



PHYSICIANS' BULLETIN

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"Focusing on Families as Our Customers"

No. 440

Vaccine Supply Shortages End Except for PCV

Childhood Vaccine Supply Problems Have Ended, CDC Says; Only PCV Still In Short Supply

The federal Centers for Disease Control and Prevention has announced that childhood vaccine supply problems in the U.S. have been resolved except for PCV. Previously, shortages included Td, DTaP, MMR, VZV and PCV vaccines. Following is a brief summary of each vaccine's status:

Td and DTaP: Shortages of both vaccines have ended. Providers should return to the normally recommended schedules for these vaccines. County of San Diego Health and Human Services Agency has informed local schools to no longer accept Temporary Exemptions for these vaccines. Physicians may expect to see students return to their offices prior to the October 1, 2002 exemption date to get caught up on vaccines because of previous exemptions issued due to shortages over the past year.

MMR and VZV: Shortages have ended and orders for these vaccines are now being filled quickly. Providers should return to the normal schedules.

PCV: The shortage of this vaccine is expected to last through the end of 2002. Providers should continue to use the revised recommendations for this vaccine. For more information about those recommendations, please see Physicians' Bulletin No. 435, issued in January, 2002. For your

Recommendations for pneumococcal conjugate vaccine use among healthy children during moderate and severe vaccine shortages (ACIP, 2001)

Age at first vaccination	No shortage*	Moderate shortage	Severe shortage
<6 months	2, 4, 6 and 12-15 months	2, 4 and 6th months (defer 4th dose)	2 doses at 2-month interval in 1st 6 months of life (defer 3rd and 4th doses)
7-11 months	2 doses at 2-month interval; 12-15 month dose	2 doses at 2-month interval; 12-15 month dose	2 doses at 2-month interval (defer 3rd dose)
12-23 months	2 doses at 2-month interval	2 doses at 2-month interval	1 dose (defer 2nd dose)
>24 months	1 dose should be considered	No vaccination	No vaccination
Reduction in vaccine doses used †		21%	46%

* The vaccine schedule for no shortage is included as a reference. Providers should not use the no shortage schedule regardless of their vaccine supply until the national shortage is resolved.

† Assumes that approximately 85% of vaccine is administered to healthy infants beginning at age <7 months; approximately 5% is administered to high-risk infants beginning at age <7 months; and approximately 10% is administered to healthy children beginning at age 7 to 24 months. Actual vaccine savings will depend on a provider's vaccine use.

convenience, the table summarizing those recommendations is reproduced above.

No Evidence That Multiple Vaccines Overwhelm Or Weaken The Immune System

In an article in the journal *Pediatrics* (2002:109:124-9) Paul A. Offit, M.D., et al concluded that the concern that multiple vaccines, especially administered at the same time, might somehow overwhelm or weaken infants' immunization systems is unfounded. Among the article's conclusions:

- 1) From the time of full-term birth, newborn infants are well equipped with both humoral (antibody) and cellular immune system capacity. They have to be, since during the

birth process they are exposed to microbes in the mother's birth canal and within hours of birth their GI tracts are heavily colonized with bacteria.

- 2) Young infants are fully capable of generating protective humoral and cellular immune system response to multiple vaccines administered simultaneously. These responses are similar regardless of whether the different vaccines are administered on the same day or weeks apart. Projections based on known features of infants' immune systems are that they could respond adequately to literally thousands of vaccines given at the same time.
- 3) At the time of vaccine

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administration to infants, the development of protective immune responses to standard vaccines is not impaired by the presence of fever, upper respiratory tract infection, otitis media, skin infection, or diarrhea.

- 4) Children who were immunized with standard vaccines in the first few months of life have, if anything, fewer infections (including non-vaccine preventable infections) than children who have not been immunized.

For the full text of the *Pediatrics* article, please visit the following web site: <http://www.pediatrics.org/cgi/content/full/109/1/124>.

