Advisory Committee on Immunization Practices (ACIP)

Amanda Cohn, MD

- CDR, USPHS
- Executive Secretary ACIP
- Senior Advisor for Vaccines
- Medical Epidemiologist

Stephan L. Foster, Pharm.D.

- CAPT (Ret) USPHS
- Professor, University of Tennessee
- Liaison Member, ACIP

Special thanks to Dr. Jean Smith, ACIP Coordinating Medical Officer for help and guidance in developing this program.

Adults: Get vaccinated to stay healthy

- Measles
- Mumps
- Rubella
- Hepatitis B
- Tetanus
- Diphtheria
- Influenza
- Pneumococcal Disease

Don't become an endangered species

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION


1. Who needs a flu vaccine?
a) You
b) You
c) You
d) All of the above
Even healthy people can get the flu.
Protect yourself and your loved ones.
Get vaccinated.
www.cdc.gov/flu

Objectives

At the end of the presentation, the participants will:

1. Understand the purpose and function of the Advisory Committee on Immunization Practices (ACIP)
2. Describe the process of developing a recommendation by the ACIP
3. Recognize the professional organizations and federal offices involved in the ACIP
4. Reconcile some of the difficult issues with the new ACIP recommendations.

Edward Jenner (1749-1823)

Louis Pasteur (1822-1895)

5/14/1796
Cowpox Inoculation

Rabies and Anthrax

Early Diseases

- Smallpox Epidemic in India (1545)
- Whooping Cough Epidemic in Paris (1578)
- Measles Documented (1676)
- Yellow Fever in American Colonies (1699)
- Diphtheria Epidemic in New England (1735)
- Rubella –German Measles Described (1740)
- Cholera Pandemics (1817)
- Diphtheria Named (1826)
- First U.S. Polio Epidemic (1894)

1884 Friedrich Loeffler
Cultivated
Corynebacterium Diphtheria

1892 – Richard Pfeiffer
"Pfeiffer Influenza Bacillus"
(1930- Haemophilus influenzae)

Vaccine Development

- 1798 – Smallpox
- 1881 – Anthrax
- 1885 – Rabies
- 1896 Cholera, Typhoid
- 1897 - Plague
- 1911 – Whole-cell pneumococcal vaccine
- 1921 – BCG Vaccine
- 1923 – Diphtheria toxoid
- 1925 – Pertussis Vaccine
- 1926 – Aluminum Adjuvant
- 1927 – Tetanus
- 1936 – Influenza Vaccine
- 1944 – Japanese Encephalitis
- 1948 – DTP
- 1955 – Polio (Salk – IPV)
- 1960 – Polio (Sabin – OPV)
  - 1963 – included all 3 types
- 1962 – Measles (Given with gamma globulin)
  - 1968 – More attenuated Measles vaccine
- 1969 – Rubella Vaccine
- 1971 – MMR
- 1977 – Pneumococcal (PPSV14)
- 1982 – Hepatitis B
- 1985 – Hib
  - 1987 - Conjugated Hib
- 1989 – Oral Typhoid
- 1995 – Varicella, Hepatitis A
- 2005 – Tdap
- 2006 – Rotavirus, HPV, Zoster

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE ARCHIVE

Prevention of *Haemophilus influenzae* Type b Infections in High-Risk Infants Treated with Bacterial Polysaccharide Immune Globulin

Mathuram Santosham, M.D., Raymond Reid, M.D., Donna M. Ambrosino, M.D., Mark C. Wolff, Ph.D., Janne Almeido-Hill, B.S., Claudette Priehs, B.S., Kathy M. Aspery, R.N., Steve Garrett, R.PH., Larry Croll, R.PH., Stephan Foster, Pharm.D., Gerald Burge. R.PH.. Peter Page. M.D.. Bonnie Zacher. L.P.N.. Richard Moxon. M.B.. B.Chir.. F.R.C.P.. and George R. Siber.

N Engl J Med 1987; 317:923-929 | October 8, 1987 | DOI: 10.1056/NEJM198710083171503

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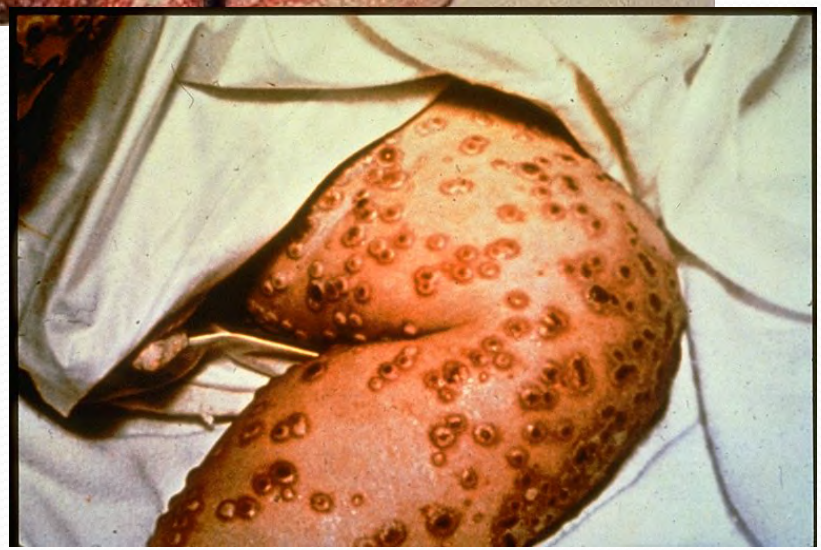
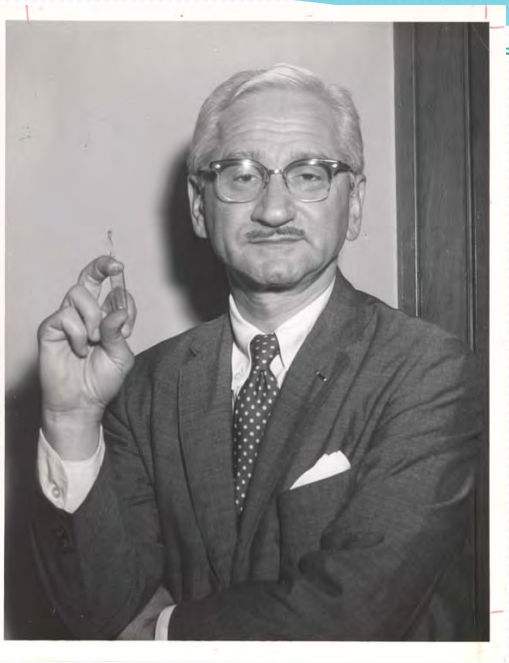
Smallpox



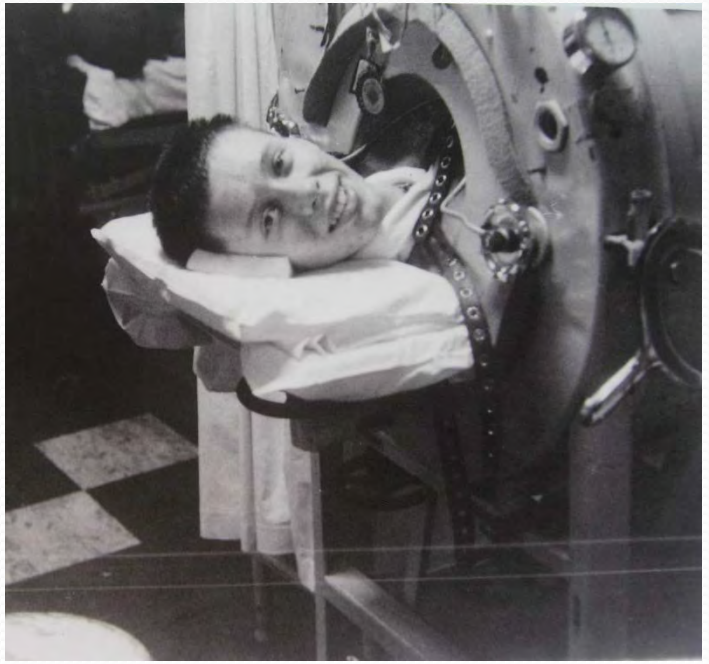
March of Dimes

1938 – National Foundation for Infantile Paralysis



Jonas Salk, MD

Albert Sabin, M.D.



Why...Why Didn't We Listen?

Effective as it is, polio vaccine helps only when used.

Polio virus is still widespread.

Don't wait until it's too late. Arrange now for immunization.

Your pharmacist works for better community health.

Last Reported Wild-type Polio Case in the Western Hemisphere

Peru, August 23, 1991


DIPHTHERIA
is deadly-
IMMUNISATION
is the
safeguard
ASK AT YOUR LOCAL COUNCIL OFFICES OR WELFARE CENTRE
Issued by the Ministry of Health and the Central Council for Health Education

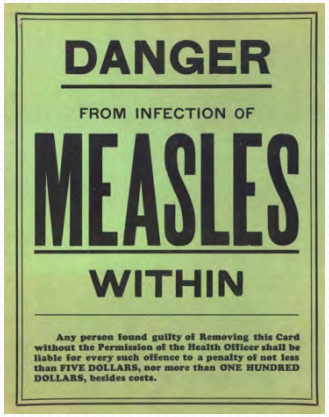

MILK TRUCKERS
DO NOT !
PICK UP MILK AT FARMS WHERE THERE ARE CASES OF DIPHTHERIA
SCARLET FEVER
INFANTILE PARALYSIS
SPINAL MENINGITIS
SMALLPOX TYPHOID
Report all cases or your route to....
FOOD AND DRUG ADMINISTRATION


Vaccine-preventable diseases
are just a plane ride away.
www.VaccinateYourBaby.org

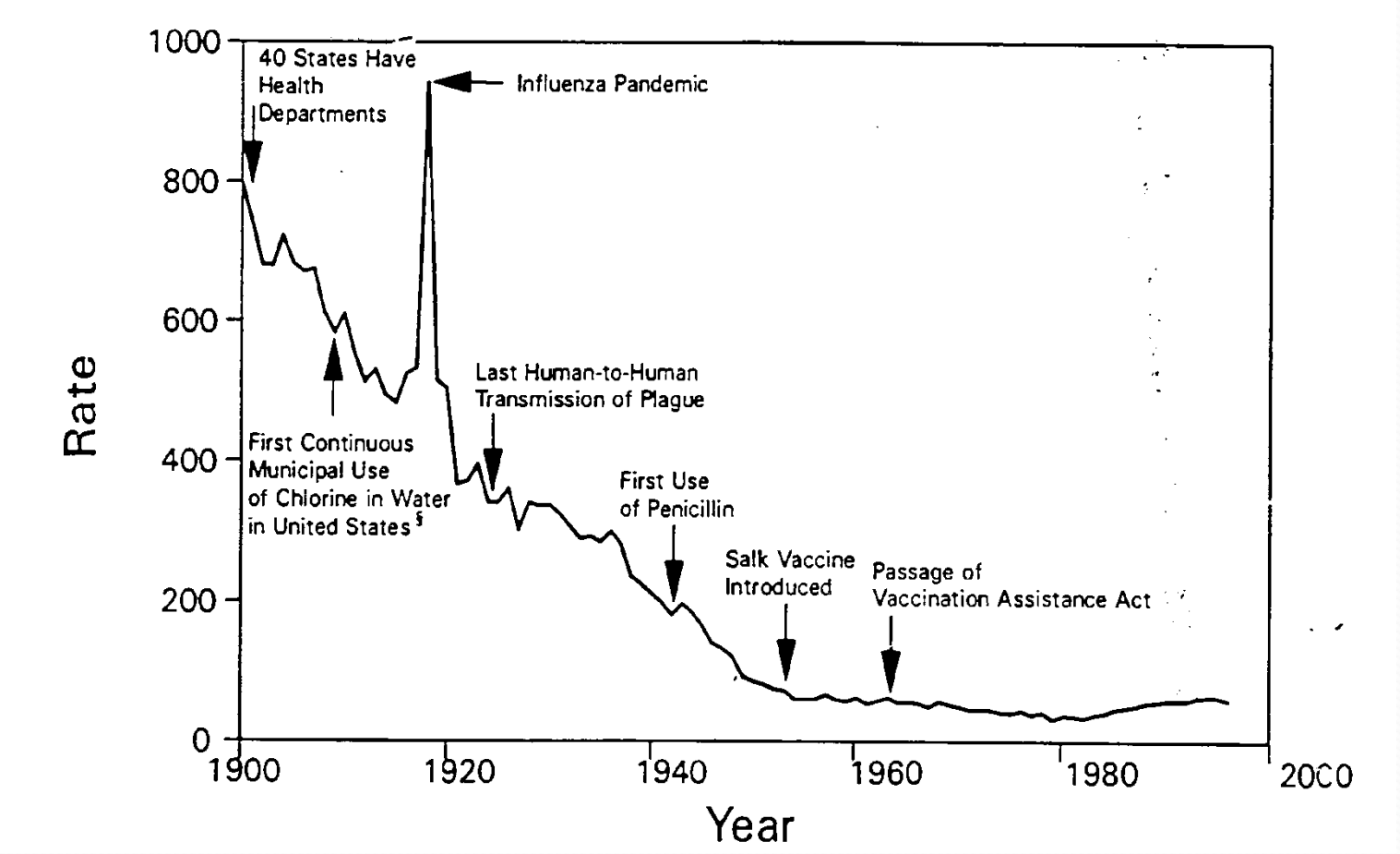

Measles only gave her spots...will your child be as lucky?
For most children measles is certainly distressing and inconvenient. But for some, it can be serious and even tragic. In fact, one child in every six who gets measles develops a secondary bacterial infection such as pneumonia or ear infection. (Most infections, of course, respond to your doctor's care.)
In about one case in 1,000 measles causes inflammation of the brain—encephalitis—an infection for which there is no specific treatment. In some of these children encephalitis causes only temporary changes; in others there is permanent damage such as mental retardation. And, some do not survive. In 1962, for example, 408 children in the United States died from measles. (Since the conquest of polio, measles causes more deaths than any other common disease of childhood.)
Even when measles is apparently mild, it may accentuate certain problems such as bed-wetting, thumb-sucking, poor school work or tantrums.
If your child hasn't had measles why take any chances? Measles is now preventable, along with other serious and common childhood diseases, through vaccination. Don't wait for your child to catch measles ...9 out of 10 unprotected children will. Call your doctor now about vaccination against measles.
The American Medical Association, the American Academy of Pediatrics, the American Academy of General Practice, the American Osteopathic Association, and the U.S. Public Health Service urge all parents to consult their physicians about measles vaccination for their children.
MERCK SHARP & DOHME


JOIN THE FIGHT
AGAINST
SMALL-POX
AND
MEASLES
BE
VACCINATED
TODAY


RUBELLA
STOP THE SPREAD
FROM CHILD TO MOTHER
Is her unborn baby safe from rubella?
Clinical manifestations of congenital rubella as observed in 344 infants correlated with time of maternal rubella.
Birth defects occur in about 50 per cent of babies born to mothers who contract rubella during their first trimester of pregnancy.
brain damage
deafness
heart defects
cataracts
enlarged liver
bone malformations


DANGER
FROM INFECTION OF
MEASLES
WITHIN
Any person found guilty of Removing this Card without the Permission of the Health Officer shall be liable for every such offence to a penalty of not less than FIVE DOLLARS, nor more than ONE HUNDRED DOLLARS, besides costs.

