



June 16, 1995 / Vol. 44 / No. RR-5

**MMWR**<sup>TM</sup>

*Recommendations  
and  
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

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## **Recommended Childhood Immunization Schedule — United States, 1995**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Public Health Service**  
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and Prevention (CDC)  
Atlanta, Georgia 30333



The *MMWR* series of publications is published by the Epidemiology Program Office, Centers for Disease Control and Prevention (CDC), Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA 30333.

SUGGESTED CITATION

Centers for Disease Control and Prevention. Recommended childhood immunization schedule—United States, 1995. *MMWR* 1995;44(No. RR-5): [inclusive page numbers].

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Copies can be purchased from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325. Telephone: (202) 783-3238.

## Contents

Introduction .....	1
Rationale for Change and Current Recommendations.....	3
Simultaneous Administration of Multiple Vaccines .....	7
Conclusion.....	7
References.....	8

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## Recommended Childhood Immunization Schedule — United States, 1995

### *Summary*

*The need for a single childhood immunization schedule prompted the unification of previous vaccine recommendations made by the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP). In addition to presenting the newly recommended schedule for the administration of vaccines during childhood, this report addresses the previous differences between the AAP and ACIP childhood vaccination schedules and the rationale for changing previous recommendations.*

### **INTRODUCTION**

Since 1988, the U.S. childhood immunization schedule has rapidly expanded to accommodate the introduction of new, universally recommended vaccines (i.e., *Haemophilus influenzae* type b [Hib] conjugate [1,2] and hepatitis B [2,3] vaccines) and recommendations for a second dose of measles-mumps-rubella vaccine (MMR) (4,5) and the use of acellular pertussis vaccines (2,6). For approximately 30 years, the Advisory Committee on Immunization Practices (ACIP) and the Committee on Infectious Diseases (COID) of the American Academy of Pediatrics (AAP)—the two groups responsible for developing vaccine recommendations for the public and private sectors—worked to develop similar schedules for routine childhood vaccination. However, some differences in the two schedules persisted. The unification of these childhood immunization schedules is essential to issuing consistent recommendations for both private and public health practitioners and for parents.

In February 1994, a working group was convened comprising members of AAP, ACIP, the American Academy of Family Physicians (AAFP), the Food and Drug Administration (FDA), the National Institutes of Health, and CDC. Representatives from state immunization programs, the Maternal and Child Health Bureau of the Health Resources and Services Administration, and vaccine manufacturers also participated. The objective of this working group was to develop a single, scientifically valid childhood immunization schedule—presented in an easily comprehensible format—that would accommodate the current recommendations of both ACIP and AAP and ensure the timely vaccination of preschool-age children. The schedule would identify a specified age for administering each vaccine dose and provide an acceptable range of ages to ensure flexibility for health-care providers. The working group also addressed the number of antigens and injections that should be administered at each visit, the number of visits required for children by 2 years of age, the availability of combined diphtheria and tetanus toxoids and pertussis (DTP)-Hib vaccines, and the capacity of the schedule to accommodate newly licensed vaccines (e.g., varicella vaccine). This report presents the recommended childhood immunization schedule (approved by ACIP, AAP, and AAFP) (Table 1) and the rationale for changing the previous recommendations. Practitioners should consult the Report of the Committee on Infectious Diseases (Red Book) (2), the vaccine-specific recommendations of ACIP, and the

**TABLE 1. Recommended childhood immunization schedule\*† — United States, January 1995**

Vaccine	Birth	2 Months	4 Months	6 Months	12 <sup>§</sup> Months	15 Months	18 Months	4 - 6 Years	11-12 Years	14-16 Years
Hepatitis B <sup>¶</sup>	HB-1	HB-2	HB-3							
Diphtheria-Tetanus-Pertussis (DTP)**		DTP	DTP	DTP	DTP or DTaP $\geq$ at 15 months			DTP or DTaP	Td	
<i>Haemophilus influenzae</i> type b <sup>††</sup>		Hib	Hib	Hib	Hib					
Poliovirus		OPV	OPV	OPV				OPV		
Measles-Mumps-Rubella <sup>§§</sup>					MMR			MMR	or	MMR

\*Recommended vaccines are listed under the routinely recommended ages. Shaded bars indicate range of acceptable ages for vaccination.