**ACIP General Recommendations:
Specific Aspects Explained**

4-Day Grace Period for Vaccine Doses Given Too Soon:

ACIP continues to recommend that vaccine doses should not be given at less than the minimum intervals or earlier than the minimum age for the dose (Table 1 of the General Recommendations, reprinted on page 5 of this Bulletin). However, a dose just a few days (specifically 1-4 days) earlier than the minimum interval or age is unlikely to have a significant negative effect on the immune response to that dose. ACIP now recommends that vaccine doses administered up to and including four days before the minimum interval or age **can be counted as valid** and thus do not need to be repeated. This 4-day grace period should NOT be used when scheduling future visits. It should be used primarily when reviewing vaccination records, i.e., of doses already received.

Repeating invalid doses: Doses administered ≥ 5 days earlier than the minimum interval or age should not be counted as valid **and should be repeated**. If a dose

was given ≥ 5 days before the minimum age the dose should be repeated when the minimum age is reached and when 4 weeks have elapsed since the invalid dose. If a dose was given ≥ 5 days before the minimum interval after a prior dose of the same vaccine, the dose should be repeated when this minimum interval has again lapsed following the invalid dose (the last column of the ACIP document's Table 1 provides these intervals--please see page 5 of this Bulletin).

Exceptions to the 4-day grace period: (a) **4th DTaP dose**--The minimum recommended interval between the 3rd and 4th DTaP doses is 6 months. However, the ACIP document indicates (in a footnote to its Table 1) that a 4th DTaP dose given **at least 4 months after the 3rd dose** can be counted and does not have to be repeated. (b) **Rabies immunization series**--**No 4-day grace periods** are allowed for the minimum intervals between successive doses of rabies vaccines.

School and child care facility entry immunization law: California's school/child care facility immunization law now allows for the new 4-day grace periods. That is, where the law specifies minimum ages for certain vaccine doses, the minimum ages will remain as the standard. However, doses received 1-4 days before those minimum ages will be accepted as meeting the immunization requirement. The California Immunization Branch has issued communications to schools, child care facilities and local health departments that describe this change.

Note that these cutoffs and timing details are being incorporated into immunization registry software so that the registry will be able to calculate these requirements for the users.

**Revised ACIP Recommendation for
Avoiding Pregnancy After Receiving
A Rubella-Containing Vaccine**

In the December 14, 2001 issue of the MMWR (Morbidity and Mortality Weekly Report) [50:1117], the ACIP (Advisory Committee on Immunization Practices) shortened its recommended period **to avoid pregnancy after receipt of rubella-containing vaccine (typically the MMR) from 3 months to 28 days**. The change in recommendation was based on review of data from several sources indicating that no cases of congenital rubella syndrome (CRS) had been identified among infants born to women who were vaccinated inadvertently against rubella within 3 months or early in pregnancy.

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For a wealth of immunization information, visit the San Diego Immunization Initiative website at www.immunization-sd.org.

The *Physicians' Bulletin* is published on an as-needed basis by the County of San Diego Health and Human Services Agency to provide updated information on health issues of concern to San Diego County's medical community.

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Editor

Sandra Ross
(619) 692-8661
P.O. Box 85222, P-511B
San Diego, CA 92186-5222

Timing the Administration of Different Live Virus Vaccines

In the November 30, 2001 issue of the MMWR (Morbidity and Mortality Weekly Report) [50:1058-61], the CDC repeats the recommendation that there are no timing restrictions between administration to a patient of the injectable live virus vaccines for VZV and for MMR and administration of the other standard childhood vaccines DTaP, Hib, Hepatitis A and B, and IPV (all of which are inactivated vaccines). However, **VZV and MMR, if not given on the same day should be spaced at least 4 weeks apart.**

