children and teens ages 7 years and older who meet the criteria described in 1 above, give one dose at the earliest opportunity and then complete the remaining doses (as needed) by observing minimum intervals of 4 weeks between the first and second doses, and 6 months between the second and third doses. A one-time dose of Tdap should be substituted for one of the doses of Td, preferably the first.
 - b. For children and teens age 11–18 years without a history of pertussis-containing vaccine given at age 7 years or older, give Tdap routinely at age 11–12 years or as catch-up at 13–18 years; no minimum interval since previous Td needs to be observed.
 - c. Give further boosters as Td every 10 years.
 - d. For pregnant adolescents who have not previously received a one-time dose of Tdap, give Tdap in the third or late second trimester (after 20 weeks gestation). If not administered during pregnancy, give Tdap in immediate postpartum period.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention, December 2011.

www.immunize.org/catg.d/p3078a.pdf • Item #P3078a (12/11)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

Standing Orders for Administering Measles, Mumps & Rubella Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure

1. Identify children and teens ages 12 months and older in need of vaccination against measles, mumps, and rubella.
2. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - pregnant now or may become pregnant within 1 month
 - known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; prolonged [14 days or longer] high-dose steroid therapy; severely immunocompromised from HIV infection)
 - b. **Precautions:**
 - recent receipt (within the previous 11 months) of antibody-containing blood product (specific interval depends on product)
 - history of thrombocytopenia or thrombocytopenic purpura
 - moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with MMR vaccine at ages 12–15 months and at 4–6 years. Administer 0.5 mL MMR vaccine subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm.
5. For children and teens who have not received MMR vaccine at the ages specified in #4, give one dose at the earliest opportunity and then schedule a second dose, if needed, by observing a minimum interval of 4 weeks between doses.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Standing Orders for Administering Varicella Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from varicella (chickenpox) by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure

1. Identify children and teens ages 12 months and older in need of vaccination against varicella. (*Note: Because HIV-infected children are at increased risk for morbidity from varicella and herpes zoster (shingles), single-antigen varicella vaccine should be considered for HIV-infected children with CD4+ T-lymphocyte percentages $\geq 15\%$ or for adolescents with CD4+ T-lymphocytes count ≥ 200 cells/ μ L.*)
2. Screen all patients for contraindications and precautions to varicella vaccine:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of varicella vaccine or to a varicella vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - pregnant now or may become pregnant within 1 month
 - having any malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems
 - receiving high-dose systemic immunosuppressive therapy (e.g., two weeks or more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent)
 - family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory
 - a child with CD4+ T-lymphocyte percentages $< 15\%$ or an adolescent with CD4+ T-lymphocytes count < 200 cells/ μ L
 - for combination MMRV only, primary or acquired immunodeficiency, including immunosuppression associated with AIDS or other clinical manifestations of HIV infections, cellular immunodeficiencies, hypogammaglobulinemia, and dysgammaglobulinemia.
 - b. **Precautions:**
 - recent receipt (within the previous 11 months) of antibody-containing blood product (specific interval depends on product)
 - moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with varicella vaccine at ages 12–15 months and at 4–6 years. Administer 0.5 mL varicella vaccine subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm for children and teens.
5. For children and teens who have not received two doses of varicella vaccine (generally given at the ages specified in #4), give a dose at the earliest opportunity and then schedule a second dose, if needed. Observe minimum intervals of 12 weeks between doses for children ages 12 years or younger and 4 weeks between doses for teens 13 years and older.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to varicella vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Technical content reviewed by the Centers for Disease Control and Prevention, July 2008.

www.immunize.org/catg.d/p3080a.pdf • Item #P3080a (7/08)

Standing Orders for Administering Meningococcal Vaccine to Children & Teens

Purpose: To reduce morbidity and mortality from meningococcal disease by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet any of the criteria below.

Procedure

1. Identify children and teens in need of vaccination against meningococcal disease based on any of the following criteria:
 - a. Age 11 through 18 years and previously unvaccinated
 - b. Anticipated first-year college student living in a residence hall and either unvaccinated or last vaccinated when younger than age 16 years (for college students ages 19 and older, see meningococcal vaccine standing orders for adults.)
 - c. Age 2 years or older meeting any of the following criteria: i) anticipated travel to a country in the “meningitis belt” of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged; ii) anticipated travel to Mecca, Saudi Arabia, for the annual Hajj; iii) diagnosis of anatomic or functional asplenia, including sickle-cell disease; iv) diagnosis of persistent complement component deficiency (an immune system disorder); v) children who are part of an outbreak of a vaccine-preventable serogroup
 - d. Military recruits
2. Screen all patients for contraindications and precautions to meningococcal vaccine:
 - a. **Contraindications:** a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component. For information on vaccine components, refer to the manufacturers’ package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precaution:** moderate or severe acute illness with or without fever
3. Provide all patients (or, in the case of a minor, parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Schedule vaccination with quadrivalent meningococcal conjugate vaccine (MCV4) as follows:
 - a. For children ages 9 through 23 months with persistent complement component deficiencies, who travel to countries with highly endemic or epidemic disease, or are affected by a current outbreak caused by a vaccine serogroup, give 2 doses of MCV4-D (Menactra [sanofi]) 3 months apart.
 - b. For unvaccinated children ages 2 through 10 years with same risk factors as in 4.a. or with anatomic or functional asplenia, give 2 doses of either MCV4-D or MCV4-CRM (Menveo [Novartis]) 2 months apart. If MCV4-D is being used, there should be a 4 week separation between the final dose of PCV13 and MCV4-D.
 - c. If child or teen is at continued risk (e.g., anatomic or functional asplenia), give MCV4 booster after 3 years if previous dose was given at age younger than 7 years or, after 5 years if previous dose was given at age 7 years or older. Then, continue boosting every 5 years thereafter.
 - d. For children and teens ages 11 through 12 years, give 1 dose with a booster dose at age 16 years.
 - e. For unvaccinated teens ages 13 through 18 years, give 1 dose with a booster at ages 16 through 18 years if previous dose was given at age 13 through 15 years.
 - f. For children and teens ages 11 through 18 years with HIV infection, give 2 doses at least 8 weeks apart.
5. Administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. (Note: a ¾" needle may be used for patients weighing less than 130 lbs [$<60\text{kg}$] for injection in the deltoid muscle only if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.) If the person has a permanent contraindication or precaution to MCV4, or if MCV4 is unavailable and immediate protection is needed, meningococcal polysaccharide vaccine (MPSV4: Menomune) is an acceptable alternative, although it must be given subcutaneously. Administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, ¾" needle) in the posterolateral fat of the upper arm (in children, the anterolateral fat of the thigh may also be used).
6. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention, February 2013.

www.immunize.org/catg.d/p3081a.pdf • Item #P3081a (2/12)

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Standing Orders for Administering *Haemophilus influenzae* type b Vaccine to Children

Purpose: To reduce morbidity and mortality from *Haemophilus influenzae* type b disease by vaccinating all children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children who meet any of the criteria below.

Procedure

- Identify infants and children ages 6 weeks through 59 months in need of vaccination against *Haemophilus influenzae* type b based on the following criteria:
 - age 6 weeks through 14 months without vaccination or with an incomplete primary series of *Haemophilus influenzae* type b (Hib) vaccine
 - age 15 months through 59 months without evidence of receiving a dose of Hib vaccine since his or her 1st birthday
- Screen all patients for contraindications and precautions to Hib vaccine:
 - Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Hib vaccine or to a Hib vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - Precautions:** moderate or severe acute illness with or without fever
- Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
- Provide routine vaccination with Hib vaccine at ages 2 months, 4 months, 6 months*, and 12–15 months. Administer 0.5 mL Hib vaccine intramuscularly in the vastus lateralis for infants (or for toddlers lacking adequate deltoid mass) or in the deltoid muscle (for toddlers and older children). Use a 22–25 g needle. Choose needle length appropriate to the child's age and body mass: infants younger than 12 mos: 1"; 12 mos–5 yrs: 1–1½".
- For children who have not received Hib vaccine at the ages specified in #4, give one dose at the earliest opportunity and then schedule subsequent doses by observing the following minimum intervals:

For Children Who Have Fallen Behind: Minimum Intervals Permissible Between Doses of Hib Vaccine (Source: www.cdc.gov/vaccines/recs/schedules)		
Interval between dose 1 and dose 2	Interval between dose 2 and dose 3	Interval between dose 3 and dose 4
4 weeks if first dose given at age younger than 12 mos 8 weeks (as final dose) if first dose given at age 12–14 mos No further doses needed if first dose given at age 15 mos or older	4 weeks* if current age younger than 12 mos 8 weeks (as final dose)* if current age 12 mos or older and second dose given at age younger than 15 mos No further doses needed if previous dose given at age 15 mos or older	8 weeks (as final dose) only necessary for children ages 12 mos–5 yrs who received 3 doses before age 12 mos

*If child's current age is younger than 12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or Comvax® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.

- Document each patient's vaccine administration information and follow up in the following places:
 - Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
- Report all adverse reactions to Hib vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Standing Orders for Administering Pneumococcal Conjugate Vaccine to Children

Purpose: To reduce morbidity and mortality from invasive pneumococcal disease by vaccinating all children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children who meet any of the criteria below.

Procedure

1. Identify infants and children in need of vaccination against invasive pneumococcal disease based on the following criteria:
 - a. age 2 through 59 months and generally healthy
 - b. age 2 through 71 months with any of the conditions described below:
 - i. chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure)
 - ii. chronic lung disease (including asthma if treated with prolonged high-dose oral corticosteroids)
 - iii. diabetes mellitus
 - iv. cerebrospinal fluid leak
 - v. candidate for or recipient of cochlear implant
 - vi. functional or anatomic asplenia (i.e., sickle cell disease or other hemoglobinopathy, congenital or acquired asplenia, or splenic dysfunction)
 - vii. immunocompromising condition, including HIV infection; chronic renal failure and nephrotic syndrome; disease associated with treatment with immunosuppressive drugs or radiation therapy (e.g., malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; or solid organ transplantation); congenital immunodeficiency (includes B-[humoral] or T-lymphocyte deficiency; complement deficiencies, particularly c1, c2, c3, and c4 deficiency; and phagocytic disorders [excluding chronic granulomatous disease])
 - c. age 6 through 18 years with any of the conditions described in categories iv through vii above.
2. Screen all patients for contraindications and precautions to pneumococcal conjugate vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PCV, to a PCV component, or to any diphtheria toxoid-containing vaccine. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:** moderate or severe acute illness with or without fever; a child who has received pneumococcal polysaccharide vaccine (PPSV) previously should wait at least 2 months before receiving PCV.
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide vaccination with PCV13 for all healthy children ages 2 through 59 months and for children with a medical condition ages 2 through 71 months according to Table 1 of the next page titled "Recommendations for Pneumococcal Vaccine Use in Children."
5. Consider administering one dose of PCV13, regardless of previous history of PCV7 or pneumococcal polysaccharide vaccine (PPSV), to children ages 6 through 18 years in categories 1.b.iv. through 1.b.vii. listed above.
6. Administer 0.5 mL PCV13 intramuscularly in the anterolateral thigh muscle for infants and toddlers (deltoid may be used for toddlers with adequate muscle mass) or in the deltoid muscle of the arm for children ages 3 yrs and older (anterolateral thigh muscle may be used if deltoid is inadequate). Use a 22–25 g needle. Choose needle length appropriate to the child's age and body mass: infants younger than age 12 mos: 1"; toddlers 1–2 yrs: 1–1¼" (anterolateral thigh) or ¾–1" (deltoid muscle); children ages 3–4 yrs: ¾–1" (deltoid) or 1–1¼" (anterolateral thigh). A ¾" needle may be used in toddlers and children if inserted in the deltoid muscle at 90° angle to the skin, which is stretched flat between thumb and forefinger.
7. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to PCV13 to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Technical content reviewed by the Centers for Disease Control and Prevention in June 2010.

www.immunize.org/catg.d/p3086.pdf • Item #P3086 (6/10)

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Recommendations for Pneumococcal Vaccine Use in Children

Table 1. Recommended Schedules for Administering Pneumococcal Conjugate Vaccine (PCV)

Child's age now	Vaccination history of PCV7 and/or PCV13	Recommended PCV13 Schedule (For minimum interval guidance for catch-up vaccination, see *)
2 through 6 months	0 doses	3 doses, 8 weeks* apart; 4th dose at age 12–15 months
	1 dose	2 doses, 8 weeks* apart; 4th dose at age 12–15 months
	2 doses	1 dose, at least 8 weeks* after the most recent dose; 4th dose at age 12–15 months
7 through 11 months	0 doses	2 doses, 8 weeks apart*; 3rd dose at age 12–15 months
	1 or 2 doses before age 7 months	1 dose at age 7–11 months; 2nd dose at age 12–15 months, at least 8 weeks after the most recent dose
12 through 23 months	0 doses	2 doses, at least 8 weeks apart
	1 dose before age 12 months	2 doses, at least 8 weeks apart
	1 dose at or after age 12 months	1 dose, at least 8 weeks after the most recent dose
	2 or 3 doses before age 12 months	1 dose, at least 8 weeks after the most recent dose
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 PCV13 dose, at least 8 weeks after the most recent PCV7 dose
24 through 59 months (healthy)	Unvaccinated or any incomplete schedule	1 dose, at least 8 weeks after the most recent dose
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 dose, at least 8 weeks after the most recent dose
24 through 71 months (with risk factor described in Table 3 below)	Unvaccinated or any incomplete schedule of less than 3 doses	2 doses, one at least 8 weeks after the most recent dose and another dose at least 8 weeks later
	Any incomplete schedule of 3 doses	1 PCV13 dose, at least 8 weeks after the most recent PCV7 dose
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 PCV13 dose, at least 8 weeks after the most recent PCV7 dose
6 through 18 years with immunocompromising condition, functional or anatomic asplenia (see specific conditions in Table 3 below), cerebrospinal fluid leak, or cochlear implant	Unvaccinated or any history of PCV7 or PPSV23	Consider 1 dose of PCV13

* Minimum interval between doses: For children younger than age 12 months: 4 weeks; for children age 12 months and older: 8 weeks.

Table 2. Recommended Schedule for Administering Pneumococcal Polysaccharide Vaccine (PPSV23) to Children

Risk Group	Schedule for PPSV23	Revaccination with PPSV23
Immunocompetent children with risk condition (see Table 3 below)	Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV	Not indicated
Children with immunocompromising condition, functional or anatomic asplenia (see specific conditions in Table 3 below)	Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV	Give 1 additional dose of PPSV23 at least 5 years following the first PPSV23; no more than 2 PPSV23 doses are recommended in a lifetime

Table 3. Underlying Medical Conditions that Are Indications for Pneumococcal Vaccination Among Children

Risk Group	Condition
Immunocompetent children	Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with prolonged high-dose oral corticosteroids); diabetes mellitus; cerebrospinal fluid leak; cochlear implant
Children with functional or anatomic asplenia	<ul style="list-style-type: none"> Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction
Children with immunocompromising conditions	<ul style="list-style-type: none"> HIV infection Chronic renal failure and nephrotic syndrome Diseases associated with treatment with immunosuppressive drugs or radiation therapy (e.g., malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation) Congenital immunodeficiency (includes B- [humoral] or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, or C4 deficiency; and phagocytic disorders [excluding chronic granulomatous disease])

Technical content reviewed by the Centers for Disease Control and Prevention, May 2010.

www.immunize.org/catg.d/p2016.pdf • Item #P2016 (5/10)

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Standing Orders for Administering Rotavirus Vaccine to Infants

Purpose: To reduce morbidity and mortality from rotavirus disease by vaccinating all infants who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate infants who meet the criteria below.

Procedure

1. Identify infants ages 6 weeks through 7 months (not for 8 months or older) who have not completed a rotavirus (RV) vaccination series.
2. Screen all patients for contraindications and precautions to rotavirus vaccine:
 - a. **Contraindications:**
 - History of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of RV vaccine or to an RV vaccine component (Note: latex rubber is contained in the Rotarix oral applicator). For information on vaccine components, refer to the manufacturers’ package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - Diagnosis of severe combined immunodeficiency (SCID)
 - History of intussusception
 - b. **Precautions:**
 - Altered immunocompetence
 - Chronic gastrointestinal disease
 - Moderate or severe acute illness with or without fever
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide routine vaccination with Rotarix at ages 2 and 4 months OR provide routine vaccination with RotaTeq at ages 2, 4, and 6 months. Administer the full dose (1 mL for Rotarix; 2 mL for RotaTeq) of vaccine by administering the entire contents of the dosing applicator of the liquid vaccine into the infant’s mouth toward the inner cheek until empty. Note that Rotarix needs to be reconstituted by the end user; RotaTeq does not.
5. For infants who have not received RV vaccine by age 2 months, give the first dose at the earliest opportunity but no later than age 14 weeks 6 days. Then schedule subsequent doses by observing minimum intervals of 4 weeks between the remaining one (if Rotarix) or two (if RotaTeq) dose(s) such that the final dose can be administered by age 8 months 0 days. Do not administer any RV vaccine beyond the age of 8 months 0 days.
6. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to RV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention, February 2012.

www.immunize.org/catg.d/p3087.pdf • Item #P3087 (2/12)

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Standing Orders for Administering Human Papillomavirus Vaccine to Children and Teens

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

1. Identify all children and teens ages 11 years and older who have not completed the HPV vaccination series.
2. Screen all patients for contraindications and precautions to HPV vaccine:
 - a. **Contraindication:** a history of a serious allergic reaction after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent HPV vaccine [HPV4: Gardasil, Merck] or latex for bivalent HPV vaccine [HPV2: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:**
 - Moderate or severe acute illness with or without fever
 - Pregnancy; delay vaccination until after completion of the pregnancy
3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Provide 1) either HPV2 or HPV4 to girls or 2) HPV4 to boys. Provide either vaccine in a 3-dose schedule at 0, 1 or 2, and 6 months. Provide routine vaccination with HPV vaccine to girls and boys at age 11 or 12 years; vaccine may be given to girls or boys as young as age 9 years. Administer 0.5 mL HPV vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. For children and teens who have not received HPV vaccine at the ages and/or intervals specified in #4, give one dose at the earliest opportunity and then schedule subsequent doses to complete the 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third doses, and at least 24 weeks between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention, February 2012.

www.immunize.org/catg.d/p3090.pdf • Item #P3090 (2/12)

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Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

(page 1 of 3)

Supplies you may need at a community immunization clinic

- | | | |
|---|--|---|
| <ul style="list-style-type: none"> <input type="checkbox"/> First-line treatment: Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen). If EpiPens are to be stocked, both EpiPen Jr. (0.15 mg) and adult EpiPens (0.30 mg) should be available. <input type="checkbox"/> Secondary treatment option: Diphenhydramine (Benadryl) injectable (50 mg/mL solution) or oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) | <ul style="list-style-type: none"> <input type="checkbox"/> Syringes: 1 and 3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl) <input type="checkbox"/> Alcohol wipes <input type="checkbox"/> Tourniquet <input type="checkbox"/> Pediatric & adult airways (small, medium, and large) <input type="checkbox"/> Pediatric & adult size pocket masks with one-way valve <input type="checkbox"/> Oxygen (if available) <input type="checkbox"/> Stethoscope | <ul style="list-style-type: none"> <input type="checkbox"/> Sphygmomanometer (blood pressure measuring device) child, adult and extra-large cuffs) <input type="checkbox"/> Tongue depressors <input type="checkbox"/> Flashlight with extra batteries (for examination of mouth and throat) <input type="checkbox"/> Wrist watch with ability to count seconds <input type="checkbox"/> Cell phone or access to an onsite phone |
|---|--|---|

Emergency medical protocol for management of anaphylactic reactions in children and teens

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
3. Drug Dosing Information:
 - a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart on next page).
 - b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 30 mg maximum dose in children and 50 mg maximum dose in adolescents (see chart on next page).
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient’s head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.
6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Notify the patient’s primary care physician.

For your convenience, approximate dosages based on weight and age are provided in the charts below. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine (the recommended dose for epinephrine is 0.01 mg/kg body weight)					
	Age Group	Range of weight (lb)	Range of weight (kg)*	Epinephrine Dose	
				1 mg/mL injectable (1:1000 dilution) intramuscular Minimum dose: 0.05 mL	EpiPen (Dey, L.P.) Epinephrine auto-injector 0.15 mg or 0.3 mg
Infants and Children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL† (or mg)	0.15 mg or 0.3 mg
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg)‡	0.3 mg

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

†Maximum dose for children

‡Maximum dose for teens

Secondary Treatment Option: Diphenhydramine (the recommended dose for diphenhydramine [Benadryl] is 1–2 mg/kg body weight)				
	Age Group	Range of weight (lb)	Range of weight (kg)*	Diphenhydramine Dose
				12.5 mg/5 mL liquid 25 mg or 50 mg tablets 50 mg/mL injectable (IV or IM)
Infants and Children	7–36 months	20–32 lb	9–14.5 kg	10 mg–20 mg
	37–59 months	33–39 lb	15–17.5 kg	15 mg–30 mg†
	5–7 years	40–56 lb	18–25.5 kg	20 mg–30 mg†
	8–12 years	57–99 lb	26–45 kg	30 mg†
Teens	13 years & older	100+ lb	46+ kg	50 mg‡

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

†Maximum dose for children

‡Maximum dose for teens

Sources

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6):S1–S57.

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2010.

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the _____ until rescinded or until _____.

name of clinic *date*

Medical Director's signature _____ Effective date _____

www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (7/11)

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Recommended and Minimum Ages and Intervals Between Doses

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	—	—
<i>Haemophilus influenzae</i> 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	—	—

- 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. Quadrivalent 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.

Guide to Contraindications and Precautions¹ to Commonly Used Vaccines* (Page 1 of 2)

Vaccine	Contraindications	Precautions ¹
Hepatitis B (HepB)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> 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])	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Severe combined immunodeficiency (SCID) History of intussusception 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Altered immunocompetence other than SCID Chronic gastrointestinal disease³ Spina bifida or bladder exstrophy³
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria, pertussis (Tdap)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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 <p>For DTaP only:</p> <ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Age younger than 6 weeks 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Inactivated poliovirus vaccine (IPV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Pneumococcal (PCV or PPSV)	<ul style="list-style-type: none"> For PCV13, severe allergic reaction (e.g., anaphylaxis) after a previous dose (of PCV7, PCV13, or any diphtheria toxoid-containing vaccine) or to a vaccine component (of PCV7, PCV13, or any diphtheria toxoid-containing vaccine) For PPSV, severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)⁴	<ul style="list-style-type: none"> 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, receiving chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy⁵ or patients with HIV infection who are severely immunocompromised)⁶ Pregnancy 	<ul style="list-style-type: none"> 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 testing⁸

Vaccine	Contraindications	Precautions ¹
Varicella (Var)⁴	<ul style="list-style-type: none"> 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, receiving chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy⁵ or patients with HIV infection who are severely immunocompromised)⁶ Pregnancy 	<ul style="list-style-type: none"> 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, if possible; delay resumption of these antiviral drugs for 14 days after vaccination.
Hepatitis A (HepA)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Influenza, injectable trivalent (TIV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, including egg protein 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of GBS within 6 weeks of previous influenza vaccine
Influenza, live attenuated (LAIV)⁴	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including egg protein Possible reactive airways disease in a child age 2 through 4 years (e.g., history of recurrent wheezing or a recent wheezing episode) Immune suppression Certain chronic medical conditions such as asthma, diabetes, heart or kidney disease⁹ Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of GBS within 6 weeks of previous influenza vaccine Receipt of specific antivirals (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) 48 hours before vaccination, if possible; avoid use of these antiviral drugs for 14 days after vaccination.
Human papilloma-virus (HPV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Meningococcal: conjugate (MCV4); polysaccharide (MPSV4)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Zoster (Zos)	<ul style="list-style-type: none"> 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, or long-term immunosuppressive therapy⁴ or patients with HIV infection who are severely immunocompromised). Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination, if possible; delay resumption of these antiviral drugs for 14 days after vaccination.

Footnotes

- 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.
- 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.
- 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) at www.cdc.gov/vaccines/pubs/acip-list.htm.
- 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.
- Substantially immunosuppressive steroid dose is considered to be 2 weeks or more of daily receipt of 20 mg (or 2 mg/kg body weight) of prednisone or equivalent.
- HIV-infected children may receive varicella and measles vaccine if CD4+ T-lymphocyte count is >15%. (Source: Adapted from American Academy of Pediatrics. *Passive Immunization*. In: Pickering LK, ed. *Red Book: 2009 Report of the Committee on Infectious Diseases*. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009.)
- 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.)
- 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.
- For details, see CDC. "Prevention and Control of Influenza: 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).

More information on vaccine components, contraindications, and precautions also is available from specific vaccine package inserts and ACIP recommendations for specific vaccines, and is summarized in Atkinson W, Wolfe S, Hamborsky J, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 12th ed. Washington, DC: Public Health Foundations, 2011 (www.cdc.gov/vaccines/pubs/pinkbook/index.html).

Recording and Documentation

Content

- Documentation
- Immunization Registry - KSWebIZ

Forms

- Immunization Administration Chart
- Vaccine Documentation/Consent Form - English
- Vaccine Documentation/Consent Form - Spanish

Resources / Website Links

KSWebIZ Email: immregistry@kdheks.gov

Recording and Documentation

One of the most important aspects of vaccine administration is accurate documentation of the immunizations a child receives. Providers should maintain accurate, up to date and easily retrievable records of a patient's immunization history. The reasons are obvious. Accurate records make sure that under immunized children will receive the correct vaccine in a timely fashion and immunizations are not duplicated. Not only is this good medical practice, but the law requires that:

“Health-care providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine. In addition, the provider is required to record the edition date of the VIS distributed and the date those materials were provided.” (MMWR; vol. 60, #2)

A number of sources including KDHE and the AAP have one page standardized forms that include all of the necessary information and are included in this manual (Immunization Administration Chart). Providers with EHRs need to make sure their systems have this information also included.

Physicians should also include documentation of signed informed consent, screening questions, and receipt of VIS statements. Again there are forms that include all of these on a single sheet and samples are included in this manual (Vaccine Documentation/ Consent Form).

Parents and guardians should also be provided a copy of the immunization records either in a booklet or standardized form. This should be updated at each visit. The importance of these records needs to be impressed upon the caregiver.

IMMUNIZATION REGISTRY - KSWEBIZ

Immunization registries, now known as Immunization Information Systems (IIS), are computerized systems that collect immunization information from multiple sources into a state wide database. These data bases are confidential, but allow access of an individual's immunization information to health care providers, public health entities, and schools. These systems help prevent duplicate vaccinations, limit missed appointments, reduce vaccine waste, and reduce staff time required to produce or locate vaccination records or certificates.

In Kansas, the IIS is known as KSWebIZ. KSWebIZ has been functional since 2005. Since that time, KSWebIZ has been steadily expanding the number of providers who are part of the system. For information on how to become a part of KSWebIZ contact the program at: immregistry@kdheks.gov.

IMMUNIZATION ADMINISTRATION CHART - CHILD

Clinic/Provider Name & Address:

NAME:						BIRTHDATE:		M	F
ADDRESS:			CITY:	STATE:	ZIP:	PHONE #:			
I agree to allow this health care provider to release information on vaccinations given to me, or to the person for whom I am authorized to consent, to the Kansas Immunization Program, other health care providers, and schools to avoid the need for unnecessary repeat vaccinations and to provide information on what immunizations have been received. I understand I am not required to agree to the release of this information in order to receive vaccinations today.									
I have been offered a copy of the Vaccine Information Statement(s) (VIS) checked below. I have read, had explained to me, and understand the information in the VIS(s). I ask that the vaccine(s) checked below be given to me or to the person named below for whom I am authorized to make this request. I consent to inclusion of this immunization data in the Kansas Immunization Registry for myself or on behalf of the person named below.									
VACCINE (CIRCLE CHOICE)	DATE GIVEN	SIGNATURE OF RECIPIENT OF VACCINE OR PERSON AUTHORIZED TO REQUEST	VACCINE MANUF.	VACCINE LOT NO.	EXP DATE	SITE GIVEN	NAME/TITLE OF ADMINISTRATOR	VIS PUB DATE	VFC/CHD CODES
DTaP/DTP/DT1						LVL RVL LD RD			
DTaP/DTP/DT2						LVL RVL LD RD			
DTaP/DTP/DT3						LVL RVL LD RD			
DTaP/DTP/DT4						LD RD			
DTaP/DTP/DT5						LD RD			
Td						LD RD			
Td						LD RD			
Td or Tdap						LD RD			
Polio 1						LSQ RSQ ORAL			
Polio 2						LSQ RSQ ORAL			
Polio 3						LSQ RSQ ORAL			
Polio 4						LSQ RSQ ORAL			
MMR/MMR-V 1						LSQ RSQ			
MMR/MMR-V 2						LSQ RSQ			
Hib 1						LVL RVL LD RD			
Hib 2						LVL RVL LD RD			
Hib 3						LVL RVL LD RD			
Hib 4						LD RD			
Hep A						LVL RVL LD RD			
Hep A 2						LVL RVL LD RD			
Hep B 1						LVL RVL LD RD			
Hep B 2						LVL RVL LD RD			
Hep B 3						LVL RVL LD RD			
HPV						LVL RVL LD RD			
HPV						LVL RVL LD RD			
HPV						LVL RVL LD RD			
Varicella 1						LSQ RSQ			
Varicella 2						LSQ RSQ			
Pneumo-conj 1						LVL RVL LD RD			
Pneumo-conj 2						LVL RVL LD RD			
Pneumo-conj 3						LVL RVL LD RD			
Pneumo-conj 4						LVL RVL LD RD			
Pneumo-conj 5						LVL RVL LD RD			
Meningo-conj 1						LD RD			
Meningo-conj 2						LD RD			
Rotavirus 1						ORAL			
Rotavirus 2						ORAL			
Rotavirus 3						ORAL			

ES: 1 = T19-MED, 2 = Uninsured, 3 = Native American or Alaskan Native, 4 = T21-SCHIP, 5 = Under Insured (RHC/FQHC only)

CHD CODES: 6 = Under Served, 7 = Under Insured (RHC/FQHC only)

IMMUNIZATION ADMINISTRATION CHART - ADULT

Clinic/Provider Name & Address:

NAME:				BIRTHDATE:						
I.D. NUMBER:		M F		TELEPHONE NUMBER:						
ADDRESS:				CITY:		STATE:		ZIP:		
<p>I agree to allow this health care provider to release information on vaccinations given to me, or to the person for whom I am authorized to consent, to the Kansas Immunization Program, other health care providers, and schools to avoid the need for unnecessary repeat vaccinations and to provide information on what immunizations have been received. I understand I am not required to agree to the release of this information in order to receive vaccinations today.</p>										
<p>I have been offered a copy of the Vaccine Information Statement(s) (VIS) checked below. I have read, had explained to me, and understand the information in the VIS(s). I ask that the vaccine(s) checked below be given to me or to the person named below for whom I am authorized to make this request. I consent to inclusion of this immunization data in the Kansas Immunization Registry for myself or on behalf of the person named below.</p>										
VACCINE (CIRCLE CHOICE)	DATE GIVEN	SIGNATURE OF RECIPIENT OF VACCINE OR PERSON AUTHORIZED TO REQUEST			VACCINE MANUF.	VACCINE LOT NO.	EXP DATE	SITE GIVEN	NAME/TITLE OF ADMINISTRATOR	VIS PUB DATE
Td								LD RD		
Td								LD RD		
Td or Tdap								LD RD		
IPV 1								LD RD		
IPV 2								LD RD		
IPV 3								LD RD		
MMR								LSQ RSQ		
MMR								LSQ RSQ		
Influenza 1								LD RD		
Influenza 2								LD RD		
Influenza 3								LD RD		
Influenza 4								LD RD		
Pneumococcal 1								SQ or IM		
Pneumococcal 2								SQ or IM		
Meningo-conj 1								LD RD		
Meningo-conj 2								LD RD		
Hep A 1								LD RD		
Hep A 2								LD RD		
Hep B 1								LD RD		
Hep B 2								LD RD		
Hep B 3								LD RD		
HPV								LD RD		
HPV								LD RD		
HPV								LD RD		
Varicella 1								LSQ RSQ		
Varicella 2								LSQ RSQ		
OTHER IMMUNIZATIONS										
Typhoid										
Cholera										
Yellow Fever										
Other										
TB TEST	DATE GIVEN	SIGNATURE OF PROVIDER	DATE READ	RESULT	TEST	DATE GIVEN	SIGNATURE OF PROVIDER	DATE READ	RESULT	

VACCINE DOCUMENTATION/CONSENT FORM

I have been offered a copy of the Vaccine Information Statement(s) (VIS) checked below. I have read, had explained to me, and understand the information in the VIS(s). I ask that the vaccine(s) checked below be given to me or to the person named below for whom I am authorized to make this request. I consent to inclusion of this immunization data in the Kansas Immunization Registry for myself or on behalf of the person named below.