†Although no changes have been made to this schedule since publication in *MMWR* (weekly) in January 1995, this table has been revised to more accurately reflect the recommendations.

§Vaccines recommended for administration at 12–15 months of age may be administered at either one or two visits.

¶Infants born to hepatitis B surface antigen (HBsAg)-negative mothers should receive the second dose of hepatitis B vaccine between 1 and 4 months of age, provided at least 1 month has elapsed since receipt of the first dose. The third dose is recommended between 6 and 18 months of age. Infants born to HBsAg-positive mothers should receive immunoprophylaxis for hepatitis B with 0.5 mL Hepatitis B Immune Globulin (HBIG) within 12 hours of birth, and 5 µg of either Merck, Sharpe, & Dohme (West Point, Pennsylvania) vaccine (Recombivax HB<sup>®</sup>) or 10 µg of SmithKline Beecham (Philadelphia) vaccine (Engerix-B<sup>®</sup>) at a separate site. For these infants, the second dose of vaccine is recommended at 1 month of age and the third dose at 6 months of age. All pregnant women should be screened for HBsAg during an early prenatal visit.

\*\*The fourth dose of DTP may be administered as early as 12 months of age, provided at least 6 months have elapsed since the third dose of DTP. Combined DTP-Hib products may be used when these two vaccines are administered simultaneously. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) is licensed for use for the fourth and/or fifth dose of DTP in children  $\geq$ 15 months of age and may be preferred for these doses in children in this age group.

†† Three *H. influenzae* type b conjugate vaccines are available for use in infants: a) oligosaccharide conjugate Hib vaccine (HbOC) (HibTITER<sup>®</sup>, manufactured by Praxis Biologics, Inc. [West Henrietta, New York] and distributed by Lederle-Praxis Biologicals [Wayne, New Jersey]); b) polyribosylribitol phosphate-tetanus toxoid conjugate (PRP-T) (ActHIB<sup>™</sup>, manufactured by Pasteur Mérieux Sérums & Vaccins, S.A. [Lyon, France] and distributed by Connaught Laboratories, Inc. [Swiftwater, Pennsylvania], and OmniHIB<sup>™</sup>, manufactured by Pasteur Mérieux Sérums & Vaccins, S.A. and distributed by SmithKline Beecham); and c) *Haemophilus* b conjugate vaccine (Meningococcal Protein Conjugate) (PRP-OMP) (PedvaxHIB<sup>®</sup>, manufactured by Merck, Sharp, & Dohme). Children who have received PRP-OMP at 2 and 4 months of age do not require a dose at 6 months of age. After the primary infant Hib conjugate vaccine series is completed, any licensed Hib conjugate vaccine may be administered as a booster dose at age 12–15 months.

§§The second dose of MMR vaccine should be administered EITHER at 4–6 years of age OR at 11–12 years of age.

Source: Advisory Committee on Immunization Practices, American Academy of Pediatrics, and American Academy of Family Physicians.

official manufacturers' package inserts or the Physician's Desk Reference (PDR) (7) for detailed information and specific recommendations for administration of vaccines.

## RATIONALE FOR CHANGE AND CURRENT RECOMMENDATIONS

In 1994, the substantial differences between the recommended AAP and ACIP schedules included the schedule for infant hepatitis B vaccination and the timing of the third dose of oral poliovirus vaccine (OPV) and the second dose of MMR (Table 2). Resolution of the differences between the schedules is described in the following sections.