Adverse Vaccine Event Reporting Procedures

To ensure that vaccines are as safe as possible and to maintain public confidence in vaccines, the U.S. maintains a system that provides for close monitoring of the incidence of adverse events, adequate scientific evaluation of possible associations, and appropriate response to newly identified risk of vaccine. In 1990, CDC and the FDA established the Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system that monitors vaccine safety. The VAERS case form is provided to physicians, health departments, and public health clinics that administer vaccine. The VAERS accepts reports of any suspected adverse event following administration of a vaccine, whether or not it is certain that the vaccine caused the event. The FDA reviews reports of serious events and conducts analyses of reports by vaccine lots. The CDC routinely reviews selected serious outcomes (e.g., anaphylaxis) and conducts additional analyses as needed to address specific concerns and to evaluate trends in reporting. Health

care providers, manufacturers, patients and parents/guardians are all encouraged to report any clinically significant adverse event believed to be related to vaccination. More information, including a reporting form, is available at www.vaers.org. Additionally, patients and parents are notified about the VAERS system on every Vaccine Information Statement (VIS) which providers are required to give whenever a routine vaccine is administered.

Immunization Q & A

How long must health care providers retain their patient immunization records?

According to the State Department of Health Services (DHS) Immunization Branch and DHS Office of Legal Services:

California Code of Regulations, Title 17, Section 75055, states that records shall be kept by health care providers on all patients registered or accepted for treatment. Following release or termination of treatment, **such records shall be kept for a minimum of seven years, except for minors whose records shall be kept at least one year after the minor has reached age 18 years** but in no case for less than seven years after release or termination of treatment.

New DTaP Vaccine Licensed

DAPTACEL® is a combined diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine from Aventis Pasteur that was licensed by the FDA earlier this year. It is approved for the first four doses of the DTaP series administered to infants and children aged 6 weeks to 7 years. Additional information about the safety of a fifth dose following four previous doses of the same acellular pertussis vaccine is being

collected and should be available before infants and children receiving DAPTACEL® exclusively are age 4-6 years and require a fifth dose.

Three DTaP vaccines are now licensed and distributed in the U.S.: Tripedia® (also from Aventis Pasteur), Infanrix® (Glaxo SmithKline), and DAPTACEL®.

August is National Immunization Awareness Month

The National Partnership for Immunization (NPI) has proclaimed August as National Immunization Awareness Month (NIAM). A pair of ads developed by the Fresno/Madera County Immunization Coalition have been adapted for statewide use. Online NPI materials for NIAM are available at www.partnersforimmunization.org/niam.html.

African-American Flu/Diabetes Campaign To Start This Fall

Despite a variety of activities and outreach efforts, African-Americans continue to have a lower rate of flu shot coverage compared to other ethnic groups. This fall, State DHS will launch a campaign designed to increase awareness about flu shots among African-American women over the age of 50. This campaign will focus on these women because, in addition to being at risk for not receiving influenza vaccine, they have a higher incidence of diabetes than the general population, and are identified as opinion “gatekeepers” for their families. Tentative plans call for print ads to appear this fall in *Essence* magazine and supplemental educational materials will be made available for distribution by the San Diego Immunization Initiative.

To get free patient educational materials, visit the San Diego Immunization Initiative website at www.immunization-sd.org.

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Evaluating Patients For Smallpox Poster Available

The recent bioterrorism events have heightened awareness in the health care community concerning the diagnosis of a possible case of smallpox--a disease that has been eradicated from the world for more than two decades. Many rash illnesses, including chickenpox, can present with vesicles and pustules. CDC, in collaboration with a number of professional and medical organizations and individuals, has developed an algorithm to guide the systematic evaluation of patients with generalized rash illnesses to determine if they have smallpox. A poster created by CDC on this subject is available from the County's Immunization Program. To order this poster, please call Pat Biritz at (619) 692-8663.

Immunization Schedule for Personal Digital Assistants (PDAs)

Shots 2000 is a quick reference guide to the 2002 Childhood Immunization Schedule designed for use in PDAs which use the Palm OS. The

program displays the 2002 schedule, and details on each vaccine are available by clicking on the vaccine names. The program is a collaboration of the ACIP, AAP and the American Academy of Family Physicians (AAFP). It's available from the Society of Teachers of Family Medicine at www.immunizationed.org.