- DT DTaP Tdap Td HepA HepB Hib HPV Influenza Meningococcal
 MMR PCV7/13 PPV23 Polio/IPV Rotavirus Varicella Other _____

_____ Signature of Patient or Parent/Guardian _____ Date _____

PATIENT INFORMATION						
Patient's Last Name:		Patient's First Name:		Phone Number:		Age:
Birth date:		Street Address:		City:	County:	State:
Zip Code:		Ethnicity: Hispanic or Latino ___ Yes ___ No		Race: (Select one or more.)		
Gender: ___ Male ___ Female		___ AS-Asian/Pacific Islander/Other	___ BL-Black or African American	___ CA-Caucasian/Mexican/Puerto Rican	___ FI-Filipino	___ HA-Hawaiian
___ IN-Native American/Alaska Native	___ JA-Japanese	___ CH-Chinese	___ NW-Other Non-White	___ UN-Unknown		
Primary Care Physician:		Street Address: City:		State: Zip:	Phone: Fax:	
PATIENT ELIGIBILITY						
___ T19-MED	___ No health insurance	___ Native Am/Alaska Native	___ Underinsured**^	___ Underserved***^	___ T21-SCHIP	___ Fully Insured

*Underinsured children: insurance does not cover immunizations. Eligible through VFC program if vaccinated at a FQHC, RHC or county health department.
 **Underserved children: Are not VFC eligible. May only be vaccinated with KIP vaccines needed at school entry at a county health department if enrolled in federal free or reduced-price school lunch program.

IMMUNIZATION SCREENING QUESTIONNAIRE	
1. Is the person to be vaccinated currently sick or experiencing a high fever?	___yes ___no
2. Has the person to be vaccinated had a serious reaction to a vaccine in the past?	___yes ___no
3. Does the person to be vaccinated have any allergies that produce a severe (anaphylactic) reaction?	___yes ___no
4. Has the person to be vaccinated had a seizure or other neurological problem?	___yes ___no
5. Does the person to be vaccinated have any medical problems that make it hard for him/her to fight infection?	___yes ___no
6. Does the person to be vaccinated have close, regular contact with someone with a weakened immune system?	___yes ___no
7. Is the person taking cortisone, prednisone, other steroids, or anti-cancer drugs, or had x-ray treatments?	___yes ___no
8. Has the person to be vaccinated received blood, plasma, or immune globulin in the past twelve months?	___yes ___no
9. Is the person to be vaccinated pregnant or thinking of becoming pregnant within the next three months?	___yes ___no

NAME _____

AGE _____

DOB _____

PROVIDER INFORMATION					
Vaccine Provider:			Clinic Site:		
Street Address:	State:	Zip Code:	Street Address:	State:	Zip Code:

(Circle the appropriate vaccine, dose, extremity, site, route, and enter the manufacturer, lot #, and expiration date.)

FOR CLINICAL USE ONLY							
VACCINE	DOSE	EXT	SITE	ROUTE	VIS DATE	MANUFACTURER LOT #	EXP DATE
DTaP DT Td Tdap	0.5 mL 1 2 3 4 5 6	RT LT	Deltoid Vastus Lat	IM			
DTaP/IPV	0.5 mL 5th DTaP--4th IPV	RT LT	Deltoid Vastus Lat	IM			
DTaP/HepB/IPV	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib/IPV	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib	0.5 mL 4	RT LT	Deltoid Vastus Lat	IM			
Hep A	0.5 mL 1.0 mL 1 2	RT LT	Deltoid Vastus Lat	IM			
Hep B	0.5 mL 1.0 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hep B/Hib	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hib	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
HPV	0.5 mL 1 2 3	RT LT	Deltoid	IM			
Influenza LAIV TIV	0.1mL 0.2mL 0.25mL 0.50mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	Intradermal Intranasal IM			
MCV4	0.5 mL 1 2	RT LT	Deltoid	IM			
MMR	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
MMR-V	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
PCV7/13	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Polio/IPV	0.5 mL 1 2 3 4 5	RT LT	Upper Arm Thigh	IM SC			
PPV23	0.5 mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	SC IM			
Rotavirus	2.0 mL 1 2 3		By Mouth	Oral			
Varicella	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
Other							

Signature and Title of Vaccine Administrator_____
Date

DOCUMENTACION DE LAS VACUNAS/FORMULARIO PARA EL CONSENTIMIENTO

Se me ha ofrecido una copia de la "Declaración sobre la información de las vacuna(s)" marcadas abajo. He leído o se me ha explicado la información en la "Declaración sobre la información de las vacuna(s)". Mis preguntas fueron contestadas a satisfacción, y yo pido que las vacuna(s) marcadas abajo sean aplicadas a mi, o a la persona nombrada abajo por quien yo doy autorización. Doy mi consentimiento para incluir la información de mis vacunas y la de las personas nombradas abajo en el Registro de Vacunas de Kansas.

DT DTaP Tdap Td HepA HepB Hib HPV Influenza Meningococcal
 MMR PCV7/13 PPV23 Polio/IPV Rotavirus Varicella Other _____

Firma de Paciente o de Padre/Guardian

Fecha

Información Del Paciente				
Apellido del paciente:	Nombre del paciente:	Número de teléfono:	Edad:	Fecha de nacimiento:
Dirección:	Ciudad:	Condado:	Estado:	Código postal:
Etnicidad: Hispano o Latino ___ Si ___ No ___ Masculino ___ Femenino	___ Asiático/Isleño del pacífico ___ Negro o Africano Americano ___ Caucásico/Mejicano/Puertorriqueño ___ Chino ___ Filipino	___ Hawaiian ___ Indio Americano/Nativo ___ Japonés ___ Otro/Non-Blanco ___ Desconocido		
Médico Primario:	Dirección: Ciudad:	Estado:	Teléfono: Fax:	
Elegibilidad del paciente: ___ T19-MED ___ No Tiene Seguro ___ Indio Americano ___ Insuficientemente Asegurados** ___ Insuficientemente Servidos*** ___ T21-SCHIP ___ Enteramente Asegurados				

**Niños con seguro insuficiente: El seguro no cubre las vacunas. Elegibles a través del programa VFC si son vacunados en un FQHC, RHC o departamento de salud del condado.

**Niños sin seguro o sin cobertura médica: No son elegibles para VFC. Sólo pueden ser vacunados con vacunas de KIP necesarias para ingresar a la escuela en un departamento de salud del condado si están inscritos en el programa federal escolar gratuito o en el program de almuerzo a precio reducido.

CUESTIONARIO DE VACUNAS	
1. Está el paciente enfermo o tiene fiebre ahora?	__ si __ no
2. El paciente que va ser vacunado ha sufrido una reacción seria con vacunas en el pasado?	__ si __ no
3. La persona que va ser vacunada tiene alguna alergia que producen serias reacciones?	__ si __ no
4. El paciente sufre de convulsiones o desorden neurológica?	__ si __ no
5. El paciente tiene problemas de salud por lo cual no puede rechazar infección?	__ si __ no
6. El paciente está alrededor de otros que no puedan rechazar infección?	__ si __ no
7. El paciente toma esteroides, medicinas contra el cáncer o ha terminado un tratamiento de rayos-x?	__ si __ no
8. El paciente ha recibido sangre, plasma o gamma globulina en los últimos 12 meses?	__ si __ no
9. Está la paciente embarazada o está planificando embarazo entre 3 meses?	__ si __ no

IMM-51S

Kansas Immunization Program

Rev. 12/31/12

NAME _____

AGE _____

DOB _____

PROVIDER INFORMATION					
Vaccine Provider:			Clinic Site:		
Street Address:	State:	Zip Code:	Street Address:	State:	Zip Code:

(Circle the appropriate vaccine, dose, extremity, site, route, and enter the manufacturer, lot #, and expiration date.)

FOR CLINICAL USE ONLY							
VACCINE	DOSE	EXT	SITE	ROUTE	VIS DATE	MANUFACTURER LOT #	EXP DATE
DTaP DT Td Tdap	0.5 mL 1 2 3 4 5 6	RT LT	Deltoid Vastus Lat	IM			
DTaP/IPV	0.5 mL 5th DTaP--4th IPV	RT LT	Deltoid Vastus Lat	IM			
DTaP/HepB/IPV	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib/IPV	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib	0.5 mL 4	RT LT	Deltoid Vastus Lat	IM			
Hep A	0.5 mL 1.0 mL 1 2	RT LT	Deltoid Vastus Lat	IM			
Hep B	0.5 mL 1.0 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hep B/Hib	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hib	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
HPV	0.5 mL 1 2 3	RT LT	Deltoid	IM			
Influenza LAIV TIV	0.1mL 0.2mL 0.25mL 0.50mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	Intradermal Intranasal IM			
MCV4	0.5 mL 1 2	RT LT	Deltoid	IM			
MMR	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
MMR-V	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
PCV7/13	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Polio/IPV	0.5 mL 1 2 3 4 5	RT LT	Upper Arm Thigh	IM SC			
PPV23	0.5 mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	SC IM			
Rotavirus	2.0 mL 1 2 3		By Mouth	Oral			
Varicella	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
Other							

Signature and Title of Vaccine Administrator _____

Date _____

Parent/Caregiver Information

Content

 Vaccine Information Sheet Information

Forms

 It's Federal Law!

 VIS: FAQs

 Instructions for the Use of Vaccine Information Statements (VIS)

Resources / Website Links

CDC: www.cdc.gov/vaccines/pubs/vis/default.htm

Index

Parent/Caregiver Information

Federal law mandates that before any child receives a vaccine, the provider is required to give a copy of the Vaccine Information Statement (VIS) for each vaccine to the parent or legal guardian. The Vaccine Information Sheets are handouts which provide information on the benefits and risks of each vaccine. These information sheets have been developed by a panel of experts working in conjunction with the CDC. The sheets are just part of the process to provide accurate information about vaccines to parents and guardians. In addition to these information sheets, providers should address any questions and concerns that the parents or guardians may have.

Providing this information is important.

- First, every parent and caregiver deserve to know accurately what the risks and benefits are for each and every vaccine.
- Second, it alerts parents and caregivers to potential reactions and may alleviate concerns about the seriousness of these events.
- Third, by providing the caregiver with accurate information on vaccine risks this helps maintain trust between the provider and the family.

VIS sheets are easily downloaded at no costs from the CDC website:
www.cdc.gov/vaccines/pubs/vis/default.htm.

The manual has included the following three documents:

- Summary of the Vaccine Information Law
- FAQs about the law and VIS
- VIS instructions



It's Federal Law!

You must give your patients current Vaccine Information Statements (VISs)

To obtain current VISs in more than 30 languages, visit the Immunization Action Coalition's website at www.immunize.org/vis

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer

questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to www.immunize.org/vis/vis_sources.asp

Most current versions of VISs

As of November 16, 2012, the most recent versions of the VISs are as follows:

DTaP/DT	5/17/07	MMR	4/20/12
Hepatitis A	10/25/11	MMRV	5/21/10
Hepatitis B	2/2/12	PCV13	4/16/10
Hib	12/16/98	PPSV	10/6/09
HPV (H. papillomavirus)		Polio	11/8/11
Cervarix	5/3/11	Rabies	10/6/09
Gardasil	2/22/12	Rotavirus	12/6/10
Influenza (inactive)	7/2/12	Shingles	10/6/09
Influenza (live)	7/2/12	Td/Tdap	1/24/12
Japanese encephalitis	12/7/11	Typhoid	5/29/12
Meningococcal	10/14/11	Varicella (chickenpox)	3/13/08
Multi-vaccine VIS		Yellow fever	3/30/11
			11/16/12

(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination.

Source: www.cdc.gov/vaccines/pubs/vis/vis-facts.htm

Top 10 Facts about VISs

Fact 1 It's federal law!

Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:

- DTaP (includes DT)
- MMR and MMRV
- Td/Tdap
- meningococcal
- Hib
- pneumococcal conjugate
- hepatitis A
- polio
- hepatitis B
- rotavirus
- HPV
- varicella
- influenza (inactivated and live vaccines)

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

Fact 2 VISs are required for both public and private sectors

Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

Fact 3 VIS must be provided before vaccine is administered to the patient

The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

Fact 4 You must provide a current VIS for each dose of vaccine

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5 You must provide VISs for combination vaccines too

There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine

coccal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Comvax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6 VISs are available in other formats, including more than 30 languages

You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must **also** offer the patient (parent/legal representative) a printed copy of the VIS to take home.

If they prefer to download the VIS onto a mobile device, direct them to CDC's VIS Mobile Downloads web page: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm

To download VISs in other languages, visit www.immunize.org/vis

By using the VISs with your patients, you are helping to develop a better educated patient population and you are doing the right thing.

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated

Signed consent is not required by federal law (although some states may require them).

Fact 8 To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:

- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

Fact 9 VISs should not be altered before giving them to patients

Providers should not change a VIS or write their own VISs. It is permissible to add a practice's name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10 Provide VISs to all patients

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient's language.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.

Vaccine Information Statements: Frequently Asked Questions

Are VISs "informed consent" forms?

No. People sometimes use the term "informed consent" loosely when referring to VISs.

There is no Federal requirement for informed consent. VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act (NCVIA). But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some states have informed consent laws. Check your state medical consent law to determine if there are any specific informed consent requirements relating to immunization. VISs can be used for informed consent as long as they conform to the appropriate state laws.

Should the VISs be used for adults getting vaccines as well as for children?

Yes. Under the NCVIA, anyone receiving a covered vaccine should be given the appropriate VIS. VISs for vaccines that may be administered to both children and adults are worded so they may be used by both. Apart from legal requirements, it is good practice to give the appropriate VIS every time a vaccine is administered, to anyone of any age.

The law states that vaccine information materials be given to a child's legal representatives. How is "legal representative" defined?

A "legal representative" is a parent or other individual who is qualified under state law to consent to the immunization of a minor. There is not an overriding Federal definition.

Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?

Ideally each VIS should be taken home. They contain information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

When do providers have to start using a new VIS?

The date for a new VISs required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately,

particularly if the vaccine's contraindications or adverse event profile have changed since the previous version.

How should we comply with the law for patients who cannot read the VISs (e.g., those who are illiterate or blind)?

The NCVIA allows providers to supplement the VISs with "visual presentations" or "oral explanations" as needed. VISs can be read to illiterate or blind patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. The VISs available on CDC's website are compatible with screen reader devices.

Why are the dates on some of the VISs so old? Are they obsolete? Why can't they be updated every year?

VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine's adverse event profile, indications, or contraindications. VISs posted on the NIP website are always be the current versions. Annually changing the dates on VISs that haven't changed otherwise could be confusing, because there would be multiple VISs in circulation that were identical but would have different dates.

Sometimes a VIS will contain a recommendation that is at odds with the manufacturer's package insert. Why?

VISs are based on the ACIP's recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those shown to be causally linked to the vaccine. ACIP may also harmonize recommendations for similar vaccines produced by different manufacturers, for which approved indications differ slightly.

What is the reading level of VISs?

VIS's generally test at about a 10th grade reading level, according to Fletch-Kincaid. However, traditional "grade level" measures may be somewhat misleading for VISs. In what may be a more useful indicator of readability, several VISs have been subjected to focus group testing among low-literacy parents in a variety of racial and ethnic groups (some not native English speakers), and were generally judged to be easy to read and understand. VISs are always reviewed for readability, within the constraints imposed by the need for technical accuracy.

How should we distribute VISs when the parent or legal representative of a minor is not present at the time the vaccination is given, for example during a school-based adolescent vaccination program?

CDC's legal advisors have proposed two alternatives for this situation:

- **Consent Prior to Administration of Each Dose of a Series.** With this alternative the VIS must be mailed or sent home with the student around the time of administration of each dose. Only those children for whom a signed consent is returned may be vaccinated. The program must place the signed consent in the patient's medical record.
- **Single Signature for Series.** This alternative is permissible only in those States where a single consent to an entire vaccination series is allowed under State law and in those schools where such a policy would be acceptable. The first dose of vaccine may be administered only after the parent or legal representative receives a copy of the VIS and signs and returns a statement that a) acknowledges receipt of the VIS and provides permission for their child to be vaccinated with the complete series of the vaccine (if possible, list the approximate dates of future doses); and b) acknowledges their acceptance of the following process regarding administration of additional doses:

Prior to administration of each dose following the initial dose, a copy of the VIS will be mailed to the parent (or legal representative) who signs the original consent at the address they provide on this statement, or the VIS will be sent home with the student; and

The vaccine information statements for the additional doses will be accompanied by a statement notifying the parent that, based on their earlier permission, the next dose will be administered to their child (state the date), unless the parent returns a portion of this statement by mail to an address provided, to arrive prior to the intended vaccination date, in which the parent withdraws permission for the child to receive the remaining dose.

The program must maintain the original consent signature and any additional dose veto statements in the patient's medical record. A record must be kept of the dates prior to additional doses that the VIS was mailed, or sent home with the adolescent.

Prior to administration of each additional dose, the provider should ask the adolescent whether he/she experienced any significant adverse events following receipt of earlier doses. If yes, the provider should consider consulting the parent or delaying the vaccination. The adolescent's response to questions about adverse reactions to previous doses should be kept in the medical record.

Questions concerning the Pediatric Multi-Vaccine VIS:

May the existing, single-vaccine VISs still be used?

Yes. The Multi-Vaccine VIS is an optional alternative to existing VISs. Providers wishing to continue using the individual VISs may do so. These will continue to be updated when recommendations change.

May the Multi-Vaccine VIS be used with combination vaccines, such as Pediarix or Comvax?

Yes. Just check the appropriate boxes on the first page as you would if you were administering the individual vaccines.

When we record the edition date of the VISs on the patient's medical record, do we record the date on the Multi-Vaccine VIS or the dates on the individual VISs?

Record the date of the Multi-Vaccine VIS for each vaccine given. If there is ever a question, this will make it clear that this VIS was used, and not the individual VISs.

Can the Multi-Vaccine VIS be used for children older than 6 months, or for adolescents or adults getting any of these vaccines?

It may be used for older children getting two or more of these vaccines during the same visit (e.g., a 12-month old getting Hib and PCV or a 4-year old getting DTaP and IPV). It should not be used for adolescents or adults.

Can the Multi-Vaccine VIS be used for catch-up doses?

Yes, as long as the doses are given to children as part of the primary series or routine pediatric boosters.

If a single-vaccine VIS is updated before the Multi-Vaccine VIS, may the multi continue to be used for that vaccine?

Sometimes there can be delays in updating a VIS. If an individual VIS for a vaccine covered on the multi gets updated before the multi does, the multi may still be used. You may give the patient the new single VIS at the same time, or explain verbally or with other written materials any changes. This is most important if the changes involve contraindications or adverse events; *in these cases be certain the patient gets up-to-date information*. It is less important if the update reflects other changes, such as changes in the routine schedule.

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide a Vaccine Information Statement (VIS) when a vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, or
- to any adult† to whom the provider intends to administer such vaccine.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

VISs should be supplemented with visual presentations or oral explanations as appropriate.

*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

†In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided, indicating:

- (1) the edition date of the Vaccine Information Statement distributed, and
- (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration, and
- (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Copies are available in English and many other languages from CDC's website at www.cdc.gov/vaccines/pubs/vis. Single camera-ready copies may also be available from State health departments.

Current VIS Editions

DTaP/DT: 5/17/07
Hib: 12/16/98
Hepatitis A: 10/25/11†
Hepatitis B: 2/2/12†
HPV (Cervarix): 5/3/11†
HPV (Gardasil): 2/22/12†
Influenza (inactivated): 7/2/12†
Influenza (live): 7/2/12†
MMR: 4/20/12†
MMRV: 5/21/10†

Meningococcal: 10/14/11†
Pneumococcal (PCV13): 4/16/10†
Polio: 11/8/11†
Rotavirus: 12/6/10†
Tdap/Td: 1/24/12†
Varicella: 3/13/08†
Multi-Vaccine*: 11/16/12†

*An optional alternative when two or more routine childhood vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, polio, or rotavirus) are administered at the same visit.

†Interim

Reference 42 U.S.C. §300aa-26
November 19, 2012



Vaccine Adverse Effects

Content

Adverse Reactions

Management of Adverse Reactions

Use of Antipyretics Prophylactically

Syncope

Tables

Table 4 - Medical Management of Vaccine Reactions

Forms

Vaccine Adverse Effects Reporting System

Resources / Website Links

Vaers: www.vaers.hhs.gov

Vaccine Adverse Effects

Despite the well documented safety of immunizations, recipients can still suffer rare adverse effects. The vast majority of these are mild with no lasting sequelae. In very rare instances more serious reactions to vaccines can occur.

Adverse reactions to vaccines can be divided into three main categories: local, systemic, and allergic. The most common reactions a child will experience will be of the local type.

Local reactions occur more commonly with inactivated vaccines. They consist of localized redness, pain and tenderness, and swelling at the site of the injection. These are generally self-limited and have no permanent sequelae.

Systemic reactions are more generalized and non-specific; fever, headache, malaise, myalgia, and anorexia. Because they are non-specific they may not even be caused by the vaccine. These symptoms may represent a viral infection for example that was just in the early stages when the child was immunized. Systemic reactions occur more often after receiving live attenuated vaccines. As a result if the symptoms are related to these vaccines they may not appear for 7-21 days.

The last types of reactions are allergic in nature. Severe allergic reactions (anaphylaxis) are very rare, but life threatening. They occur at a rate of <1/500,000 doses. Screening prior to immunization administration (see Recording and Documents for screening forms) helps reduce the chances of anaphylaxis.

Providers should report any clinically significant event that is a result of a vaccination. The Vaccine Adverse Event Reporting System has been in place since 1990 for providers to make these reports. This system allows both private and public immunization providers to report adverse effects of vaccines and will keep the results in a centralized database. The telephone number to call for answers to questions and to obtain VAERS forms is (800) 822-7967, or visit the VAERS website: www.vaers.hhs.gov. VAERS now accepts reports of adverse reactions through their online system.

MANAGEMENT OF ADVERSE REACTIONS

For most local reactions, cold compresses, analgesics/antipyretics, and antipruritics will suffice. Table 4 offers a good summary of the treatments for vaccine reactions including anaphylaxis.

USE OF ANTIPYRETICS PROPHYLACTICALLY

Many providers recommend pre-treatment with acetaminophen prior to administration of immunizations. The thought is this will decrease the reactions following the vaccines. There were some studies in the 1980s showing this practice was a benefit. These were all done when whole cell DPT was being used. Since acellular DPT is now the standard there has not been any good evidence that prophylactic acetaminophen is of a benefit. There has been some concern that the use of antipyretics prior to the vaccines may actually decrease the immune response. In February 2011, the AAP published a Clinical Report: Fever and Antipyretic Use in Children. They summarized the usage of antipyretics prior to administration of immunizations as follows:

“Despite insufficient evidence, many pediatricians recommend the routine practice of pretreatment with acetaminophen or ibuprofen before a patient receives immunizations to decrease the discomfort associated with the injections and subsequently at the injection sites and to minimize the febrile response. In addition, results of 1 recent study suggested the possibility of decreased immune response to vaccines in patients treated early with antipyretics.”

Therefore, the usage of antipyretics prior to administering immunizations remains controversial. The provider must decide the best way to counsel patients on this topic.

SYNCOPE

Some patients, especially adolescents, may experience a syncopal episode after receiving immunizations. These are most likely vaso-vagal in origin. Syncope and its associated signs and symptoms usually last only a short time (seconds to minutes) and resolve when the patient is placed in a position, such as lying down, to restore adequate blood flow to the brain. If syncope develops, patients should be observed until symptoms resolve. In many instances some manifestations of an impending syncopal episode may present themselves so personnel should be aware of this and take appropriate measures such as having the recipient sit or lie down for 15 minutes after vaccination.



VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967

P.O. Box 1100, Rockville, MD 20849-1100

PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

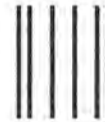
VAERS Number _____

Date Received _____

Patient Name: Last _____ First _____ M.I. _____		Vaccine administered by (Name): _____		Form completed by (Name): _____	
Address _____ _____		Responsible Physician _____ Facility Name/Address _____ _____		Relation <input type="checkbox"/> Vaccine Provider <input type="checkbox"/> Patient/Parent to Patient <input type="checkbox"/> Manufacturer <input type="checkbox"/> Other Address (if different from patient or provider) _____ _____	
City _____ State _____ Zip _____ Telephone no. (____) _____		City _____ State _____ Zip _____ Telephone no. (____) _____		City _____ State _____ Zip _____ Telephone no. (____) _____	
1. State _____	2. County where administered _____	3. Date of birth mm / dd / yy	4. Patient age _____	5. Sex <input type="checkbox"/> M <input type="checkbox"/> F	6. Date form completed mm / dd / yy
7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any			8. Check all appropriate: <input type="checkbox"/> Patient died (date mm / dd / yy) <input type="checkbox"/> Life threatening illness <input type="checkbox"/> Required emergency room/doctor visit <input type="checkbox"/> Required hospitalization (____ days) <input type="checkbox"/> Resulted in prolongation of hospitalization <input type="checkbox"/> Resulted in permanent disability <input type="checkbox"/> None of the above		
9. Patient recovered <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN			10. Date of vaccination mm / dd / yy AM Time _____ PM	11. Adverse event onset mm / dd / yy AM Time _____ PM	
12. Relevant diagnostic tests/laboratory data					
13. Enter all vaccines given on date listed in no. 10					
Vaccine (type)		Manufacturer	Lot number	Route/Site	No. Previous Doses
a. _____		_____	_____	_____	_____
b. _____		_____	_____	_____	_____
c. _____		_____	_____	_____	_____
d. _____		_____	_____	_____	_____
14. Any other vaccinations within 4 weeks prior to the date listed in no. 10					
Vaccine (type)		Manufacturer	Lot number	Route/Site	No. Previous doses
a. _____		_____	_____	_____	_____
b. _____		_____	_____	_____	_____
15. Vaccinated at: <input type="checkbox"/> Private doctor's office/hospital <input type="checkbox"/> Military clinic/hospital <input type="checkbox"/> Public health clinic/hospital <input type="checkbox"/> Other/unknown		16. Vaccine purchased with: <input type="checkbox"/> Private funds <input type="checkbox"/> Military funds <input type="checkbox"/> Public funds <input type="checkbox"/> Other/unknown		17. Other medications	
18. Illness at time of vaccination (specify)		19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)			
20. Have you reported this adverse event previously? <input type="checkbox"/> No <input type="checkbox"/> To health department <input type="checkbox"/> To doctor <input type="checkbox"/> To manufacturer		Only for children 5 and under			
		22. Birth weight _____ lb. _____ oz.		23. No. of brothers and sisters	
21. Adverse event following prior vaccination (check all applicable, specify)		Only for reports submitted by manufacturer/immunization project			
Adverse Event _____ Onset Age _____ Type Vaccine _____ Dose no. in series _____		24. Mfr./imm. proj. report no.		25. Date received by mfr./imm.proj.	
<input type="checkbox"/> In patient _____ <input type="checkbox"/> In brother or sister _____		26. 15 day report? <input type="checkbox"/> Yes <input type="checkbox"/> No		27. Report type <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up	
Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.					