Crude Death Rate for Infectious Disease – U.S. 1900-1996



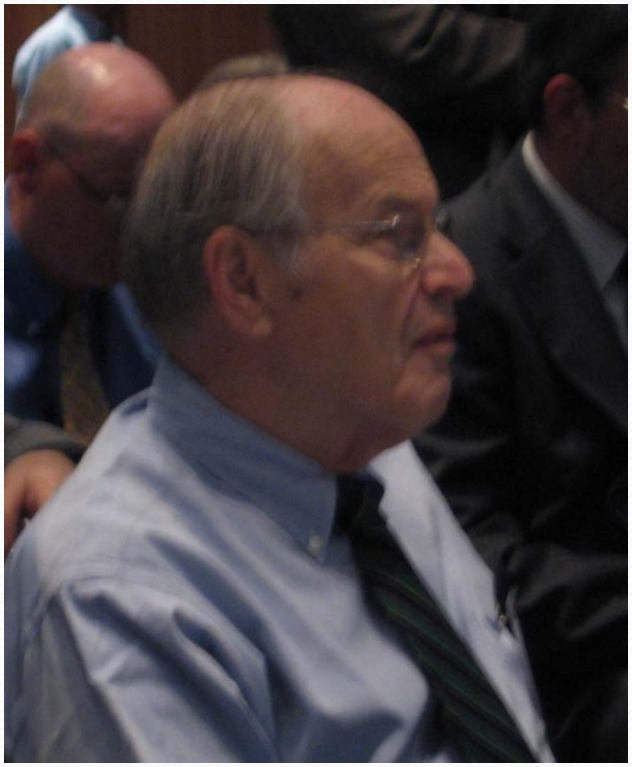
MMWR, July 30,1999, Vol. 48, No.29

Vaccine-Preventable Diseases in the 21st Century

Disease	Max. Cases	Year	Cases 2011	Cases 2012	Cases 2013	Cases 2014	Cases 2015
Diphtheria	206,939	1921	0	1	0	1	0
Hib	~20,000	1980's	14	30	18	27	23
Measles	894,134	1941	220	55	189	668	189
Mumps	152,209	1968	404	229	438	1151	1057
Pertussis	265,209	1934	18,719	48,277	24,231	28,660	18,166
Rubella CRS	2.5 Million ~30,000	1964-1965	4 0	9 3	9 0	8 1	5 1
Tetanus	601	1948	36	37	19	21	25
Varicella	221,983	1984	14,513	13,447	9,987	9058	8370

Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed.; May 2012
JAMA. 2007;298:2155–263
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6452md.htm?s_cid=mm6452md_w

Vaccine Legends



Samuel Katz, M.D.

Paul Offitt, M.D. & Stanley Plotkin, M.D.

Dr. Thomas Frieden, Director CDC

Vaccination Laws

- 1798 – Marine Health Service Established
  - Precursor to USPHS
- 1813
  - "An Act to Encourage Vaccination"
  - U.S. Vaccine Agency
  - U.S. Post Office ships Smallpox Vaccine free
- 1855 Massachusetts mandates vaccination for children
- 1874 – Germany Mandates smallpox vaccination
- 1894 – New York City regulates diphtheria Antitoxin for purity and potency
- 1898 – Regulation of Vaccine Supply – Pennsylvania
- 1902 – Biologics Control Act
  - Creates Hygienic Laboratory of the U.S.P.H.S.
    - Later became NIH in 1930
- 1906 – Pure Food and Drugs Act
- 1905 – Supreme Court upholds mandatory vaccination
- 1922 – School Vaccination Laws upheld in court
- 1944 – Public Health Services Act – Consolidated US Public Health Service
- 1955 – Polio Vaccination Assistance Act
- 1962 – Vaccination Assistance Act – CDC support of vaccination
- 1963- Federal Immunization Grant Program established
- 1963 - Creation of Immunization Branch of CDC (later National Immunization Program)
- 1964 – Immunization Practices Advisory Committee to USPHS formed (ACIP)
- 1972 – Division of Biologics Standards (NIH) transferred to FDA
- 1972 – Federal Advisory Committee Act (ACIP designation as Federal Advisory Group)
- 1986- National Childhood Vaccine Injury Act – Established VAERS
- 1986 – National Vaccine Program (NVP) established – Coordinate all vaccine programs
- 1988 – Nation Vaccine Injury Compensation Program (NVICP)
- 1988 – Center for Biologics Evaluation and Research (CBER) within FDA created
- 1993- Vaccines for Children Program established (VFC)
- 1993 – National Immunization Program (NIP) established
- 2003 – Project Bioshield Act

Origins of the ACIP

- Vaccination Assistant Act of 1962
  - Instructed Secretary HEW Anthony Celebrezze to develop advisory committee
- ACIP was established in 1964
  - Chaired by the Surgeon General of US Public Health Service James Goddard
- Role: to provide advice and guidance to Director, CDC and Office of the Secretary of the Department of Health and Human Services on most effective means to prevent vaccine-preventable diseases in the civilian population
  - Vaccines and related agents (e.g., antisera, immune globulins, antiviral agents)
  - FDA-licensed vaccines (and unlicensed vaccines if warranted)
- ACIP votes on recommendations for vaccines covered by all 3 *Office of Infectious Diseases* Centers (OID: NCIRD, NCHHSTP, NCEZID*) and reports directly to the Director of CDC

*NCIRD: National Center for Immunization and Respiratory Diseases
NCHHSTP: National Center for HIV/AIDS, Hepatitis, STD, and TB Prevention
NCEZID: National Center for Emerging and Zoonotic Infectious Diseases

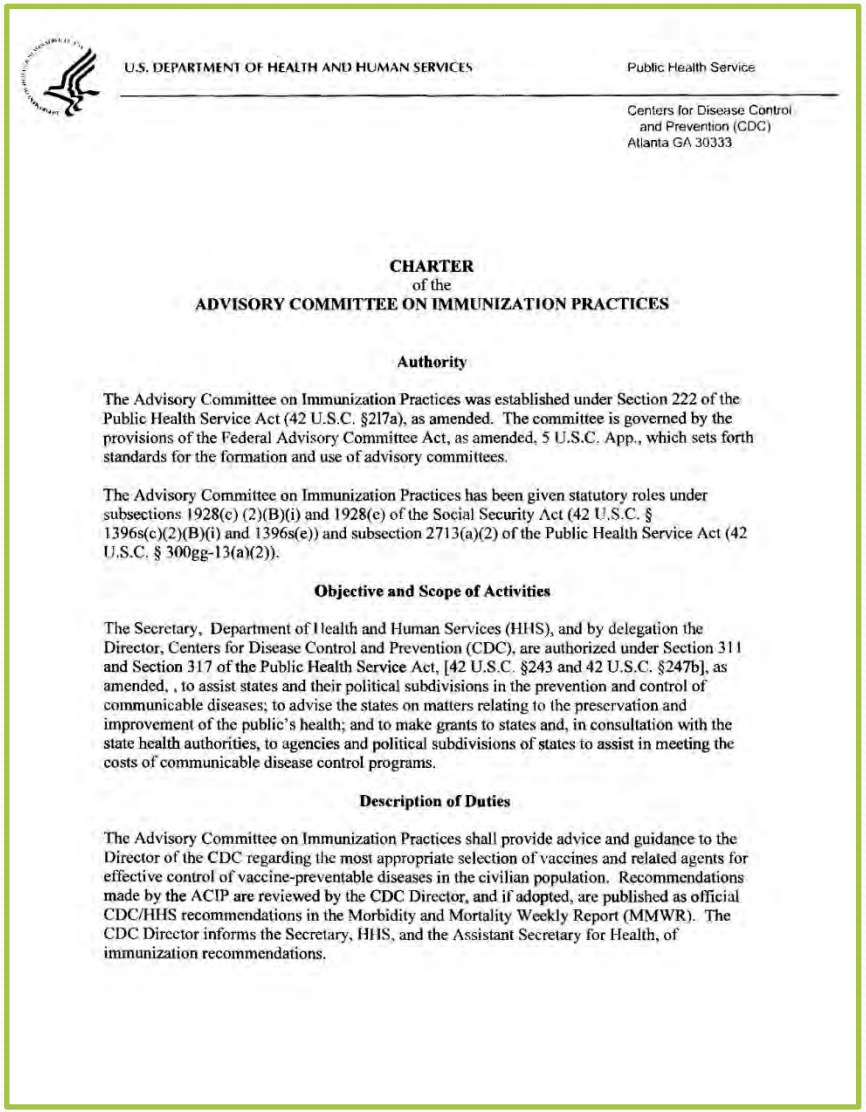
Federal Advisory Committee Act

- Federal Advisory Committee Act (FACA) – enacted by Public Law 92-463 on October 6, 1972
- Mechanism to seek advice and recommendations of US citizens in Federal Government's decision- making process
  - Committees provide relevant, objective advice
  - Meetings open to public; all committee documents available for public inspection
- ACIP designated as FACA committee in 1972
- Currently ~1000 Federal Advisory Committees in the US, advising 50 federal agencies
  - 21 federal advisory committees at CDC

Vaccines for Children Program

- Vaccines for Children (VFC) Program – established in August 1993, operational since October 1994
  - Unique statutory authority established by Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. § 1396a) *gives ACIP authority to determine vaccines included in the VFC Program*
- VFC is a federal entitlement program - current cost is ~$4 billion annually
  - http://www.cdc.gov/vaccines/programs/vfc/index.html
- Eligible children (0 through 18 years of age):
  - Medicaid eligible; uninsured; American Indian/Alaska native: underinsured
- Currently, approximately 48% of young children in the US are entitled to VFC
- During ACIP meetings members vote first on vaccine recommendation; then take a separate vote on whether to include the vaccine in VFC
- Not affected by Affordable Care Act

Legal Authority: the Charter (2014-2016)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

CHARTER
of the
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Authority

The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

The Advisory Committee on Immunization Practices has been given statutory roles under subsections 1928(c) (2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, , to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

Description of Duties

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Director of the CDC regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations.

Purpose of Advisory Committee on Immunization Practices

- Review scientific data and vote on vaccine recommendations
- Present findings and discuss vaccine research and scientific data related to vaccine effectiveness and safety, clinical trial results, and manufacturers' labeling or package insert information
- Outbreaks of vaccine-preventable disease or changes in vaccine supply are reviewed
- Vaccine recommendations include the age(s) when the vaccine should be given, number of doses needed, dosing interval, and precautions and contraindications to administration of vaccines
- Approve vaccines Covered by Vaccines For Children's Program

First Meeting of the ACIP – Communicable Disease Center, Atlanta, GA, May 25-26, 1964

Agenda

Surgeon General's Advisory Committee on Immunization Practice
Room 207
Communicable Disease Center
May 25-26, 1964

Monday, May 25 – 9:30

1.	Introduction - Committee purpose and function	Dr. Goddard
2.	Previous Immunization Advisory Committees	Dr. Langmuir
3.	Definition of committee responsibility	Dr. Goddard
	a. Relationship to "Red Book" Committee	
	b. Relationship to other committees on immunization, e.g. APHA, AFEB, etc.	
4.	Simplification of Immunization Schedules	Dr. Bell
5.	Influenza	
	a. Influenza; 1963-1964, national and international	Dr. Silverman
	b. Influenza strains	Dr. Robinson
	c. Vaccine use - 1963	Dr. Henderson
	d. Field studies of vaccine efficacy - 1963-64	Dr. Henderson
	e. Vaccine composition	Dr. Murray
	f. Blood group antibodies induced by vaccine	Dr. Henderson
	g. Recommendations - 1964-65	
	(1) Probability of outbreaks	
	(2) Recommendations for vaccine use	
	(3) Recommendations regarding field studies	

Tuesday, May 26 – 9:00

6.	Rubella	
	a. Status report - probability of vaccines	Dr. Murray
	b. Immune globulin in prophylaxis	Drs. Murray & Henderson
	c. Recommendation regarding immune globulin in prophylaxis	
7.	Rubeola	
	a. Status report - vaccine use	Dr. Henderson
	b. Combination schedules employing killed and live vaccines	Dr. Guinee
	c. Recommendations regarding use of combined killed and live vaccines	

8.	Smallpox	
	a. Status report - vaccine use	Dr. Henderson
	b. Complications of vaccination	Dr. Millar
	c. Smallpox Control in the U.S.	Dr. Langmuir
	d. Changes proposed by the World Health Organization in the international vaccination requirements	
9.	Simultaneous administration of live vaccines	Drs. Henderson & Murray
10.	Concluding discussion	

Communicable Disease Center, Clifton Rd, 1970

Composition of ACIP

- 15 voting members including chair)
  - US citizens; external to federal government
  - 4 year term
  - ACIP steering committee nominates, HHS selects
  - One consumer representative
  - Members screened for conflicts of interest upon appointment, annually through term, and at every ACIP meeting
- 8 *ex officio members* – represent other government agencies involved in immunization
  - (CMS, DoD, DVA, FDA,HRSA,IHS, NIH,NVPO (non-voting)
- 30 liaison organizations –
  - representatives of professional societies and organizations involved with immunization programs (non-voting)
- Behind the scenes: ACIP Work Groups

Support from the Centers for Disease Control and Prevention

- ACIP secretariat (Executive Secretary, Medical Officer)
- Lead staff for each work group
- Subject matter experts for each work group
- Vaccine safety expertise
- Economic analysis expertise
- Evidence based recommendations expertise
- Funding

Expertise & Perspective of ACIP Members

- Pediatrics
- Internal medicine
- Family medicine
- Infectious diseases
- State/local health department
- Public health, preventive medicine
- Nursing
- Pharmacy
- Immunology
- Vaccine research and policy
- Economics, cost-effectiveness
- Consumer concerns

Potential Financial Conflicts of Voting Members

- Screened for Potential for Appearance of Conflicts of Interest
- Examples of prohibited activities
  - Employment by vaccine manufacturer
    - Includes Spouse and Family
  - Holding of patents
  - Honoraria
  - Travel reimbursement
- Must file reports yearly
- Must Disclose at every meeting
- If potential conflict – no vote

Ex Officio Members (8)

- Centers for Medicaid & Medicare Services (CMS)
- Department of Defense (DOD)
- Department of Veterans Affairs (DVA)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institute of Health (NIH)
- National Vaccine Program Office (NVPO)

Liaison Organizations *

- Organizations with broad involvement in immunization; organization funds participation of representative
- Designated representative brings perspective of the organization; keeps organization & membership apprised of ACIP deliberations and recommendations
- Members serve on work groups
- Members attend and participate in every ACIP meeting
- Four organizations assist with development and publication of immunization schedules “harmonized” with ACIP (AAFP, AAP, ACOG, ACP)

*non-voting

Liaison Organizations (30)

1. American Academy of Family Physicians
2. American Academy of Pediatrics
3. American Academy of Physician Assistants
4. American Geriatric Society
5. America's Health Insurance Plans
6. American College Health Association
7. American College of Nurse Midwives
8. American College of Obstetricians and Gynecologists
9. American College of Physicians
10. American Medical Association
11. American Nurses Association
12. American Osteopathic Association
13. American Pharmacists Association
14. Association of Immunization Managers
15. Association of State and Territorial Health Officials
16. Association for Prevention Teaching and Research
17. Biotechnology Industry Organization
18. Canadian National Advisory Committee on Immunization
19. Council of State and Territorial Epidemiologists
20. Infectious Diseases Society of America
21. National Association of County and City Health Official
22. National Association of Pediatric Nurse Practitioners
23. National Foundation for Infectious Diseases
24. National Immunization Council & Child Health Program (Mexico)
25. National Medical Association
26. National Vaccine Advisory Committee
27. Pediatric Infectious Diseases Society
28. Pharmaceutical Research & Manufacturers of America
29. Society for Adolescent Health & Medicine
30. Society for Healthcare Epidemiology of America

Meetings

- 3 regularly Scheduled Meetings
  - February, June, October
  - Dates posted 4 years in advance
- Announced in Federal Register at lease 15 days before meeting
- Location-CDC
- Members of the Public Invited
- All attendees must register

Meeting Agendas

- Subject matter solicited
  - CDC experts
  - ACIP members
  - Academic Consultants
  - Workgroups
- Discussions (may or may note have a vote on issue)
  - Vaccine Efficacy/ Effectiveness
  - Safety
  - Supply
  - Data on vaccines in development
  - Information on newly licensed vaccines
  - Outbreaks of Vaccine preventable diseases

Process

- Three 2-day meetings annually – February, June, and October. Held in CDC Global Communications Center
- Follow FACA* rules and procedures: meetings must be open to the public with time for public comment
- Meeting slides, live webcast archive, minutes posted on ACIP website within 90 days of mtg
- Recommendations become final once approved by CDC Director, adopted by HHS/CDC and published in MMWR
- Vaccine recommendations are recommendations only – not mandates. States and professional organizations usually endorse or follow ACIP recommendations

* Federal Advisory Committee Act

Vaccine Recommendations of the ACIP

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Related Links

Vaccines & Immunizations

VFC Resolutions

ACIP Web Site

CDC

ACIP Vaccine Recommendations

Advisory Committee for Immunization Practices (ACIP)

Vaccine-Specific ACIP Recommendations

- Anthrax
- BCG
- DTaP
- Hepatitis A
- Hepatitis B
- Hib
- HPV **UPDATED**
- Influenza **UPDATED**
- Japanese Encephalitis
- Measles, Mumps and Rubella
- MMRV
- Meningococcal **UPDATED**
- Pneumococcal
- Polio
- Rabies
- Rotavirus
- Smallpox (Vaccinia)
- Tdap/Td
- Typhoid **UPDATED**
- Varicella (Chickenpox)
- Yellow Fever **UPDATED**
- Zoster (Shingles)

ACIP Abbreviations

These abbreviations provide a uniform approach to vaccine references used in ACIP Recommendations that are published in the *MMWR*, the *Pink Book*, and the AAP *Red Book*; and in the U.S. immunization schedules for children, adolescents, and adults.