Immunization Deferral Postcards Available

VFC (Vaccines for Children) providers were asked to maintain a list of the children for whom one or more immunizations were deferred due to vaccine shortages. The postcards, which remind parents to make an appointment for their child to receive previously deferred immunizations, are available from the County of San Diego HHS Immunization Program (see images below). To order these postcards, call Pat Biritz at (619) 692-8663.

Summary of Pediatric Immunization Recommendations Poster Available

The State Department of Health Services Immunization Branch large

"Everything" poster summarizing ACIP, AAFP (American Academy of Family Physicians) and AAP (American Academy of Pediatrics) 2002 recommendations on vaccine schedules, contraindications, etc. is available from the County's Immunization Program. To order these posters, call Pat Biritz at (619) 692-8663.

7th Edition Pink Book and 2002 Immunization Works CD Available

According to the CDC's National Immunization Program (NIP), the 7th edition of Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) is available from the Public Health Foundation for \$25 at <http://bookstore.phf.org>. The updated 2002 Immunization Works CD is available from the CDC through its online order form https://www2.cdc.gov/nchstp_od/PIWeb/niporderform.asp. This disk includes ACIP recommendations, Vaccine Information Statements, the Pink Book, and other NIP documents.

Immunization Deferral Postcard

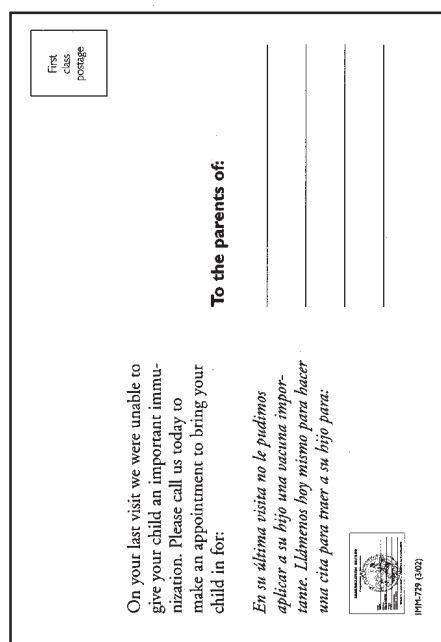
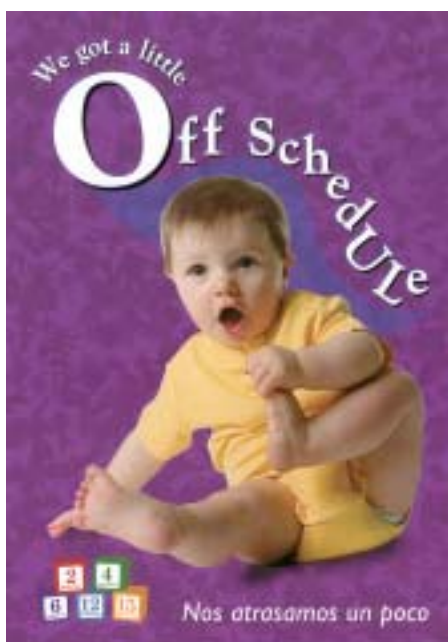