Form VAERS-1 (FDA)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE



VAERS
P.O. Box 1100
Rockville MD 20849-1100



DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

(page 1 of 3)

Supplies you may need at a community immunization clinic

- | | | |
|---|--|---|
| <ul style="list-style-type: none"> <input type="checkbox"/> First-line treatment: Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen). If EpiPens are to be stocked, both EpiPen Jr. (0.15 mg) and adult EpiPens (0.30 mg) should be available. <input type="checkbox"/> Secondary treatment option: Diphenhydramine (Benadryl) injectable (50 mg/mL solution) or oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) | <ul style="list-style-type: none"> <input type="checkbox"/> Syringes: 1 and 3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl) <input type="checkbox"/> Alcohol wipes <input type="checkbox"/> Tourniquet <input type="checkbox"/> Pediatric & adult airways (small, medium, and large) <input type="checkbox"/> Pediatric & adult size pocket masks with one-way valve <input type="checkbox"/> Oxygen (if available) <input type="checkbox"/> Stethoscope | <ul style="list-style-type: none"> <input type="checkbox"/> Sphygmomanometer (blood pressure measuring device) child, adult and extra-large cuffs) <input type="checkbox"/> Tongue depressors <input type="checkbox"/> Flashlight with extra batteries (for examination of mouth and throat) <input type="checkbox"/> Wrist watch with ability to count seconds <input type="checkbox"/> Cell phone or access to an onsite phone |
|---|--|---|

Emergency medical protocol for management of anaphylactic reactions in children and teens

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
3. Drug Dosing Information:
 - a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart on next page).
 - b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 30 mg maximum dose in children and 50 mg maximum dose in adolescents (see chart on next page).
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient’s head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.
6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Notify the patient’s primary care physician.

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For your convenience, approximate dosages based on weight and age are provided in the charts below. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine (the recommended dose for epinephrine is 0.01 mg/kg body weight)					
	Age Group	Range of weight (lb)	Range of weight (kg)*	Epinephrine Dose	
				1 mg/mL injectable (1:1000 dilution) intramuscular Minimum dose: 0.05 mL	EpiPen (Dey, L.P.) Epinephrine auto-injector 0.15 mg or 0.3 mg
Infants and Children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL [†] (or mg)	0.15 mg or 0.3 mg
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) [‡]	0.3 mg

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

[†]Maximum dose for children

[‡]Maximum dose for teens

Secondary Treatment Option: Diphenhydramine (the recommended dose for diphenhydramine [Benadryl] is 1–2 mg/kg body weight)				
	Age Group	Range of weight (lb)	Range of weight (kg)*	Diphenhydramine Dose 12.5 mg/5 mL liquid 25 mg or 50 mg tablets 50 mg/mL injectable (IV or IM)
Infants and Children	7–36 months	20–32 lb	9–14.5 kg	10 mg–20 mg
	37–59 months	33–39 lb	15–17.5 kg	15 mg–30 mg [†]
	5–7 years	40–56 lb	18–25.5 kg	20 mg–30 mg [†]
	8–12 years	57–99 lb	26–45 kg	30 mg [†]
Teens	13 years & older	100+ lb	46+ kg	50 mg [‡]

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

*Rounded weight at the 50th percentile for each age range

[†]Maximum dose for children

[‡]Maximum dose for teens

Sources

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6):S1–S57.

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2010.

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the _____ until rescinded or until _____.

name of clinic *date*

Medical Director's signature _____ Effective date _____

Storage and Handling

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Storage and Handling

Tables

Table 5 – Vaccine Storage and Handling Chart/Protect Vaccines

Table 6 - Contact Information for Manufacturers and Distributors

Forms

Checklist for Safe Vaccine and Storage and Handling

Vaccine Storage and Handling Plan Worksheet

Vaccine Refrigerator Set-Up

Vaccine Freezer Set-Up

Temperature Log for Vaccines

Emergency Response Worksheet

Standards for Pediatric Immunization Practices

Storage and Handling

Resources / Website Links

Storage and Handling Toolkit: www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

CDC Pink Book: www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html

Vaccine Manual: www.kdheks.gov/immunize/imm_manual_pdf/index.html

AAP: www2.aap.org/immunization/pediatricians/storageand-handling.html

Storage and Handling

INTRODUCTION

Proper storage and handling of vaccines is critical for maintaining the safety and potency of the vaccines. Time needs to be spent becoming familiar with these procedures. This portion of the manual is a brief overview emphasizing key elements. It is not meant to replace more detailed references produced by the CDC and KDHE. These references are listed at the end of this section and each facility should have copies readily available.

BACKGROUND

Vaccines are fragile biological products. They are very sensitive to two factors: light and temperature. If vaccines are not carefully managed and protected from these elements then they can lose potency. The effect of this is that the patient may not develop an adequate immune response. Therefore, vaccines that are exposed to improper temperatures or light cannot be used, resulting in wastage of the vaccine and the significant costs incurred from unusable vaccine. If a patient has inadvertently received a vaccine that has not been stored adequately they need to have the immunization repeated. This can damage patient-provider trust and relationships.

COLD CHAIN

This is a term that is used to indicate that the vaccine has been continuously exposed to proper temperatures from the time of manufacture to the time of administration. During much of this time the provider has the responsibility to make sure the temperature exposures are appropriate and the cold chain is maintained.

SAFE TEMPERATURES

Different vaccines will require different temperature ranges. As a general rule live vaccines will tolerate freezing, but will deteriorate rapidly. Inactivated vaccines are damaged by narrower temperature fluctuations including freezing.

Freezer temperatures should be maintained at -58 F to +5 F (-50C to -15C). Refrigerator temperatures should be +35F to 46F (+2C to +8C). The desired average temperature in refrigerators is 40F.

Not all vaccines will follow these general rules. For example, some live vaccines cannot be frozen. Thus it is vital to know the proper temperatures for the individual vaccines. The proper temperatures for each vaccine are shown in Table 5 Vaccine Storage and Handling Chart.

Varicella vaccine may be stored in refrigerated temperatures (35F to 46F) for 72 hours prior to reconstitution with diluent. Once it is removed from the freezer it must be used within 72 hours. After it is reconstituted it must be used within 30 minutes.

LIGHT

Many vaccines are light sensitive and can be made inactive by both sunlight and fluorescent light. This is especially true of live vaccines. MMR, Varicella and ProQuad are examples of vaccines that may be inactivated by light exposure. It is recommended that all vaccines be kept in their original packaging until they are ready for administration.

STORAGE AND HANDLING PLANS

Facilities need to have written plans for storage and handling that staff can use as management guides and source of reference. These plans need to be followed precisely. The following topics need to be covered in a facility's plan:

- Ordering and accepting vaccines
- Storage and handling protocols
- Inventory
- Management of compromised vaccines
- Emergency storage and retrieval

To help facilities in developing these plans a sample checklist and plan worksheet are provided at the end of this section. Some points to remember when developing these plans:

- The plan should be easily accessible for staff to use.
- Make sure backup facilities have proper equipment.
- Emergency transport materials readily available.
- List of contacts for compromised vaccines.
- Never discard vaccines unless directed to do so by a state or local immunization program or the vaccines manufacturer.

PERSONNEL AND TRAINING

Proper vaccine storage and handling is important enough that one person, the Vaccine Coordinator, needs to be in charge. By having one person in charge it will assure that all of the functions listed below are coordinated and there is someone who is responsible for assuring the system functions smoothly. Trying to do these functions by committee can result in numerous breakdowns in the process.

The Vaccine Coordinator’s responsibilities include:

- Ordering vaccines
- Overseeing the receipt and storage of vaccines
- Organizing the storage units in freezers and refrigerators
- Overseeing the temperature monitoring
- Inspecting the storage units on a daily basis
- Overseeing stock rotation and monitoring expiration dates
- Maintaining records and documentation
- Training

Relying on one individual without a backup coordinator though can also lead to problems. It is suggested that a back-up coordinator be chosen and be familiar with the duties to be able to readily step in if the time should arise.

Training should be ongoing with refresher courses. Anyone who “touches” vaccines including administrative staff who may receive the vaccines at delivery should be part of the training process. All new employees should be trained as part of their orientation. In addition, refresher courses should be done whenever new guidelines or new vaccines become available. It is also recommended that the entire staff attend a refresher course at least on an annual basis.

INVENTORY

Inventory of the vaccines should be done on a monthly basis. When ordering vaccines three factors enter in the decision making; the projected demand, the current supply, and the facility’s storage capacity.

RECEIVING VACCINES

One of the most important steps is to make sure delivery will be made during office hours when someone knowledgeable is present. Vaccines must be stored immediately after receipt. Check the date of shipment and compare it to the arrival date. If longer than 48 hours has transpired there could be a break in the cold chain. If there are any questions contact the manufacturer. Table 6 has a list of manufacturers and contact information. Always record the contents of the shipment.

EQUIPMENT - REFRIGERATORS AND FREEZERS

One of the areas of vaccine administration that seems to cause the most confusion is proper equipment. The two most obvious pieces of equipment are the refrigerators and freezers.

The CDC recommends that practices use stand-alone freezers and stand-alone refrigerators (no freezer compartment). The reason for this is that these single units allow for better and more even temperature control. Freezing of refrigerated vaccines affects potency more than any other exposure problem. Vaccines in combo units are more susceptible to this hazard.

While the CDC doesn't recommend combo units they do allow the use of a refrigerator/freezer combo unit while employing only the refrigerator unit. Most combo units share a single condenser and the freezing air is vented into the refrigerator to help keep the refrigerator cool. If you are using this type of unit here are some tips to remember:

- Don't use the top shelf to store vaccines as this is where the freezer vent is most likely located
- Don't turn off the freezer portion as this helps keep the refrigerator cool.
- Add water bottles (top shelf) to decrease the risk of vaccines becoming too cold.

Using both the refrigerator and freezer units in combo units is suboptimal and as stated above is not recommended, but if this type is used, they must have a separate thermostat control of both the refrigerator and freezer components along with separate outside doors for each. **Small dorm refrigerators are not acceptable and cannot be used.** These are defined as small combo units with one door.

All units are required to have good seals for doors and good temperature maintenance. In addition, all units must be dedicated to vaccine storage only, allow for good air circulation around each storage bin, and allow four inch minimum space between the walls of the unit and the room.

The CDC understands that this may involve a significant cost factor for practices to change to new equipment. They recommend changes be made as soon as possible, but don't offer any timeline. They are studying the most cost efficient ways to make these changes.

We have included a graphic summary of both refrigerator and freezer setups to assist providers.

EQUIPMENT - THERMOMETERS

In order to be sure that vaccines are in the proper temperature environment thermometers are a must. **Each** vaccine storage unit (refrigerators and freezers) must have a thermometer and the availability of a backup unit in case of equipment failure. Requirements for thermometers are that they be calibrated with a Certificate of Traceability and Calibration Testing. Thermometer recalibration must be performed annually or according to the manufacturer's recommendation by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. The thermometer should be:

- Digital
- Provide continuous reading
- Measure minimum/maximum temperatures
- Alarm for temperatures out of range
- Have a low battery indicator
- Ability to be read outside of storage unit without need to open door

Thermometers must provide accurate information of the temperature of the vaccines which are liquid. Because of this **air thermometers are unacceptable**. Thermometers with glycol-filled probes are what are needed. As an alternative, thermometers with glass beads in the probes are currently acceptable, but there is a need for more data on their reliability. They may prove to be unacceptable by the CDC in the future.

MONITORING

One of the key functions of the Vaccine Coordinator is monitoring the temperatures in the storage units. All units need to have thermometer readings checked and recorded a minimum of twice daily. A log should be maintained and attached to each unit in a readily visible location. A sample of such a log is provided. Data from the log should be maintained for three years. Continuous monitoring with an alarm system is recommended. Even if continuous monitoring is employed, manual monitoring **twice daily** should be done. Consideration should be made for an alarm notification system that will alert a staff member after hours if there is a temperature excursion. If a practice has a large vaccine inventory this is highly recommended. Remember - these alarm systems are not fool proof so daily monitoring must be maintained.

For accurate monitoring the placement of the thermometer probe should be considered. Determine where the most reliable reading location is; away from cold and hot spots. Don't place the probe in doors, against walls, close to vents, or on a floor of the unit.

EQUIPMENT - POWER SUPPLY

Equipment must stay in working order at all times. The first item to assure is that the proper power supply will be met. Some key procedures can assure that accidental loss of power will not occur. First, don't use outlets with built in circuit breakers. Safety lock plugs are best and don't use power strips. Posting of warning signs on storage units, and breaker switches that the power is never to be shut off is a simple procedure that can save a practice its vaccines. If there is a power failure most units will be able to maintain temperatures for a short time if the doors remain closed. If you anticipate the power outage will last greater than two hours then institute the office Emergency and Retrieval Plan (see below). Finally, a backup generator should be considered as a power source in the event of a more generalized power outage such as storms or disaster situations.

VACCINE PLACEMENT

The placement of vaccines in the storage units needs to be mentioned. Proper placement is important to maintain proper vaccine temperatures. To assure this, vaccines must be placed away from the unit's walls and vents and vaccine bins should not be crowded. Above all, follow the manufacturer's instructions on storage.

Proper placement can also prevent administration errors. It is recommended that vaccines be kept in their original containers and grouped together so as to prevent confusion. Proper labeling of bins is important. All diluents are not the same so if a diluent needs refrigeration placing it with the appropriate vaccine can help prevent improper mixing.

TEMPERATURE EXCURSIONS

Any reading outside of the normal ranges is an excursion and needs to be addressed immediately. The total amount of time the temperature is out of the normal range is important and needs to be documented. For example, if temperature is out of range for 10 minutes in the morning and 5 minutes in the afternoon the total time is 15 minutes. **When the temperature is out of range for any significant time, or if you are unsure, contact the manufacturer or the State Health Department. Never discard vaccines unless instructed to do so by the manufacturer or the State Health Department.**

POWER OUTAGES AND EMERGENCY RETRIEVAL PLANS

As mentioned above, if there is a power failure the first step is to keep the units doors closed. This will allow a short time to decide whether or not to institute the facility's Emergency Retrieval Plan. This plan will set up the protocol to transport vaccine safely to an alternate site while maintaining the cold chain. Obviously, it is important to set up this plan before it is needed. A sample plan is included along with a checklist. Here are some key points to remember:

- Establish a proper backup facility. This facility needs to have the proper equipment available to store vaccines. Examples of such facilities are local health departments, hospitals, other outpatient clinics, or medical facilities. Agreements should be made prior to the event.
- Use only appropriate transport containers. There are a number of possibilities that can be used. There are medical grade portable refrigerators and freezers that can be obtained, but these can be rather expensive. Hard sided coolers with 2 inch walls are a less expensive alternative. Another inexpensive transport method is to keep the transport coolers the vaccines are shipped in. These will also include coolant packs and insulation materials. These can be used by the practice and costs nothing.
- Materials for transport should be ready to use and easily available. These include frozen coolant packs and insulation material such as bubble wrap or Styrofoam pellets to maintain temperature during transport. The CDC does not recommend the use of dry ice. Portable temperature probes are needed to monitor maintenance of the cold chain.
- Never put the containers in the trunks of vehicles when transporting. The temperature swings in trunks is too great to assure the cold chain.

Monitor temperatures hourly.

If questions arise contact the State Immunization Program or the vaccine manufacturers.

Transportation of varicella vaccine poses some different circumstances. The vaccine is kept frozen and is very fragile. Therefore the CDC recommends transport in a portable freezer unit. If this is not available you can transport in refrigerator unit temperatures, but the vaccine then must be used within 72 hours and cannot be refrozen.

REFERENCES

The following references should be used by all providers and made available to staff. They give detailed information on storage and handling issues.

The most extensive is the VACCINE STORAGE and HANDLING TOOLKIT published by the CDC in November 2012. A copy of this can be downloaded on line at:
www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

A somewhat shorter, but equally good reference is the chapter on VACCINE STORAGE and HANDLING in the CDC PINK BOOK and also published by the CDC and can be obtained from the web at: www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html

Two other references that might prove helpful are:

The STANDARDS for PEDIATRIC IMMUNIZATION PRACTICES from the AAP (a copy is included in this manual) and the VACCINE MANUAL from Kansas Immunization Program at: www.kdheks.gov/immunize/imm_manual_pdf/index.html

VACCINE STORAGE AND HANDLING CHART

VACCINE	SHIPPING/ARRIVAL	STORAGE REQUIREMENTS	SHELF LIFE/EXPIRATION	RECONSTITUTION	SPECIAL INSTRUCTIONS
DTaP /DT DTaP/HepB/IPV DTaP/HIB/IPV * DTap/IPV Tdap/Td	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) *Protect From Light	Check expiration date on vial or manufacturer-filled syringe	Shake vial vigorously before withdrawal and use immediately Do not use if resuspension does not occur after shaking	Rotate Stock so that earliest expiration date is used first
Hepatitis A & B	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F)	Check expiration date on vial or manufacturer-filled syringe	Shake vial vigorously before withdrawal and use immediately	Rotate Stock so that earliest expiration date is used first
HIB	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) Protect From Light	Check expiration date	Shake vial vigorously before withdrawal and use immediately Do not use if resuspension does not occur after shaking	Rotate Stock so that earliest expiration date is used first
Influenza Trivalent Inactivated	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) Protect From Light	Use during current influenza season	Shake vial vigorously before withdrawal and use immediately	Rotate Stock so that earliest dated material is used first
Influenza Live Attenuated	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F)	Use during current influenza season	Intranasal single use sprayer. Split dose equally between nostrils.	Dispose of sprayer in sharps container
IPV	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F)	Check expiration date on vial or manufacturer-filled syringe	Shake vial vigorously before withdrawal and use immediately	Rotate Stock so that earliest expiration date is used first
MCV Meningococcal Conjugate	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) Protect From Light	Check expiration date	Shake vial vigorously before withdrawal and use immediately	Rotate Stock so that earliest expiration date is used first
PCV Pneumococcal Conjugate	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F)	Check expiration date	Shake vial vigorously before withdrawal and use immediately Do not use if resuspension does not occur after shaking	Rotate Stock so that earliest expiration date is used first
MMR	Maintain at - 58°F and +46°F o r -50°C and +8° C	MAY PLACE IN FREEZER OR REFRIGERATOR Protect From Light	Check expiration date	Use only the diluent supplied to reconstitute the vaccine. Administer immediately. Do not freeze after vaccine is reconstituted. Must be used within 8 hrs of reconstitution.	Do not expose diluents to freezing temperatures. Diluent may be stored at room temperature or in refrigerator.
Varivax	Maintain at - 58°F and +5°F o r -50°C and -15° C	PLACE IN FREEZER IMMEDIATELY Needs sealed and separate freezer compartment Protect From Light	Check expiration date	Use only the diluent supplied to reconstitute the vaccine. Administer immediately. Do not freeze after vaccine is reconstituted. Must be discarded if not used within 30 minutes of reconstitution	MUST STAY FROZEN!! Rotate stock so that earliest expiration date is used first
ProQuad Varivax/MMR	Maintain at - 58°F and +5°F o r -50°C and -15° C	PLACE IN FREEZER IMMEDIATELY Needs sealed and separate freezer compartment Protect From Light	Check expiration date	Use only the diluent supplied to reconstitute the vaccine. Administer immediately. Do not freeze after vaccine is reconstituted. Must be discarded if not used within 30 minutes of reconstitution	MUST STAY FROZEN!! Rotate stock so that earliest dated material is used first
RotaTaq RV5 Rotarix RV1	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) Protect From Light	Check expiration date	RV5 single dosing tube should be used <u>immediately</u> after the cap is removed. RV1 diluent stored at room temperature 68°F and 77°F (20° C and 25° C). May be used up to 24 hrs after reconstitution	Oral use only Rotate Stock so that earliest expiration date is used first
HPV	DO NOT EXPOSE TO FREEZING TEMPERATURES	DO NOT FREEZE Refrigerate immediately At 2-8°C (35°-46°F) Protect From Light	Check expiration date on vial or manufacturer-filled syringe	Shake vial vigorously before withdrawal and use immediately	Rotate Stock so that earliest expiration date is used first

PROTECT VACCINES

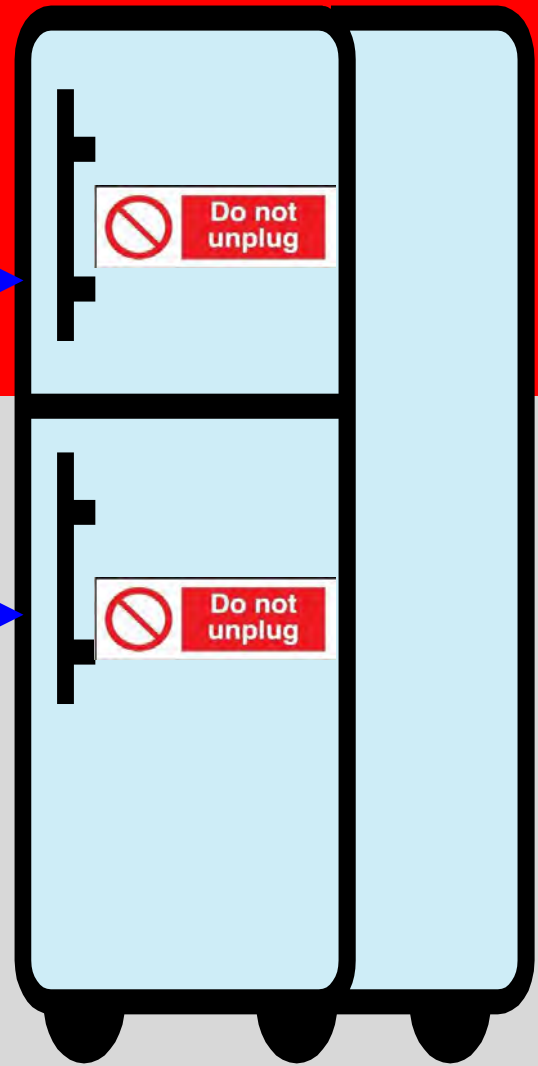
Maintain freezer temperature
-58°F to +5°F or (-50°C to -15° C)

MMR* †
MMRV*
Varicella*
Zoster*

Maintain refrigerator temperature at
35–46°F and (2–8°C)

DTaP, DT, Td, Tdap
Hepatitis A Hepatitis B
Hib*
Human papillomavirus (HPV*)
Influenza (TIV*/LAIV)
Polio (IPV)
Meningococcal (MCV4* & MPSV4)
MMR* †
Pneumococcal (PCV & PPV)
Rotavirus*

*Do not expose to light.
† May be stored in freezer or refrigerator



Vaccine Handling Tips

Order Vaccines Carefully:

Inventory your vaccine at least monthly and before placing an order. Vaccines must never be used past their expiration date.

Store Vaccines Correctly:

Refrigerate or freeze immediately upon receiving the vaccine shipment. Do not store vaccine in the doors or crispier of the vaccine storage units. Place vaccines in the middle of the storage unit and allow enough room between the boxes so there is adequate air circulation.

Always use the vaccine with the earliest expiration date first. Move vaccine with the earliest expiration date to the front and mark it to be used first. Keep vials in their boxes.

Document Temperatures:

Document temperatures at a minimum of 2 times a day. Once at the beginning and once at the end of the clinic day. If temperatures are out of proper range document the action taken to safeguard the vaccine

Stabilize Temperature:

Store ice packs in the freezer. Store large jugs of water in the refrigerator door. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezer doors are opened frequently or left open. Frequent opening of the refrigerator unit's doors can lead to inside temperature variations, which could affect the vaccine's efficacy. For this reason you should not store food or beverages in the refrigerator or freezer.

Secure Temperatures:

Safeguard the electrical supply to the refrigerator. Make sure the vaccine storage unit is plugged into a secured outlet where it cannot be disconnected accidentally. Label the unit, electrical outlets, and circuit breakers with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case of interruption of power (use DO NOT UNPLUG stickers). If your building has auxiliary power, use the outlet supplied by that system.

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either YES or NO.

Establish Storage and Handling Policies

- YES NO 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.
- YES NO 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.
- YES NO 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.
- YES NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

- 5. We maintain a vaccine inventory log that we use to document the following:
 - YES NO a. Vaccine name and number of doses received
 - YES NO b. Date we received the vaccine
 - YES NO c. Condition of vaccine when we received it
 - YES NO d. Vaccine manufacturer and lot number
 - YES NO e. Vaccine expiration date

Use Proper Storage Equipment

- YES NO 6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).
- YES NO 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.
- YES NO 8. We have planned back-up storage units(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

- YES NO 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.
- YES NO 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

- YES NO 11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.
- YES NO 12. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).

(Maintain Correct Temperatures continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

(Maintain Correct Temperatures continued from page 1)

- YES NO 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.
- YES NO 14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.
- YES NO 15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).
- YES NO 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

- YES NO 17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.
- YES NO 18. We do NOT store any food or drink in any vaccine storage unit.
- YES NO 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.
- YES NO 20. We have removed all vegetable and deli bins from the storage unit.
- YES NO 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).
- YES NO 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.
- YES NO 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

- YES NO 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.
- YES NO 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.
- YES NO 26. The logs show whom to call if the temperature in the storage unit goes out of range.
- YES NO 27. When we change the thermostat setting, we document it in the daily log sheet's note section.
- YES NO 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.
- YES NO 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.
- YES NO 30. We keep the temperature logs on file for at least 3 years.

Take Emergency Action As Needed

31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
- YES NO a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.
- YES NO b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
- YES NO c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.
- YES NO d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.
- YES NO e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

Routine Vaccine Storage and Handling Plan Worksheet

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit. See the CDC's [Vaccine Storage and Handling Plans](http://www.cdc.gov/vaccines/recs/storage/guide/default.htm) (<http://www.cdc.gov/vaccines/recs/storage/guide/default.htm>.)

Checklist of Resources for the Routine Vaccine Storage and Handling Plan

- Up-to-date contact information
 - Primary and backup vaccine coordinators
 - State and local health department immunization program
 - Manufacturers of the vaccines in your inventory
 - Refrigerator and freezer maintenance and repair company(ies)
 - Vaccine storage unit alarm company (if applicable)
 - Sources for packing materials and certified calibrated thermometers
- Descriptions of the roles and responsibilities of the primary and backup vaccine coordinators
- Summaries of the storage requirements for each vaccine and diluent in your inventory
- Protocols for vaccine storage unit temperature monitoring
- Protocols for vaccine storage equipment maintenance
- Protocols for the correct placement of vaccine(s) within storage units
- Protocols for responding to vaccine storage and handling problems
- Protocols for vaccine inventory management
- Protocols for transporting and receiving vaccine shipments
- Policies for preparing vaccine for administration
- Protocols for proper disposal of vaccines (expired/wasted/used) and supplies
- Samples of the forms used in your vaccination program

Vaccine Coordinators

Vaccine Coordinators	Title	Telephone Numbers
Primary		
Backup		

Resources Contact List

Resources	Contact Person (Title)		Telephone Numbers
State Health Department Immunization Program			
Local Health Department Immunization Program			
Emergency Resources	Company Name	Contact Person	Telephone Numbers (home, cell, beeper)
Electric Power Company			
Emergency Resources	Company Name	Contact Person (Title)	Telephone Numbers (home,cell,beeper)
Generator Repair Company (if applicable)			
Generator Fuel Source (if applicable)			
Refrigeration Repair Company			
Temperature Alarm Monitoring Company if Applicable			

Kansas Immunization Program
1000 SW Jackson Ste 075
Topeka, KS 66612-1274
Phone 785-296-5959; Fax 785-296-6510

Packing Materials

Insulated Containers or Coolers			
Fillers (e.g., crumpled paper, bubble wrap)			
Refrigerated/Frozen Packs			
Warm Monitors (for shipping)			
Certified Calibrated Thermometers			

Roles and Responsibilities

1) Accepts Vaccine Deliveries, Unpacks & Stores Vaccine

Name	Title	Telephone Number
Primary		
Backup		

2) Monitors and Records Twice Daily Temperatures & Maintain Temperature Log Files

Name	Title	Telephone Number
Primary		
Backup		

3) Conducts Monthly Inventory; Orders Vaccines; Labels for use; Rotates stock

Name	Title	Telephone Number
Primary		
Backup		

4) Reviews & updates clinic policies & procedures; Assures equipment working order/certifications current

Name	Title	Telephone Number
Primary		
Backup		

Kansas Immunization Program
1000 SW Jackson Ste 075
Topeka, KS 66612-1274
Phone 785-296-59592; Fax 785-296-6510

REV: 2011 Oct

Contact Information: Selected Vaccine Manufacturers & Distributors

Manufacturer/Website	Phone Number	Products
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm www.cdc.gov/laboratory/drugsevice/index.html	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals www.biotestpharma.com/products/nabiHB.html	800-458-4244	HBIG
Novartis Vaccines www.novartisvaccines.com/us/index.shtml	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributor for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807	HBIG, IGIM, RIG, TIG

February 2012

Vaccine Refrigerator Setup

Storing Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Refrigerate all vaccines except MMRV, Varicella, and Zoster.

Refrigerator in a Combination Unit

Usable space is limited (inside dashed lines).

The diagram shows a refrigerator with several shelves. A dashed blue line indicates the usable space. On the shelves, there are boxes for 'Dtap', 'IPV', 'VFC Vaccine', 'PCV', 'Rota', 'Hep A1', 'Hep B1', 'VFC Vaccine', 'MPV/MC', 'Tdap', 'HPV', 'Flu', and 'Privately purchased vaccine'. A temperature gauge shows 40°F. The door is open, showing drawers and a shelf with water bottles. Callouts include: 'Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.', 'Group vaccines by pediatric, adolescent, and adult types.', 'Separate the VFC vaccine supply from privately purchased vaccine.', 'Keep baskets 2-3 inches from walls and other baskets.', 'Keep vaccines in their original boxes until you are ready to use them.', 'Store only vaccine and other medication in vaccine storage units.', 'Keep vaccines with shorter expiration dates to front of shelf. If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program. (Boxes: Expires in 9 months, Expires in 3 months)', 'Keep temperatures between 35°F to 46°F. Aim for 40°F. Below 35°F is too cold! Call VFC. Above 46°F is too warm! Call VFC.', 'Keep vaccine away from all cold air vents. The vents blow in very cold air from the freezer which can damage vaccines.', 'No food in refrigerator.', 'No vaccine in doors.', 'No vaccine in solid plastic trays or containers.', 'No vaccine in drawers or on floor of refrigerator.'

If you have any problems with your refrigerator, keep the refrigerator door shut and notify the Kansas VFC Program.

VFC Program Office (785) 296-5591

Kansas Department of Health & Environment

www.kdheks.gov/immunize

Courtesy of the California Department of Health, Immunization Branch

Vaccine Freezer Setup

Preparing for Vaccine Storage

- 1** Put cold packs in areas where vaccines should not be stored, including the freezer door and on the top shelf of the freezer.