### OPV

Since 1963, OPV has been the recommended vaccine for inducing long-lasting immunity to poliomyelitis. The primary series has consisted of two doses administered during infancy at approximately 2-month intervals beginning at 6–8 weeks of age, a third dose recommended at 6 weeks to 14 months after the second dose (generally administered at 15–18 months of age), and a fourth dose administered at 4–6 years of age. In late 1993, ACIP recommended that the third dose of OPV be administered at 6 months of age (8), whereas AAP recommended that this dose be administered at 6–18 months of age (2).

A study comparing two infant immunization schedules (one recommending vaccination at approximately 2, 4, 6, and 12 months of age and one at 2, 4, and 12 months of age) indicated high seroconversion rates (i.e., 96%–100%) and similar geometric mean antibody titers (measured after three doses) when following either schedule (9). Several other studies have evaluated the seroresponse to OPV administered at 2, 4, and 6 months; 2, 4, and 12 months; and 2, 4, and 18 months of age (10–13). These data indicated excellent response to all serotypes of OPV when the third dose was administered at 6, 12, or 18 months of age (Table 3).

**Recommendation:** Because immune response is not affected by administering the third dose of OPV at as early as 6 months of age, and because earlier scheduling can ensure a higher rate of completion of the OPV primary series at a younger age, the third dose of OPV should be administered routinely at 6 months of age. Vaccination at as late as 18 months of age remains an acceptable alternative.

**TABLE 2. Differences between the American Academy of Pediatrics' (AAP) and the Advisory Committee on Immunization Practices' (ACIP) childhood immunization schedules, by selected vaccine — United States, 1994**

Vaccine or vaccine dose	AAP recommendation	ACIP recommendation
OPV-3*	6–18 mos	6 mos
Hepatitis B	0–2, 1–4,† 6–18 mos	Birth, 1–2, 6–18 mos OR 2, 4, 6–18 mos
MMR-2 <sup>‡</sup>	11–12 yrs	4–6 yrs

\*The third dose of oral poliovirus vaccine.

†Provided that at least 1 month has elapsed between the first and second doses.

<sup>‡</sup>The second dose of measles-mumps-rubella vaccine.

**TABLE 3. Percentage of children with serum-neutralizing antibody to poliovirus types 1 (p1), 2 (p2), and 3 (p3) after two and three doses of oral poliovirus vaccine, by age at vaccination and study**

Age at vaccination (mos)	Study	After two doses (%)			After three doses (%)		
		p1	p2	p3	p1	p2	p3
2, 4, 6	Hardy (9)	93	100	91	97	100	96
	Cohen-Abbo (10)	89	100	93	99	100	99
2, 4, 12	Hardy (9)	92	99	90	96	100	96
	Faden (11)	100	100	100	100	100	100
2, 4, 18	McBean (12)	92	100	96	97	100	100
	Modlin (13)	95	100	90	95	100	100

## MMR

### First Dose

During 1989 and 1990, more than 55,000 cases of measles were reported in the United States. Nearly 25% of these cases occurred among children  $\leq 15$  months of age, including approximately 9% among children 12–15 months of age (CDC, unpublished data). At that time, the recommended age for routine measles vaccination was 15 months of age. Recent studies have examined the impact of vaccine-induced immunity on maternally derived transplacental antibody levels; these studies have indicated that younger women (i.e., women who were born after 1956 and who are therefore more likely to have vaccine-induced immunity) transfer lower titers of measles antibodies to their newborn infants than older women (who are more likely to have had natural measles infection). The transplacental antibody acquired by these younger mothers' infants wanes earlier, causing their children to become susceptible to measles at a younger age (14,15). This finding suggests that children born to younger mothers might respond well to measles vaccine administered at 12 months of age. In one recent study in which children randomly received measles vaccine at either 12 or 15 months of age (16), the measles antibody response to MMR was 93% when the vaccine was administered at 12 months of age; at 15 months of age, the antibody response was 98%. Among children of mothers born after 1961, who probably had received measles vaccine and were less likely to have had measles infection than women born in previous years, the seroconversion rate was 96% among children vaccinated at 12 months of age and 98% among those vaccinated at 15 months of age.