Comprehensive ACIP Recommendations

www.cdc.gov/vaccines/acip

ACIP Meeting – Global Communications Center

Advisory Committee On Immunization Practices

Advisory Committee On Immunization Practices

ACIP Work Groups

- Gather, analyze and prepare information for presentation to ACIP
  - WG proceedings are confidential; not subject to FACA law, but are subject to FOIA requests
  - WGs do not vote or determine policy
  - WGs present draft policy options to ACIP for review and vote in open, public meetings
- Work by teleconference/webinar throughout the year
- WG must be chaired by an ACIP member and include at least 1 other ACIP member
  - Other members: lead CDC staff (SME), liaison representatives, ex officio members, invited consultants; other CDC staff including ISO provide technical input and support
  - Vaccine manufacturers may not serve on WGs, but may be invited to present data

ACIP Work Groups – March 2016

1. Adult immunization
2. Child/adolescent immunization
3. General recommendations
4. Influenza
5. Human papillomavirus vaccines
6. Meningococcal vaccines
7. Pneumococcal vaccines
8. Herpes zoster vaccine
9. Japanese encephalitis / yellow fever vaccines
10. Hexavalent vaccine
11. Cholera vaccine

Pending (2016): RSV vaccine (older adults); hepatitis vaccine (older adults, hepB)

First 4 Work Groups are permanent

Factors for Deliberations

- Morbidity and Mortality
- Available Scientific Literature
- Safety, efficacy, effectiveness
- Cost effectiveness
- Availability of vaccine
- Clinical Trial Results
- Package Labeling
- Recommendations of other organizations
- Incorporation of recommendations into programs
- Public Comments

Example – HPV Vaccines Work Group

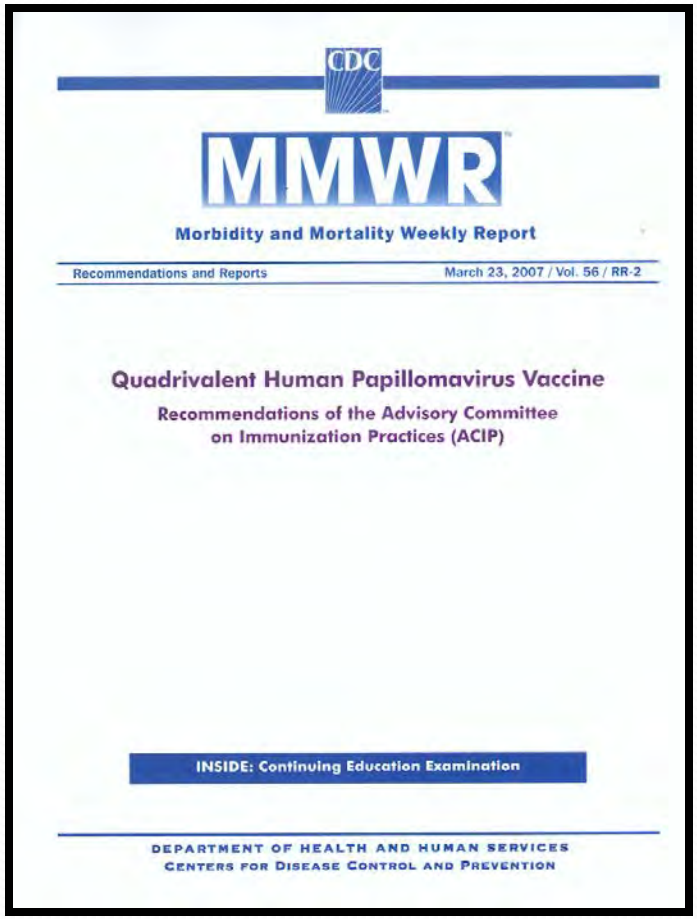
- **Established in 2004**
  - Chaired by ACIP member; one additional ACIP member
  - CDC Lead (subject matter expert)
  - Other members (liaison representatives, invited consultants, FDA etc)
  - Prepared for vote on quadrivalent HPV vaccine in 2006
- **Reviewed safety data post licensure for 4vHPV in 2007**
- **Prepared for vote on 2vHPV use in females and 4vHPV use in males (permissive) – 2009**
- **Prepared for vote on routine use of 4vHPV in males - 2011**

Background Information for Development of HPV Vaccine Recommendations

- Vaccine and clinical trials
- HPV epidemiology and HPV related disease
- Sexual behavior
- Vaccine acceptability
- Impact and cost effectiveness
- Program/implementation issues

Recommendations for Quadrivalent HPV Vaccine

- First HPV vaccine recommendation statement – published in March 2007
- 4vHPV only
- Routine vaccination
  - Females 11 through 12 years of age
- Catch-up
  - Females 13 through 26 years of age


CDC

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports — March 23, 2007 / Vol. 56 / RR-2

Quadrivalent Human Papillomavirus Vaccine

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Updated ACIP HPV Vaccine Recommendations–August 2014

- 4vHPV – females and males, routine
- 2vHPV – females and males, routine
- Catch-up – females and males

- *February 2015 ACIP meeting: newly licensed 9vHPV vaccine use in females (MMWR 03-27-2015)*


Please note: An erratum has been published for this issue. To view the erratum, please click here.

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 63 / No. 5

August 29, 2014

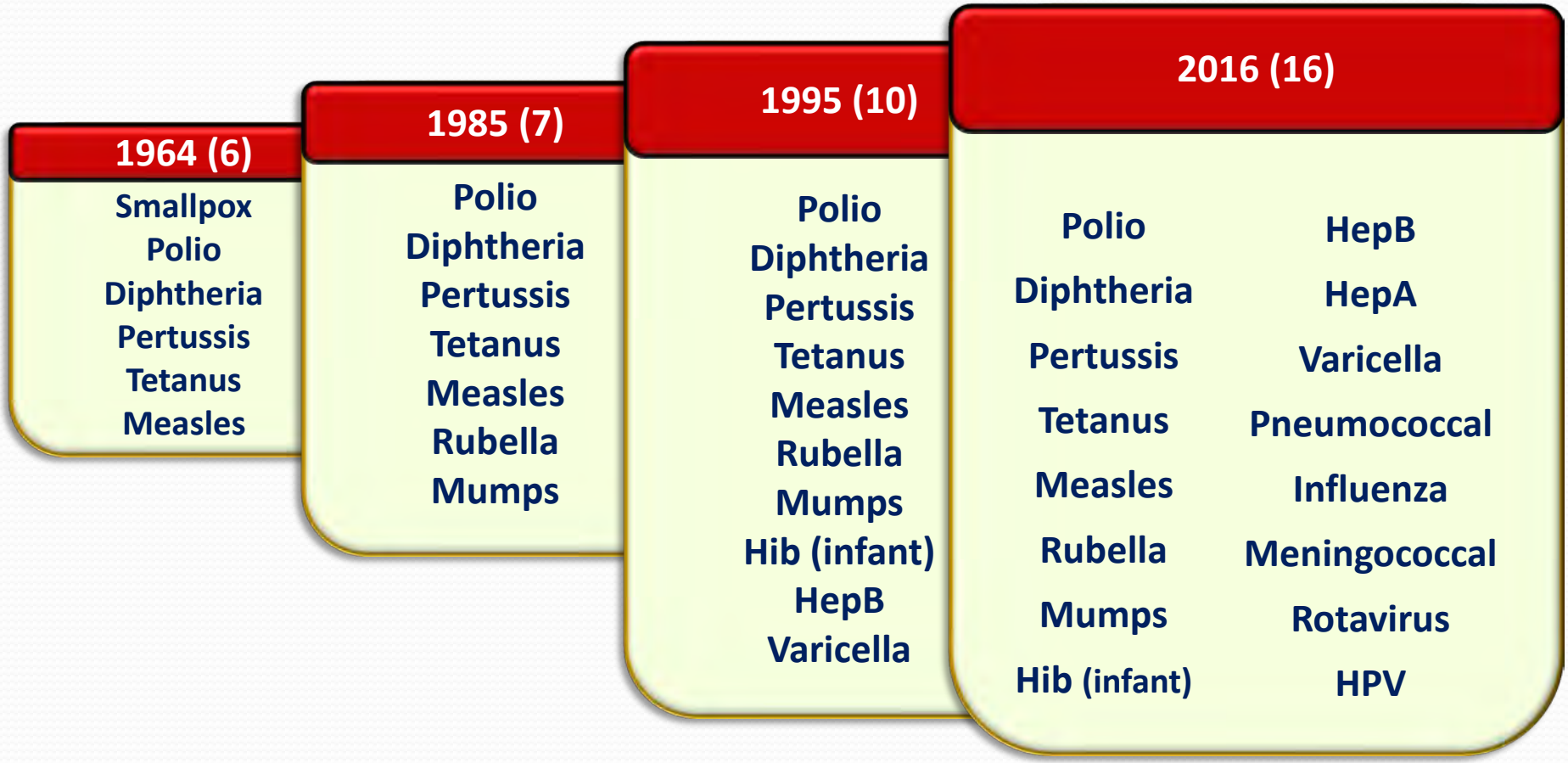
Human Papillomavirus Vaccination

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

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

Number of Diseases Prevented by Vaccines Included in the Routine Child/Adolescent Immunization Schedule



1983

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td¶¶	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

†For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

§DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

¶OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

††MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

§§Up to the seventh birthday.

¶¶Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

1983 childhood immunization schedule

1989

TABLE 2. Recommended schedule for active immunization of normal infants and children*

Recommended age†	Vaccine(s)§	Comments
2 mos	DTP#1¶, OPV#1**	OPV and DTP can be given earlier in areas of high endemicity
4 mos	DTP#2, OPV#2	6-wk to 2-mo interval desired between OPV doses
6 mos	DTP#3	An additional dose of OPV at this time is optional in areas with a high risk of poliovirus exposure
15 mos††	MMR§§, DTP#4, OPV#3	Completion of primary series of DTP and OPV
18 mos	HbCV¶¶	Conjugate preferred over polysaccharide vaccine***
4–6 yrs	DTP#5†††, OPV#4	At or before school entry
14–16 yrs	Td§§§	Repeat every 10 yrs throughout life

*See Table 3 for the recommended immunization schedules for infants and children up to their seventh birthday not immunized at the recommended times.

†These recommended ages should not be construed as absolute, e.g., 2 months can be 6–10 weeks. However, MMR should not be given to children <12 months of age. If exposure to measles disease is considered likely, then children 6 through 11 months old may be immunized with single-antigen measles vaccine. These children should be reimmunized with MMR when they are approximately 15 months of age.

§For all products used, consult the manufacturers' package enclosures for instructions regarding storage, handling, dosage, and administration. Immunobiologics prepared by different manufacturers can vary, and those of the same manufacturer can change from time to time. The package inserts are useful references for specific products, but they may not always be consistent with current ACIP and American Academy of Pediatrics immunization schedules.

¶DTP = Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed. DTP may be used up to the seventh birthday. The first dose can be given at 6 weeks of age and the second and third doses given 4–8 weeks after the preceding dose.

**OPV = Poliovirus Vaccine Live Oral, Trivalent: contains poliovirus types 1, 2, and 3.

††Provided at least 6 months have elapsed since DTP#3 or, if fewer than 3 doses of DTP have been received, at least 6 weeks since the last previous dose of DTP or OPV. MMR vaccine should not be delayed to allow simultaneous administration with DTP and OPV. Administering MMR at 15 months and DTP#4 and OPV#3 at 18 months continues to be an acceptable alternative.

§§MMR = Measles, Mumps, and Rubella Virus Vaccine, Live. Counties that report ≥5 cases of measles among preschool children during each of the last 5 years should implement a routine 2-dose measles vaccination schedule for preschoolers. The first dose should be administered at 9 months or the first health-care contact thereafter. Infants vaccinated before their first birthday should receive a second dose at about 15 months of age. Single-antigen measles vaccine should be used for children aged <1 year and MMR for children vaccinated on or after their first birthday. If resources do not allow a routine 2-dose schedule, an acceptable alternative is to lower the routine age for MMR vaccination to 12 months.

¶¶HbCV = Vaccine composed of Haemophilus influenzae b polysaccharide antigen conjugated to a protein carrier. Children <5 years of age previously vaccinated with polysaccharide vaccine between the ages of 18 and 23 months should be revaccinated with a single dose of conjugate vaccine if at least 2 months have elapsed since the receipt of the polysaccharide vaccine.

***If HbCV is not available, an acceptable alternative is to give Haemophilus influenzae b polysaccharide vaccine (HbPV) at age ≥24 months. Children at high risk for *Haemophilus influenzae* type b disease where conjugate vaccine is not available may be vaccinated with HbPV at 18 months of age and revaccinated at 24 months.

†††Up to the seventh birthday.

1989 childhood immunization schedule

1994

TABLE 3. Recommended schedule for routine active vaccination of infants and children*

Vaccine	At birth (before hospital discharge)	1–2 months	2 months†	4 months	6 months	6–18 months	12–15 months	15 months	4–6 years (before school entry)
Diphtheria-tetanus-pertussis§			DTP	DTP	DTP			DTaP/DTP¶	DTaP/DTP
Polio, live oral			OPV	OPV	OPV**				OPV
Measles-mumps-rubella							MMR		MMR††
Haemophilus influenzae type b conjugate									
HbOC/PRP-T §,§§			Hib	Hib	Hib		Hib¶¶		
PRP-OMP§§			Hib	Hib			Hib¶¶		
Hepatitis B***									
Option 1	HepB	HepB†††				HepB†††			
Option 2		HepB†††		HepB†††		HepB†††			

*See Table 4 for the recommended immunization schedule for infants and children up to their seventh birthday who do not begin the vaccination series at the recommended times or who are >1 month behind in the immunization schedule.