Two thermometers are needed to ensure accurate temperatures. Many practices use a digital thermometer as the primary thermometer and a liquid-filled or dial thermometer as the back-up.

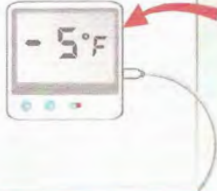


In a stand-alone freezer, place the digital thermometer probe and the back-up thermometer in the center of the freezer, next to the vaccine.



In a combination unit freezer, place the probe of the digital thermometer and the back-up thermometer in the center of the freezer floor.

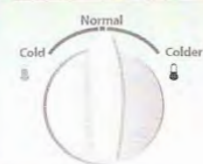
- 3** Attach the display of the digital thermometer to the outside of refrigerator, either on the door or on the side.



- 4** Plug in the freezer. Secure with plug guard/cover. Post "Do Not Unplug" sign.



- 5** Set the freezer temperature. If the freezer has a thermostat, set it at -5°F.



If it has a dial with a range of numbers, set it in the middle. The next morning, check the temperature and adjust it until it stabilizes below 0°F.

- 6** Once the temperature has stabilized, start recording temperatures on the temperature log twice a day.

Do not store vaccines in the freezer until the temperature stays below 0°F for 3–5 days.



Temperature Log for Vaccines (Fahrenheit)

VFC PIN #: _____

Month: _____

Year: _____

Days 1-15

Place an "X" in the box that corresponds with the temperature. The hashed zones represent unacceptable temperature ranges. If the temperature recorded in the this zone: 1. Store the vaccine order proper conditions as quickly as possible; 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected; 3. Call the Kansas Immunization Program at 785-296-5591 for further assistance; 4. Document the action taken in the section provided below.

Rev 8-24-04

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time															
°F Temp															
>49°															
48°															
47°															
46°															
45°															
44°															
43°															
42°															
41°															
40°															
39°															
38°															
37°															
36°															
35°															
34°															
33°															
32°															
31°															
30°															
29°															
<28°															
>8°															
7°															
6°															
5°															
4°															
<3°															
Staff Initials															

Take Immediate Action if Temperature is in the Shaded Area!

Vaccine Storage Troubleshooting Report (If additional space needed, attach documentation.)

Date	Time	Unit Temp	Problem	Action Taken	Results	Initials

Kansas Immunization Program • 1000 SW Jackson, Suite 210, Topeka, KS 66612-1274 • Phone 785-296-5591 • Fax 785-296-6510 • www.kdhe.state.ks.us/immunize

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current _____ max. _____ min. _____
2. Temperature of freezer: current _____ max. _____ min. _____
3. Air temperature of room where refrigerator is located: _____
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

*Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____

Manufacturers

- Crucell Vaccines Inc. (800) 533-5899
- CSL Biotherapies, Inc. (888) 435-8633
- GlaxoSmithKline (888) 825-5249
- MedImmune, Inc. (877) 633-4411
- Merck & Co., Inc. (800) 672-6372
- Novartis Vaccines (800) 244-7668
- Pfizer Inc. (800) 438-1985
- sanofi pasteur (800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

Adopted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

SAMPLE

Vaccine emergency Management Plan

Your practice is responsible for developing and implementing a vaccine emergency management plan. Power outages and natural disasters sometimes result in vaccine being allowed to warm above recommended temperatures. Your office should develop an emergency/disaster plan that will keep your vaccine safe and stored at the recommended temperatures in the event of an extended power outage. **IMPORTANT:** If the power outage is due to a weather emergency or natural disaster, the KS Dept of Health & Environment (KDHE) will replace your stock. If the VFC vaccine is spoiled/wasted due to non-weather related power outages or human error (examples: storage unit door left open or ajar, the unit being unplugged) your facility is responsible for the spoiled/wasted vaccine. You may contact your insurance company to determine whether they will subrogate the cost of the spoiled/wasted vaccine.

In the event of a power outage the following steps should be followed:

1. Determine the cause of the power outage; mechanical failure of the unit, circuit breaker, etc.
2. Determine duration of power outage.
3. Take inventory of VFC vaccine, including lot numbers and expiration dates.
4. Document the current temperature of the failed vaccine storage unit.*
 - a. Refrigerator temperature – must be between 36 F and 46 F (2 C and 8 C).
 - b. Freezer temperature – must be +5 F (minus 15 C) or colder.

IMPORTANT: If temperatures are not within the specified range, the vaccine should be placed back in recommended storage, but clearly separated from the undamaged supply. Contact the VFC office at (785) 296-5591. **Do not use the vaccine** until a VFC representative at the KDHE has been contacted for instructions on how to proceed. Depending on manufacturer specifications, there is a possibility that the vaccine is viable. If the VFC representative determines that your VFC vaccine is spoiled/wasted, return VFC vaccine (including partial vials) to the KDHE Warehouse at 1000 SW Jackson St, Suite 210, Topeka KS 66612-1274. **Do not discard spoiled/wasted VFC vaccine.**

Plan for Emergency Storage of Vaccine

1. Contact your practice's designated emergency personnel.
2. Before transporting vaccine, call emergency vaccine storage site to ensure power is maintained. (Possible emergency storage sites for vaccines: local hospitals, 24-hour pharmacies, or other medical practices).
3. Utilize insulated coolers, ice packs and dry ice (for Varicella vaccine only) to ensure cold chain procedures for transport to emergency storage facility.

Emergency Personnel Contacts

Name	Title	Home Phone	Cellular	Pager

Emergency Vaccine Storage Site

Facility Name	Address	Phone #	Contact Person

Name of Power Company	Phone Number of Power Company

All staff, including the custodial and security guard when applicable, should receive a copy of this plan in writing and be required to review the plan. All staff should know the standard procedure to follow and where/how the individual vaccine are to be stored.

NOTE: Your VFC representative will ask for a copy of the Vaccine Emergency Management Plan during site visits.

THE STANDARDS FOR PEDIATRIC IMMUNIZATION PRACTICE

Does your child's health care provider meet the Standards?

In May 1992, responding to a recent resurgence of measles, the U.S. Public Health Service and a diverse group of medical and public health experts established the Standards for Pediatric Immunization Practices. These Standards, which were approved by the U.S. Public Health Service and endorsed by the American Academy of Pediatrics, represent the most desirable practices for all health care providers and [immunization programs](#).

[While addressed to health professionals, the Standards provide the public with guidelines on what should be expected of the providers and programs responsible for their child's immunization care. And while the language published in 1992 applies to childhood vaccinations, much of it applies to adult immunizations as well. The full text follows, with an explanation of each standard, as adapted from the National Vaccine Advisory Committee's \(NVAC's\) discussions of the Standards.](#) ⁽¹⁾

STANDARDS FOR PEDIATRIC IMMUNIZATION PRACTICES

Preamble

Ideally, immunizations should be given as part of comprehensive child health care. This is the ultimate goal toward which the nation must strive if all of America's children are to benefit from the best primary [disease prevention our health care system has to offer](#).

[Overall improvement in our primary care delivery system requires intensive effort and will take time. However, we should not wait for changes in this system before providing immunizations more effectively to our children. Current health care policies and practices in all settings result in the failure to deliver vaccines on schedule to many of our vulnerable preschool-aged children. This failure is due primarily to barriers that impeded vaccine delivery and to missed opportunities during clinic visits. Changes in policies and practices can immediately improve coverage. The present system should be geared to "user-friendly," family-centered, culturally sensitive, and comprehensive primary health care that can provide rapid, efficient, and consumer-oriented services to the users, i.e., children and their parents. The failure to do so is evidenced by the recent resurgence of measles and measles-related childhood mortality, which may be an omen of other vaccine-preventable disease outbreaks.](#)

[Present childhood immunization practices must be changed if we wish to protect the nation's children and immunize 90% of two-year-olds by the year 2000.](#)

The following standards for pediatric immunization practices address these issues. These standards are recommended for use by all health professionals in the public and private sector who administer vaccines to or manage immunization services for infants and children. These Standards represent the most desirable immunization practices which health providers should strive to achieve to the extent possible. By adopting these Standards, providers can begin to enhance and change their own policies and practices. While not all providers will have the funds necessary to implement the Standards immediately, those providers and programs lacking the resources to implement the Standards fully should find them a useful tool in better delineating immunization needs and in obtaining additional resources in the future in order to achieve the Healthy People 2000 immunization objective.

Standard 1:

Immunization services are readily available.

By readily available, NVAC meant that the times immunization services are provided should be in keeping with the schedules of today's working parents, as well as the needs of parents who are at home full- or part-time. NVAC suggested non-traditional times, such as weekends, evenings, early mornings, and lunch-hours, as possibilities. NVAC also suggested integrating immunization services into days and hours when other child health services, such as the Special Supplemental Food Program for Women, Infants, and Children (WIC) are offered. NVAC also recommended that providers should keep an adequate stock of vaccines on hand, to prevent missed immunizations or the need for return visits.

Standard 2:

No barriers or unnecessary prerequisites to the receipt of vaccines exist.

NVAC viewed "by appointment only" systems as barriers to immunization in both public and private settings and suggested walk-in services with waiting times of no more than 30 minutes. NVAC suggested that such services should be provided in conjunction with rapid and efficient screening (to assess the child's current health and vaccination status, for example) and should not be contingent on receiving other comprehensive health services. NVAC determined that, unless a child has symptoms of illness, or the visit is a combined-purpose visit, a physical examination is not required at the time of an immunization. It is sufficient for the provider to observe the child's general state of health, ask the parent or guardian if the child is well, and question the parent or guardian about possible contraindications (reasons why the child should not be immunized). Since every child needs consistent health care, parents who bring their child for "walk-in" immunization services should be counseled about the need for a personal primary care provider and should be given a referral to such a provider. In public clinics, immunizations should be provided according to a schedule (standing orders), rather than

depending on individual written orders or referrals. This approach sidesteps the possibility of records being misplaced or immunization anniversaries being overlooked.

Standard 3:

Immunization services are available free or for a minimal fee.

No child should miss immunizations because the parents cannot afford the fee. For this reason, public clinics holding federal contracts for provision of immunizations must post a sign indicating that no one will be denied immunization services because of inability to pay. NVAC recommended that fees in both the public and the private sector should be reasonable.

Standard 4:

Providers utilize all clinical encounters to screen and, when indicated, immunize children.

Every health care worker who sees your child should be alert to your child's immunization status, even in an emergency room setting or the office of a specialist. If the immunizations are not up-to-date, immunization should be made available to your child during that visit or you should be referred back to the primary provider for immunization services.

Standard 5:

Providers educate parents and guardians about immunization in general terms.

NVAC raised concerns not only about the need for information, but also that information should be presented in terms you can understand, including in another language, if necessary. The provider should discuss with you the reasons why immunizations are so important, the diseases they prevent, the recommended immunization schedules, and why it's important for the immunizations to be given at the right ages. Also, your provider should instruct you to bring your child's immunization record to each visit, a step that will prevent both missed immunizations and unnecessary immunizations. You should have an opportunity to discuss questions and raise any concerns, and your provider should have materials that you can take home to read and refresh your understanding of what was said.

Standard 6:

Providers question parents or guardians about contraindications and, before immunizing a child, inform them in specific terms about the risks and benefits of the immunizations their child is to receive.

According to NVAC, you should be asked questions to determine (1) whether your child has ever had an adverse event in connection with an immunization, and (2) whether your child has any conditions or circumstances that indicate that immunization should be

withheld or delayed (for example, "Has your child had any fever in the past few days?"). You have a right to know about the benefits as well as the risks of vaccines. For this reason, the U.S. federal government requires both public and private health-care providers to give you printed materials, called Vaccine Information Statements, regarding measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), and polio vaccinations, when your child will be having any of these. Furthermore, your health-care provider should review these statements with you. Another type of printed material, called Important Information Statements, is required in public health clinics, and recommended in private settings, to inform you regarding other vaccinations, such as hepatitis B or Haemophilus influenzae type b. All of these materials should be current and available in appropriate languages. Your provider should also ask you if you have read the materials and whether you have any questions about the information you have been given.

Standard 7:

Providers follow only true contraindications.

Your provider should exercise informed, good judgment about what constitutes a medically sound reason for withholding an immunization, using the guidelines published by the Advisory Committee on Immunization Practices, the Committee on Infectious Diseases of the American Academy of Pediatrics, and the American Academy of Family Physicians.

Standard 8:

Providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit.

Available evidence suggests that simultaneous administration of childhood immunizations is safe and effective. Measles, mumps, rubella vaccine should always be used in combination form for childhood immunizations. Simultaneous administration or combined-form vaccines reduce the number of visits or shots that are needed and help to ensure that your child completes all needed vaccinations.

Standard 9:

Providers use accurate and complete recording procedures.

This standard specifies the orderly approach that should be taken to ensure accurate record-keeping, so that needed vaccinations will not be missed and unnecessary vaccinations will not be given. Immunization providers are required by law to record what vaccine was given, the date the vaccine was given (month, day, year), the name of the manufacturer of the vaccine, the lot number, the signature and title of the person who gave the vaccine, and the address where the vaccine was given. NVAC believes that in addition, the parent or guardian should be given a permanent record to keep and carry to office visits for updates. If this record is lost, a replacement with complete immunization

data should be provided. Providers should verify vaccination histories from previous providers whenever possible, and if the provider of an immunization is not the primary care physician, a report of vaccines given should be sent to the primary care provider.

Standard 10:

Providers co-schedule immunization appointments in conjunction with appointments for other child health services.

This standard recommends efficient use of the parent's and child's time, as well as an opportunity to provide immunizations that might otherwise be missed.

Standard 11:

Providers report adverse events following immunization promptly, accurately, and completely.

You, as a parent, should be encouraged to report any adverse events that are or appear to be associated with a vaccination. In turn, your health-care provider should record the event fully in the medical record and promptly report any such events that are clinically significant to the national Vaccine Adverse Event Reporting System ([VAERS](#)), [regardless of whether the event is believed to be related to the vaccine. The toll-free telephone number for VAERS is 1-800-822-7967.^{\(2\)}](#)

Standard 12:

Providers operate a tracking system.

Your health-care provider is responsible for keeping accurate, up-to-date records of your child's immunizations and for alerting you when immunizations are due. Computer systems make this easier, but providers who have not converted their records to computer storage should maintain a manual system. Children who are at high risk for not completing their immunization series should be given special attention in the tracking system.

Standard 13:

Providers adhere to appropriate procedures for vaccine management.

To keep their potency, vaccines must be handled and stored appropriately, according to the directions in the manufacturer's package inserts. A good sign in any medical office is that one qualified individual is charged with responsibility for monitoring the vaccine supplies: how many are on hand, where they are stored, how they are handled (e.g., are they returned to the refrigerator promptly?), and the expiration dates that are stamped on the bottles.

Standard 14:

Providers conduct semi-annual audits to assess immunization coverage levels

and to review immunization records in the patient populations they serve.

Audits are an essential and routine measure in any type of health care. Hospitals audit how many beds are in use in a given period, the type and number of surgical procedures performed, how many patients died while in the hospital and why, the types of medications prescribed, and the charges for services. Clinics perform similar audits. Individual practitioners may be less inclined to do in-depth audits, but a random sample of records can reveal the percent of children who are up-to-date by their second birthday, identify missed opportunities for simultaneous immunization, and assess the quality of the records that are being kept. These are vital steps to assure quality care for your child. How do you know if your provider performs such audits? Ask the office nurse.

Standard 15:

Providers maintain up-to-date, easily retrievable medical protocols at all locations where vaccines are administered.

A medical protocol is a detailed description of how a procedure will be done. Today's medical technology is changing at unprecedented speed, so health-care providers cannot rely entirely on memory or previous experience for how to use medical equipment or medications. They must have technical information at hand, either in a computer database or in printed "handbook" form that can be used by both experienced and new staff. If you see your physician, nurse, or pharmacist checking for a dosage, the name of a medication, or other information, interpret it as a sign that this health professional is committed to accuracy, safety, and state-of-the-art care.

Standard 16:

Providers operate with patient-oriented and community-based approaches.

Health-care workers spend the majority of their days indoors, working long and intensely focused days. Sometimes they become so attached to their routines that any suggestion that things should be done differently is viewed as an affront. Nevertheless, if your provider is not asking you if things are going well, don't hesitate to speak up. If you are finding it difficult to bring your child in during the day for immunizations, say so. If the waits are so long that your child is becoming fussy and you are on the verge of walking out, your provider needs to know this. Under this standard, providers in the public sector are especially obligated to look to the community to be sure that their services are reaching everyone, not just the people who come in routinely. They should be using a variety of methods to inform the public about immunizations and should be publicizing the places and times that these are available.

Standard 17:

Vaccines are administered by properly trained individuals.

This does not mean that only a physician or nurse should administer vaccinations. In

fact, specifying so may create barriers to immunization. In emergency circumstances--for example, after a natural disaster--the need for typhoid or other immunizations may suddenly be in the thousands per day, and available medical personnel would not be able to meet this need. In the fall, the demand for flu shots can be very high, overwhelming normal office routines and resulting in long, tedious waits. In low-income neighborhoods, the demand for no-cost publicly funded immunizations may be high. The tendency for meeting these needs today is to use non-traditional sites, even grocery stores, and to use non-traditional providers to administer vaccinations. In many states, pharmacists can routinely give immunizations. Few people would think of their dentist as an immunization provider, but why not? In each of these cases, immunizations can be safe as long as the people giving the vaccines have been appropriately trained and all other protocols, such as using sterile methods and keeping accurate records, are kept.

Standard 18:

Providers receive ongoing education and training on current immunization recommendations.

Vaccines, immunization techniques, and vaccination schedules change periodically. For example, the recommended method of administering polio vaccine was recently changed from oral polio vaccine to a series of injections using the inactivated form of the vaccine. The change is important because it establishes a safer method. Your health-care provider should be up-to-date on this and other changes in immunization recommendations.

Whom to call if you have specific vaccine safety questions

For additional information on your vaccine safety questions, call:

CDC/National Immunization Program Resource Center

1-800-232-2522 (English)

1-800-232-0233 (Spanish)

Footnotes

1. National Immunization Program. Standards for Pediatric Immunization Practices [monograph]. 7th printing. Washington, DC: Department of Health and Human Services, United States Public Health Service, Centers for Disease Control and Prevention, February 1996.

2. Food and Drug Administration. Vaccine adverse event reporting system [brochure]. Washington, DC: FDA, no date.

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Resources / Website Links

AAP: www.aap.org

pediatrics.aappublications.org/content/122/4/718.full.html

CDC: www.cdc.gov

www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html

KDHE: www.kdheks.gov

Vaccine Hesitancy

WHY ARE PARENTS REFUSING VACCINES?

Vaccines are one of the most important public health achievements and save countless lives of children each year. Despite this, in a recent survey 85% of pediatricians have had a parent refuse a recommended vaccine in the previous year. So why are providers seeing an increase in parents questioning having their children receive the recommended immunizations? A number of factors are playing a role.

- For one thing the success of vaccines has made these preventable diseases almost invisible to the public. A look at the top ten child health concerns in the public's mind and infectious diseases are nowhere on the list. Studies show that when epidemics occur, immunization rates increase, and then when the epidemic abates the immunization rates start to drift downward again.
- Another factor is the changes we are experiencing in the health care system. The public no longer has the faith in medicine that it had and has come to realize that medicine does have limitations. As a result complementary and alternative medicines are put on equal footing despite a lack of scientific evidence of efficacy. Consumerism has become an important component with the resultant questioning of provider recommendations. This in itself would not be harmful if patients were able to get information from reliable sources but this is often is not the case. Too often parents are getting misinformation on the risks of vaccines from internet sites not based on science or worse yet from celebrities with personal agendas.
- Finally the media with the now continuous exposure distorts events and will misinterpret scientific research. All of these factors have resulted in providers now having to justify and convince parents on the need to immunize their children.

DEMOGRAPHICS

With the recent increase in parents that are questioning immunizations and the recommended schedules a number of studies have looked at parents who choose not vaccinate their children. While providers see many more parents hesitant about having their children receiving all or some of the recommended immunizations the number of parents who actually refuse to vaccinate their children is still small. Overall in this country < 1% of the parents refuse all immunizations. It is very unlikely these parents will change their minds on immunizations and providers should understand that it may be impossible to convince this group. Approximately 30% of the parents though are what is called "vaccine hesitant." They may have concerns about certain vaccines or schedules and they are interested in receiving more information. It is this group that providers have a chance to convince about the importance of vaccines and the need to receive the immunizations. Studies that have looked at vaccine hesitant parents find that it is the health care provider that has the most influence on these parents decision making.

Vaccine hesitant parents tend to be white, non-Hispanic, married, slightly older, and with higher salaries. They have a higher rate of college education. This seems ironic in view of

the tremendous scientific evidence in support of vaccines. But scientific reasoning loses importance when emotions become involved and this has become a very emotional issue for so many of these parents. The main emotion involved is **fear**. Fear that vaccines are unsafe, will overload the immune system, or will cause the disease itself. Providers need to know specifically what are the parental concerns and fears if they are to help these parents make informed decisions.

For more information on vaccine hesitant parents we suggest the following sites.
pediatrics.aappublications.org/content/122/4/718.full.html
www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html

GENERAL TIPS ON SPEAKING TO PARENTS

The most important thing you can do as a provider when discussing vaccines is to **LISTEN** to the parents. Implicit in this is that the provider will need to **TAKE TIME** during the visit to hear the parents concerns. Let them talk **WITHOUT INTERRUPTING**. It is important for providers to **NOT BE OFFENDED** by the questions. Remember this is emotional topic for them and the main emotion at play is fear - concerning the safety of their child. Therefore concerns that seem irrational to providers may be very rational to parents. Nothing will do more to gain parents trust with a provider than knowing they can freely ask questions and the provider will hear them out **WITHOUT BEING JUDGMENTAL**. Being **HONEST** about possible adverse effects along without describing the benefits of immunizations further enhances their trust in the provider. This can provide a lead into **CORRECTING MISCONCEPTIONS** about vaccines. It also gives the provider an opportunity to provide good websites and **OTHER SOURCES OF INFORMATION**. Sometimes too much science can turn parents off so personal **ANECDOTES** especially concerning your own children and grandchildren receiving immunizations can be helpful. Above all speak to parents in **SIMPLE, STRAIGHT FORWARD LANGUAGE** without medical jargon. Lastly, **RESPECT PARENTAL AUTHORITY** in their decision making.

TEN TIPS FOR SPEAKING TO VACCINE HESITANT PARENTS

- LISTEN
- TAKE TIME
- WELCOME QUESTIONS
- DON'T INTERRUPT
- DON'T BE OFFENDED
- DON'T BE JUDGMENTAL
- BE HONEST
- CORRECT MISCONCEPTIONS/PROVIDE INFORMATION SITES
- SPEAK WITHOUT USING MEDICAL JARGON
- RESPECT PARENTAL AUTHORITY

TALKING POINTS ON SPECIFIC VACCINE QUESTIONS

Autism

Probably the biggest fear of parents is that vaccines cause autism. This first came to the public concern following a study published in the Lancet purporting a link to MMR vaccine (see below) and autism. Numerous celebrities came into the picture declaring autism was caused by vaccines. The media spotlights of course gave these individuals much air time. The Lancet study has since been refuted after it was found out the main author falsified data and was receiving financial incentives from attorneys representing parents of children suing vaccine manufacturers. This information didn't come to light until much damage had been done. Numerous well controlled studies have been done since this original article came out and none of these studies show a link between vaccines and autism. Still the misinformation on vaccines and autism persists. Some key points:

- Autism is a genetic disorder that science hasn't determined a cause.
- Interestingly vaccines have been studied more than anything else in terms of a possible link and studies have continued to show that there is no link between the two.
- Studies looking at mercury which was used as a vaccine preservative have shown no association (see below).
- In 2004, the Institute of Medicine (IOM) reported on a large study looking at Autism and Vaccines and came to the conclusion there was no link.

MMR Vaccine

In 1998, Dr. Andrew Wakefield published a study in the Lancet that linked the MMR vaccine to Autism. The study has since been discredited and Dr. Wakefield had his license stripped as a result. Some key points:

- The original article has been discredited and no articles since have found a connection.
- The IOM has examined this issue and has not found a link.
- The National Vaccine Compensation Program in three separate rulings has declared there is no link.
- Measles is not a benign illness with a rate of encephalitis 1-2/1000 and death also 1-2/1000.
- Mumps also can cause significant problems causing orchitis in 4/10 adult males with the infection and meningitis in 4-6%.

Thimerosal

Another claim by vaccine opponents has been that the small amount of mercury used as a preservative in some vaccines was the cause of autism. As a result of concerns, despite a lack of evidence of any actual link, thimerosal was removed from children's vaccines in 2001. The result has been that since 2001 autism rates have actually increased. Some key points:

- With the exception of some flu vaccines mercury is no longer used as a preservative.
- Autism rates have continued to rise despite the removal of mercury.
- The mercury used in preservatives was ethyl mercury, rather than methyl mercury, which is found in nature. Ethyl mercury is less likely to cause harm.
- A large study of over 500,000 children done by the CDC and the Danish Medical Research Council showed no association between thimerosal and autism.

Too Many Shots

One of the newest attacks on vaccine safety purports that children are getting “too many shots” and their immune systems are unable to handle this overload of antigens. Again science doesn't support this claim. Key points:

- The average child is exposed to between 2,000-6,000 different antigens each day normally.
- Small pox vaccine alone had 200 different antigens and in the current vaccine schedules the total number of antigens of ALL vaccines in the first two years of life is slightly greater than 200 (211 to be exact).
- In 1980, the number of antigens from fewer vaccines was over 3,000. So today children are actually being exposed to fewer antigens with more vaccines.
- The January 2013, IOM issued a report concerning the current immunization schedule and the number of antigens a child is exposed to. The report stated: “In this most comprehensive examination of the immunization schedule to date, the IOM committee uncovered no evidence of major safety concerns associated with adherence to the childhood immunization schedule...”

Alternative Schedules

Concern about exposure to too many antigens as mentioned above has led some parents to request “alternative vaccine schedules.” These schedules spread out the receipt of vaccines over a much longer time span. This soon gained popularity after a pediatrician, Dr. Bob Sears, published a book advocating for an alternative schedule (see Dr. Paul Offit’s article refuting the recommendations in this book). Once again science doesn’t support these claims, but as we have seen when dealing with emotions, facts take a back seat. Key points:

- Based on misinformation about the immune system (see information above under “Too Many Shots”).
- The IOM in January 2013 published a report looking at the current recommended schedule and concluded no safety issues are associated with the schedule.
- There is no scientific evidence the alternative schedules offer a benefit.
- An alternative vaccine schedule means coming into the office for more visits and may actually put more stress on the child.

Natural Immunity is Better

Some parents believe that “natural immunity” is better for the child than immunity from vaccines. While natural immunity may last longer there is no evidence that it is somehow better. Experience with vaccines has shown that while periodic booster shots may be needed vaccines have proven to be effective in decreasing the disease burden.

Not Serious Diseases

This is somewhat related to the above argument. Most parents have not seen the diseases vaccines prevent. As a result they rely on anecdotes from relatives that “they had the measles and it wasn’t so bad.” These diseases are serious and in many instances deadly. The following information has been gleaned from the CDC’s Pink Book and the AAP’s Red Book. This information can be used when talking to parents about the seriousness of the diseases.

Measles

- 1/20 will get pneumonia
- 1/10 will get an ear infection
- 1/1000 will get encephalitis
- 2/1000 will die
- Kills 1 million children each year worldwide
- Symptoms of high fever of 103-105 are common
- Will require isolation for at least four days after the onset of the rash

Chickenpox

- Hospitalizations two-three per 1000 cases
- One death per 60,000 cases
- Complications include serious bacterial skin infections, pneumonia, dehydration, encephalitis
- Will require isolation for at least five days after onset of rash

Pertussis

- Paroxysmal cough can last up to six weeks
- Greater than 60% of children less than six months of age with pertussis will be hospitalized
- 1/10 children less than six months of age will develop pneumonia
- 1/100 children less than two months of age with pertussis will die
- Children with pertussis should be excluded from school and daycare until they have completed a five day course of therapy.

Haemophilus Influenzae type B (HIB)

- Complications include pneumonia, meningitis, epiglottitis, cellulitis
- 2-5/100 children with meningitis die despite appropriate antibiotic treatment
- 20% of children with meningitis develop permanent hearing loss

Pneumococcus

- Complications include pneumonia, meningitis, blood stream infection, ear infection
- 5/100 children with meningitis will die despite antibiotic treatment
- 1/100 children with blood stream infections die despite antibiotics

We have included a number of handouts that can be given to parents on these concerns. In addition, the following web sites can be passed on to parents for vaccine information:

AAP: www.aap.org

CDC: www.cdc.gov

KDHE: kdheks.gov

WHEN PARENTS REFUSE IMMUNIZATIONS

Despite our best efforts some parents are going to refuse to vaccinate their children. They may refuse all immunizations or only certain ones. It is highly recommended that you carefully document your discussion and their refusal. We have provided a sample form that was produced by the AAP for this purpose. In addition we have included a handout from the CDC that can be given along with VIS material. It is recommended that this topic be revisited at subsequent preventative care visits and you again provide the information and document this discussion. The decision to continue to keep these patients in your practice is a personal one. While the American Academy of Pediatrics recommends providers continue to see them in their offices they understand this is a decision that can only be made by the provider.

Facts About Childhood Vaccine Ingredients

Groups challenging the safety of immunizations have raised allegations that certain Food and Drug Administration (FDA) approved ingredients in vaccines are “toxins.” In many instances, these allegations are completely incorrect. In others, the claims are taken out of context.

Toxins are typically defined by dose or level of exposure. Even something as benign and essential as water can be toxic if consumed in large quantities. Another example is chlorine, which can be a highly toxic chemical and was used as a weapon in World War I. Yet small amounts of chlorine are present in the tap water we drink every day. Without that chlorine, tap water would not be safe to drink.

Vaccines are extensively tested and highly regulated products. Prior to their approval by FDA for use in the market, vaccines are required to undergo significant clinical trials. These trials test the safety of all components in a vaccine. Tests are first conducted in adults and then in older children and only when safety is demonstrated in these populations will the product then be tested in young children.