**Recommendation:** The slightly lower response to the first dose of measles vaccine when administered at 12 months of age compared with administration at 15 months of age has limited clinical importance because a second dose of MMR is recommended routinely for all children, enhancing the likelihood of seroconversion among children who do not respond to the first dose. In addition, earlier scheduling of the first dose of measles vaccine can improve vaccination coverage. In 1994, both AAP and ACIP recommended administration of the first dose of MMR vaccine at 12–15 months of age (2,8); this schedule is still recommended.

## Second Dose

In 1989, both ACIP and AAP recommended that all children receive a second dose of measles-containing vaccine; however, ACIP recommended administering the second dose at 4–6 years of age (5), and AAP recommended this dose at 11–12 years of age (4). Most states have implemented school entry requirements based on one or both of these recommendations. Currently, 12 states require administration of the second dose of measles vaccine before children enter kindergarten (i.e., at 4–6 years of age), 12 require this dose before entry to middle school (i.e., at 11–12 years of age), and 13 states require that the second dose be administered before children enter either kindergarten or middle school.

**Recommendation:** Because response to the second dose is high when administered to children in either age group (CDC, unpublished data), and because state-specific laws govern the administration of the second dose of MMR, the second dose of MMR can be administered at either 4–6 years of age or 11–12 years of age.

## Hepatitis B

Universal hepatitis B vaccination of infants was recommended in 1991 (3,17). Although a protective serologic response (i.e.,  $\geq 10$  mIU/mL) has been demonstrated in >95% of hepatitis B vaccine recipients who received vaccine according to several schedules beginning at birth or 2 months of age (Table 4), higher antibody titers were achieved when the third dose was administered at 12 or 15 months of age (18,19). Available data indicate that higher titers of antibody ensure longer persistence of antibody (20–22); however, the effect of high antibody levels on long-term protection against disease is not known.

**TABLE 4. Percentage of children who seroconverted and geometric mean titers (GMTs) after vaccination with hepatitis B vaccine, by age at first dose and vaccination schedule**

Age at first dose/ Vaccination schedule (mos)	Total no. children	No. mos between first dose and measurement	No. doses received*	Percentage of children who seroconverted <sup>†</sup>	GMT
<b>Birth</b>					
0, 1, 2, 12	62	9	3	95	110
	46	13	4	100	647
0, 1, 6	78	9	3	96	262
0, 2, 4	49	9	3	98	99
0, 2, 6	50	9	3	98	216
<b>2 mos</b>					
2, 4, 6	82	7	3	98	202
2, 4, 6, 15 <sup>§</sup>	32	14	4	100	1,793
2, 4, 12	41	11	3	100	1,633
2, 4, 12 (18)	52	11	3	98	1,358
2, 4, 15	38	14	3	97	1,527
2, 4, 15 (18)	50	14	3	100	3,424

\*At the time of measurement.

<sup>†</sup>Children who had  $\geq 10$  mIU/mL of antibody to hepatitis B surface antigen.

<sup>§</sup>A subset of the infants vaccinated at 2, 4, and 6 months of age.

Source: David West, Merck Research Laboratories.

**Recommendation:** The routine hepatitis B vaccination series should begin at birth, with the second dose administered at 2 months of age, for infants whose mothers are hepatitis B surface antigen (HBsAg) negative. Acceptable ranges are from birth through 2 months of age for the first dose and from 1 through 4 months of age for the second dose, provided that at least 1 month elapses between these doses. The third dose should be administered at 6–18 months of age. Limited available data suggest an augmented response when the third dose is administered after 12 months of age (Merck Research Laboratories, unpublished data, 1994). Infants of HBsAg-positive mothers should receive the first dose of vaccine at birth (along with immunoprophylaxis with hepatitis B immune globulin); the second dose at 1 month of age; and the third dose at 6 months of age.