† Can be administered as early as 6 weeks of age.

§ Two DTP and Hib combination vaccines are available (DTP/HbOC [TETRAMUNE™]; and PRP-T [ActHIB™, OmniHIB™] which can be reconstituted with DTP vaccine produced by Connaught).

¶ This dose of DTP can be administered as early as 12 months of age provided that the interval since the previous dose of DTP is at least 6 months. *Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) is currently recommended only for use as the fourth and/or fifth doses of the DTP series among children aged 15 months through 6 years (before the seventh birthday).* Some experts prefer to administer these vaccines at 18 months of age.

** The American Academy of Pediatrics (AAP) recommends this dose of vaccine at 6–18 months of age.

†† The AAP recommends that two doses of MMR should be administered by 12 years of age with the second dose being administered preferentially at entry to middle school or junior high school.

§§ HbOC: [HibTITER®] (Lederle Praxis). PRP-T: [ActHIB™, OmniHIB™] (Pasteur Merieux). PRP-OMP: [PedvaxHIB®] (Merck, Sharp, and Dohme). A DTP/Hib combination vaccine can be used in place of HbOC/PRP-T.

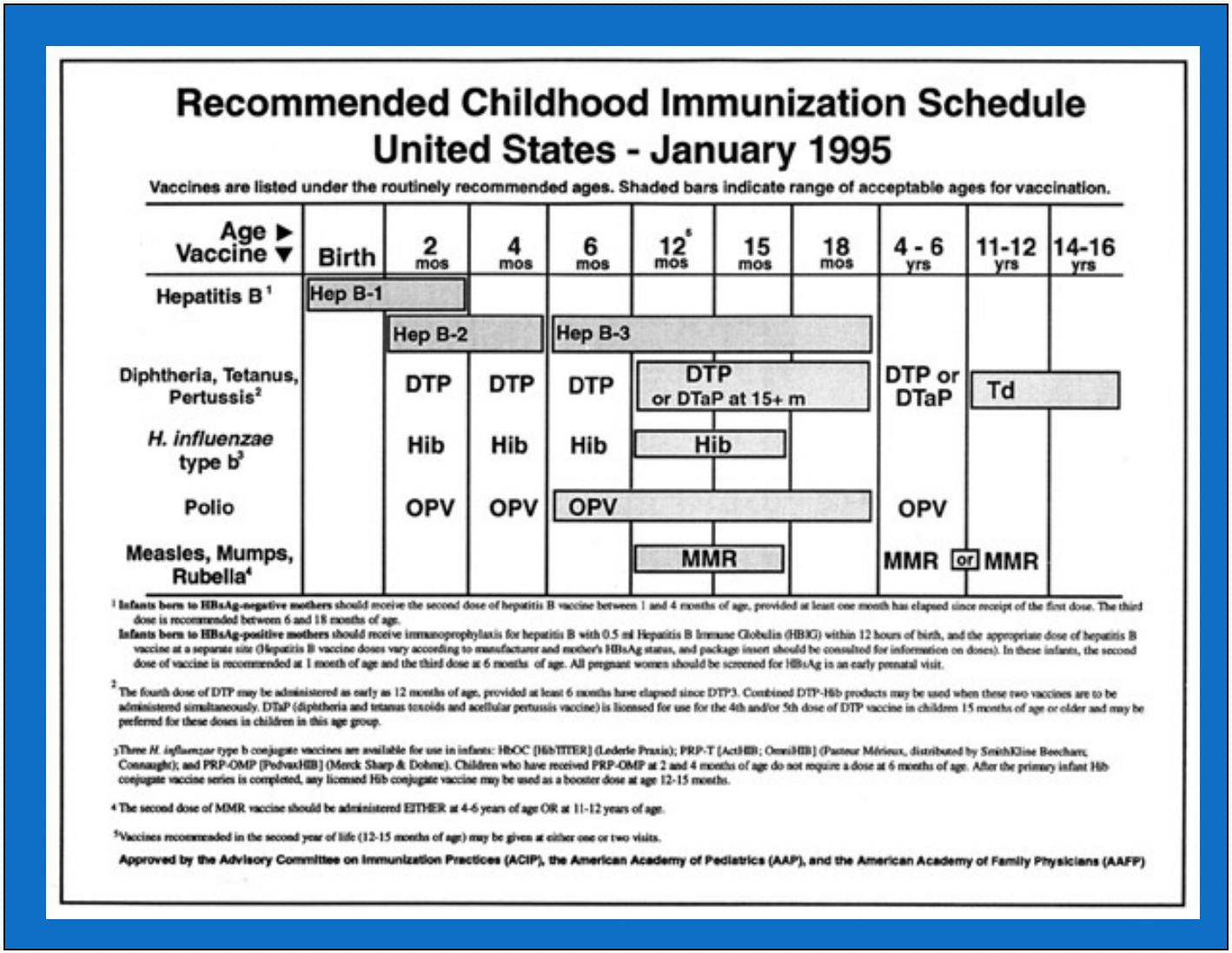
¶¶ After the primary infant Hib conjugate vaccine series is completed, any of the licensed Hib conjugate vaccines may be used as a booster dose at age 12–15 months.

*** For use among infants born to HBsAg-negative mothers. The first dose should be administered during the newborn period, preferably before hospital discharge, but no later than age 2 months. Premature infants of HBsAg-negative mothers should receive the first dose of the hepatitis B vaccine series at the time of hospital discharge or when the other routine childhood vaccines are initiated. (All infants born to HBsAg-positive mothers should receive immunoprophylaxis for hepatitis B as soon as possible after birth.)

††† Hepatitis B vaccine can be administered simultaneously at the same visit with DTP (or DTaP), OPV, Hib, and/or MMR.

1994 childhood immunization schedule

1995



Recommended Childhood Immunization Schedule
United States - January 1995

Vaccines are listed under the routinely recommended ages. Shaded bars indicate range of acceptable ages for vaccination.

Age ▶ / Vaccine ▼	Birth	2 mos	4 mos	6 mos	12[5] mos	15 mos	18 mos	4 - 6 yrs	11-12 yrs	14-16 yrs
Hepatitis B[1]	Hep B-1	Hep B-2		Hep B-3						
Diphtheria, Tetanus, Pertussis[2]		DTP	DTP	DTP	DTP or DTaP at 15+ m			DTP or DTaP	Td	
H. influenzae type b[3]		Hib	Hib	Hib	Hib					
Polio		OPV	OPV	OPV				OPV		
Measles, Mumps, Rubella[4]					MMR			MMR	or MMR	

[1] **Infants born to HBsAg-negative mothers** should receive the second dose of hepatitis B vaccine between 1 and 4 months of age, provided at least one 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 the appropriate dose of hepatitis B vaccine at a separate site (Hepatitis B vaccine doses vary according to manufacturer and mother's HBsAg status, and package insert should be consulted for information on doses). In 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 in an early prenatal visit.

[2] The fourth dose of DTP may be administered as early as 12 months of age, provided at least 6 months have elapsed since DTP3. Combined DTP-Hib products may be used when these two vaccines are to be administered simultaneously. DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is licensed for use for the 4th and/or 5th dose of DTP vaccine in children 15 months of age or older and may be preferred for these doses in children in this age group.

[3] Three *H. influenzae* type b conjugate vaccines are available for use in infants: HbOC [HibTITER] (Lederle Praxis); PRP-T [ActHIB; OmniHIB] (Pasteur Mérieux, distributed by SmithKline Beecham, Connaught); and PRP-OMP [PedvaxHIB] (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 used as a booster dose at age 12-15 months.

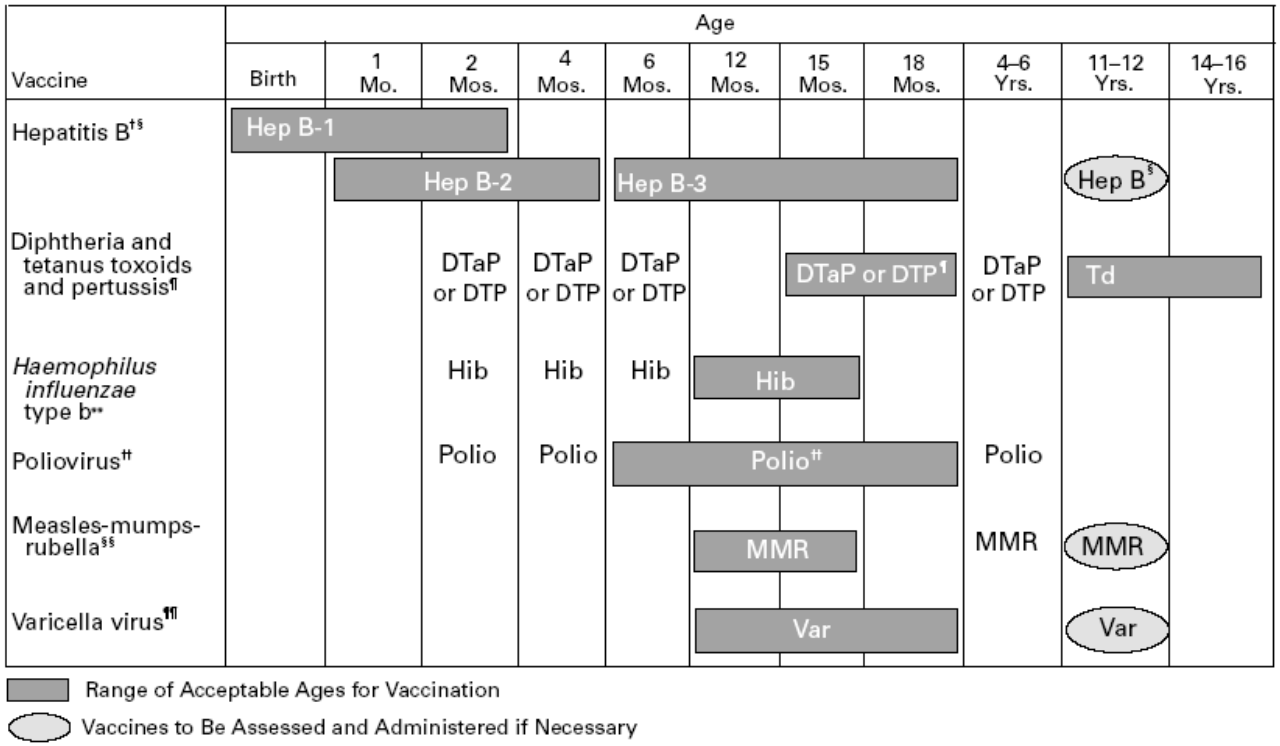
[4] The second dose of MMR vaccine should be administered EITHER at 4-6 years of age OR at 11-12 years of age.

[5] Vaccines recommended in the second year of life (12-15 months of age) may be given at either one or two visits.

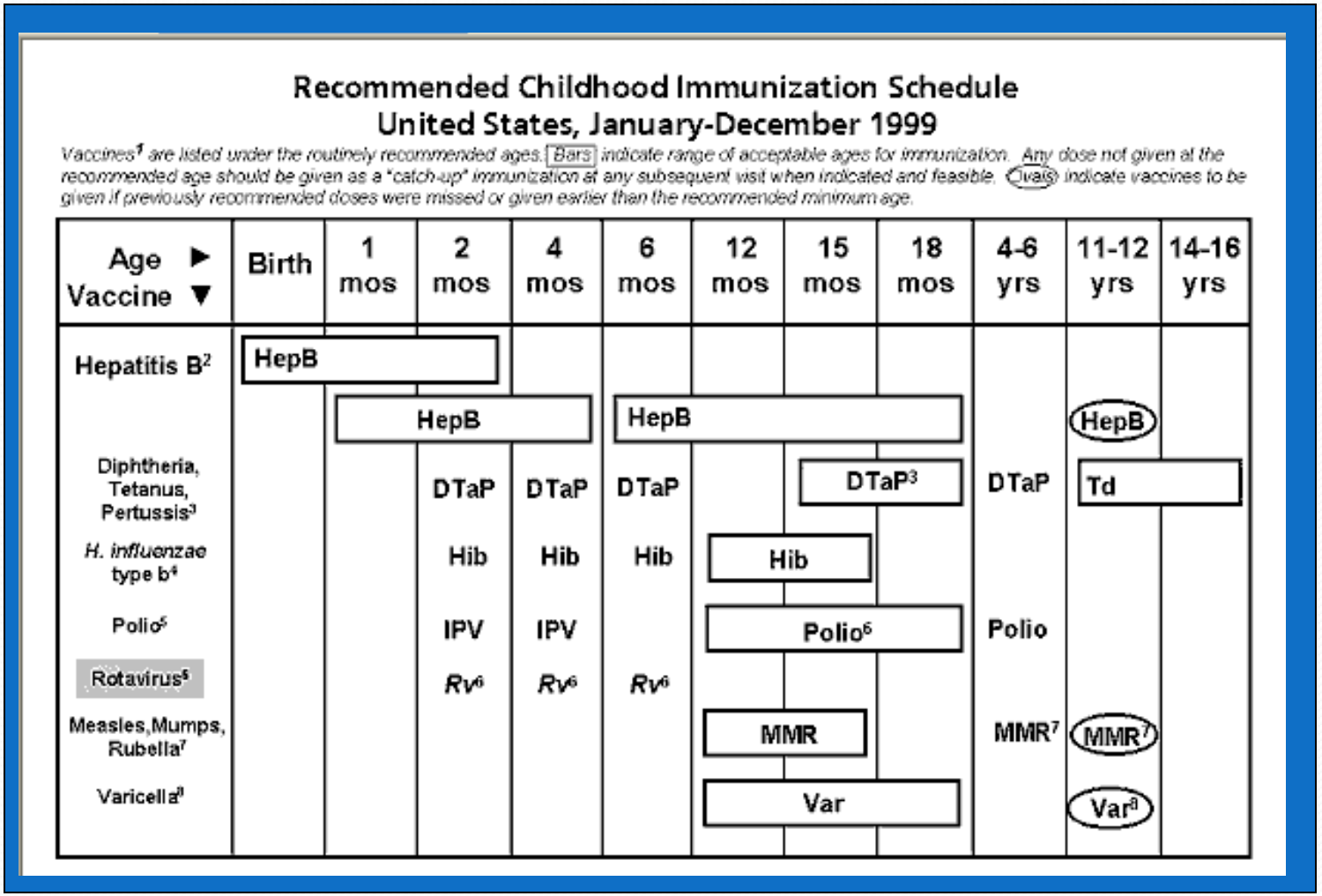
Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)

1998

FIGURE 1. Recommended childhood immunization schedule* — United States, January–December 1998