Vaccine trials are rigorous. As examples, the recently approved vaccines for rotavirus had 70,000 children in clinical trials and the pneumococcal conjugate vaccine had close to 40,000 children.

New vaccines are evaluated for their effects in the presence of existing vaccines. Vaccine trials are designed to test whether a given vaccine is safe and effective even when given in conjunction with other recommended vaccines. To withhold existing lifesaving vaccines from a group participating in a clinical trial would be unethical as it would leave that group of children exposed to serious infectious diseases.

Vaccines are made by weakening a natural virus or bacteria, by using a portion of the virus or bacteria, or by using an empty virus shell. The weakened product is designed to stimulate an immune response to a disease without triggering symptoms of a true infection. In addition to the “active” ingredients, vaccines may contain small amounts of other ingredients, some of which are naturally occurring in the environment and find their way into our bodies each day through a variety of sources.

Below is factual information related to the myths perpetuated about vaccine ingredients:

Mercury

Preservatives prevent bacterial and fungal contamination from developing in vaccines prior to their administration and prevent contamination during complex manufacturing processes. Thimerosal, an ethylmercury-based preservative, was used in the United States from the

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1930s until 2001 to prevent contamination in some childhood vaccines. By 2001, thimerosal was no longer used as a preservative in children's vaccines. Today, the only vaccine with thimerosal as a preservative that a young child in the United States might encounter is influenza vaccine and that vaccine is also available in a preservative-free version. Organizations such as the World Health Organization, the Centers for Disease Control and Prevention, the FDA, the Institute of Medicine and various medical associations have already taken a position that the alleged link between thimerosal in vaccines and autism, or other neurological disorders, is unsupported by all credible scientific evidence.

Aluminum

Adjuvants enhance and stimulate the immune system's response to vaccines, making immunizations more effective. Without an adjuvant, patients could need to receive more shots in a vaccine series or face lower immunity and less protection from disease. The most common adjuvant in vaccines is aluminum, a natural element found in the environment that has been used safely in vaccines for 75 years. Aluminum is in food, water, infant formula and even breast milk.

Formaldehyde

Formaldehyde can be used as an antimicrobial. Formaldehyde effectively inactivates the organisms and biological substances used in vaccines. Formaldehyde is present in the environment and is a byproduct of metabolism so it is already present in the human body.

Addressing False Claims

Antifreeze

There is no antifreeze in vaccines. Polyethylene glycol, a chemical used in the purification of certain vaccines, may be confused with ethylene glycol, which is used in antifreeze but not in vaccines. Although their names are similar, these are two different chemicals. Polyethylene glycol is widely and safely used in many personal care products, such as skin creams and toothpaste.

Other Ingredients

Claims have been made that various substances used to support the growth of viruses used in vaccines are present in the final vaccine product. This is untrue and is akin to saying there are trees in apple juice just because the apples originated on trees. In the case of vaccines, viruses are grown initially in cell lines of various types. Then, the viruses are harvested and go through multiple processing and purification steps over months of time before the final product is ready for use.

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Below are facts about the specific allegations raised:

Aborted Human Fetus Cells

Vaccines do not contain human cells or tissue. Human cell lines are used in the early stages of production of some vaccines because viruses need a living cell in which to grow. These cell lines were derived from fetal tissue more than 40 years ago. The same two cell lines are reproduced and used repeatedly so that no new fetal tissue is required in the ongoing production of vaccines. As with all viral vaccines, multiple purification steps ensure that cells are not in the final vaccine product.

Chick Embryos

There are no chick embryos in childhood vaccines. Many influenza vaccines begin with viral growth in chicken eggs and then undergo multiple purification steps. Some residual egg proteins may be present in the final vaccine product. Chicken eggs and their proteins are routinely consumed as part of the human diet.

Monkey Kidneys

There are no monkey kidneys in vaccines. Monkey kidney tissue is used to support the growth of certain viruses for making vaccines; for example, it was used to support the growth of the weakened polio virus that went into the oral polio vaccine. Multiple purification steps ensure that no kidney cells are present in the final product.

Fetal Bovine Serum

When viruses are growing in cells, they need a source of nutritional ingredients. In some instances, fetal bovine serum is the source of these growth factors. Once the viruses are harvested, they undergo multiple processing and purification steps before the final product is released to the market.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$44.5 billion in 2007 in discovering and developing new medicines. Industry-wide research and investment reached a record \$58.8 billion in 2007.

PhRMA Internet Address: <http://www.phrma.org>

For information on stories of hope and survival, visit: <http://sharingmiracles.com/>

For information on how innovative medicines save lives, visit: <http://www.innovation.org>

For information on the Partnership for Prescription Assistance, visit: <http://www.pparx.org>

For information on the dangers of imported drugs, visit: <http://www.buysafedrugs.info>

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Q. How can parents sort out conflicting information about vaccines?

A. Decisions about vaccine safety must be based on well-controlled scientific studies.

Parents are often confronted with “scientific” information found on television, on the Internet, in magazines and in books that conflicts with information provided by healthcare professionals. But few parents have the background in microbiology, immunology, epidemiology and statistics to separate good scientific studies from poor studies. Parents and physicians benefit from the expert guidance of specialists with experience and training in these disciplines.

Committees of these experts are composed of scientists, clinicians and other caregivers who are as passionately devoted to our children's health as they are to their own children's health. They serve the Centers for Disease Control and Prevention (www.cdc.gov/vaccines), the American Academy of Pediatrics (www.aap.org) and the Infectious Diseases Society of America (www.nni.org), among other groups. These organizations provide excellent information to parents and healthcare professionals through their Web sites. Their task is to determine whether scientific studies are carefully performed, published in reputable journals and, most importantly, reproducible. Information that fails to meet these standards is viewed as unreliable.

When it comes to issues of vaccine safety, these groups have served us well. They were the first to figure out that intestinal blockage was a rare consequence of the first rotavirus vaccine, and the vaccine was quickly discontinued. And they recommended a change from the oral polio vaccine, which was a rare cause of paralysis, to the polio shot when it was clear that the risks of the oral polio vaccine outweighed its benefits.

These groups have also investigated possible relationships between vaccines and asthma, diabetes, multiple sclerosis, SIDS and autism. No studies have reliably established a causal link between vaccines and these diseases — if they did, the questioned vaccines would be withdrawn from use.

Q. Are vaccines still necessary?

A. Although several of the diseases that vaccines prevent have been dramatically reduced or eliminated, vaccines are still necessary:

- to prevent common infections

Some diseases are so common in this country that a choice not to get a vaccine is a choice to get infected. For example, choosing not to get the pertussis (whooping cough) vaccine is a choice to risk a serious and occasionally fatal infection.

- to prevent infections that could easily re-emerge

Some diseases in this country continue to occur at very low levels (for example, measles, mumps and *Haemophilus influenzae* type b, or Hib). If immunization rates in our schools or communities are low, outbreaks of these diseases are likely to occur. This is exactly what happened in the late 1980s and early 1990s when thousands of children were hospitalized with measles and more than 120 died. Children were much more likely to catch measles if they weren't vaccinated. Recent measles outbreaks in Europe also provide evidence of how quickly a disease can re-emerge.

- to prevent infections that are common in other parts of the world
- Although some diseases have been completely eliminated (polio) or virtually eliminated (diphtheria) from this country, they still occur commonly in other parts of the world. Children are paralyzed by polio in India and sickened by diphtheria in India and other countries in the southeastern region of Asia. Because there is a high rate of international travel, outbreaks of these diseases are only a plane ride away.

Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 12th Edition. Atkinson W, Wolfe S, Hamborsky J, eds. Washington, DC: Public Health Foundation; 2011.

Q. Do vaccines contain additives?

A. Many vaccines contain trace quantities of antibiotics or stabilizers.

Antibiotics are used during the manufacture of vaccines to prevent inadvertent contamination with bacteria or fungi. Trace quantities of antibiotics are present in some vaccines. However, the antibiotics contained in vaccines (neomycin, streptomycin or polymyxin B) are not those commonly given to children. Therefore, children with allergies to antibiotics such as penicillin, amoxicillin, sulfa, or cephalosporins can still get vaccines.

Gelatin is used to stabilize live viral vaccines and is also contained in many food products. People with known allergies to gelatin contained in foods may have severe allergic reactions to the gelatin contained in vaccines. However, this reaction is extremely rare.

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Q. Are vaccines safe?

A. Because vaccines are given to people who are not sick, they are held to the highest standards of safety. As a result, they are among the safest things we put into our bodies.

How does one define the word safe? If safe is defined as “free from any negative effects,” then vaccines aren't 100 percent safe. All vaccines have possible side effects. Most side effects are mild, such as fever, or tenderness and swelling where the shot is given. But some side effects from vaccines can be severe. For example, the pertussis vaccine is a very rare cause of persistent inconsolable crying, high fever or seizures with fever. Although these reactions do not cause permanent harm to the child, they can be quite frightening.

If vaccines cause side effects, wouldn't it be “safer” to just avoid them? Unfortunately, choosing to avoid vaccines is not a risk-free choice — it is a choice to take a different and much more serious risk. Discontinuing the pertussis vaccine in countries like Japan and England led to a tenfold increase in hospitalizations and deaths from pertussis. Recently, a decline in the number of children receiving measles vaccine in the United Kingdom and the United States led to an increase in measles hospitalizations.

When you consider the risk of vaccines and the risk of diseases, vaccines are the safer choice.

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Q. Do children get too many shots?

A. Newborns commonly manage many challenges to their immune systems at the same time.

Because some children could receive as many as 25 shots by the time they are 2 years old and as many as five shots in a single visit to the doctor, many parents wonder whether it is safe to give children so many vaccines.

Although the mother's womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune systems. From the moment of birth, thousands of different bacteria start to live on the surface of the skin and intestines. By quickly making immune responses to these bacteria, babies keep them from invading the bloodstream and causing serious diseases.

In fact, babies are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in the bodies. Therefore, vaccines given in the first two years of life are a raindrop in the ocean of what an infant's immune system successfully encounters and manages every day.

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Q. Is the amount of aluminum in vaccines safe?

A. Yes. All of us have aluminum in our bodies and most of us are able to process it effectively. The two main groups of people who cannot process aluminum effectively are severely premature infants who receive large quantities of aluminum in intravenous fluids and people who have long-term kidney failure and receive large quantities of aluminum, primarily in antacids. In both cases the kidneys are not working properly or at all and the people are exposed to large quantities of aluminum over a long period of time.

The amount of aluminum in vaccines given during the first six months of life is about 4 milligrams, or four-thousandths of a gram. A gram is about one-fifth of a teaspoon of water. In comparison, breast milk ingested during this period will contain about 10 milligrams of aluminum and infant formulas will contain about 40 milligrams. Soy-based formulas contain about 120 milligrams of aluminum.

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Q. Do vaccines cause autism?

A. Carefully performed studies clearly disprove the notion that vaccines cause autism.

Because the signs of autism may appear in the second year of life, at around the same time children receive certain vaccines, and because the cause of autism is unknown, some parents wondered whether vaccines might be at fault. These concerns focused on three hypotheses — autism was caused by the measles-mumps-rubella (MMR) vaccine, thimerosal, an ethylmercury-containing preservative used in vaccines, or receipt of too many vaccines too soon.

A large body of medical and scientific evidence now strongly refutes these notions. Multiple studies have found that vaccines do not cause autism. These studies included hundreds of thousands of children, occurred in multiple countries, were conducted by multiple investigators and were well controlled.

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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

Q. Does my child need to still get vaccines if I am breastfeeding?

A. Yes. The types of immunity conferred by breastfeeding and immunization are different. Specifically, the antibodies that develop after immunization are made by the baby's own immune system and, therefore, will remain in the form of immunologic memory; this is known as active immunity. In contrast, antibodies in breast milk were made by the maternal immune system, so they will provide short-term protection, but will not last more than a few weeks. These antibodies are usually not as diverse either, so the baby may be protected against some infections but remain susceptible to others. Immunity generated from breast milk is called passive immunity. Passive immunity was practiced historically when patients exposed to diphtheria were given antitoxin produced in horses; antitoxins to snake venoms are also an example of passive immunity.

Q. How can a "one-size-fits-all" approach to vaccines be OK for all children?

A. The recommended immunization schedule is not the same for all children.

In fact, recommendations for individual vaccines often vary based upon individual differences in current and long-term health status, allergies and age. Each vaccine recommendation, often characterized by a single line on the immunization schedule, is supported by about 25 to 40 additional pages of specific instructions for healthcare providers who administer vaccines. In addition, an approximately 60-page document titled "General Recommendations on Immunization" serves as the basis for all vaccine administration. The recommendations are updated as needed by the CDC and a comprehensive update is published every few years.

Q. What is the harm of separating, spacing out or withholding some vaccines?

A. Although the vaccine schedule can look intimidating, it is based upon the best scientific information available and is better tested for safety than any alternative schedules.

Experts review studies designed to determine whether the changes are safe in the context of the existing schedule. These are called concomitant-use studies.

Separating, spacing out or withholding vaccines causes concern because infants will be susceptible to diseases for longer periods of time. When a child should receive a vaccine is determined by balancing when the recipient is at highest risk of contracting the disease and when the vaccine will generate the best immune response.

Finally, changing the vaccine schedule requires additional doctor's visits. Research measuring cortisol, a hormone associated with stress, has determined that children do not experience more stress when receiving two shots as compared with one shot. Therefore, an increased number of visits for individual shots will mean an increase in the number of stressful situations for the child without benefit. In addition, there is an increased potential for administration errors, more time and travel needed for appointments, potentially increased costs and the possibility that the child will never get some vaccines

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Vaccines and Autism: What you should know

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Some parents are concerned that vaccines can cause autism. Their concerns center on three areas: the combination measles-mumps-rubella (MMR) vaccine; thimerosal, a mercury-containing preservative previously contained in several vaccines; and the notion that babies receive too many vaccines too soon.

Q. What are the symptoms of autism?

A. Symptoms of autism, which typically appear during the first few years of life, include difficulties with behavior, social skills and communication. Specifically, children with autism may have difficulty interacting socially with parents, siblings and other people; have difficulty with transitions and need routine; engage in repetitive behaviors such as hand flapping or rocking; display a preoccupation with activities or toys; and suffer a heightened sensitivity to noise and sounds. Autism spectrum disorders vary in the type and severity of the symptoms they cause, so two children with autism may not be affected in quite the same way.

Q. What causes autism?

A. The specific cause or causes of autism in all children are not known. But one thing is clear: Autism spectrum disorders are highly genetic. Researchers figured this out by studying twins. They found that when one identical twin had autism, the chance that the second twin had autism was greater than 90 percent. But when one fraternal twin had autism, the chance that the second twin had autism was less than 10 percent. Because identical twins have identical genes and fraternal twins don't, these studies proved the genetic basis of autism. More recently, researchers have successfully identified some of the specific genes that cause autism.

Some parents wonder whether environmental factors — defined as anything other than genetic factors — can cause autism. It's possible. For example, researchers found that thalidomide, a sedative, can cause autism if used during early pregnancy. Also, if pregnant women are infected with the rubella virus (German measles) during early pregnancy, their babies are more likely to have autism.

Q. Does the MMR vaccine cause autism?

A. No. In 1998, a British researcher named Andrew Wakefield raised the notion that the MMR vaccine might cause autism. In the medical journal *The Lancet*, he reported the stories of eight children who developed autism and intestinal problems soon after receiving the MMR vaccine. To determine whether Wakefield's suspicion was correct, researchers performed a series of studies comparing hundreds of thousands of children who had received the MMR vaccine with hundreds of thousands who had never received the vaccine. They found that the risk of autism was the same in both groups. The MMR vaccine didn't cause autism.

Some parents wary of the safety of the MMR vaccine stopped getting their children immunized. As immunization rates dropped, particularly in the United Kingdom and, to some extent, the United States, outbreaks of measles and mumps led to hospitalizations and deaths that could have been prevented.

Q. Does thimerosal cause autism?

A. No. Multiple studies have shown that thimerosal in vaccines does not cause autism. Thimerosal is a mercury-containing preservative that was used in vaccines to prevent contamination. In 1999, professional groups called for thimerosal to be removed from vaccines as a precaution. Unfortunately, the precipitous removal of thimerosal from all but some multidose preparations of influenza vaccine scared some parents. Clinicians were also confused by the recommendation.

Since the removal of thimerosal, several studies have been performed to determine whether thimerosal causes autism. Hundreds of thousands of children who received thimerosal-containing vaccines were compared to hundreds of thousands of children who received the same vaccines free of thimerosal. The results were clear: The risk of autism was the same in both groups; thimerosal in vaccines did not cause autism.

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Vaccines and Autism: What you should know

Q. Is autism caused by children receiving too many vaccines too soon?

A. Several facts make it very unlikely that babies are overwhelmed by too many vaccines given too early in life.

First, before they are licensed, new vaccines are always tested alone or in combination with existing vaccines. These studies determine whether new vaccines alter the safety and efficacy of existing vaccines and, conversely, whether existing vaccines affect the new vaccine. These studies, called concomitant use studies, are performed every time a new vaccine is added to the existing vaccination schedule.

Second, although the number of vaccines has increased dramatically during the past century, the number of immunological components in vaccines has actually decreased. One hundred years ago, children received just one vaccine, for smallpox. The smallpox vaccine contained about 200 immunological components. Today, with advances in protein purification and recombinant DNA technology, the 14 vaccines given to young children contain only about 150 immunological components.

Third, the immunological challenge from vaccines is minuscule compared to what babies typically encounter every day. The womb is sterile, containing no bacteria, viruses, parasites or fungi. But when babies leave the womb and enter the world, they are immediately colonized by trillions of bacteria that live on the linings of their nose, throat, skin and intestines. Each bacterium contains between 2,000 and 6,000 immunological components. And babies often make an immune response to these bacteria to prevent them from entering the bloodstream and causing harm. The challenge that vaccines present is tiny in comparison to that from the environment.

Fourth, children have an enormous capacity to respond to immunological challenges. Susumu Tonegawa, a molecular biologist who won a Nobel Prize for his work, showed that people have the capacity to make between 1 billion and 100 billion different types of antibodies. Given the number of immunological components contained in modern vaccines, a conservative estimate would be that babies have the capacity to respond to about 100,000 different vaccines at once. Although this sounds like a huge number, when you consider the number of challenges that babies face from bacteria in their environment, it's not.

Here's another way to understand the difference in scale between immunological challenges from vaccines and natural challenges from the environment. The quantity of bacteria that live on body surfaces is measured in grams (a gram is the weight of about one-fifth of a teaspoon of water). The quantity of immunological components contained in vaccines is measured in micrograms or nanograms (millionths or billionths of a gram).

Q. Are the studies showing that neither the MMR vaccine nor thimerosal causes autism sensitive enough to detect the problem in small numbers of children?

A. The studies showing that neither the MMR vaccine nor thimerosal causes autism, called epidemiological studies, are very sensitive. For example, epidemiological studies have shown that a rotavirus vaccine used between 1998 and 1999 in the United States caused intestinal blockage in one out of every 10,000 vaccine recipients; that measles vaccine caused a reduction in the number of cells needed to stop bleeding (platelets) in one out of every 25,000 recipients; and that an influenza (swine flu) vaccine used in the United States in 1976 caused a type of paralysis called Guillain-Barré syndrome in one out of every 100,000 recipients.

About one out of every 100 children in the United States is diagnosed with an autism spectrum disorder. Even if vaccines caused autism in only 1 percent of autistic children, the problem would have easily been detected by epidemiological studies.

Q. If I am concerned that vaccines cause autism, what is the harm in delaying or withholding vaccines for my baby?

A. A recent study by Michael Smith and Charles Woods found that children who were fully vaccinated in the first year of life were not more likely to develop autism than those whose parents had chosen to delay vaccines. Further, all of the evidence shows that vaccines don't cause autism, so delaying or withholding vaccines will not lessen the risk of autism; it will only increase the period of time during which children are at risk for vaccine-preventable diseases. Several of these diseases, like chickenpox, pertussis (whooping cough) and pneumococcus (which causes bloodstream infections, pneumonia and meningitis) are still fairly common. Delaying or withholding vaccines only increases the time during which children are at unnecessary risk for severe and occasionally fatal infections.

All of the evidence shows that vaccines don't cause autism, so delaying or withholding vaccines will not lessen the risk of autism; it will only increase the period of time during which children are at risk for vaccine-preventable diseases.

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Some parents are concerned that thimerosal, a mercury-containing preservative contained in the influenza vaccine, causes autism. However, a series of biological and epidemiological studies have shown this concern to be unfounded. Here is a summary of the evidence showing that, while some things do cause autism, mercury in vaccines isn't one of them.

All mercury isn't the same: methylmercury vs. ethylmercury

Mercury is a naturally occurring element found in the earth's crust, air, soil and water. Since the earth's formation, volcanic eruptions, weathering of rocks and burning of coal have caused mercury to be released into the environment. Once released, certain types of bacteria in the environment can change mercury to methylmercury. Methylmercury makes its way through the food chain in fish, animals and humans. At high levels, it can be toxic to people.

Thimerosal — a preservative still used in some versions of the influenza vaccine — contains a different form of mercury called ethylmercury. Studies comparing ethylmercury and methylmercury suggest that they are processed differently in the human body. Ethylmercury is broken down and excreted much more rapidly than methylmercury. Therefore, ethylmercury (the type of mercury in the influenza vaccine) is much less likely than methylmercury (the type of mercury in the environment) to accumulate in the body and cause harm.



Evidence that mercury doesn't cause autism

- In 1971, Iraq imported grain that had been fumigated with methylmercury. Farmers ate bread made from this grain. The result was one of the worst single-source mercury poisonings in history. Methylmercury in the grain caused the hospitalization of 6,500 Iraqis and killed 450. Pregnant women also ate the bread and delivered babies with epilepsy and mental retardation. But they didn't deliver babies with an increased risk of autism.
- Several large studies compared the risk of autism in children who received vaccines containing thimerosal to those who received vaccines without thimerosal. The studies were consistent, clear and reproducible — the incidence of autism was the same in both groups. Denmark, a country that abandoned thimerosal as a preservative in 1991, actually saw an increase in autism beginning several years later.
- Studies of the head size, speech patterns, vision, coordination and sensation of children poisoned by mercury show that the symptoms of mercury poisoning are different from the symptoms of autism.
- Methylmercury is found in low levels in water, infant formula and breast milk. Although it is clear that large quantities of mercury can damage the nervous system, there is no evidence that the small quantities contained in water, infant formula and breast milk do. An infant who is exclusively breast-fed will ingest more than twice the quantity of mercury than was ever contained in vaccines and 15 times the quantity of mercury contained in the influenza vaccine.

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Thimerosal: What you should know

What is known about the cause of autism?

- First, like cystic fibrosis or sickle cell disease, autism clearly has a genetic basis. Researchers found that when one identical twin had autism, the chance that the other twin had autism was about 90 percent; for fraternal twins, the chance was less than 10 percent.
- Second, although autism clearly has a genetic basis, environmental factors can also cause the disease. For example, children whose mothers took thalidomide during pregnancy had birth defects, including malformed ears and shortened limbs. But they also had a significantly greater incidence of autism than babies born to mothers who never took thalidomide. Thalidomide clearly caused autism, but only if mothers took it early in pregnancy. If mothers took thalidomide in the second or third trimester of pregnancy, their babies weren't at increased risk of autism.
- The thalidomide experience showed that there was a vulnerable time early in pregnancy when a drug could possibly cause autism. Echoes of the thalidomide story are found in babies infected with rubella virus. Babies born to mothers who suffered rubella early in their pregnancies develop birth defects involving the eyes, ears, brain and heart. They also are at greater risk of developing autism; but, as with thalidomide, only if the baby is exposed to rubella early during pregnancy. Babies don't develop autism if they are infected with the virus soon after birth. Taken together, these findings suggest that a virus or a drug can cause autism, and that there is a vulnerable time early during pregnancy when the baby is at risk. However, during the second or third trimester of pregnancy, or after the child is born, the window for environmental factors causing autism has apparently closed.
- Women in the United States also occasionally received mercury when they were pregnant. It happened when doctors found that the mother's blood type was not compatible with her baby's blood type. To prevent this blood mismatch from hurting the baby, mothers were given RhoGam, a product that contained thimerosal as a preservative. However, consistent with the observation in Iraq, babies exposed to thimerosal in RhoGam did not have a greater risk for autism than babies whose mothers never received RhoGam. Although thalidomide and rubella virus can cause autism in pregnancy, scientific evidence clearly indicates that mercury doesn't.

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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

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Q&A

VOLUME 2, SPRING 2012

Too Many Vaccines? What you should know

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Today, young children receive vaccines to protect them against 14 different diseases. Because some vaccines require more than one dose, children can receive as many as 26 inoculations by 2 years of age and up to five shots at one time. For this reason, some parents now ask their doctors to space out, separate or withhold vaccines. The concern that too many vaccines might overwhelm a baby's immune system is understandable, but the evidence that they don't is reassuring.

Q. What are the active components in vaccines?

A. Vaccines contain parts of viruses or bacteria that induce protective immune responses. These active ingredients are called immunological components.

Vaccines that protect against bacterial diseases are made from either inactivated bacterial proteins (e.g., diphtheria, tetanus and whooping cough [pertussis]) or bacterial sugars called polysaccharides (e.g., *Haemophilus influenzae* type b [Hib] and pneumococcus). Each of these bacterial proteins or polysaccharides is considered an immunological component, meaning that each evokes a distinct immune response.

Vaccines that protect against viral diseases (e.g., measles, mumps, rubella, polio, rotavirus, hepatitis A, hepatitis B, chickenpox and influenza) are made of viral proteins. Just like bacterial proteins, viral proteins induce an immune response.

Q. Do children encounter more immunological components from vaccines today than they did 30 years ago?

A. No. Although children receive more vaccines now than ever before, most people would probably be surprised to learn that the number of immunological components in vaccines has dramatically decreased.

Thirty years ago, children received vaccines which protected against seven diseases: measles, mumps, rubella, diphtheria, tetanus, pertussis and polio. The total number of bacterial and viral proteins contained in these vaccines was a little more than 3,000.

Today, children receive vaccines that protect against 14 diseases, but the total number of immunological components in these vaccines is only about 150. This dramatic reduction is the result of scientific advances that have allowed for purer, safer vaccines.

Q. Can too many vaccines overwhelm an infant's immune system?



A. No. Compared to the immunological challenges that infants handle every day, the challenge from the immunological components in vaccines is minuscule. Babies begin dealing with immunological challenges at birth. The mother's womb is a sterile environment, free from viruses, bacteria, parasites

and fungi. But after babies pass through the birth canal and enter the world, they are immediately colonized with trillions of bacteria, which means that they carry the bacteria on their bodies but aren't infected by them. These bacteria live on the skin, nose, throat and intestines. To make sure that colonizing bacteria don't invade the bloodstream and cause harm, babies constantly make antibodies against them.

Colonizing bacteria aren't the only issue. Because the food that we eat and the dust that we breathe contain bacteria, immunological challenges from the environment are unending. Viruses are also a problem. Children in the first few years of life are constantly exposed to a variety of different viruses that cause runny noses, cough, congestion, fever or diarrhea.

Given that infants are colonized with trillions of bacteria, that each bacterium contains between 2,000 and 6,000 immunological components and that infants are infected with numerous viruses, the challenge from the 150 immunological components in vaccines is minuscule compared to what infants manage every day.

For the latest information on all vaccines, visit our website at

vaccine.chop.edu

Too Many Vaccines? What you should know

Q. How many vaccines can children effectively handle at one time?

A. A lot more than they're getting now. The purpose of vaccines is to prompt a child's body to make antibodies, which work by preventing bacteria and viruses from reproducing themselves and causing disease. So, how many different antibodies can babies make? The best answer to this question came from a Nobel Prize-winning immunologist at the Massachusetts Institute of Technology named Susumu Tonegawa, who first figured out how people make antibodies.

Tonegawa discovered that antibodies are made by rearranging and recombining many different genes, and found that people can make about 10 billion different antibodies. Given the number of antibody-producing cells in a child's bloodstream, and the number of immunological components contained in vaccines, it is reasonable to conclude that babies could effectively make antibodies to about 100,000 vaccines at one time. Although this number sounds overwhelming, remember that every day children are defending themselves against a far greater number of immunological challenges in their environment.

Q. How do we know that multiple vaccines can be given safely?

A. The Food and Drug Administration (FDA) requires extensive safety testing before vaccines are licensed. Before a new vaccine can be licensed by the FDA, it must first be tested by something called "concomitant use studies." Concomitant use studies require new vaccines to be tested with existing vaccines.

These studies are performed to make sure the new vaccine doesn't affect the safety or effectiveness of existing vaccines given at the same time, and vice versa. Because concomitant use studies have been required for decades, many studies have been performed showing that children can be inoculated with multiple vaccines safely.

Q. What is the harm of separating, spacing out or withholding vaccines?

A. Delaying vaccines can be risky. The desire by some parents to separate, space out or withhold vaccines is understandable. This choice, however, is not necessarily without consequence.

First, delaying vaccines only increases the time during which children are susceptible to certain diseases, some of which are still fairly common. Chickenpox, whooping cough (pertussis), influenza and pneumococcus still cause hospitalizations and deaths in previously healthy children every year. And before the chickenpox vaccine, every year about 70 children died from the disease.

Second, spacing out or separating vaccines will require children to visit the doctor more often for shots. Researchers have found that children experience similar amounts of stress, as measured by secretion of a hormone called cortisol, whether they are getting one or two shots at the same visit. This study suggests that although children are clearly stressed by receiving a shot, two shots aren't more stressful than one. For this reason, more visits to the doctor created by separating or spacing out vaccines will actually increase the trauma of getting shots.

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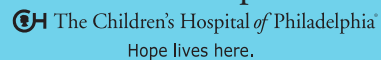


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Facts for Parents About Vaccine Safety from the American Academy of Pediatrics

The AAP understands that parents may have concerns about vaccinating their children. Vaccines are one of the most successful medical advances of all time. Vaccine safety is an issue of great importance to the AAP and to pediatricians, who support ongoing research and increased funding in this area. In addition, the AAP supports further research into the causes of autism.

[Información para padres acerca la inocuidad de las vacunas](#)

(PDF File)

The following information is to help parents and caregivers to understand some of the common issues and questions surrounding this topic.

WHAT IS AUTISM?