### **Diphtheria and Tetanus Toxoids and Pertussis Vaccine (DTP)**

Since the late 1940s, the approved schedule for DTP has consisted of a primary series of three doses administered at 4–8 week intervals and a fourth (i.e., reinforcing) dose administered 6–12 months after the third dose. Although the fourth dose has been administered routinely at 15–18 months of age, it may be administered as early as 12 months of age, provided that at least 6 months elapse between the third and fourth dose. No recent data are available comparing the immunogenicity of DTP or diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) when administered at 12–14 months with immunogenicity at 15–18 months of age when vaccine is either administered alone or simultaneously with MMR and Hib vaccines.

**Recommendation:** The current schedule for DTP vaccination is still recommended—including the option that the fourth dose may be administered at as early as 12 months of age if 6 months elapse after the third dose. Thus, the fourth dose of DTP can be scheduled with other vaccines that are administered at 12–18 months of age. DTaP currently is licensed for use only as the fourth and/or fifth dose of the DTP series for children  $\geq 15$  months of age (2,6).

### **Tetanus and Diphtheria Toxoids, Adsorbed, For Adult Use (Td)**

For most persons who received a dose of DTP vaccine at 4–6 years of age, the first dose of Td is administered at 14–16 years of age and every 10 years thereafter to maintain adequate protection against tetanus and diphtheria (6). A recent U.S. serologic survey of tetanus immunity (23) indicated that tetanus immunity in the majority of the population decreases with time after the administration of the recipient's most recent vaccination. Among persons 6–16 years of age who had received their most recent tetanus vaccination 6–10 years previously, 28% had tetanus antibody titers lower than protective levels, which suggested that Td could be administered as early as 11–12 years of age.

**Recommendation:** The booster dose of Td should be administered at 11–12 years of age, although vaccination at 14–16 years of age is an acceptable alternative. The earlier scheduling of this dose at 11–12 years of

age encourages a routine preadolescent preventive care visit. During this visit, the practitioner should also administer a second dose of measles-containing vaccine to those persons who have not already received this dose and should ensure that children who previously have not received hepatitis B vaccine begin the vaccination series. Adolescent hepatitis B vaccination currently is recommended by AAP (2); ACIP will issue a similar recommendation. A routine visit at 11–12 years of age also will facilitate administration of other needed vaccines to adolescents.

## **SIMULTANEOUS ADMINISTRATION OF MULTIPLE VACCINES**

Simultaneous administration of vaccines has been recommended through the administration of combined vaccines (e.g., DTP vaccine, trivalent OPV, and MMR vaccine) or administration of multiple vaccines at different sites or by different routes (e.g., simultaneous administration of DTP, OPV, and Hib). Several studies have examined the safety and immunogenicity of simultaneously administered MMR and Hib (24,25); DTP, OPV, and MMR (26,27); DTP, OPV, and Hib (25,28); hepatitis B, DTP, and OPV (29–31); and hepatitis B and MMR (Merck Research Laboratories, unpublished data, 1993). Hepatitis B vaccine, the vaccine most recently licensed for use among infants, has been shown to be safe and effective when administered from birth through 15 months of age with other routinely recommended childhood vaccines (D. Greenberg, personal communication, 1994) (32). The available safety and immunogenicity data for vaccines currently recommended by ACIP and AAP have been reviewed recently (33). Although data are limited concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTP, OPV, MMR, and Hib vaccines, with or without hepatitis B vaccine), data from numerous studies have indicated no interference between routinely recommended childhood vaccines (either live, attenuated or killed) (33). These findings support the simultaneous use of all vaccines as recommended.

## **CONCLUSION**

The development of a unified childhood immunization schedule approved by ACIP, AAP, and AAFP represents the beginning of a process that will ensure continued collaboration among the recommending groups, the pharmaceutical manufacturing industry, and FDA to maintain and work toward further simplification of a unified schedule. The recommended childhood immunization schedule will be updated and published annually.

Since the development of these recommendations in January 1995, FDA has licensed varicella zoster virus vaccine for use among susceptible persons  $\geq 12$  months of age. The ACIP will publish recommendations for this new vaccine, and these recommendations will be incorporated into the 1996 Recommended Childhood Immunization Schedule.

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