1999

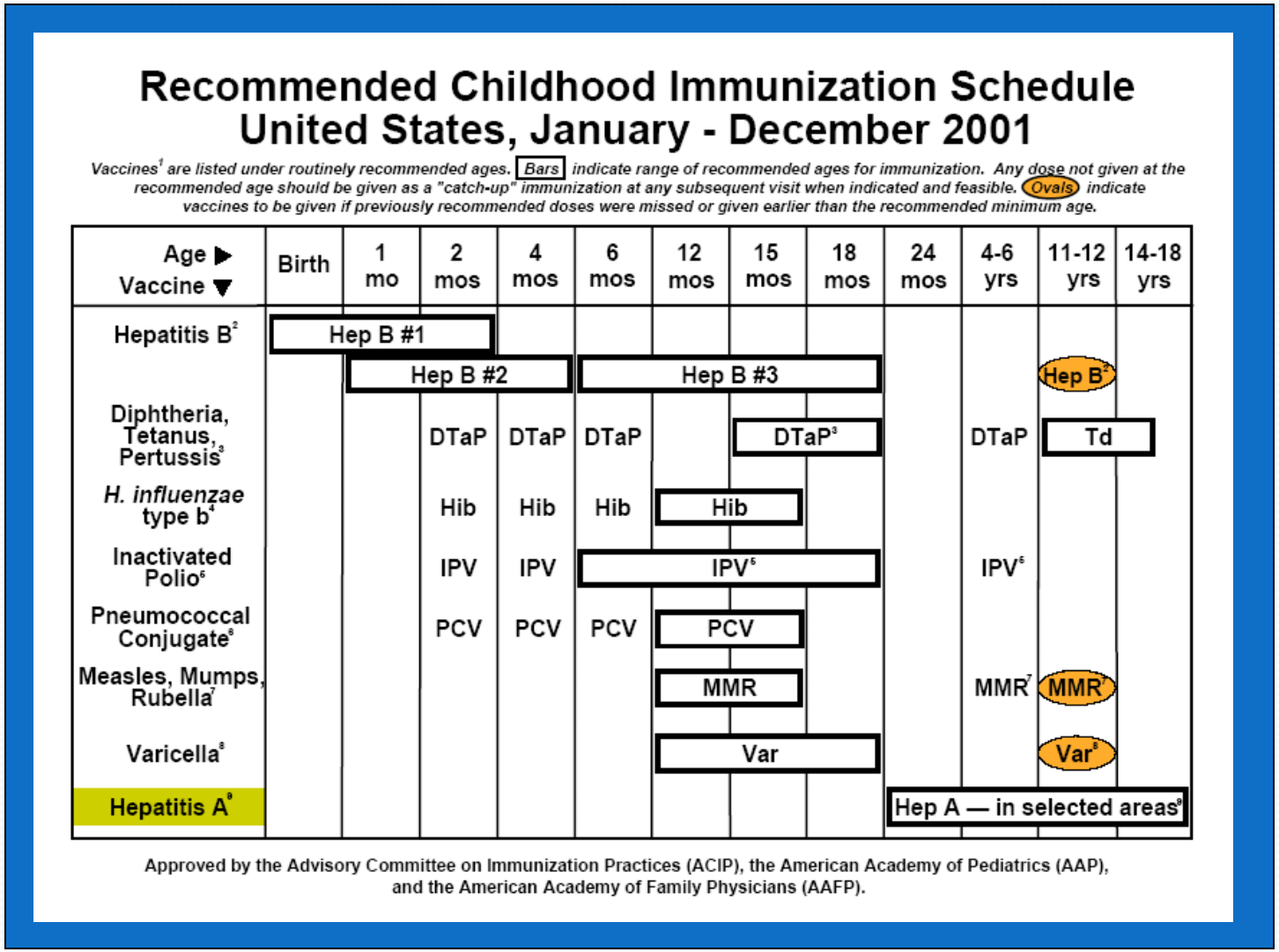


Recommended Childhood Immunization Schedule
United States, January-December 1999

Vaccines[1] are listed under the routinely recommended ages. Bars indicate range of acceptable ages for immunization. Any dose not given at the recommended age should be given as a "catch-up" immunization at any subsequent visit when indicated and feasible. Ovals indicate vaccines to be given if previously recommended doses were missed or given earlier than the recommended minimum age.

Age ▶ / Vaccine ▼	Birth	1 mos	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	4-6 yrs	11-12 yrs	14-16 yrs
Hepatitis B[2]	HepB										
		HepB			HepB					HepB	
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP		DTaP[3]		DTaP	Td	
H. influenzae type b[4]			Hib	Hib	Hib	Hib					
Polio[5]			IPV	IPV		Polio[5]			Polio		
Rotavirus[5]			*Rv*[6]	*Rv*[6]	*Rv*[6]						
Measles, Mumps, Rubella[7]						MMR			MMR[7]	MMR[7]	
Varicella[8]						Var				Var[8]	

2001


Recommended Childhood Immunization Schedule
United States, January - December 2001
Vaccines[1] are listed under routinely recommended ages. Bars indicate range of recommended ages for immunization. Any dose not given at the recommended age should be given as a "catch-up" immunization at any subsequent visit when indicated and feasible. Ovals indicate vaccines to be given if previously recommended doses were missed or given earlier than the recommended minimum age.
Age ▶
Vaccine ▼
Birth
1 mo
2 mos
4 mos
6 mos
12 mos
15 mos
18 mos
24 mos
4-6 yrs
11-12 yrs
14-18 yrs
Hepatitis B[2]
Hep B #1
Hep B #2
Hep B #3
Hep B[2]
Diphtheria, Tetanus, Pertussis[3]
DTaP
DTaP
DTaP
DTaP[3]
DTaP
Td
H. influenzae type b[4]
Hib
Hib
Hib
Hib
Inactivated Polio[5]
IPV
IPV
IPV[5]
IPV[5]
Pneumococcal Conjugate[6]
PCV
PCV
PCV
PCV
Measles, Mumps, Rubella[7]
MMR
MMR[7]
MMR[7]
Varicella[8]
Var
Var[8]
Hepatitis A[9]
Hep A — in selected areas[9]
Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

2002

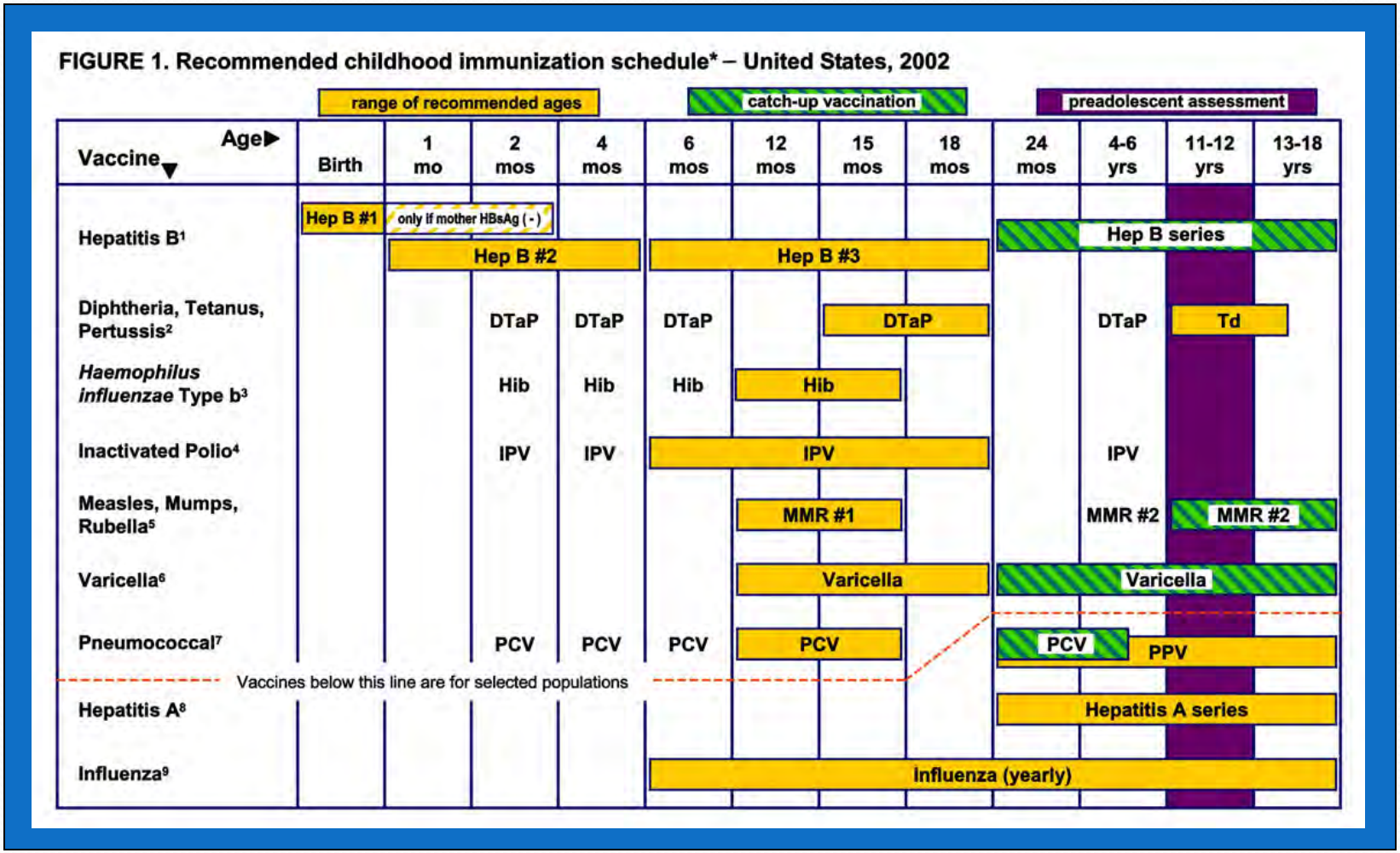
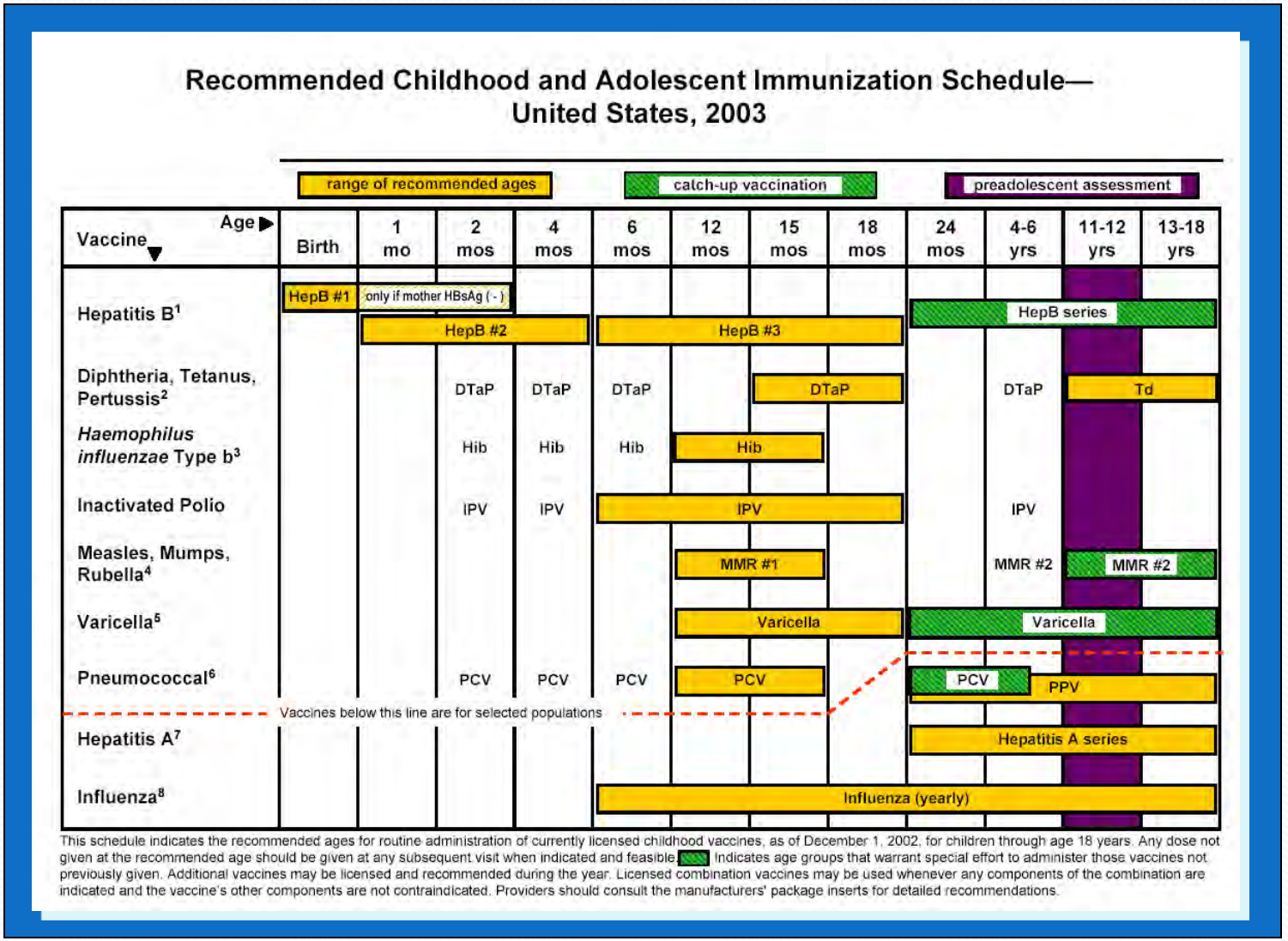
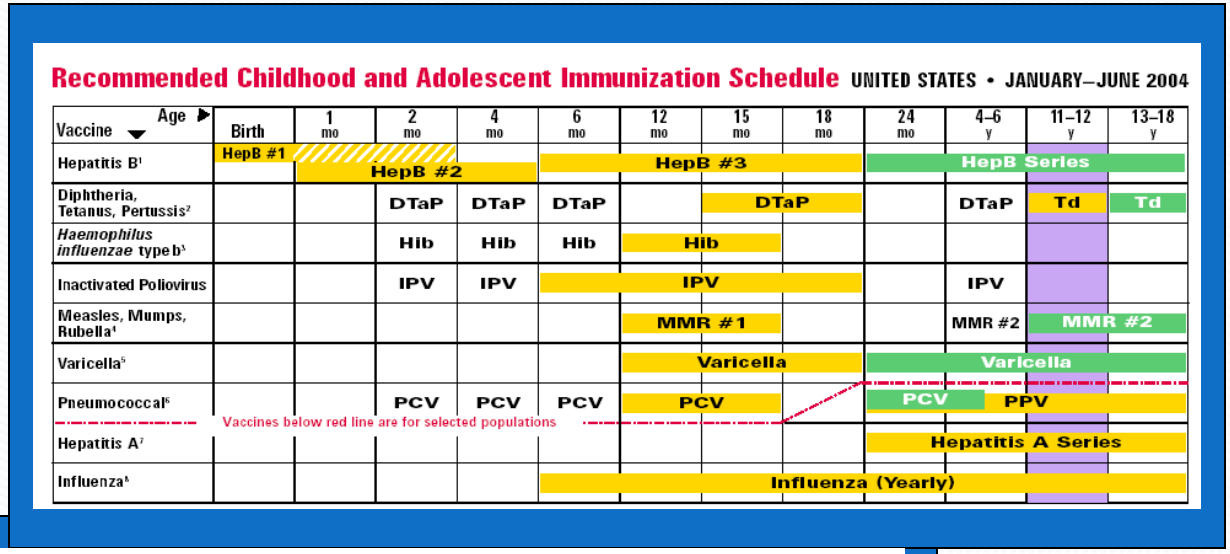


FIGURE 1. Recommended childhood immunization schedule* – United States, 2002
range of recommended ages
catch-up vaccination
preadolescent assessment
Vaccine
Age
Birth
1 mo
2 mos
4 mos
6 mos
12 mos
15 mos
18 mos
24 mos
4-6 yrs
11-12 yrs
13-18 yrs
Hepatitis B[1]
Hep B #1
only if mother HBsAg (-)
Hep B #2
Hep B #3
Hep B series
Diphtheria, Tetanus, Pertussis[2]
DTaP
DTaP
DTaP
DTaP
DTaP
Td
Haemophilus influenzae Type b[3]
Hib
Hib
Hib
Hib
Inactivated Polio[4]
IPV
IPV
IPV
IPV
Measles, Mumps, Rubella[5]
MMR #1
MMR #2
MMR #2
Varicella[6]
Varicella
Varicella
Pneumococcal[7]
PCV
PCV
PCV
PCV
PCV
PPV
Vaccines below this line are for selected populations
Hepatitis A[8]
Hepatitis A series
Influenza[9]
Influenza (yearly)

2003


Recommended Childhood and Adolescent Immunization Schedule—
United States, 2003
range of recommended ages
catch-up vaccination
preadolescent assessment
Age ▶
Vaccine ▼
Birth
1 mo
2 mos
4 mos
6 mos
12 mos
15 mos
18 mos
24 mos
4-6 yrs
11-12 yrs
13-18 yrs
Hepatitis B[1]
HepB #1
only if mother HBsAg (-)
HepB #2
HepB #3
HepB series
Diphtheria, Tetanus, Pertussis[2]
DTaP
DTaP
DTaP
DTaP
DTaP
Td
Haemophilus influenzae Type b[3]
Hib
Hib
Hib
Hib
Inactivated Polio
IPV
IPV
IPV
IPV
Measles, Mumps, Rubella[4]
MMR #1
MMR #2
MMR #2
Varicella[5]
Varicella
Varicella
Pneumococcal[6]
PCV
PCV
PCV
PCV
PCV
PPV
Vaccines below this line are for selected populations
Hepatitis A[7]
Hepatitis A series
Influenza[8]
Influenza (yearly)
This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2002, for children through age 18 years. Any dose not given at the recommended age should be given at any subsequent visit when indicated and feasible. Indicates age groups that warrant special effort to administer those vaccines not previously given. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated. Providers should consult the manufacturers' package inserts for detailed recommendations.