- Autism is not a specific disease, but rather a collection of disorders of brain development called "autism spectrum disorders," or ASDs.
- Studies show that the prevalence of autism has risen. The apparent increase in autism may be due to a combination of factors. For example, more and more behaviors and disorders are being included in the definition of ASD than in the past. Also, the public and the medical profession recognize these disorders more often.
- According to the Centers for Disease Control and Prevention (CDC), about 1 in 150 children have an ASD.
- Although many theories have been discussed, the cause or causes of autism are not known.
- Autism has a strong genetic basis. Currently about 10 percent of cases are connected with genetic conditions such as Fragile X or Prader-Willi syndromes. According to a January 2008 study, researchers have discovered another genetic mutation that could account for higher risk in another 1 percent of autism cases.
- More research is being done every year to try to identify the causes and improve efforts to prevent, diagnose and treat ASDs. The nation's top experts in pediatric neurology, genetics, and other fields are moving closer to answers about this group of disorders.
- Early diagnosis is crucial. Pediatricians should screen all children for ASDs at 18 and 24 months. They should also listen carefully to parents about their child's development. The AAP provides its members with comprehensive tools and education to assist them with both diagnosis and follow-up. Parents are the most reliable sources of information.

- When a child is diagnosed with an ASD, the child's family and caregivers should be given information and support. The child should be involved in autism intervention programs as early as possible to get the most benefit.

WHAT IS MITOCHONDRIAL DISEASE?

A recent case that was awarded compensation through the federal Vaccine Injury Compensation Program involved a child with a mitochondrial disorder or mitochondrial disease. This case has raised questions about what environmental triggers might bring on or worsen autism-like symptoms in children with such disorders.

- Mitochondria produce the energy needed for cells to function normally. There are a number of genetic disorders that cause mitochondria to produce less energy than cells need. Symptoms of these disorders can be very mild or quite severe. In some of the disorders, symptoms do not develop for many years. Some of the rarer mitochondrial disorders affect the brain and cause worsening neurologic symptoms over time. In many cases, an event that requires more energy, such as an infection, fever or other illness, can lead to the development of symptoms.
- Although details of the case and the decision cannot be disclosed by the U.S. Department of Health and Human Services, the agency published a statement on March 3, 2008, which said: "HRSA (the Health Resources and Services Administration) has reviewed the scientific information concerning the allegation that vaccines cause autism and has found no credible evidence to support the claim."

According to the Centers for Disease Control and Prevention (CDC), this was a unique case and information about it has not been accurately characterized in the media and other public forums. It represents one special case and does not change the immunization recommendations for children in whom vaccines are otherwise recommended. More information is available at the CDC Web site: www.cdc.gov.

According to the United Mitochondrial Disease Foundation, "There are no scientific studies documenting that childhood vaccinations cause mitochondrial diseases or worsen mitochondrial disease symptoms. In the absence of scientific evidence, the UMDF cannot confirm any association between mitochondrial diseases and vaccines."

WHAT ABOUT VACCINE SAFETY?

- Every physician is mandated to report adverse effects of vaccines to the Vaccine Adverse Event Reporting System (VAERS) so that the event may be studied further. Any adverse effects are acted upon immediately when there appears to be an association. For example, a Rotavirus vaccine that was found to be associated with an intestinal condition called intussusception was taken off of the market. The VAERS Web site is available at <http://vaers.hhs.gov/>
- From time to time, rumors circulate that thimerosal, a mercury-based preservative once used in several vaccines (and still used in some flu vaccine), could contribute to ASDs. However, valid scientific studies have shown there is no link. The American Academy of Pediatrics (AAP), the American Medical Association (AMA), the CDC, and the Institute of Medicine (IOM) agree that science does not support a link between thimerosal in vaccines and autism. For the IOM report, please go to <http://www.iom.edu/CMS/3793/4705/4717.aspx>
- Some parents are concerned about "combination" vaccines, which protect against more than one disease with a single shot. For example, the MMR vaccine protects against measles, mumps and rubella. These vaccines have been studied carefully and found to be safe. All vaccines contain

antigens, which cause the immune system to do its work to fight (and protect the body from) infections. It is important to remember that children are exposed to many antigens during normal activities, such as playing outside or eating food, or when sick with an infection. Healthy children's immune systems are equipped to handle these multiple exposures.

WHY ARE VACCINES IMPORTANT?

- It is most important that parents and pediatricians continue to rely on immunizations to protect all children from preventable—and potentially deadly—illnesses. Many vaccine-preventable diseases can have dangerous consequences, including seizures, brain damage, blindness, and even death. These diseases still exist even though many young parents today have never seen a case, due to the success of the nation's current immunization program. Death and harm from chickenpox, measles, meningitis and other diseases are still a threat to children who are not protected.
- Some specifics: Before Hib vaccine became available, there were approximately 20,000 cases annually. Hib was the most common cause of bacterial meningitis in children in the U.S. Hib meningitis once killed 600 children each year in this country, and those who survived often had deafness, seizures and/or mental retardation.
- Measles is another example of a vaccine-preventable disease with serious consequences. Currently in the U.S., up to 20 percent of people with measles are hospitalized. This is one of the most infectious diseases in the world; if vaccinations were stopped, each year about 2.7 million deaths from measles worldwide could be expected. A recent outbreak of measles in San Diego, California, 11 children contracted measles and none had been vaccinated. This is the highest number of measles cases San Diego has seen in 17 years. It is believed to have started with a child who caught measles in Switzerland and then returned to the U.S.
- Likewise, it would only take one case of polio from another country to bring the disease back to the U.S. if people are not protected by vaccination.
- In order for vaccines to protect everyone, an estimated 85 to 95 percent of the population must be immunized. Studies have shown that children who are not immunized are more likely to become infected with measles and pertussis. Younger children often are the most vulnerable; 90 percent of deaths from pertussis are in infants younger than 6 months old.
- It is not advisable to skip or delay vaccines, as this will leave the child vulnerable to disease for a longer period of time. Parents should follow the immunization schedule provided by the CDC and its Advisory Committee on Immunization Practices, the AAP, and the American Academy of Family Physicians (AAFP) each year. This schedule is designed by experts to ensure maximum protection and safety for children at various ages. Parents should discuss any concerns with their child's pediatrician.
- Serious events occur more often from the actual infection or disease, rather than from the vaccine; therefore, the vaccine is much safer.

More information for parents and caregivers is available on the AAP Web site at the following links:

- On Autism:
<http://www.aap.org/healthtopics/Autism.cfm>
- On Vaccines:

<http://www.aap.org/advocacy/releases/autismparentfacts.htm>

5/29/2009

<http://www.cispiimmunize.org/>

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VACCINE INFORMATION STATEMENT

Your Baby's First Vaccines

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

Your baby will get these vaccines today:

- | | |
|--------------------------------------|------------------------------------|
| <input type="checkbox"/> DTaP | <input type="checkbox"/> Polio |
| <input type="checkbox"/> Hib | <input type="checkbox"/> Rotavirus |
| <input type="checkbox"/> Hepatitis B | <input type="checkbox"/> PCV13 |

(Provider: Check appropriate boxes.)

Ask your doctor about "combination vaccines," which can reduce the number of shots your baby needs.

Combination vaccines are as safe and effective as these vaccines when given separately.



These vaccines protect your baby from **8 serious diseases**:

- diphtheria
- tetanus
- pertussis (whooping cough)
- *Haemophilus influenzae* type b (Hib)
- hepatitis B
- polio
- rotavirus
- pneumococcal disease

ABOUT THIS VACCINE INFORMATION STATEMENT

Please read this Vaccine Information Statement (VIS) before your baby gets his or her immunizations, and take it home with you afterward. Ask your doctor if you have any questions.

This VIS tells you about the benefits and risks of six routine childhood vaccines. It also contains information about reporting an adverse reaction and about the National Vaccine Injury Compensation Program, and how to get more information about vaccines and vaccine-preventable diseases. (Individual VISs are also available for these vaccines.)

HOW VACCINES WORK

Immunity from Disease: When children get sick with an infectious disease, their immune system usually produces protective "antibodies," which keep them from getting the same disease again. But getting sick is no fun, and it can be dangerous or even fatal.

Immunity from Vaccines: Vaccines are made with the same bacteria or viruses that cause disease, but they have been weakened or killed – or only parts of them are used – to make them safe. A child's immune system produces antibodies, just as it would after exposure to the actual disease. This means the child will develop immunity in the same way, but without having to get sick first.

VACCINE BENEFITS: WHY GET VACCINATED?

Diseases have injured and killed many children over the years in the United States. **Polio** paralyzed about 37,000 and killed about 1,700 every year in the 1950s. **Hib disease** was once the leading cause of bacterial meningitis in children under 5 years of age. About 15,000 people died each year from **diphtheria** before there was a vaccine. Up to 70,000 children a year were hospitalized because of **rotavirus** disease. **Hepatitis B** can cause liver damage and cancer in 1 child out of 4 who are infected, and **tetanus** kills 1 out of every 5 who get it.

Thanks mostly to vaccines, these diseases are not nearly as common as they used to be. But they have not disappeared, either. Some are common in other countries, and if we stop vaccinating they will come back here. This has already happened in some parts of the world. When vaccination rates go down, disease rates go up.



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

Vaccine Information
Statement (Interim)
42 U.S.C. § 300aa-26
11/16/2012

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Childhood vaccines can prevent these 8 Diseases

1. DIPHTHERIA

Signs and symptoms include a thick covering in the back of the throat that can make it hard to breathe. **Diphtheria can lead to** breathing problems, and heart failure.

2. TETANUS (Lockjaw)

Signs and symptoms include painful tightening of the muscles, usually all over the body. **Tetanus can lead to** stiffness of the jaw so victims can't open their mouth or swallow.

3. PERTUSSIS (Whooping Cough)

Signs and symptoms include violent coughing spells that can make it hard for a baby to eat, drink, or breathe. These spells can last for weeks. **Pertussis can lead to** pneumonia, seizures, and brain damage.

4. HIB (*Haemophilus influenzae type b*)

Signs and symptoms can include trouble breathing. There may not be any signs or symptoms in mild cases. **Hib can lead to** meningitis (infection of the brain and spinal cord coverings); pneumonia; infections of the blood, joints, bones, and covering of the heart; brain damage; and deafness.

5. HEPATITIS B

Signs and symptoms can include tiredness, diarrhea and vomiting, jaundice (yellow skin or eyes), and pain in muscles, joints and stomach. But usually there are no signs or symptoms at all. **Hepatitis B can lead to** liver damage, and liver cancer.

6. POLIO

Signs and symptoms can include flu-like illness, or there may be no signs or symptoms at all. **Polio can lead to** paralysis (can't move an arm or leg).

7. PNEUMOCOCCAL DISEASE

Signs and symptoms include fever, chills, cough, and chest pain. **Pneumococcal disease can lead to** meningitis (infection of the brain and spinal cord coverings), blood infections, ear infections, pneumonia, deafness, and brain damage.

8. ROTAVIRUS

Signs and symptoms include watery diarrhea (sometimes severe), vomiting, fever, and stomach pain. **Rotavirus can lead to** dehydration and hospitalization.

Any of these diseases can lead to death.

How do babies catch these diseases?

Usually from contact with other children or adults who are already infected, sometimes without even knowing they are infected. A mother with **Hepatitis B** infection can also infect her baby at birth. **Tetanus** enters the body through a cut or wound; it is not spread from person to person.

Routine Baby Vaccines

Vaccine	Number of Doses	Recommended Ages	Other Information
DTaP (diphtheria, tetanus, pertussis)	5	2 months, 4 months, 6 months, 15-18 months, 4-6 years	Some children should not get pertussis vaccine. These children can get a vaccine called DT.
Hepatitis B	3	Birth, 1-2 months, 6-18 months	Children may get an additional dose at 4 months with some "combination" vaccines.
Polio	4	2 months, 4 months, 6-18 months, 4-6 years	
Hib (<i>Haemophilus influenzae</i> type b)	3 or 4	2 months, 4 months, (6 months), 12-15 months	There are 2 types of Hib vaccine. With one type the 6-month dose is not needed.
PCV13 (pneumococcal)	4	2 months, 4 months, 6 months, 12-15 months	Older children with certain chronic diseases may also need this vaccine.
Rotavirus	2 or 3	2 months, 4 months, (6 months)	Not a shot, but drops that are swallowed. There are 2 types of rotavirus vaccine. With one type the 6-month dose is not needed.

Annual **flu vaccination** is also recommended for children 6 months of age and older.

Precautions

Most babies can safely get all of these vaccines. But some babies should not get certain vaccines. Your doctor will help you decide.

- A child who has ever had a serious reaction, such as a life-threatening allergic reaction, after a vaccine dose should not get another dose of that vaccine. *Tell your doctor if your child has any severe allergies, or has had a severe reaction after a prior vaccination.* (Serious reactions to vaccines and severe allergies are rare.)
- A child who is sick on the day vaccinations are scheduled might be asked to come back for them.

Talk to your doctor . . .

- . . . before getting **DTaP vaccine**, if your child ever had any of these reactions after a dose of DTaP:
 - A brain or nervous system disease within 7 days,
 - Non-stop crying for 3 hours or more,
 - A seizure or collapse,
 - A fever of over 105°F.
- . . . before getting **Polio vaccine**, if your child has a life-threatening allergy to the antibiotics neomycin, streptomycin or polymyxin B.
- . . . before getting **Hepatitis B vaccine**, if your child has a life-threatening allergy to yeast.
- . . . before getting **Rotavirus Vaccine**, if your child has:
 - SCID (Severe Combined Immunodeficiency),
 - A weakened immune system for any other reason,
 - Digestive problems,
 - Recently gotten a blood transfusion or other blood product,
 - Ever had intussusception (bowel obstruction that is treated in a hospital).
- . . . before getting **PCV13** or **DTaP** vaccine, if your child ever had a severe reaction after any vaccine containing diphtheria toxoid (such as DTaP).

Risks

Vaccines can cause side effects, like any medicine.

Most vaccine reactions are **mild**: tenderness, redness, or swelling where the shot was given; or a mild fever. These happen to about 1 child in 4. They appear soon after the shot is given and go away within a day or two.

Other Reactions: Individual childhood vaccines have been associated with other mild problems, or with moderate or serious problems:

DTaP Vaccine

Mild Problems: Fussiness (up to 1 child in 3); tiredness or poor appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1-7 days (up to 1 child in 30) – usually after the 4th or 5th dose.

Moderate Problems: Seizure (1 child in 14,000); non-stop crying for 3 hours or longer (up to 1 child in 1,000); fever over 105°F (1 child in 16,000).

Serious problems: Long term seizures, coma, lowered consciousness, and permanent brain damage have been reported. These problems happen so rarely that it is hard to tell whether they were actually caused by the vaccination or just happened afterward by chance.

Polio Vaccine / Hepatitis B Vaccine / Hib Vaccine

These vaccines have not been associated with other mild problems, or with moderate or serious problems.

Pneumococcal Vaccine

Mild Problems: During studies of the vaccine, some children became fussy or drowsy or lost their appetite.

Rotavirus Vaccine

Mild Problems: Children who get rotavirus vaccine are slightly more likely than other children to be irritable or to have mild, temporary diarrhea or vomiting. This happens within the first week after getting a dose of the vaccine.

Serious Problems: Studies in Australia and Mexico have shown a small increase in cases of intussusception within a week after the first dose of rotavirus vaccine. So far, this increase has not been seen in the United States, but it can't be ruled out. If the same risk were to exist here, we would expect to see 1 to 3 infants out of 100,000 develop intussusception within a week after the first dose of vaccine.

What if my child has a serious problem?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

For More Information

- Ask your doctor or other healthcare professional.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Prevalence of Parental Concerns About Childhood Vaccines

The Experience of Primary Care Physicians

Allison Kempe, MD, MPH, Matthew F. Daley, MD, Mary M. McCauley, MSTC, Lori A. Crane, PhD, MPH, Christina A. Suh, MD, Allison M. Kennedy, MPH, Michelle M. Basket, BS, Shannon K. Stokley, MPH, Fran Dong, MS, Christine I. Babbel, MSPH, Laura A. Seewald, BS, L. Miriam Dickinson, PhD

Background: Little is known about the effects of increased parental vaccine safety concerns on physicians' vaccine communication attitudes and practices.

Purpose: To assess among pediatricians and family medicine (FM) physicians: (1) prevalence of parental requests to deviate from recommended vaccine schedules; (2) responses to such requests; and (3) attitudes about the burden and success of vaccine communications with parents.

Methods: Survey of nationally representative samples of pediatricians and FM physicians (N=696) conducted during February to May 2009 with analysis in 2010.

Results: Response rates were 88% for pediatricians and 78% for FM physicians. Overall, 8% of physicians reported that $\geq 10\%$ of parents refused a vaccine and 20% reported that $\geq 10\%$ of parents requested to spread out vaccines in a typical month. More pediatricians than FM physicians reported always/often requiring parents to sign a form if they refused vaccination (53% vs 31%, $p < 0.0001$); 64% of all physicians would agree to spread out vaccines in the primary series at least sometimes. When talking with parents with substantial concerns, 53% of physicians reported spending 10–19 minutes and 8% spending ≥ 20 minutes. Pediatricians were more likely than FM physicians to report their job less satisfying because of parental vaccine concerns (46% vs 21%, $p < 0.0001$). Messages most commonly reported as “very effective” were personal statements such as what they would do for their own children.

Conclusions: The burden of communicating with parents about vaccines is high, especially among pediatricians. Physicians report the greatest success convincing skeptical parents using messages that rely on their personal choices and experiences.

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Introduction

Vaccines are among the most effective public health interventions ever introduced.^{1,2} Routine childhood immunization in the U.S. has led to declines in mortality of 96%–100% during the 20th century for the nine diseases for which universal vaccination was recom-

mended before 1990.³ However, the effectiveness of routine vaccination in nearly eliminating once common diseases has resulted in the public's lack of appreciation for the severity of these diseases and the perception that children may no longer be susceptible to these diseases.^{4,5} Against this backdrop of decreased concern about vaccine-preventable diseases, perceptions that vaccines pose safety concerns have grown, and the vaccine schedule has become more crowded and confusing.^{4,5} Unproven theories regarding vaccine adverse effects and emotional case reports are widely available.⁶ The combination of these factors may lead increasing numbers of parents to refuse vaccines or insist on delaying some vaccines.^{7,8}

The effects of heightened parental concerns on immunization delivery are not well understood. Although healthcare providers are consistently named parents'

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most trusted source of vaccine information,^{7–9} relatively little is known about the extent to which parents voice their concerns to their children's doctors and how this affects clinical practice. The objectives of this study were to assess the following among national samples of pediatricians and family medicine (FM) physicians: (1) perceived prevalence of parents' vaccine safety concerns and requests to deviate from recommended vaccine schedules; (2) physician communication practices regarding vaccination and responses to parental requests to deviate from vaccination schedules; (3) vaccine communication barriers; and (4) physician attitudes regarding the burden and success of communicating with parents about vaccines.

Methods

Study Setting

From February to May 2009, a survey was administered to two national networks of primary care physicians. The human subjects review board at the University of Colorado Denver approved the present study as exempt research not requiring written informed consent.

Population

Recognizing that all methods for drawing unbiased physician samples suffer from limitations,¹⁰ a method was developed for obtaining rapid and high response rates to surveys about policy-relevant immunization issues, as part of a CDC-funded project. Networks of physicians were recruited from the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) who agreed to respond to several surveys a year. After obtaining approximately twice the number of recruits needed for each network, a quota strategy was applied to ensure the representativeness of the samples.^{10,11} A population-based sampling matrix was constructed using demographic and practice data from randomly drawn samples of the AAP and AAFP memberships.

Using population-based estimates, quotas were created for each cell of the 36-cell matrix, which crossed U.S. regions, practice location, and type of practice. Cells were then filled by randomly selecting from the pool of recruits to yield a total of approximately 400 physicians in each network. As described elsewhere,¹⁰ the representativeness of these networks has been examined in a systematic manner. Demographic characteristics, practice attributes, and reported attitudes about a range of vaccination issues were similar when network physicians were compared with physicians of the same specialty who were randomly sampled from the American Medical Association (AMA) master physician listing.¹⁰

Survey Design

The survey instrument was developed collaboratively with the CDC with input from advisory groups of pediatricians and family physicians from six representative states. It was pilot tested in national samples of physicians and modified based on piloting. Portions of the survey regarding desirability of vaccination were theoretically based on the Health Belief Model.¹² Potential parental immunization concerns, barriers to physicians communicating

about vaccines with parents, and potential physician strategies for communicating with parents were based on the literature, previous surveys,^{13–15} and issues raised by physician advisory groups.

The survey provided the following definitions: *vaccine refusal* was "outright refusal without acknowledging that the vaccine would be considered at a later date"; *spreading out* was "postponing one or more vaccines with the intent of receiving them later." Physicians were asked to report percentages of parents who refused or asked to spread out vaccines rather than numbers of patients per given time period, in order to adjust for differences in the amount of children seen by providers in different settings and specialties.

Survey Administration

Physicians were surveyed by Internet or mail, based on preference. The Internet survey was administered using a web-based program (Vovici Corp., Dulles VA). The Internet group received an initial email and up to eight email reminders, whereas the mail group received up to three mailed surveys. The Internet group received one final paper survey by mail if they had not responded.

Analytic Methods

Internet and mail surveys were pooled for all analyses, as physician attitudes have been found to be comparable when obtained by either method.¹⁶ Items regarding physician attitudes, current practices, and potential barriers to vaccine use were asked using 4-point Likert-type scales. Chi-squares were used for comparisons of characteristics of respondents and nonrespondents, and Kolmogorov–Smirnov tests in comparisons of overall distributions of responses to Likert-type scales between respondents in the two specialties. Significant differences between specialties were footnoted in each table and differences of importance discussed in the text. Ninety-five percent CIs are presented in parentheses after each survey response point estimate.

Results

Response rates were 88% (366/416) for pediatricians and 78% (330/423) for FM physicians. Nine (3%) pediatricians and 68 FM physicians (21%) subsequently were excluded because they reported not giving vaccines to children aged <2 years. Respondents did not differ significantly from nonrespondents by physician demographic factors, practice region, location, type of practice, and number of providers (Table 1).

Prevalence of Safety Concerns and Parental Requests to Deviate from Recommended Vaccine Schedules

Compared to 5 years ago, 43% (95% CI=39%, 47%) of physicians thought parents' level of concern had greatly increased; 28% (95% CI=24%, 32%) thought it had moderately increased; and 29% (95% CI=26%, 33%) that it had stayed the same or decreased.

In a typical month, 60% (95% CI=56%, 63%) of physicians reported refusals for 1%–4% of children and 8% of physicians (6%–10%) reported refusals for ≥10% of children; 79% (95% CI=75%, 82%) reported at least one vaccine

refusal in a typical month. Eighty-nine percent (95% CI=86%, 91%) reported at least one request to spread out vaccines in a typical month; 20% (95% CI=17%, 23%) of physicians reported that more than 10% of parents requested to spread out vaccines in a typical month. Table 2 identifies the major issues physicians perceived to be contributing to vaccine refusal in parents of young children.

Vaccine Communication Practices and Responses to Parental Requests to Deviate from Vaccination Schedules

Addressing vaccine concerns at prenatal visits was relatively common; beyond that, few physicians reported using any methods to provide vaccination information outside of well visits (Table 3). Most physicians used information sheets about the severity of vaccine-preventable diseases (57%, 95% CI=53%, 61%), but fewer used any other aids, such as listing of websites (29%, 95% CI=25%, 32%); detailed information sheets about specific concerns such as autism (28%, 95% CI=24%, 31%); pictures of children affected by vaccine-preventable diseases (7%, 95% CI=5%, 9%); or graphs demonstrating decreasing mortality from diseases (4%, 95% CI=3%, 6%).

Table 1. Comparison of survey respondents versus nonrespondents and additional characteristics of respondents, % unless otherwise indicated

Characteristic	Respondents (n=696)	Nonrespondents (n=143)	p-value ^a
Age (years; M)	50.1	49.3	0.37
Male gender	50	62	0.01
Region of the country	—	—	—
Midwest	25	24	0.81
Northeast	20	17	—
South	33	35	—
West	21	24	—
Location of practice	—	—	—
Urban, inner-city	35	34	0.79
Urban non-inner-city/suburban	46	48	—
Rural	19	19	—
Type of practice	—	—	—
Private	79	76	0.91
Community or hospital-based	17	19	—
MCO	4	5	—
Practice size	—	—	—
1 (solo) physician	13	14	0.36
2–5 physicians	42	46	—
≥6 physicians	44	39	—
Patient insurance	—	—	—
SCHIP and Medicaid	—	—	—
<10%	34	—	—
≥10%	66	—	—
Uninsured	—	—	—
<10%	79	—	—
≥10%	21	—	—
Patient race/ethnicity	—	—	—
Black/African-American	—	—	—
<10%	53	—	—
≥10%	47	—	—
Hispanic/Latino	—	—	—
<10%	52	—	—
≥10%	48	—	—

^ap-value represents comparison between respondents and nonrespondents; statistical analyses used: chi-square, t test

SCHIP, State Child Health Insurance Program

As shown in Table 3, overall, 40% (95% CI=40%, 47%) of physicians reported always or often requiring parents to sign a form if they refused vaccination. Significant interspecialty differences were seen; 53% (95% CI=47%,

Table 2. Based on the physician's experience, how much do each of the following contribute to vaccine refusal among parents of children aged <2 years in their practice (n=614)

Concern/belief	A lot	Some	A little/not at all
Concern that their child will suffer long-term complications from vaccines ^a	68 (64, 72)	24 (20, 27)	8 (6, 10)
Concern that their child could develop autism as a result of vaccination ^a	62 (58, 66)	25 (22, 29)	12 (10, 15)
Concern about possible ill effects of thimerosal ^a	33 (29, 36)	39 (35, 42)	29 (25, 32)
Belief that their child is unlikely to get a vaccine-preventable disease	32 (29, 36)	37 (34, 41)	30 (27, 34)
Concern that vaccines will weaken their child's immune system ^a	18 (15, 21)	35 (31, 38)	48 (44, 52)
General worries about vaccines without a specific concern ^a	19 (16, 22)	43 (39, 47)	38 (34, 42)
Belief that vaccine-preventable diseases are not severe enough to warrant vaccination	11 (9, 14)	43 (39, 47)	46 (42, 50)
Concern that their child will suffer immediate, short-term effects (such as fever, pain, or excessive crying)	10 (7, 12)	29 (25, 33)	61 (57, 65)
Opinion that vaccination recommendations are driven by profit considerations of drug companies	6 (4, 8)	24 (20, 27)	70 (66, 74)
Belief that vaccines are not very effective	2 (1, 3)	17 (14, 20)	81 (78, 84)

Note: Values are % (95% CI). Boldface indicates significance.

^aPediatricians more likely than family medicine physicians to report ($p<0.001$ by Kolmogorov–Smirnov test)

58%) of pediatricians reported this practice compared with 31% (95% CI=26%, 37%) of FM physicians ($p<0.001$ by Kolmogorov–Smirnov test). The majority of physicians in both specialties would agree to spread out vaccines in the primary series at least sometimes. Among pediatricians, 25% (95% CI=20%, 29%) would dismiss families from their practice always, often, or sometimes if they refused vaccines in the primary series, whereas only 3% (95% CI=1%, 5%) of FM physicians reported doing so ($p<0.001$ by Kolmogorov–Smirnov test).

Barriers to Vaccine Communication

Among all physicians, the most commonly reported barriers (either *major* or *somewhat of a barrier*) to vaccination discussions were the amount of time these discussions take (62%, 95% CI=58%, 66%); other health issues taking precedence (37%, 95% CI=33%, 41%); perceiving that discussion would be unlikely to change parents' minds (27%, 95% CI=23%, 31%); physicians not knowing enough about vaccine safety evidence (20%, 95%

Table 3. Frequency of practices for dealing with risk communication (n=605)

	Often or always	Sometimes	Never/rarely
Require parents to sign a form if they refuse vaccination ^a	44 (40, 47)	18 (15, 21)	39 (35, 42)
Address vaccine concerns at a prenatal visit ^a	31 (28, 35)	32 (28, 36)	37 (33, 40)
Dismiss families from their practice if they refuse vaccines in the primary series for their child	10 (8, 13)	5 (4, 7)	84 (81, 87)
Agree to spread out vaccines in the primary series ^b	13 (10, 16)	51 (47, 55)	36 (33, 40)
Send information about vaccines to parents before visits ^b	9 (7, 12)	9 (7, 12)	81 (78, 84)
Schedule an extra visit solely to address vaccine concerns	2 (1, 4)	16 (13, 39)	81 (78, 84)
Refer parents who are concerned about vaccine safety to one provider in the practice with interest and expertise in this area	0 (0, 0)	4 (2, 5)	96 (95, 98)
Hold group information meetings for parents to be educated about vaccine safety	0 (0, 0)	1 (0, 1)	99 (99, 100)

Note: Values are % (95% CI). Boldface indicates significance.

^aPediatricians more likely than family medicine physicians to use ($p<0.001$ by Kolmogorov–Smirnov test)

^bPediatricians more likely than family medicine physicians to use ($p<0.01$ by Kolmogorov–Smirnov test)

CI=17%, 23%); thinking that parents would not understand risk/benefit information (19%, 95% CI=16%, 22%); and physicians not knowing how to communicate about risk (19%, 95% CI=15%, 22%).

Physician Attitudes Regarding Burden and Success of Vaccine Communication

Most physicians reported comfort with addressing parental questions and concerns and endorsed the importance of establishing parents' trust and the appropriateness of parents questioning whether their child needed vaccinations (Table 4). Pediatricians were more likely to report that their job was less satisfying because of the need to discuss parents' questions or concerns about vaccines and to perceive that when parents disagreed with their recommendations it showed a lack of respect for their medical judgment and experience ($p<0.001$ by Kolmogorov–Smirnov test). However, few physicians had considered stopping administering vaccines because of the burden of discussing vaccine risks and benefits with parents.