Table 1 from ACIP's General recommendations on immunization

TABLE 1. Recommended and minimum ages and intervals between vaccine 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 B1 [†]	Birth–2 mos	Birth	1–4 mos	4 wks
Hepatitis B2	1–4 mos	4 weeks	2–17 mos	8 wks
Hepatitis B3 [§]	6–18 mos	6 mos [¶]	—	—
Diphtheria and tetanus toxoids and acellular pertussis (DTaP)1	2 mos	6 wks	2 mos	4 wks
DTaP2	4 mos	10 wks	2 mos	4 wks
DTaP3	6 mos	14 wks	6–12 mos	6 mos ^{**}
DTaP4	15–18 mos	12 mos	3 yrs	6 mos [¶]
DTaP5	4–6 yrs	4 yrs	—	—
<i>Haemophilus influenzae</i> , type b (Hib)1 ^{††}	2 mos	6 wks	2 mos	4 wks
Hib2	4 mos	10 wks	2 mos	4 wks
Hib3 ^{§§}	6 mos	14 wks	6–9 mos	8 wks
Hib4	12–15 mos	12 mos	—	—
Inactivated poliovirus vaccine (IPV)1	2 mos	6 wks	2 mos	4 wks
IPV2	4 mos	10 wks	2–14 mos	4 wks
IPV3	6–18 mos	14 wks	3.5 yrs	4 wks
IPV4	4–6 yrs	18 wks	—	—
Pneumococcal conjugate vaccine (PCV)1 ^{†††}	2 mos	6 wks	2 mos	4 wks
PCV2	4 mos	10 wks	2 mos	4 wks
PCV3	6 mos	14 wks	6 mos	8 wks
PCV4	12–15 mos	12 mos	—	—
Measles, mumps, and rubella (MMR)1	12–15 mos ^{¶¶}	12 mos	3–5 yrs	4 wks
MMR2	4–6 yrs	13 mos	—	—
Varicella ^{***}	12–15 mos	12 mos	4 wks ^{***}	4 wks ^{***}
Hepatitis A1	≥2 yrs	2 yrs	6–18 mos [¶]	6 mos [¶]
Hepatitis A2	≥30 mos	30 mos	—	—
Influenza ^{††††}	—	6 mos [¶]	1 mo	4 wks
Pneumococcal polysaccharide (PPV)1	—	2 yrs	5 yrs ^{§§§}	5 yrs
PPV2	—	7 yrs ^{§§§}	—	—

* Combination vaccines are available. Using licensed combination vaccines is preferred over separate injections of their equivalent component vaccines (Source: CDC. Combination vaccines for childhood immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). MMWR 1999;48[No. RR-5]:5). 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 antigens.

† A combination hepatitis B-Hib vaccine is available (Comvax[®], manufactured by Merck Vaccine Division). This vaccine should not be administered to infants aged <6 weeks because of the Hib component.

§ Hepatitis B3 should be administered ≥8 weeks after Hepatitis B2 and 16 weeks after Hepatitis B1, and it should not be administered before age 6 months.

¶ Calendar months.

** The minimum interval between DTaP3 and DTaP4 is recommended to be ≥6 months. However, DTaP4 does not need to be repeated if administered ≥4 months after DTaP3.

†† For Hib and PCV, children receiving the first dose of vaccine at age ≥7 months require fewer doses to complete the series (see CDC. *Haemophilus b* conjugate vaccines for prevention of *Haemophilus influenzae*, type b disease among infants and children two months of age and older: recommendations of the ACIP. MMWR 1991;40[No. RR-1]:1–7, and CDC. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2000;49[No. RR-9]:1–35).

§§ For a regimen of only polyribosylribitol phosphate-meningococcal outer membrane protein (PRP-OMP, PedvaxHib[®], manufactured by Merck), a dose administered at age 6 months is not required.

¶¶ During a measles outbreak, if cases are occurring among infants aged <12 months, measles vaccination of infants aged ≥6 months can be undertaken as an outbreak control measure. However, doses administered at age <12 months should not be counted as part of the series (Source: CDC. Measles, mumps, and rubella — vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]:1–57).

*** Children aged 12 months–13 years require only one dose of varicella vaccine. Persons aged ≥13 years should receive two doses separated by ≥4 weeks.

††† Two doses of inactivated influenza vaccine, separated by 4 weeks, are recommended for children aged 6 months–9 years who are receiving the vaccine for the first time. Children aged 6 months–9 years who have previously received influenza vaccine and persons aged ≥9 years require only one dose per influenza season.

§§§ Second doses of PPV are recommended for persons at highest risk for serious pneumococcal infection and those who are likely to have a rapid decline in pneumococcal antibody concentration. Revaccination 3 years after the previous dose can be considered for children at highest risk for severe pneumococcal infection who would be aged <10 years at the time of revaccination (see CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46[No. RR-8]:1–24).