2004



Recommended Childhood and Adolescent Immunization Schedule UNITED STATES • JANUARY–JUNE 2004

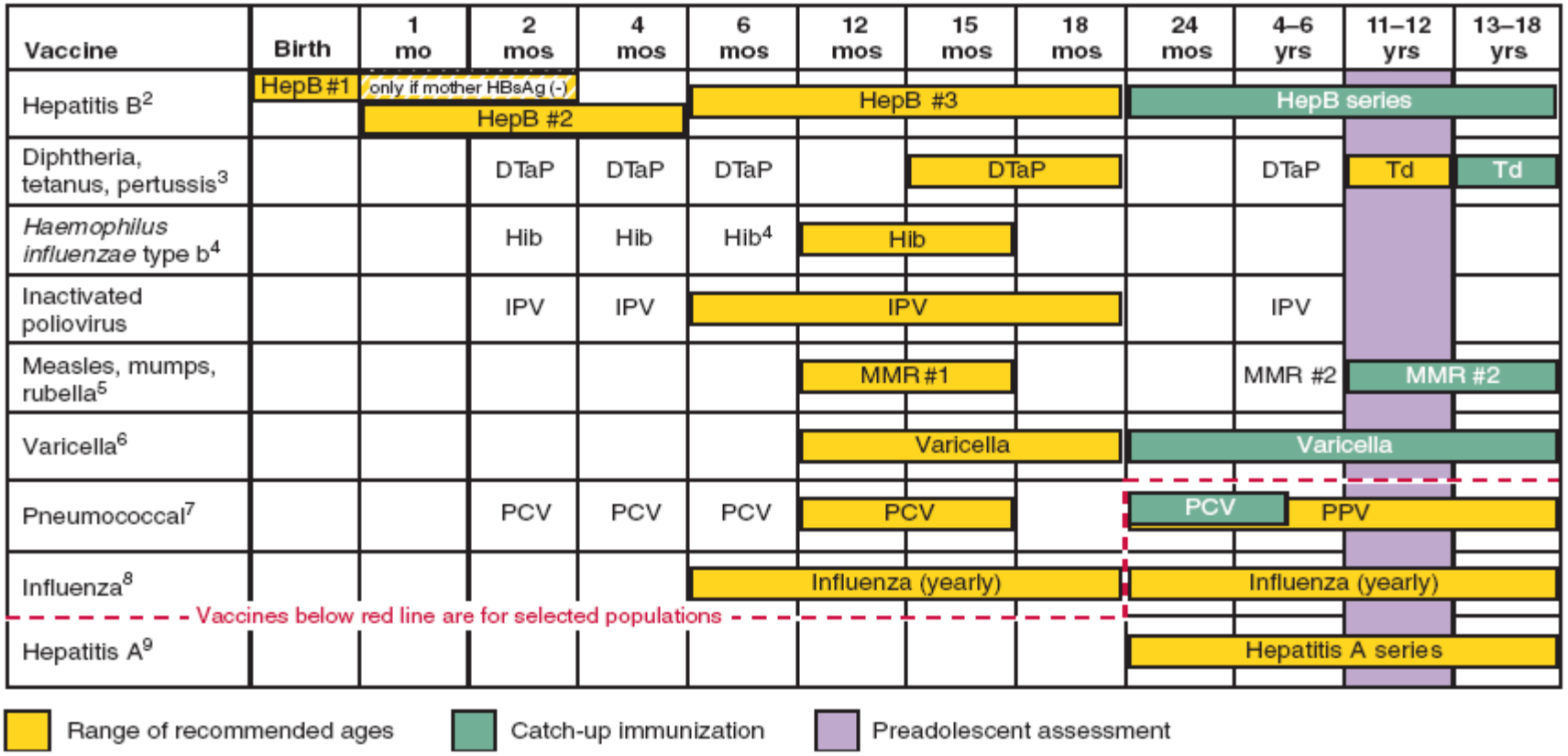
Vaccine \ Age	Birth	1 mo	2 mo	4 mo	6 mo	12 mo	15 mo	18 mo	24 mo	4–6 y	11–12 y	13–18 y
Hepatitis B[1]	HepB #1	HepB #2			HepB #3				HepB Series			
Diphtheria, Tetanus, Pertussis[2]			DTaP	DTaP	DTaP		DTaP			DTaP	Td	Td
Haemophilus influenzae type b[3]			Hib	Hib	Hib	Hib						
Inactivated Poliovirus			IPV	IPV	IPV					IPV		
Measles, Mumps, Rubella[4]						MMR #1				MMR #2	MMR #2	
Varicella[5]						Varicella			Varicella			
Pneumococcal[6]			PCV	PCV	PCV	PCV			PCV	PPV		
			Vaccines below red line are for selected populations									
Hepatitis A[7]									Hepatitis A Series			
Influenza[8]					Influenza (Yearly)							

FIGURE. Recommended childhood and adolescent immunization schedule[1] — United States, July–December 2004

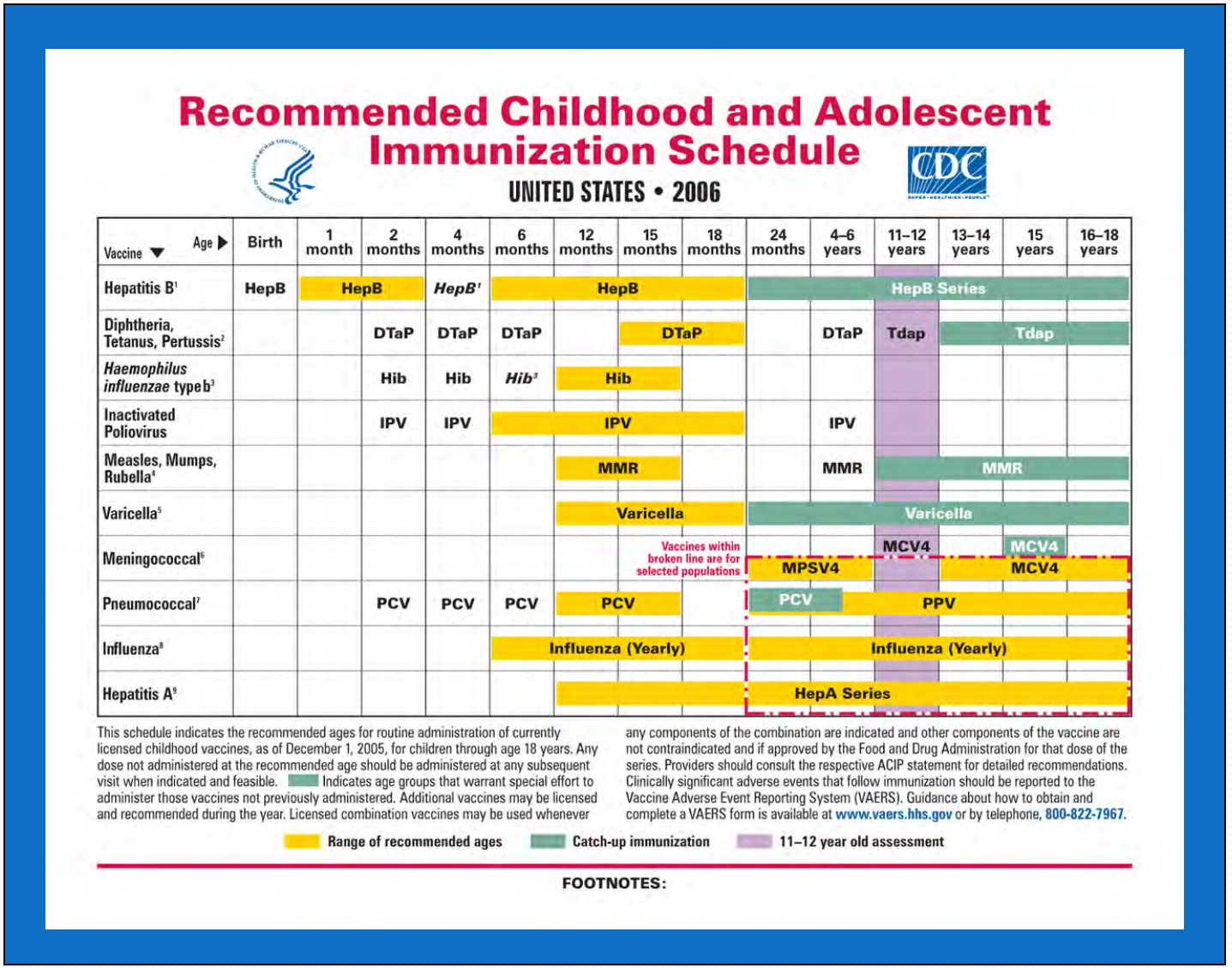
Vaccine	Birth	1 mo	2 mo	4 mo	6 mo	12 mo	15 mo	18 mo	24 mo	4–6 y	11–12 y	13–18 y
	Range of recommended ages				Catch-up vaccination				Preadolescent assessment			
Hepatitis B[2]	HepB #1	only if mother HBsAg (–)	HepB #2		HepB #3				HepB series			
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP		DTaP			DTaP	Td	Td
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib						
Inactivated Poliovirus			IPV	IPV	IPV					IPV		
Measles, Mumps, Rubella[5]						MMR #1				MMR #2	MMR #2	
Varicella[6]						Varicella			Varicella			
Pneumococcal[7]			PCV	PCV	PCV	PCV			PCV	PPV		
Influenza[8]					Influenza (yearly)				Influenza (yearly)			
			Vaccines below this line are for selected populations									
Hepatitis A[9]									HepA series			

2005

FIGURE. Recommended childhood and adolescent immunization schedule,[1] by vaccine and age — United States, 2005



2006



Recommended Childhood and Adolescent Immunization Schedule

UNITED STATES • 2006

Vaccine ▼ / Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	24 months	4–6 years	11–12 years	13–14 years	15 years	16–18 years
Hepatitis B[1]	HepB	HepB		*HepB*[1]	HepB				HepB Series					
Diphtheria, Tetanus, Pertussis[2]			DTaP	DTaP	DTaP		DTaP			DTaP	Tdap	Tdap		
Haemophilus influenzae type b[3]			Hib	Hib	*Hib*[3]	Hib								
Inactivated Poliovirus			IPV	IPV	IPV					IPV				
Measles, Mumps, Rubella[4]						MMR				MMR	MMR			
Varicella[5]						Varicella			Varicella					
Meningococcal[6]							Vaccines within broken line are for selected populations		MPSV4		MCV4	MCV4	MCV4	
Pneumococcal[7]			PCV	PCV	PCV	PCV			PCV		PPV			
Influenza[8]					Influenza (Yearly)				Influenza (Yearly)					
Hepatitis A[9]						HepA Series								

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2005, for children through age 18 years. Any dose not administered at the recommended age should be administered at any subsequent visit when indicated and feasible. Indicates age groups that warrant special effort to administer those vaccines not previously administered. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective ACIP statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Range of recommended ages | Catch-up immunization | 11–12 year old assessment

FOOTNOTES:

2007

FIGURE 1. Recommended immunization schedule for persons aged 0–6 years — United States, 2007

Vaccine ▼ / Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB		See footnote 1	HepB				HepB Series		
Rotavirus[2]			Rota	Rota	Rota						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP		DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	*Hib*[4]	Hib		Hib			
Pneumococcal[5]			PCV	PCV	PCV	PCV				PCV	PPV
Inactivated Poliovirus			IPV	IPV	IPV						IPV
Influenza[6]					Influenza (Yearly)						
Measles, Mumps, Rubella[7]						MMR					MMR
Varicella[8]						Varicella					Varicella
Hepatitis A[9]						HepA (2 doses)				HepA Series	
Meningococcal[10]										MPSV4	

Range of recommended ages

Catch-up immunization

Certain high-risk groups

FIGURE 2. Recommended immunization schedule for persons aged 7–18 years — United States, 2007

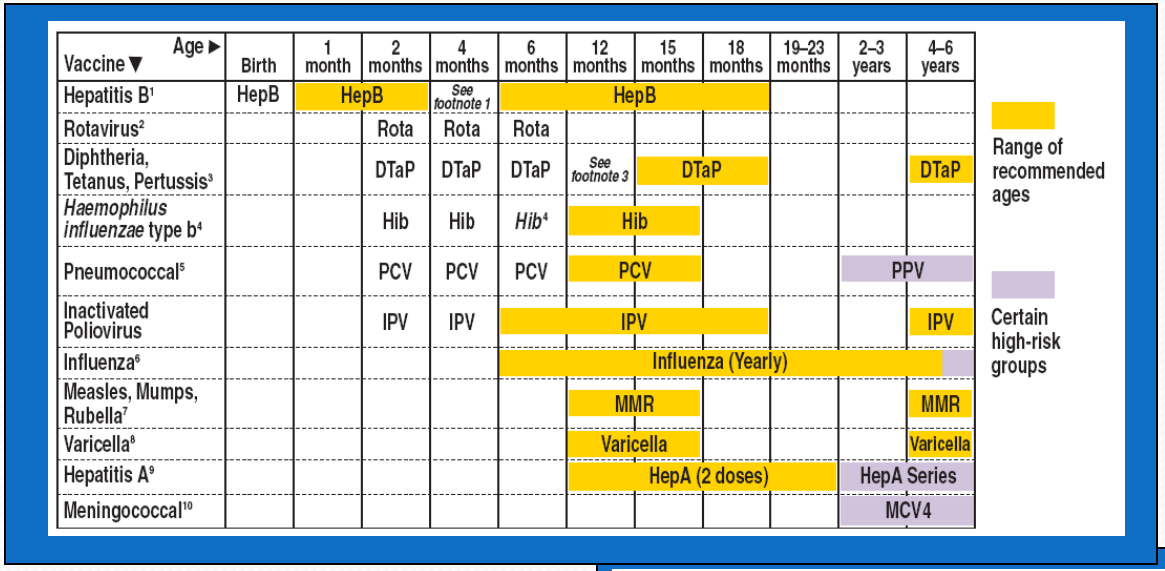
Vaccine ▼ / Age ▶	7–10 years	11–12 YEARS	13–14 years	15 years	16–18 years
Tetanus, Diphtheria, Pertussis[1]	See footnote 1	Tdap	Tdap		
Human Papillomavirus[2]	See footnote 2	HPV (3 doses)	HPV Series		
Meningococcal[3]	MPSV4	MCV4	MCV4	MCV4[3]	
Pneumococcal[4]	PPV				
Influenza[5]	Influenza (Yearly)				
Hepatitis A[6]	HepA Series				
Hepatitis B[7]	HepB Series				
Inactivated Poliovirus[8]	IPV Series				
Measles, Mumps, Rubella[9]	MMR Series				
Varicella[10]	Varicella Series				