When discussing vaccines for the first time with first-time parents of infants, 49% (95% CI=45%, 53%) of physicians in both specialties reported personally spending ≤ 4 minutes; 42% (95% CI=38%, 46%) reported spending 5–9 minutes; and 9% (95% CI=7%, 11%) reported spending ≥ 10 minutes. However, when discussing vaccines with parents who had substantial concerns about vaccines, only 4% (95% CI=2%, 5%) of physicians reported spending ≤ 4 minutes; 36% (95% CI=32%, 39%) reported spending 5–9 minutes; 53% (95%

CI=49%, 57%) reported spending 10–19 minutes; and 8% (95% CI=5%, 10%) reported spending ≥ 20 minutes. The two communication practices most commonly reported as *very effective* in convincing skeptical parents to vaccinate their children were personal statements by physicians about what they would do for their children or about their personal experiences with vaccine safety among their patients (Figure 1).

Discussion

The results of this national survey suggest that primary care physicians perceive that parental concerns about vaccine safety are increasingly frequent, and that vaccine refusal and requests to delay vaccination are also increasing. The data presented here also demonstrate how much time and effort physicians spend discussing childhood immunizations. Differences existed by specialty, notably that pediatricians report lower levels of job satisfaction as a result of this issue and a higher likelihood of dismissing parents from their practice or requiring them to sign a form if they refused vaccines. Most physicians reported that time constraints and competing demands in primary care were the major barriers to these discussions. However, about one in five reported that they did not believe that parents would understand risk/benefit information about vaccines or that they themselves did not know enough about evidence of vaccine safety. Most perceived that personal messages, such as what they would do with their own children, resulted in the most success in convincing skeptical parents.

Table 4. Physician attitudes toward communicating with parents about the risks and benefits of vaccination ($n=619$)

	Strongly agree	Somewhat agree	Somewhat/strongly disagree
Physician feels comfortable addressing parents' questions or concerns about vaccines.	84 (81, 87)	16 (13, 18)	1 (0, 2)
Establishing trust is the most important part of convincing skeptical parents to accept vaccines.	60 (56, 64)	34 (30, 38)	6 (4, 7)
Parents who question whether or not their child should have a vaccine are doing their job as responsible parents.	23 (20, 26)	51 (47, 55)	26 (22, 29)
The physician believes his or her job is less satisfying because of the need to discuss parents' questions or concerns about vaccines. ^a	6 (4, 7)	30 (26, 33)	65 (61, 68)
When parents disagree with the physician's recommendations about vaccination, he or she feels it shows a lack of respect for his or her medical judgment and experience. ^a	4 (2, 5)	29 (26, 33)	67 (63, 71)
The physician has considered no longer administering vaccines in his or her practice because of the burden of discussing vaccine risks and benefits with parents.	0 (0, 1)	4 (2, 5)	96 (95, 98)

Note: Values are % (95% CI). Boldface indicates significance.

^aPediatricians more likely than family medicine physicians to report ($p<0.001$ by Kolmogorov–Smirnov test)

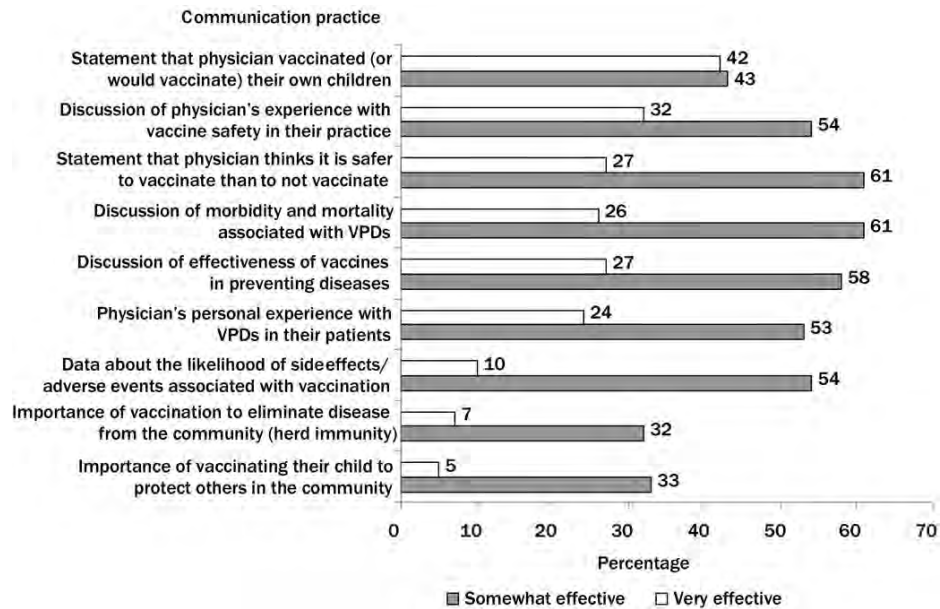


Figure 1. Perceived effectiveness of risk-communication practices (pediatricians/family medicine physicians combined), $n=605$
 Note: All 95% CIs around point estimates $< \pm 5\%$.
 VPD, vaccine-preventable disease

A comparison of the rates of vaccine refusals reported here with earlier studies suggests that such requests have increased. A national survey¹⁷ of FM and pediatric physicians in 2000 found that 93% of pediatricians and 60% of FM physicians reported one or more parental vaccine refusals in the past year. In the present study, 89% of respondents reported at least one vaccine refusal per month, with almost 10% reporting that 10% or more of parents refuse one or more vaccines in a typical month. The current study's data also demonstrate that requests to spread out vaccines are more common than refusals, which is consistent with previous parental survey findings.⁵ The increased number of vaccines recommended during the past decade should be considered, however. In 2000,¹⁸ 13–16 separate administrations were recommended in the primary series, whereas in 2009,¹⁹ this had grown to 20–28 separate administrations for the primary series plus yearly influenza immunization.

The observed between-specialty differences may reflect the fact that childhood immunizations are a much larger part of pediatric as compared to FM practice and, therefore, the burden of communication about vaccines may be felt more by pediatricians. These differences may also reflect differences in the attitudes of parents who seek care from a pediatrician as opposed to an FM physician, although the authors found no papers reporting this finding. Having parents sign a form when they refuse vaccines may be more common among pediatricians because of the readily available Refusal to Vaccinate form provided

by the American Academy of Pediatrics.²⁰ Among both specialties, the percentages requesting parental signature were substantially higher than those reported in a 2004 study¹⁷ that suggested approximately one fifth of pediatric and FM physicians would have parents sign a form if they refused a vaccine.

Overall, physicians reported the top barrier to communicating about vaccinations was the time it takes and the competing demands of primary care. Further, a recent study²¹ suggested that nurses in pediatric offices spend roughly three times the amount of time as physicians discussing vaccines with parents. Because the numbers of parents with vaccine questions and concerns are reportedly increasing, the time burden of communicating about vaccines appears to be substantially increasing for physicians and nurses in private practice.

Physicians perceived that the most effective way of convincing skeptical parents was a personal message. The strength of such messages relies on the parents' trust in their provider's judgment and experience. Previous data^{5,22} from parents' perspectives have shown that assurances from trusted providers were the main reasons parents changed their minds about delaying or refusing vaccines.

Recent data from National Immunization Surveys show minimal change in overall 4:3:1:3:3:1 vaccine coverage from 2007 (77.4%) to 2008 (76.1%), suggesting the increase in parental vaccine concerns is not having a direct impact on coverage nationally.^{23,24} However, pockets of vaccine refusal have produced outbreaks in pertussis,²⁵ measles,^{25,26}

and increases in reports of *Haemophilus influenzae* type b disease among unvaccinated children.²⁷ Importantly, national immunization rates also do not convey the high cost that physicians are paying in their efforts to keep vaccination rates up.¹⁷ Although only 4% of physicians in the present study reported they currently were considering no longer administering vaccines because of the communication burden, this percentage potentially translates to thousands of children being unable to receive vaccines at their site of primary care.

The current study has important strengths and limitations. It is the only national study in the past 5 years to document vaccine risk communication practices and how practitioners perceive this communication affects primary care practice. The surveyed physicians are generally representative of members of the AAP and the AAFP,¹⁰ and the response rate was high. Despite this, however, those who agreed to be surveyed may not express similar views as those who declined to be surveyed or who did not respond. In addition, the sentinel networks may not be representative of physicians who are not members of the AAP or AAFP. Finally, the data rely on self-report rather than observation of practice.

The current data have important implications for primary care. Given the difficulties physicians have providing anticipatory guidance on all the subjects recommended for routine pediatric care within the short duration of a well child visit,^{28–31} the amount of time they spend discussing vaccines may limit discussion of other preventive topics. If dissatisfaction with lengthy vaccine communications continues to grow, this issue may contribute to “burn-out” of primary care physicians. Most importantly, the data presented here suggest that the current paradigm of relying on only a time-limited encounter-based discussion of the benefits and risks of vaccines may not be sufficient to deal with current levels of parental concern. Increased use of social marketing as a behavior-change strategy, similar to tobacco-cessation programs and aimed at hesitant parents who have concerns that may be successfully addressed rather than at parents who refuse vaccines, has been advocated.⁶

In addition, communication efforts at the level of the community, state, or nation to directly counter misinformation about vaccines in the media and on the Internet, to reinforce social norms to vaccinate, and to increase awareness of the dangers of vaccine-preventable diseases may be important in reinforcing information provided by physicians. Within the practice, more efficient ways to deliver information and answer parents’ questions such as group visits or educational interventions to increase discussion with only slight increases in time may be helpful.^{7,32} When educational and reassuring messages fail and parents refuse vaccines, there are currently little evi-

dence-based data regarding vaccine risk communication to guide physicians about the most effective ways to respond,³³ highlighting the need for comparative effectiveness studies in the area of parental vaccine refusal.

Conclusion

Increased parental concerns about vaccine safety and the time constraints of the traditional well child visit are hampering primary care physicians’ immunization delivery efforts. More innovative and comprehensive approaches to risk/benefit communication with parents about vaccines are needed.

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Strategies for Health Care Professionals

Immunization professionals and parents agree: times have changed.

Because of questions or concerns about vaccines, well-child visits can be stressful for parents. As their infant's health care provider, you remain parents' most trusted source of information about vaccines. This is true even for parents with the most questions and concerns. Your personal relationship uniquely qualifies you to help support parents in understanding and choosing vaccinations.

However, time for infant health evaluation at each well visit is at a premium, as you check physical, cognitive, and other milestones and advise parents on what to expect in the coming months. Therefore, making time to talk about vaccines may be stressful for *you*. But when an infant is due to receive vaccines, nothing is more important than making the time to assess the parents' information needs as well as the role they desire to play in making decisions for their child's health, and then following up with communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or anecdote or some mix of the two—works for most parents you see. But keep a watchful eye to be sure that you are connecting with each parent to maintain trust and keep lines of communication open.

We hope that these brief reminders—and the materials that you, your staff, and parents can find on our website— will help ensure your continued success in immunizing infants and children. Success may mean that all vaccines are accepted when you recommend them, or that some vaccines are scheduled for another day. If a parent refuses to vaccinate, success may simply mean keeping the door open for future discussions about choosing vaccination.



THIS RESOURCE COVERS:

- What you may hear from parents about their vaccine safety questions and how to effectively address them
- Proven communication strategies and tips for having a successful vaccine conversation with parents
- This brochure is part of a comprehensive set of educational materials for health care professionals and parents available at <http://www.cdc.gov/vaccines/conversations>

Nurses, physician assistants, and other office staff play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates: from providing parents with educational materials, to being available to answer their questions, to making sure that families who may opt for extra visits for vaccines make and keep vaccine appointments.



What You May Hear From Parents

As you plan for responding to parents' concerns, it may be useful to think of parental questions in the following categories.

Questions about whether vaccines cause autism

Parents may encounter poorly designed and conducted studies, misleading summaries of well-conducted studies, or anecdotes made to look like science—claiming that vaccines cause autism. Many rigorous studies show that there is no link between MMR vaccine or thimerosal and autism. Visit <http://www.cdc.gov/vaccines/conversations> for more information to help you answer parents' questions on these two issues. If parents raise other possible hypotheses linking vaccines to autism, four items are key: (1) patient and empathetic reassurance that you understand that their infant's health is their top priority, and it also is your top priority, so putting children at risk of vaccine-preventable diseases without scientific evidence of a link between vaccines and autism is a risk you are not willing to take; (2) your knowledge that the onset of regressive autism symptoms often coincides with the timing of vaccines but is not caused by vaccines; (3) your personal and professional opinion that vaccines are very safe; and (4) your reminder that vaccine-preventable diseases, which may cause serious complications and even death, remain a threat.

"All those people who say that the MMR vaccine causes autism must be on to something."

"Autism is a burden for many families and people want answers—including me. But well designed and conducted studies that I can share with you show that MMR vaccine is not a cause of autism."

Questions about whether vaccines are more dangerous for infants than the diseases they prevent

Today, parents may not have seen a case of a vaccine-preventable disease firsthand. Therefore, they may wonder if vaccines are really necessary, and they may believe that the risks of vaccinating infants outweigh the benefits of protecting them from infection with vaccine-preventable diseases. Visit <http://www.cdc.gov/vaccines/conversations> for up-to-date information on diseases and the vaccines that prevent them that you can share with parents. You may be able to provide information from your own experience about the seriousness of the diseases, the fact that cases and outbreaks of vaccine-preventable diseases are occurring now in the U.S., and that even when diseases are eliminated in the U.S., they can make a rapid return in children and adults who are not immunized if travelers bring the diseases into the U.S. You also can remind parents about ongoing efforts to ensure the safety of vaccines, including the large-scale reporting system, Vaccine Adverse Event Reporting System (<http://www.vaers.hhs.gov>), used

to alert FDA and CDC to any possible problems with a vaccine so that they can be studied in more detail.

"What are all these vaccines for? Are they really necessary?"

"I know you didn't get all these vaccines when you were a baby. Neither did I. But we were both at risk of serious diseases like Hib and pneumococcal meningitis. Today, we're lucky to be able to protect our babies from 14 serious diseases with vaccines."

Questions about the number of vaccines and vaccine ingredients

Some parents may have a general concern that there are too many vaccines. With respect to timing and spacing of vaccines, the childhood vaccine schedule is designed to provide protection at the earliest possible time against serious diseases that may affect infants early in life. *The Childhood Immunization Schedule* fact sheet (<http://www.cdc.gov/vaccines/conversations>) may be useful for those parents, as well as for parents who have specific questions. Some parents may be able to specify their concerns: whether each vaccine is needed, whether giving several vaccines at one time can cause harm, whether vaccine ingredients are harmful, or how well each vaccine works. For these parents, you can specifically reinforce the seriousness of the diseases prevented by vaccines, and share your knowledge that no evidence suggests that a healthy child's immune system will be damaged or overwhelmed by receiving several vaccines at one time. *Understanding Vaccine Ingredients* (<http://www.cdc.gov/vaccines/conversations>) can help you counter myths that have circulated about vaccine ingredients. You may need to share with some parents that not only should each vaccine series be started on time to protect infants and children as soon as possible, but each multi-dose series must be completed to provide the best protection.

"I'm really not comfortable with my 2-month-old getting so many vaccines at once."

"There's no proven danger in getting all the recommended 2-month vaccines today. Any time you delay a vaccine you leave your baby vulnerable to disease. It's really best to stay on schedule. But if you're very uncomfortable, we can give some vaccines today and schedule you to come back in two weeks for the rest, but this is not recommended."

Questions about known side effects

It is reasonable for parents to be concerned about the possible reactions or side effects listed on the Vaccine Information Statements, especially fever, redness where a shot was given, or fussiness that their child may experience following vaccination. Remind parents to watch for the possible side effects and provide information on how they should treat them and how they can contact you if they observe something they are concerned about. To reinforce how rare serious side effects really are, share your own experience, if any, with seeing a serious side effect from a vaccine.

"I'm worried about the side effects of vaccines. I don't want my child to get any vaccines today."

"I'll worry if your child *doesn't* get vaccines today, because the diseases can be very dangerous—most, including Hib, pertussis, and measles, are still infecting children in the U.S. We can look at the Vaccine Information Statements together and talk about how rare serious vaccine side effects are."

Questions about unknown serious adverse events

Parents who look for information about vaccine safety will likely encounter suggestions about as-yet-unknown serious adverse events from vaccines. It is not unreasonable that parents find this alarming. You can share what the world was like for children before there were vaccines. And you can share that increases in health problems such as autism, asthma, or diabetes don't have a biologic connection to vaccination. We have no evidence to suggest that vaccines threaten a long, healthy life. We know lack of vaccination threatens a long and healthy life.

"You really don't know if vaccines cause any long-term effects."

"We have years of experience with vaccines and no reason to believe that vaccines cause long-term harm. I understand your concern, but I truly believe that the risk of diseases is greater than any risks posed by vaccines. Vaccines will get your baby off to a great start for a long, healthy life."

Communication Strategies—How to Have a Successful Dialogue

A successful discussion about vaccines involves a two-way conversation, with both parties sharing information and asking questions. These communication principles can help you connect with parents by encouraging open, honest, and productive dialogue.

Take advantage of early opportunities such as the prenatal, newborn, 1-week, and 1-month visits to initiate a dialogue about vaccines. These also are good opportunities to provide take-home materials or direct parents to immunization websites that you trust. This gives parents time to read and digest reputable vaccine information before the first and all future immunizations. And when parents have questions, you can build on the reputable information that they already have reviewed. With parents who have many questions, consider an extended visit to discuss vaccinating their child.

Take time to listen.

If parents need to talk about vaccines, give them your full attention. Despite a full schedule, resist the urge to multi-task while a parent talks. Maintain eye contact with parents, restate their concerns to be sure you understand their viewpoint, and pause to thoughtfully prepare your reply. Your willingness to listen will likely play a major role in helping parents with their decisions to choose vaccination.

Solicit and welcome questions.

If parents seem concerned about vaccines but are reluctant to talk, ask them open-ended questions and let them know that you want to hear their questions and concerns.

Put yourself in parents' shoes and acknowledge parents' feelings and emotions, including their fear and desire to protect their children. Remind parents that you know why they are concerned—their infant's health is their top priority. Remind them that it is yours, too.

Keep the conversation going.

If parents come to you with a long list of questions or information from the Web or other sources, don't interpret this as a lack of respect for you. Instead, acknowledge that spending time to research vaccines means that this is an important topic for the parents. If you appear offended by questions, or if you imply that a parent's questions are uncalled for, dialogue may shut down and trust may be eroded.



Science versus anecdote?

Too much science will frustrate some parents. Too little science will frustrate others. For some parents, too much anecdotal information won't hit the mark. For others, a story from your experience about an unprotected child who became ill, or knowing that children in your family have received all of their vaccines, will be exactly on target. Which approach to use will depend on your knowledge of the family. Watch and listen. Be prepared to use the mix of science and personal stories that will be most effective in addressing parents' questions.

Acknowledge benefits and risks.

Always discuss honestly the known side effects caused by vaccines. But don't forget to remind parents of the overwhelming benefit of preventing potentially serious diseases with vaccines. It's honest to say that not vaccinating is a risk that will worry you.

Respect parents' authority.

Many parents today want to work in partnership with their child's physician. Of course, you work in partnership with parents every day, for example, by eliciting reports from them about how their infants are progressing. By talking respectfully with parents about their immunization concerns, you can build on this partnership, build trust, and support parents in the decision to choose vaccination.

Reduce the stress of shots.

Show parents ways they can make the vaccination visit less stressful for the child. It can begin by reinforcing that crying is a normal response for the child and suggesting that they stay calm so that the child does not become aware of their stress. For infants, you can suggest that parents use a favorite blanket or toy to distract the baby from the pain of the shots, and that they touch and soothe the baby, talk softly, and smile and make eye contact during the shots. After shots for infants, mothers may wish to cuddle or breastfeed. For toddlers, there are many more

options to distract from the pain of the shot, including telling a favorite story, singing, or taking deep breaths and blowing out the pain. After the shots, toddlers can be praised for getting through the shots and reassured that everything is OK.

After the Office Visit

Document parents' questions and concerns.

A thorough record of your discussion will be an invaluable reference during the child's future visits.

Follow up.

If parents express extreme worry or doubt, contact them a few days after the visit. A caring call or e-mail will provide comfort and reinforce trust.

What If Parents Refuse to Vaccinate?

Excluding children from your practice when their parents decline immunizations is not recommended. It can put the child at risk of many different health problems—not just vaccine-preventable diseases. Remember, unvaccinated infants did not decide for themselves to remain unvaccinated. They need your care. Make sure that parents are fully informed about clinical presentations of vaccine-preventable diseases, including early symptoms. Diseases like pertussis and measles are highly contagious and may present early as a non-specific respiratory illness. Parents who refuse vaccines should be reminded at every visit to call before bringing the child into the office, clinic, or emergency department when the child is ill so appropriate measures can be taken to protect others. When scheduling an office visit for an ill child who has not received vaccines, take all possible precautions to prevent contact with other patients, especially those too young to be fully vaccinated and those who have weakened immune systems.

If a parent refuses to vaccinate, you can share the fact sheet *If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities* (<http://www.cdc.gov/vaccines/conversations>), which explains the risks involved with this decision including risks to other members of their community, and the additional responsibilities for parents, including the fact that, when their child is ill, they should always alert health care personnel to their child's vaccination status to prevent the possible spread of vaccine-preventable diseases. You also can tell the parent that you would like to continue the dialogue about vaccines during the next visit, and then make sure to do so. You may wish to have them sign AAP's *Refusal to Vaccinate* form (<http://www.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf>) each time a vaccine is refused so that you have a record of their refusal in their child's medical file.

Remember, not all parents want the same level of medical or scientific information about vaccines. By assessing the level of information that a particular parent wants, you can communicate more effectively and build trust.

For the information resources mentioned in this sheet, and others, look for *Provider Resources for Vaccine Conversations with Parents* at <http://www.cdc.gov/vaccines/conversations> or call **800-CDC-INFO** (800-232-4636). These resources are free to download and ready for color or black and white printing and reproduction.

If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities.

Last updated October 2009

If you choose to delay some vaccines or reject some vaccines entirely, there can be risks. Please follow these steps to protect your child, your family, and others.

With the decision to delay or reject vaccines comes an important responsibility that could save your child's life, or the life of someone else.

Any time that your child is ill and you:

- call 911;
- ride in an ambulance;
- visit a hospital emergency room; or
- visit your child's doctor or any clinic

you must tell the medical staff that your child has not received all the vaccines recommended for his or her age.

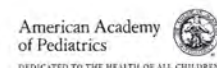
Keep a vaccination record easily accessible so that you can report exactly which vaccines your child has received, even when you are under stress.

Telling healthcare professionals your child's vaccination status is essential for two reasons:

- When your child is being evaluated, the doctor will need to consider the possibility that your child has a vaccine-preventable disease. Many of these diseases are now uncommon, but they still occur, and the doctor will need to consider that your child may have a vaccine-preventable disease.
- The people who help your child can take precautions, such as isolating your child, so that the disease does not spread to others. One group at high risk for contracting disease is infants who are too young to be fully vaccinated. For example, the measles vaccine is not usually recommended for babies younger than 12 months. Very young babies who get measles are likely to be seriously ill, often requiring hospitalization. Other people at high risk for contracting disease are those with weaker immune systems, such as some people with cancer and transplant recipients.

Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child's doctor or nurse to be sure your child's medical record is up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child's school, childcare facility, and other caregivers about your child's vaccination status.
- Be aware that your child can catch diseases from people who don't have any symptoms. For example, Hib meningitis can be spread from people who have the bacteria in their body but are not ill. You can't tell who is contagious.



When there is vaccine-preventable disease in your community:

- It may not be too late to get protection by getting vaccinated. Ask your child's doctor.
- If there are cases (or, in some circumstances, a single case) of a vaccine-preventable disease in your community, you may be asked to take your child out of school, childcare, or organized activities (for example, playgroups or sports).
- Your school, childcare facility, or other institution will tell you when it is safe for an unvaccinated child to return. Be prepared to keep your child home for several days up to several weeks.
- Learn about the disease and how it is spread. It may not be possible to avoid exposure. For example, measles is so contagious that hours after an infected person has left the room, an unvaccinated person can get measles just by entering that room.
- Each disease is different, and the time between when your child might have been exposed to a disease and when he or she may get sick will vary. Talk with your child's doctor or the health department to get their guidelines for determining when your child is no longer at risk of coming down with the disease.

Be aware.

- Any vaccine-preventable disease can strike at any time in the U.S. because all of these diseases still circulate either in the U.S. or elsewhere in the world.
- Sometimes vaccine-preventable diseases cause outbreaks, that is, clusters of cases in a given area.
- Some of the vaccine-preventable diseases that still circulate in the U.S. include whooping cough, chickenpox, Hib (a cause of meningitis), and influenza. These diseases, as well as the other vaccine-preventable diseases, can range from mild to severe and life-threatening. In most cases, there is no way to know beforehand if a child will get a mild or serious case.
- For some diseases, one case is enough to cause concern in a community. An example is measles, which is one of the most contagious diseases known. This disease spreads quickly among people who are not immune.

If you know your child is exposed to a vaccine-preventable disease for which he or she has not been vaccinated:

- Learn the early signs and symptoms of the disease.
- Seek immediate medical help if your child or any family members develop early signs or symptoms of the disease.

IMPORTANT: Notify the doctor's office, urgent care facility, ambulance personnel, or emergency room staff that your child has not been fully vaccinated before medical staff have contact with your child or your family members. They need to know that your child may have a vaccine-preventable disease so that they can treat your child correctly as quickly as possible. Medical staff also can take simple precautions to prevent diseases from spreading to others if they know ahead of time that their patient may have a contagious disease.

- Follow recommendations to isolate your child from others, including family members, and especially infants and people with weakened immune systems. Most vaccine-preventable diseases can be very dangerous to infants who are too young to be fully vaccinated, or children who are not vaccinated due to certain medical conditions.
- Be aware that for some vaccine-preventable diseases, there are medicines to treat infected people and medicines to keep people they come in contact with from getting the disease.
- Ask your healthcare provider about other ways to protect your family members and anyone else who may come into contact with your child.
- Your family may be contacted by the state or local health department who track infectious disease outbreaks in the community.

If you travel with your child:

- Review the CDC travelers' information website (www.cdc.gov/travel) before traveling to learn about possible disease risks and vaccines that will protect your family. Diseases that vaccines prevent remain common throughout the world, including Europe.
- Don't spread disease to others. If an unimmunized person develops a vaccine-preventable disease while traveling, to prevent transmission to others, he or she should not travel by a plane, train, or bus until a doctor determines the person is no longer contagious.

For more information on vaccines, ask your child's healthcare provider, visit www.cdc.gov/vaccines/parents, or call **800-CDC-INFO** (800-232-4636)



Documenting Parental Refusal to Have Their Children Vaccinated

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Despite our best efforts to educate parents about the effectiveness of vaccines and the realistic chances of vaccine-associated adverse events, some will decline to have their children vaccinated. Within a 12-month period, 85% of pediatricians report encountering a parent who refused or delayed one or more vaccines and 54% report encountering a parent who refused all vaccines. Even though scientific data solidly support the fact that vaccines are safe and effective, concern over harmful side effects, often taken out of context in the media and on unmonitored and biased Web sites, cause substantial and often unrealistic fears.

All parents and patients should be informed about the risks and benefits of preventive and therapeutic procedures, including vaccination. In the case of vaccination, federal law mandates this discussion. Despite doctors' and nurses' best efforts to explain the importance of vaccines and to address parental concerns about vaccine safety, some families will refuse vaccination for their children. Others will ultimately accept some or all vaccinations after repeated discussions during which the provider has listened to the parents concerns and addressed them in a non-condescending manner. The use of this or a similar form demonstrates the importance you place on appropriate immunizations, focuses the parents' attention on the unnecessary risk for which they are accepting responsibility, and may in some instances induce a wavering parent to accept your recommendations.

Providing parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempting to understand the parent's reason for refusing one or more vaccines, and maintaining a supportive relationship with the family are all part of a good risk management strategy. The American Academy of Pediatrics (AAP) encourages documentation of the healthcare provider's discussion with a parent about the serious risks of what could happen to their unimmunized or under-immunized child. Provide the parents the appropriate Vaccine Information Statement (VIS) for each vaccine and answer their questions. For parents who refuse one or more recommended immunizations, document your conversation, the provision of the VIS(s), and have the parent sign the vaccine refusal form and keep the form 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 physicians 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.

This form may be used as a template for such documentation but should not be considered a legal document and should not substitute for legal advice from a qualified attorney.

This form may be duplicated **or changed** to suit your needs and your patients' needs.

The Section on Infectious Diseases and other contributing sections and committees hope this form will be helpful to you as you deal with parents who refuse immunizations. It will be available on the AAP Web site (www.aap.org/bookstore), the Section on Infectious Diseases Web site (<http://www.aap.org/sections/infectdis/index.cfm>), and the Web site for the Academy's Childhood Immunization Support Program (www.cispimmunize.org).

Sincerely,

/s/

Meg Fisher, MD, FAAP

Chairperson

AAP Section on Infectious Diseases

/s/

Ed Rothstein, MD, FAAP

AAP Section on Infectious Diseases

Refusal to Vaccinate

Child's Name: _____ Child's ID # _____
 Parent's/Guardian's Name: _____
 My child's doctor/nurse, _____ has advised me that my child (named above) should receive the following vaccines:

Recommended

- Hepatitis B vaccine
- Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine
- Diphtheria tetanus (DT or Td) vaccine
- Haemophilus influenzae* type b (Hib) vaccine
- Pneumococcal conjugate or polysaccharide vaccine
- Inactivated poliovirus (IPV) vaccine
- Measles-mumps-rubella (MMR) vaccine.
- Varicella (chickenpox) vaccine
- Influenza (flu) vaccine
- Meningococcal conjugate or polysaccharide vaccine
- Hepatitis A vaccine
- Rotavirus vaccine
- Human papillomavirus vaccine
- Other _____

Declined

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I have read the Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents. I have had the opportunity to discuss this with my child's doctor or nurse, who has answered all of my questions regarding the recommended vaccine(s). I understand the following:

- The **purpose** of and the need for the recommended vaccine(s)
- The **risks and benefits** of the recommended vaccine(s)
- If my child does not receive the vaccine(s) according to the medically accepted schedule, **the consequences** may include:
 - Contracting the illness the vaccine should prevent (The outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness. Other severe and permanent effects from these vaccine-preventable diseases are possible as well)
 - Transmitting the disease to others
 - Requiring my child to stay out of child care or school during disease outbreaks
- My child's doctor or nurse, the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations.

Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled "Declined."

I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others with which my child might come into contact.

I know that I may readdress this issue with my child's doctor or nurse at any time and that I may change my mind and accept vaccination for my child anytime in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Parent/Guardian Signature _____ Date _____
 Witness _____ Date _____

I have had the opportunity to rediscuss my decision not to vaccinate my child and still decline the recommended immunizations.

Parent's initials _____ Date _____ Parent's initials _____ Date _____
 Parent's initials _____ Date _____ Parent's initials _____ Date _____



Parental Refusal to Accept Vaccination: Resources for Pediatricians

The following are some of the resources available to help pediatricians develop a productive dialogue with vaccine-hesitant parents and answer questions about vaccine risks and benefits:

Web sites

1. **AAP's Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.cispimmunize.org
2. **The Immunization Education Program (IEP) of the Pennsylvania Chapter of the American Academy of Pediatrics**
Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns, evaluating anti-vaccine claims, sources of accurate immunization information on the Web; and talking with parents about vaccine safety.
<http://www.paiep.org/>
3. **The Immunization Action Coalition (IAC)**
The IAC works to increase immunization rates by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. Their "Unprotected People Reports" are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.
<http://www.immunize.org/reports/>
4. **Centers for Disease Control and Prevention (CDC) National Immunization Program**
Information about vaccine safety, including Parents' Guide to Childhood Immunizations.
<http://www.cdc.gov/vaccines/hcp.htm>
5. **National Network of Immunization Information (NNii)**
Includes the NNii Resource Kit – Communicating with Patients about Immunizations. A guide to help answer patients' questions and provide the facts about immunizations.
www.immunizationinfo.org
6. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes Common Concerns About Vaccines, Are Vaccines Safe, and A Look at Each Vaccine.
www.vaccine.chop.edu
7. **Institute for Vaccine Safety, Johns Hopkins University**
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
8. **The Canadian Coalition for Immunization Awareness and Promotion (CCIAP)**
CCIAP aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers, including "How to advise parents unsure about immunization" by Scott A. Halperin, MD.
<http://immunize.cpha.ca/en/default.aspx>

Journal Articles

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2. Dias M, Marcuse EK. When parents resist immunizations. *Contemp Pediatr*. 2000;17:75-86
3. Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112:1394-1397
4. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109:124-129
5. Diekema DS, and American Academy of Pediatrics, Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115:1428-1431

Books

1. Offit PA, Bell LM. *Vaccines: What Every Parent Should Know*. New York, NY: IDG Books; 1999
2. Humiston SG, Good C. *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. Atlanta, GA: Peachtree Publishers; 2000
3. Fisher MC. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Elk Grove Village, IL: American Academy of Pediatrics; 2005
4. Marshall GS. *The Vaccine Handbook: A Practical Guide for Clinicians*. 2nd ed. West Islip, NY: Professional Communications, Inc.; 2008.
5. Myers, MG and Pineda D. *Do Vaccines Cause That? A Guide for Evaluating Vaccine Safety Concerns*. Immunizations for Public Health. 2008

Reliable Immunization Resources for Parents

Web sites

1. **AAP's Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.cispimmunize.org
2. **Why Should I Immunize My Child?**
A description of the individual diseases and the benefits expected from vaccination.
www.cispimmunize.org/fam/why.html
3. **The Immunization Education Program (IEP) of the Pennsylvania Chapter of the American Academy of Pediatrics**
Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns; evaluating anti-vaccine claims; sources of accurate immunization information on the Web; and talking with parents about vaccine safety.
<http://www.paiep.org/>
4. **Centers for Disease Control and Prevention National Immunization Program**
Information about vaccine safety, including Parents' Guide to Childhood Immunizations
<http://www.cdc.gov/vaccines/spec-grps/parents.htm>
5. **National Network of Immunization Information (NNii)**
Includes the NNii Resource Kit – Communicating with Patients about Immunizations. A guide to help answer patients' questions and provide the facts about immunizations.
www.immunizationinfo.org
6. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes Common Concerns About Vaccines, Are Vaccines Safe, and A Look at Each Vaccine.
www.vaccine.chop.edu
7. **Institute for Vaccine Safety, Johns Hopkins University**
Provides an independent assessment of vaccines and vaccine safety to help guide decision makers and educate physicians, the public and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
8. **The Canadian Coalition for Immunization Awareness and Promotion (CCIAP)**
CCIAP aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers, including "How to advise parents unsure about immunization" by Scott A. Halperin, MD.
<http://immunize.cpha.ca/en/default.aspx>
9. **Vaccinate Your Baby**
The Every Child by Two site serves as a central resource of vaccine information for parents. The site links to the latest research and studies about vaccines, an interactive timeline on the benefits of vaccines, information about vaccine safety and ingredients and the importance of adhering to the recommended schedule.
www.vaccinateyourbaby.org

Books:

1. Offit PA, Bell LM. *Vaccines: What Every Parent Should Know*. New York, NY: IDG Books; 1999
2. Humiston SG, Good C. *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. Atlanta, GA: Peachtree Publishers; 2000
3. Fisher MC. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Elk Grove Village, IL: American Academy of Pediatrics; 2005
4. Myers, MG and Pineda D. *Do Vaccines Cause That? A Guide for Evaluating Vaccine Safety Concerns*. Immunizations for Public Health. 2008

Talking to Families Resource Listing

Talking to Parents Recent news stories have led to even more parents questioning the safety of vaccines. In order to help you address parental concerns, the AAP and CDC encourage you to visit: <http://www.aap.org/moc/docs/030708VICP.cfm> for speaking points on recent cases in the news. Also visit the following sites for more information:

- Answers to frequently asked questions on infant immunization and vaccine safety:
<http://www.cdc.gov/vaccines/vpd-vac/faqs-vpd-vac.htm>

- In the news-
<http://www.aap.org/en-us/search/pages/results.aspx?k=autism%20news&s=All%20sites>

- Information on vaccine safety concerns-
<http://www.cdc.gov/vaccinesafety/Concerns/Index.html>
<http://www.immunizationinfo.org/issues/vaccine-safety/concerns-about-vaccine-safety>

- Resources for providers on parental hesitancy-
<http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html>

- Mitochondrial disorder FAQ from CDC-
<http://www.cdc.gov/ncbddd/autism/mitochondrial-faq.html>

- Fighting for the reputation of vaccines-
<http://pediatrics.aappublications.org/cgi/content/full/121/3/621>

- Aluminum Adjuvants in Vaccines
The National Network for Immunization Information provides information to address parental concerns about aluminum in vaccines. To access the website, visit:
http://www.immunizationinfo.org/vaccine_components_detail.cfv?id=61

- What to Expect – Guide to Immunizations
The What to Expect Foundation has created a practical parent guide called What to Expect – Guide on Immunizations which can be downloaded for free at:
http://www.whattoexpect.org/resources/WhattoExpect_Guideto_Immunizations.pdf

- Facts for Parents About Vaccine Safety:
<http://www2.aap.org/immunization/families/VaccineSafety1pagerEnglish.pdf>
<http://www2.aap.org/immunization/families/VaccineSafety1pagerSpanish.pdf>

- Vaccine Safety: The Facts
http://www2.aap.org/immunization/families/VaccineSafety_parenthandout.pdf

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Manual: [www2.aap.org/immunization/pediatricians/pdf/
ImmunizationTrainingGuide.pdf](http://www2.aap.org/immunization/pediatricians/pdf/ImmunizationTrainingGuide.pdf)

CPT Code Book

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Payment and Billing

Providing immunizations correctly and safely requires a large amount of time and effort from the provider and the office staff. Therefore, for providers to continue to offer this important public health service it is vitally important that they receive adequate payment for these services. Knowledge of the billing and hence coding rules will assure that providers are paid appropriately.

Providers can bill for the vaccine product and for the costs that are part of the immunization process. Thus there are two fees: a vaccine charge and an administration fee. Included in these costs are such items as: physician work/time, personnel costs, storages costs, insurance costs to cover losses, “wastage” and lost opportunity costs, to name a few. The AAP has published a brief summary of the Business aspects of Vaccines which is included. A listing of codes used for immunizations can be found in the standard CPT Code Book.

The following are hints on payments taken from the Maximizing Office Based Immunization in Kansas (MOBI-KS) program from the KAAP:

- Code for the products being given.
- The way CPT has developed the vaccine administrative codes is such that they are meant to be used for the work you and your staff do to keep your patient population up-to-date.
- Use Immunization Codes Properly.

1. The Immunization Administration section lists the specific codes of 90460-90461 with their definitions and the 90471-72 series as well. It’s important to use them properly.

2. The first set is for the individual antigen given per vaccine. Some vaccines have more than one antigen, such as Pediarix, which has five. In this case, you would use 90460 once and 90461 four times. If more than one vaccine is given, each vaccine uses 90460 once and then finishes with the number of 90461s according to the rest of the number of antigens.

3. The second set, 90471-72 is used for patients over 18 years old. This set is used for each vaccine given rather than by the antigens. It follows the old system prior to 2011.

4. In addition, use the CPT code for each vaccine product as well.



The Business Case for Pricing Vaccines

One of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid for the full costs (direct and indirect) of vaccine product-related expenses and vaccine administration expenses as well as the margin for overall overhead expenses. Because the private physician practice is the backbone of the immunization delivery infrastructure, public and private sector payers must recognize that a pediatric practice is really a business entity and must run on sound, generally accepted business principles to remain viable. Vaccines are among the top overhead expenses for the pediatric practice. Therefore, payments must ensure recovery of the total direct and indirect practice expenses and a margin for both the vaccine product and the vaccine administration office costs and the time spent counseling families on the indications for and potential adverse effects of each vaccine product.

The number of vaccines continues to increase and the costs have become increasingly high, necessitating a more business-like approach to payment because of the increased potential for uncompensated costs. For most states, which are nonuniversal purchase, the direct and indirect expenses in maintaining the vaccine product must be accounted for in a compensation formula that incorporates these factors in the vaccine purchase as well as a margin to incentivize immunizations. For universal purchase states, this means having an acceptable immunization administration fee that also covers compensation for indirect vaccine acquisition and maintenance expenses as there are no direct vaccine purchase costs and no mechanism for paying indirect expenses.

Several studies published in the *Pediatrics* supplement, “Financing of Childhood and Adolescent Vaccines,”¹ underscore the need for appropriate payment to cover the total costs for immunizations. In one major study, a cross-sectional survey of private practices in 5 states (California, Georgia, Michigan, New York, and Texas) concluded that there is a wide variation in payment for vaccines and administration fees by payers, resulting in the “need for providers to seek opportunities to reduce costs and increase reimbursements.”²

Vaccine Product-Related Expenses: This is separately reportable from the immunization administration.

Some payers mistakenly try to maintain that inadequate vaccine payments can be made up by nominal immunization administration fees. ***However, these are two separate expenses, and both need to be appropriately covered by payers. The payment for vaccines is a legitimate expense that must cover the total direct and indirect expenses as listed below.***

1. ***Purchase price (acquisition cost) of the vaccine:*** This is the amount paid by the physician for the vaccine. Although discounts may exist, these are not available to all pediatric practices and may be time limited. An accurate and verifiable public source on the current manufacturer's price for vaccines can be accessed on the CDC vaccine price list for the private sector at: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm> The AAP believes that the CDC private payer vaccine price list should be used as a transparent methodologic basis for vaccine acquisition and invoice cost as part of the total cost of the vaccine.
2. ***Personnel costs for ordering and inventory:*** Medical office staff (clinical and administrative) time to monitor vaccine stock; place orders; negotiate costs, delivery, and payment terms; and ensure safe storage procedures (locks, alarms, temperature controls, etc)
3. ***Storage costs:*** Vaccines must be stored at very specific temperature ranges and, therefore, require special

monitoring and storage equipment. The practice expense component of the total immunization administration code pays for part of the vaccine storage costs; however, there are certain expenses that are **not** included that must be compensated: freezer(s), freezer lock(s), freezer alarm system(s), and generators for continued electrical supply (all of which are depreciated).

4. **Insurance against loss of the vaccine:** Professional liability malpractice insurance does not cover vaccine product, so additional insurance coverage is needed by the practice.

5. **Recovery of costs attributable to inventory shrinkage, wastage, and nonpayment:** In the retail market, inventory shrinkage refers to the uncompensated loss of product due to theft, vendor error, and administrative error. Additionally, there is an estimated wastage/nonpayment of at least 5% (this should be accurately accounted for in each office). This includes drawing up the vaccine and having the patient/family reconsider and refuse, resulting in subsequent nonpayment, or a loss of dose that may occur in attempting to vaccinate an uncooperative/combatative patient. This would also include collection costs in response to nonpayment by the patient or third-party payer.

6. **Lost opportunity costs:** This is the cost of maintaining a large vaccine inventory. Between \$10,000 and \$15,000 in inventory is maintained per pediatrician or other provider of vaccines. Every business with this level of money tied up in product inventory must receive an appropriate return on its investment, and so should every pediatric practice.

So what would be appropriate payment for vaccine product expenses for the total direct and indirect costs?

Payments must:

- Be free of any discounts and based on a transparent and verifiable data source, such as the CDC vaccine price list for the private sector, available at: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>.
- Cover the vaccine purchase price as well as all related office expenses as noted above and a return on the investment for the dollars invested in vaccine inventory.

When the direct and indirect expenses are totaled for the vaccine product, estimates range from 17% to 28% depending on the practice. Therefore, payments for the vaccine should be at the level that covers the total vaccine expenses.

Pediatric practices are the public health infrastructure for the nation's childhood immunization program. It is imperative to incentivize pediatricians to participate in immunization efforts by appropriate payment for vaccines.

References

¹ Financing of Childhood and Adolescent Vaccines. *Pediatrics*. 2009;124(Suppl 5). Available at: http://pediatrics.aappublications.org/content/vol124/Supplement_5/

² Freed GL, Cowan AE, Gregory S, Clark SJ. Variation in provider vaccine purchase prices and payer reimbursement. *Pediatrics*. 2009;124(Suppl 5):S459-S465. Available at: http://pediatrics.aappublications.org/cgi/content/full/124/Supplement_5/S459



The Business Case for Pricing Immunization Administration

One of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid for the full costs (direct and indirect) of vaccine product-related expenses and vaccine administration expenses as well as the margin for overall overhead expenses. Because the private physician practice is the backbone of the immunization delivery infrastructure, payers must recognize that a pediatric practice is really a business entity and must run on sound, generally accepted business principles to remain viable. Vaccines are among the top overhead expenses for the pediatric practice. Therefore, payments must ensure reimbursement for the total direct and indirect practice expenses and a margin for both the vaccine product and the vaccine administration office costs and the time spent counseling families on the indications for and potential side effects of each vaccine product.

Immunization Administration Expenses: *This service is separately reportable from the vaccine product.* Some payers mistakenly try to maintain that inadequate vaccine payments can be made up by nominal immunization administration fees. ***However, these are two separate expenses and both need to be appropriately covered by payers.***

Several studies published in the *Pediatrics* supplement, “Financing of Childhood and Adolescent Vaccines”¹, underscore the need for appropriate payment to cover the total costs for immunizations. In one study on variable costs for immunizations by pediatric practices in Colorado it was determined that the variable costs of vaccine administration exceeded reimbursement from some insurers and health plans.²

The Centers for Medicare and Medicaid Services (CMS) uses its Medicare Resource-Based Relative Value Scale (RBRVS), which assigns relative value units (RVUs) to services based on the resources utilized. The RVUs of a *Current Procedural Terminology* (CPT) code take into account the physician work, practice expenses, and professional insurance liability expenses associated with that service. For immunization administration, these components are detailed below.

1. Physician Work Component: The total value of physician work contained in the Medicare RBRVS physician fee schedule includes:

- Physician time required to perform the service
- Technical skill and physical effort
- Mental effort and judgment
- Psychological stress associated with the physician’s concerns about the iatrogenic risk to the patient

2. Practice Expense Component: Medicare RBRVS uses both direct and indirect practice expenses to determine practice expense RVUs, including the resources used within the facility or physician’s office (or patient’s home) in providing the service. The practice expense component of the immunization administration fee includes: 1) clinical staff time (RN/LPN/MA blend, including time for vaccine registry input, refrigerator/freezer temperature log monitoring/documentation, and refrigerator/freezer alarm monitoring/documentation); 2) medical supplies (1 pair non-sterile gloves, 7 feet of exam table paper, 1 OSHA-compliant syringe with needle, 1 CDC information sheet, 2 alcohol swabs, 1 band-aid) and; 3) medical equipment (exam table, dedicated full size vaccine refrigerator with alarm/lock [commercial grade], and refrigerator/freezer vaccine temperature monitor/alarm).

3. Professional Liability Insurance Expense Component: The professional liability insurance RVUs assigned to

Effective 01/01/2011

a code are based on CMS historic malpractice claims data.

These three components are combined to create total RVUs (see Table below).

2011 Medicare Relative Value Units for Immunization Administration

CPT code and description	Physician Work RVUs	Practice Expense RVUs (Non-Facility)	Professional Insurance Liability RVUs	Total RVUs (Non-Facility)	Total RVUs x 2011 Medicare conversion factor (\$33.9764) = Medicare Amount (Non-Facility)
90460 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first vaccine/toxoid component *	0.17	0.50	0.01	0.68	\$23.10
90461 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine/toxoid component *	0.15	0.18	0.01	0.34	\$11.55
90471 Immunization administration, one injection **	0.17	0.50	0.01	0.68	\$23.10
90472 Immunization administration, each additional injection**	0.15	0.18	0.01	0.34	\$11.55
90473 Immunization administration by intranasal/oral route, first administration**	0.17	0.50	0.01	0.68	\$23.10
90474 Immunization administration by intranasal/oral route, each additional vaccine **	0.15	0.18	0.01	0.34	\$11.55

* CPT codes 90460 and 90461 are reported for patients under 19 years of age and when counseling is performed on the patient by the physician or other qualified health care professional. It should also be noted that the following codes are reported per vaccine component rather than per injection/administration and make no distinction between routes of administration (i.e., injectable versus oral/intranasal).
 **These codes are reported for older patients (i.e., those 19 years and older) or if there is no counseling performed on the patient or the healthcare professional counseling does not meet state requirements for an "other qualified healthcare professional". It should also be noted that the following codes are reported per injection/administration and allow distinction between routes of administration (i.e., injectable versus oral/intranasal).

As a separately reported service, payments for immunization administration need to adequately cover those costs to the practice which are separate from the direct and indirect costs associated with the vaccine product. Insurers understand business principles including the concept of return on investment and expect it in their business. There is no reason physicians should accept carrier refusal to pay separately and adequately for the vaccine product **and** the administration/counseling. Viable businesses pass on their increased costs to their purchasers to maintain profitability. The pediatric practice has a legitimate business case to make for separate and adequate payment for vaccines and immunization administration and carriers need to provide adequate payments to cover the total direct and indirect expenses for both the vaccine product and the administration.

Pediatric practices are the public health infrastructure for the nation's childhood immunization program. It is imperative to incentivize pediatricians to participate in immunization efforts by appropriate payment for immunization administration.

References

1. Financing of Childhood and Adolescent Vaccines; Pediatrics Supplement 2009 Available at: http://pediatrics.aappublications.org/content/vol124/Supplement_5/
2. Judith E. Glazner, MS, Brenda Beaty, MSPH and Stephen Berman, MD
 Cost of Vaccine Administration Among Pediatric Practices Pediatrics 2009; 124:S492-S498 Available at: http://pediatrics.aappublications.org/cgi/content/abstract/124/Supplement_5/S492

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 Current Procedural Terminology © 2010 American Medical Association. All Rights Reserved. For information on AAP private payer advocacy, contact Lou Terranova, Senior Health Policy Analyst, at lterranova@aap.org

Vaccines: A Survival Guide for Pediatric Practices

Do you know if vaccines are providing an operating margin or a loss to your practice? If you have not run the numbers recently, consider the exercise below. As the price of vaccines increases and the schedule becomes more complex, vaccines have become a

loss leader for many pediatric practices. In order to effectively negotiate with private payers, pediatricians need to know exactly how much vaccines are costing them. Total the costs listed below to calculate the true cost of immunizing for your practice.

Calculating Direct Costs

Purchase price of vaccine
(include excise tax) _____

Sales or usage tax
(purchase price * % tax) _____

Calculating Overhead Costs

(Choose a timeframe - such as month or quarter - for which to calculate the following costs.)

Personnel costs to order and inventory vaccines _____

- ((Hours spent ordering vaccines + hours spent monitoring storage of vaccines)/ number of vaccines ordered) * hourly salary of administrative or clerical staff

Personnel costs for negotiating prices and tracking unpaid claims _____

- (Hours spent negotiating/number of vaccines administered) * hourly salary of staff

Storage costs _____

- (Cost of refrigerator + cost of freezer + cost of alarm/lock/temperate monitoring device + cost of generators in case of power outage + kilowatts used by refrigerator)/number of vaccines stored
- Rent and bills for vaccine-related appointments

Insurance costs against vaccine loss _____

- Cost of insurance/number of vaccines ordered

Wastage/non-payment _____

- Cost of vaccines ordered * 5%

Lost opportunity costs _____

- Cost of vaccines stored at any given time * reasonable return on investment
- Extra time spent explaining vaccines in a room that could be used for another appointment

Personnel costs for entering data into a registry _____

- Hours spent entering one vaccine into registry * hourly salary of staff

Calculating Administration Expenses

(See Business Case for Pricing Vaccines and Immunization Administration for the relative values used by Medicare.)

Physician Work _____

- Average time spent (in hours) with patient/parent answering vaccine questions * hourly salary of physician

Practice Expense _____

- Staff time (in hours) administering vaccine * hourly salary (including distribution of VIS and answering questions)
- Medical supplies (1 pair non-sterile gloves, 7 feet of exam table paper, 1 OSHA-compliant syringe with needle, 1 CDC

information sheet, 2 alcohol swabs, 1 band-aid) and medical equipment (exam table)

Professional Liability Insurance (as defined in the Business Case for Pricing Vaccines) _____

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American Academy
of Pediatrics



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Participating in a Group Purchasing Organization

Group purchasing organizations (GPOs) are able to combine orders from practices, hospitals, nursing homes, and other medical facilities in order to receive volume discounts from specific vendors. Vaccine purchasing programs are one type of GPO. While the AAP does not have access to the lists of GPOs that may work with pediatric practices, pediatricians may wish to further investigate the following types of groups.

- **Health Industry Group Purchasing Association (HIGPA):** This member organization includes GPOs, manufacturers, and distributors. Contact HIGPA or link directly to members by visiting this Web site: www.higpa.org/member_orgs/Member_Orgs.asp.
- **Pediatrician-led Groups:** Some groups are exclusive to pediatricians or pediatric products. While these groups may not be as large as those from HIGPA, they may meet more of pediatricians' needs. Learn more about one pediatrician-led group at www.pediafed.com/vpp.
- **Distributors with GPO Component:** Some distributors offer pediatric-specific GPOs. Visit www.cispimmunize.org/pro/manufacturers.html for a list of distributors to call.
- **Practice Management Groups:** In addition to other consulting services, practice management groups may offer a vaccine purchasing agreement.
- **Hospitals or Nursing Homes:** These groups in your area may have their own vaccine purchasing agreements. If you are affiliated with the hospital, they may allow you to order through them.

Most GPOs require that you order all vaccines through them, although they may only contract with 2 or 3 manufacturers. Make sure the GPO you choose contracts with all of the vaccine manufacturers whose products you wish to use.

Negotiating Contracts

A new PediaLink education module has been developed to help pediatricians negotiate the best possible contract with private payers. The *Contract Negotiations With Payers* module presents techniques and processes to confidently conduct successful negotiations. Key topics include technical considerations, model contracts, negotiation styles, and a 4-phase negotiation process model.

This 5-hour module is targeted to pediatricians and their staff who have limited experience in negotiating payer contracts or who need a refresher course in this area. *Contract Negotiations With Payers* is available at: www.pedialink.org/cme/_coursefinder/CMEdetail.cfm?aid=31177&area=liveCME.

Some tips from the module are below:

- Review the carrier contract for provisions on vaccine and immunization administration payments.
- Insist that there be provisions to address payment for new vaccines, vaccine price increases, and new immunization recommendations in a timely manner by the payer. See the Vaccine Addendum at www.aap.org/securemoc/reimburse/VaccineAddendumtoPayerContracts.pdf.
- If your practice is efficient and effective with high immunization rates then the health plan benefits as well with a higher HEDIS score. This is a good strategy for negotiation.
- Participate in your chapter's Pediatric Council to educate payers about true costs.
- Fill out an AAP Hassle Factor form on payers who perform poorly. See the Hassle Factor form at www.aap.org/moc/reimburse/hasslefactor.
- Currently, many parents are having difficulty obtaining HPV vaccine for their adolescent girls due to high capital outlay for pediatricians coupled with low payment by insurers. These parents are complaining to their insurers and employers, creating dissatisfied customers. It is in the insurers' and employers' best interests to pay for immunizations fairly to maintain customer satisfaction.



Contract Negotiations With Payers
Differentiate Your Practice Through a Better Contract

Vaccine Financing Resources

- Vaccine Coding Table- www.cispimmunize.org/pro/pdf/AttachmentB_VaccineCodingTable.pdf
- Business Case for Pricing Vaccines and Immunization Administration - www.cispimmunize.org/pro/pdf/The%20Business%20Case%20for%20Pricing%20New%20Vaccines.pdf
- AAP Task Force on Immunization White Paper- www.cispimmunize.org/immunizationcongress.htm
- Talking Points for Pediatricians on Vaccine Financing Issues at www.aap.org/moc/reimburse/talkingpoints.htm

- Vaccine Contract Addendum at www.aap.org/securemoc/reimburse/VaccineAddendumtoPayerContracts.pdf

General Resources

- Private Payer Advocacy pages: www.aap.org/moc/reimburse
- Childhood Immunization Support Project (CISP): www.cispimmunize.org
- Practice Management Online: <http://practice.aap.org>

For questions about immunization, please contact esobczyk@aap.org.
For questions about private payer advocacy, please contact lterranova@aap.org.

Vaccines for Children (VFC)

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KDHE: www.kdheks.gov/immunize/vfc_program.html

VFC FAQs: www.cdc.gov/vaccines/programs/vfc/awardees/questions/index.html

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Vaccines for Children (VFC)

The Vaccines for Children Program (VFC) is a federally funded program that provides vaccines to children whose parents or guardians are unable to pay for the costs. Money for the program comes from the CDC through the Centers for Medicare and Medicaid Services (CMS). Children who are age 18 and under are eligible for VFC if they meet the following criteria:

- Medicaid/CHIP eligible
- Uninsured
- American Indian or Alaska Native
- Underinsured

Underinsured can receive VFC only through Federally Qualified Health Centers (FQHC) or Rural Health Centers.

Being part of the VFC program can offer some big advantages to providers. First, there is no up-front money to pay for the vaccines as the VFC program covers these costs. This cuts down overhead and means you don't have money tied up in inventory. Secondly, the provider can charge an administrative fee. In the early years of the program, these fees were quite low, however, for many years now the administrative fees have risen to where they more than cover any expenses a practice incurs providing the immunizations. It is a big benefit to patients because they do not have to go somewhere else to receive the vaccines. As the immunization schedule and preventative care visits coincide, there is less likelihood of missed immunizations and/or preventative care visits. Providing immunizations at the provider's office is consistent with the concept of the medical home. Thirdly, this makes it easier for families who may have trouble finding transportation for additional trips to get immunizations. Finally, there is less time missing work for parents, many of whom are in low paying jobs with little or no benefits.

Interested providers can go to the following website to find out more about the Kansas VFC program. This site includes provider enrollment information.

www.kdheks.gov/immunize/vfc_program.html

Additional Resource: FAQs on VFC

www.cdc.gov/vaccines/programs/vfc/awardees/questions/index.html

VACCINES FOR CHILDREN PROGRAM (VFC)



INFORMATION FOR HEALTHCARE PROVIDERS FROM CDC

VFC WILL BENEFIT YOUR PATIENTS AND YOUR PRACTICE!



Are you a VFC provider?

Being a VFC provider is a sound investment in your practice and in your patients. It reduces your up-front costs because you will not have to pay to purchase vaccines for VFC-eligible children. Also, you can charge an administrative fee to offset your costs of doing business. Your patients benefit because they won't have to go somewhere else to get the vaccines they need, and there is no charge to you, the provider.

Children and adolescents are eligible if it is before their 19th birthdays and they meet one or more of the following criteria:

- ▶ Medicaid-eligible
- ▶ Uninsured
- ▶ American Indian or Alaska Native
- ▶ Underinsured (Underinsured children are only eligible for VFC Vaccines through FQHC/RHC.)

What do you mean by "underinsured?"

Underinsured means your patient has health insurance, but it won't cover the vaccine(s) because:

- ▶ It doesn't cover any vaccines.
- ▶ It doesn't cover certain vaccines.
- ▶ It covers vaccines, but it has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount has been reached, your patient is eligible.

What are the benefits of VFC?

The VFC program provides routine vaccines to all states, the District of Columbia, and territories for participating healthcare providers. All vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by CDC and HHS are covered under the VFC Program at no cost to the participating healthcare provider. You don't have to be a Medicaid provider to participate in VFC. Any healthcare provider authorized to prescribe vaccines under your state law can be a VFC provider.

How can you become a VFC provider?

- ▶ Contact your State/Territory VFC coordinator. You can find him or her at <http://www.cdc.gov/vaccines/programs/vfc/contacts-state.htm>. All you need to do is ask for a Provider Enrollment Package to be mailed to you.
- ▶ Complete the State Provider Enrollment forms and return them as soon as possible.
- ▶ Prepare your office and staff for a site visit to go over the administrative requirements of the program and to ensure proper storage and handling of vaccines when you receive them.
- ▶ Once you're enrolled, tell parents you are now a VFC provider.

The VFC Program will:

- ▶ Keep your patients in their medical home.
- ▶ Reduce your up-front costs.
- ▶ Help provide quality care to vulnerable children and adolescents.

For more information about the VFC program, go to www.cdc.gov/vaccines/programs/vfc/. Get an answer to your specific question by e-mailing cdcinfo@cdc.gov or calling 800-CDC-INFO (232-4636) anytime.

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IMMUNIZE KANSAS KIDS