Range of recommended ages

Catch-up immunization

Certain high-risk groups

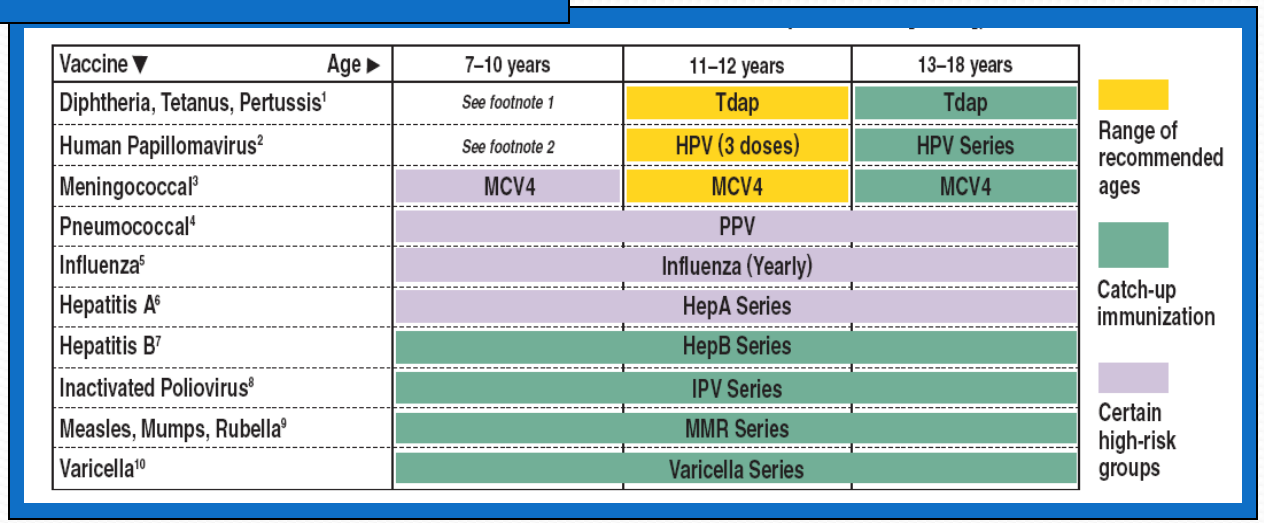
2008



Vaccine ▼ / Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB		See footnote 1	HepB						
Rotavirus[2]			Rota	Rota	Rota						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	See footnote 3	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	*Hib*[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPV	
Inactivated Poliovirus			IPV	IPV	IPV						IPV
Influenza[6]					Influenza (Yearly)						
Measles, Mumps, Rubella[7]						MMR					MMR
Varicella[8]						Varicella					Varicella
Hepatitis A[9]						HepA (2 doses)				HepA Series	
Meningococcal[10]										MCV4	

Range of recommended ages

Certain high-risk groups



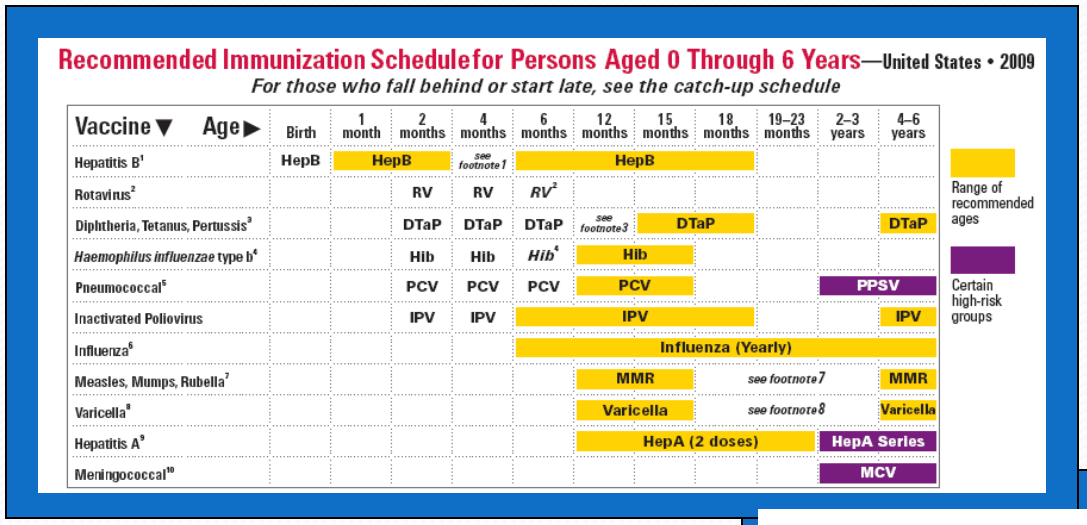
Vaccine ▼ / Age ▶	7–10 years	11–12 years	13–18 years
Diphtheria, Tetanus, Pertussis[1]	See footnote 1	Tdap	Tdap
Human Papillomavirus[2]	See footnote 2	HPV (3 doses)	HPV Series
Meningococcal[3]	MCV4	MCV4	MCV4
Pneumococcal[4]	PPV		
Influenza[5]	Influenza (Yearly)		
Hepatitis A[6]	HepA Series		
Hepatitis B[7]	HepB Series		
Inactivated Poliovirus[8]	IPV Series		
Measles, Mumps, Rubella[9]	MMR Series		
Varicella[10]	Varicella Series		

Range of recommended ages

Catch-up immunization

Certain high-risk groups

2009



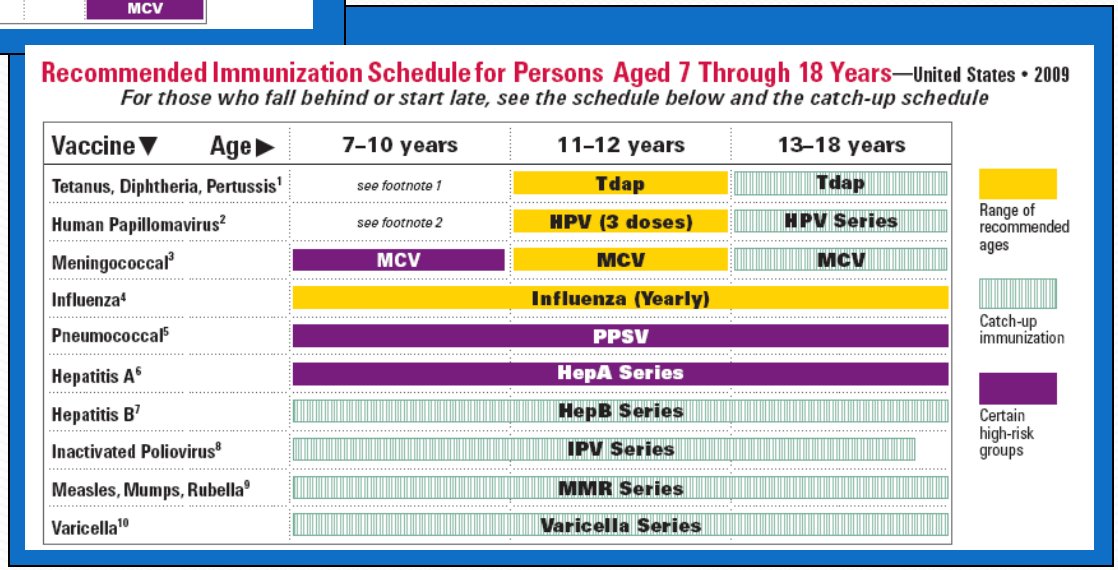
Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2009

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼ Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB		see footnote 1	HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	see footnote 3	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus			IPV	IPV	IPV						IPV
Influenza[6]					Influenza (Yearly)						
Measles, Mumps, Rubella[7]						MMR	see footnote 7				MMR
Varicella[8]						Varicella	see footnote 8				Varicella
Hepatitis A[9]						HepA (2 doses)				HepA Series	
Meningococcal[10]										MCV	

Range of recommended ages

Certain high-risk groups



Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2009

For those who fall behind or start late, see the schedule below and the catch-up schedule

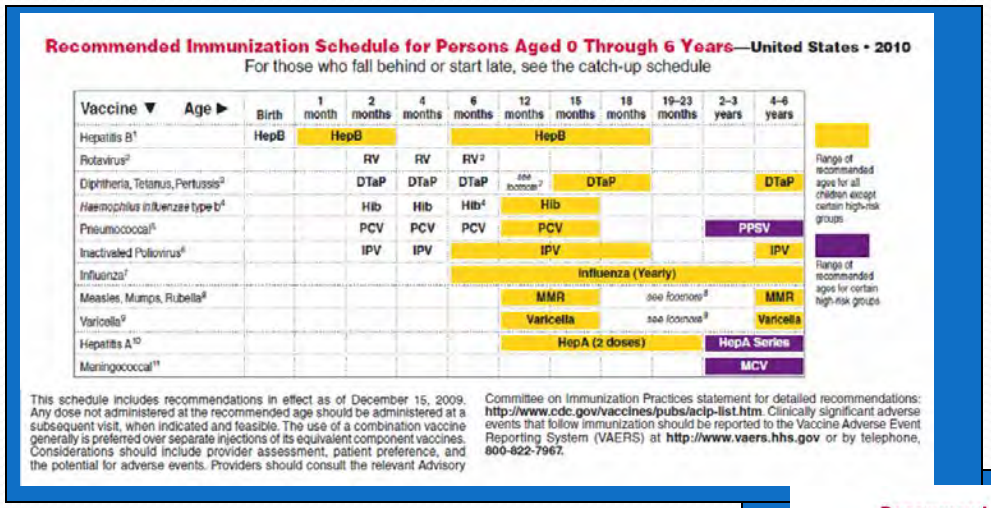
Vaccine ▼ Age ▶	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis[1]	see footnote 1	Tdap	Tdap
Human Papillomavirus[2]	see footnote 2	HPV (3 doses)	HPV Series
Meningococcal[3]	MCV	MCV	MCV
Influenza[4]	Influenza (Yearly)		
Pneumococcal[5]	PPSV		
Hepatitis A[6]	HepA Series		
Hepatitis B[7]	HepB Series		
Inactivated Poliovirus[8]	IPV Series		
Measles, Mumps, Rubella[9]	MMR Series		
Varicella[10]	Varicella Series		

Range of recommended ages

Catch-up immunization

Certain high-risk groups

2010



Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

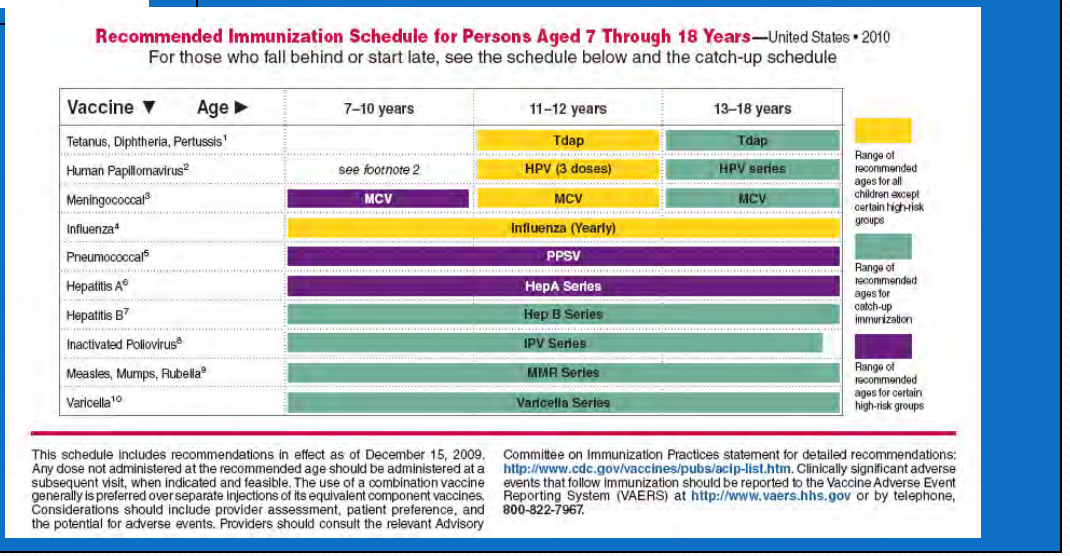
For those who fall behind or start late, see the catch-up schedule

Vaccine ▼ Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB			HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	see footnote 3	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus[6]			IPV	IPV		IPV					IPV
Influenza[7]					Influenza (Yearly)						
Measles, Mumps, Rubella[8]						MMR	see footnote 8				MMR
Varicella[9]						Varicella	see footnote 9				Varicella
Hepatitis A[10]						HepA (2 doses)				HepA Series	
Meningococcal[11]										MCV	

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 15, 2009. 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. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: **http://www.cdc.gov/vaccines/pubs/acip-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**.



Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2010

For those who fall behind or start late, see the schedule below and the catch-up schedule

Vaccine ▼ Age ►	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis[1]		Tdap	Tdap
Human Papillomavirus[2]	see footnote 2	HPV (3 doses)	HPV series
Meningococcal[3]	MCV	MCV	MCV
Influenza[4]	Influenza (Yearly)		
Pneumococcal[5]	PPSV		
Hepatitis A[6]	HepA Series		
Hepatitis B[7]	Hep B Series		
Inactivated Poliovirus[8]	IPV Series		
Measles, Mumps, Rubella[9]	MMR Series		
Varicella[10]	Varicella Series		

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 15, 2009. 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. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: **http://www.cdc.gov/vaccines/pubs/acip-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**.

2011

FIGURE 1. Recommended immunization schedule for persons aged 0 through 6 years — United States, 2011 (for those who fall behind or start late, see the catch-up schedule [Table])

Vaccine ▼ Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB			HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	see footnote[3]	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus[6]			IPV	IPV	IPV						IPV
Influenza[7]					Influenza (Yearly)						
Measles, Mumps, Rubella[8]						MMR		see footnote[8]			MMR
Varicella[9]						Varicella		see footnote[9]			Varicella
Hepatitis A[10]						HepA (2 doses)				HepA Series	
Meningococcal[11]										MCV4	

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

FIGURE 2. Recommended immunization schedule for persons aged 7 through 18 years — United States, 2011 (for those who fall behind or start late, see the schedule below and the catch-up schedule [Table])

Vaccine ▼ Age ►	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis[1]		Tdap	Tdap
Human Papillomavirus[2]	see footnote[2]	HPV (3 doses)(females)	HPV series
Meningococcal[3]	MCV4	MCV4	MCV4
Influenza[4]	Influenza (Yearly)		
Pneumococcal[5]	Pneumococcal		
Hepatitis A[6]	HepA Series		
Hepatitis B[7]	Hep B Series		
Inactivated Poliovirus[8]	IPV Series		
Measles, Mumps, Rubella[9]		MMR Series	
Varicella[10]	Varicella Series		

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

Recommended Immunization Schedule for Persons Aged 0-18 Years: 2012

FIGURE 1: Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012
(for those who fall behind or start late, see the catch-up schedule [Figure 3])

Vaccine ▼ Age ▶	Birth	1 month	2 months	4 months	6 months	9 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	Hep B	HepB			HepB							
Rotavirus[2]			RV	RV	RV[2]							
Diphtheria, tetanus, pertussis[3]			DTaP	DTaP	DTaP		see footnote[3]	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]		Hib					
Pneumococcal[5]			PCV	PCV	PCV		PCV				PPSV	
Inactivated poliovirus[6]			IPV	IPV	IPV							IPV
Influenza[7]					Influenza (Yearly)							
Measles, mumps, rubella[8]							MMR		see footnote[8]			MMR
Varicella[9]							Varicella		see footnote[9]			Varicella
Hepatitis A[10]							Dose 1[10]				HepA Series	
Meningococcal[11]						MCV4 — see footnote [11]						

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

Range of recommended ages for all children and certain high-risk groups

FIGURE 2: Recommended immunization schedule for persons aged 7 through 18 years—United States, 2012
(for those who fall behind or start late, see the schedule below and the catch-up schedule [Figure 3])

Vaccine ▼ Age ▶	7–10 years	11–12 years	13–18 years
Tetanus, diphtheria, pertussis[1]	1 dose (if indicated)	1 dose	1 dose (if indicated)
Human papillomavirus[2]	*see footnote*[2]	3 doses	Complete 3-dose series
Meningococcal[3]	See footnote[3]	Dose 1	Booster at 16 years old
Influenza[4]	Influenza (yearly)		
Pneumococcal[5]	See footnote [5]		
Hepatitis A[6]	Complete 2-dose series		
Hepatitis B[7]	Complete 3-dose series		
Inactivated poliovirus[8]	Complete 3-dose series		
Measles, mumps, rubella[9]	Complete 2-dose series		
Varicella[10]	Complete 2-dose series		

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

2013

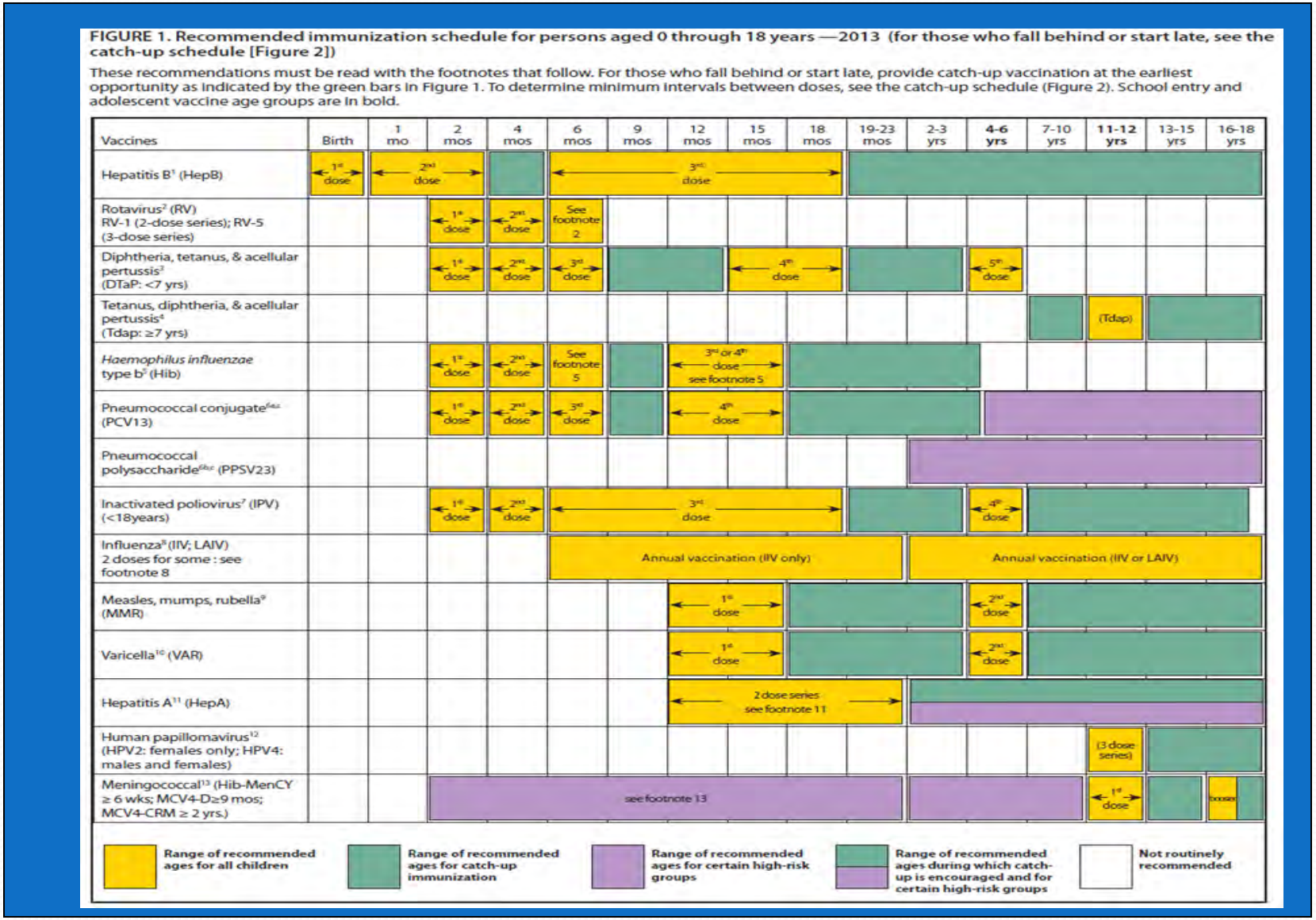


FIGURE 1. Recommended immunization schedule for persons aged 0 through 18 years —2013 (for those who fall behind or start late, see the catch-up schedule [Figure 2])

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.

Vaccines	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)	1st dose	2nd dose			3rd dose											
Rotavirus[2] (RV) RV-1 (2-dose series); RV-5 (3-dose series)			1st dose	2nd dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis[3] (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			4th dose				5th dose				
Tetanus, diphtheria, & acellular pertussis[4] (Tdap: ≥7 yrs)														(Tdap)		
Haemophilus influenzae type b[5] (Hib)			1st dose	2nd dose	See footnote 5		3rd or 4th dose see footnote 5									
Pneumococcal conjugate[6a,c] (PCV13)			1st dose	2nd dose	3rd dose		4th dose									
Pneumococcal polysaccharide[6b,c] (PPSV23)																
Inactivated poliovirus[7] (IPV) (<18years)			1st dose	2nd dose	3rd dose							4th dose				
Influenza[8] (IIV; LAIV) 2 doses for some : see footnote 8					Annual vaccination (IIV only)						Annual vaccination (IIV or LAIV)					
Measles, mumps, rubella[9] (MMR)							1st dose					2nd dose				
Varicella[10] (VAR)							1st dose					2nd dose				
Hepatitis A[11] (HepA)							2 dose series see footnote 11									
Human papillomavirus[12] (HPV2: females only; HPV4: males and females)														(3 dose series)		
Meningococcal[13] (Hib-MenCY ≥ 6 wks; MCV4-D≥9 mos; MCV4-CRM ≥ 2 yrs.)			see footnote 13											1st dose	booster	

Range of recommended ages for all children

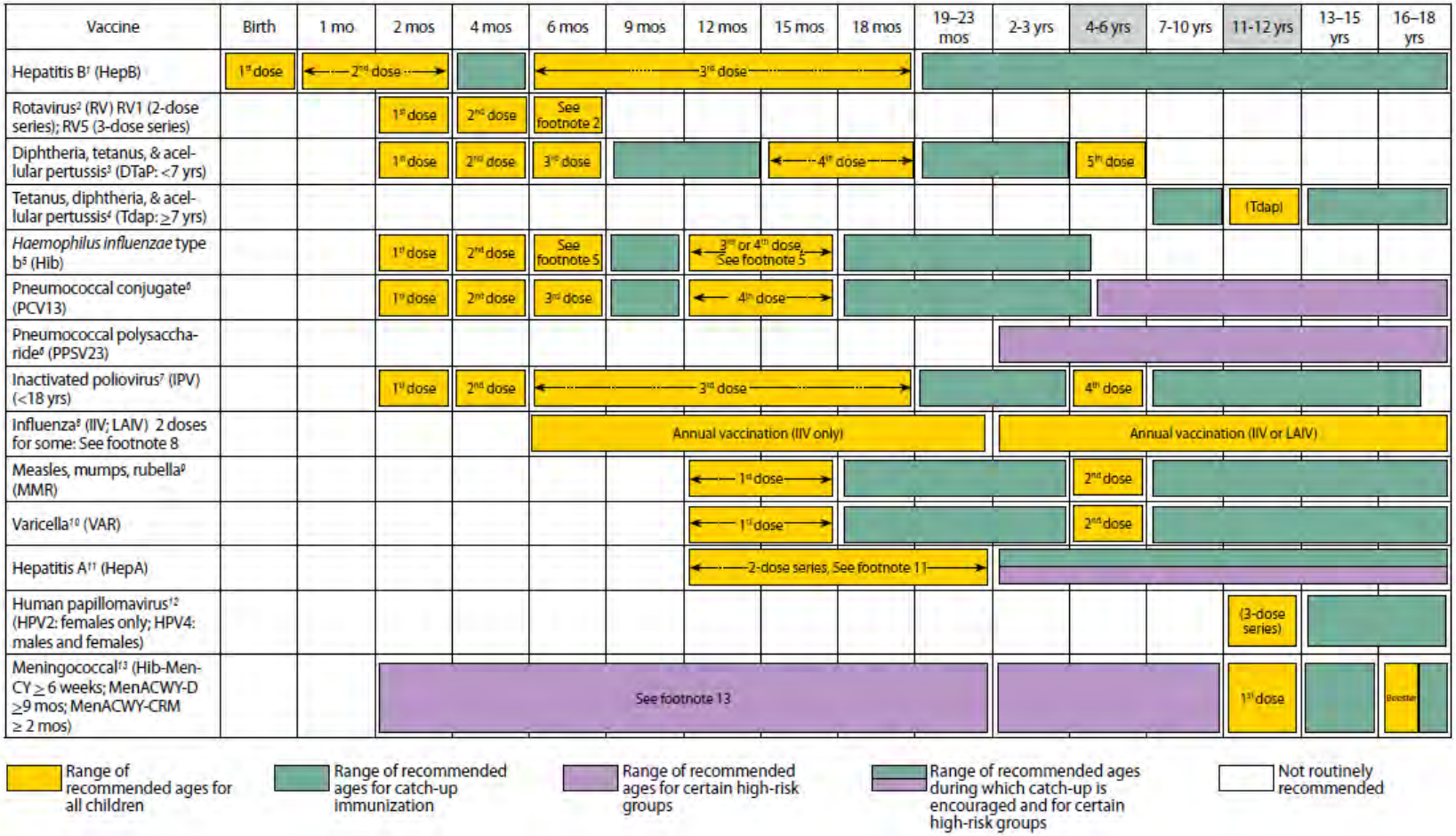
Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

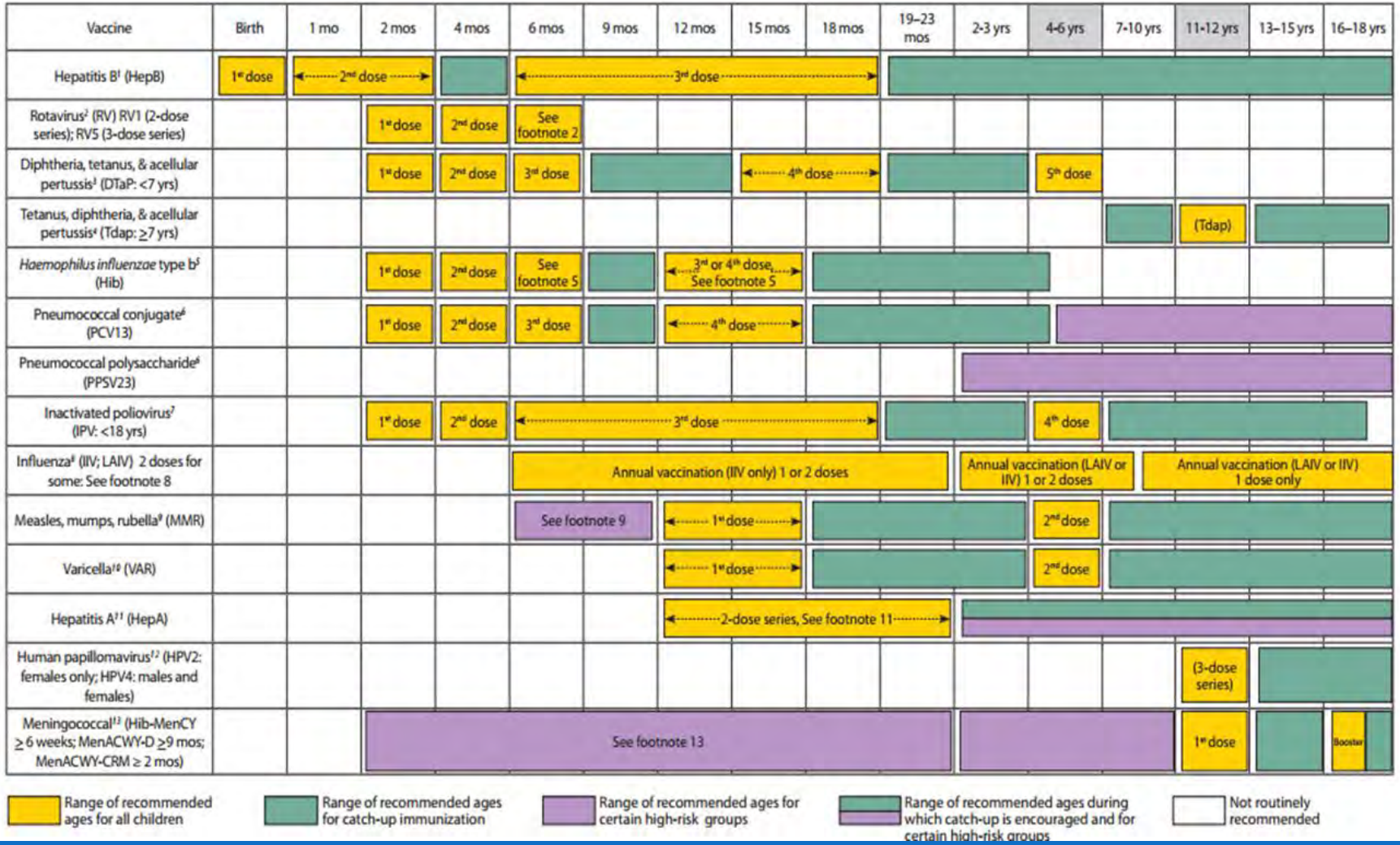
Range of recommended ages during which catch-up is encouraged and for certain high-risk groups

Not routinely recommended

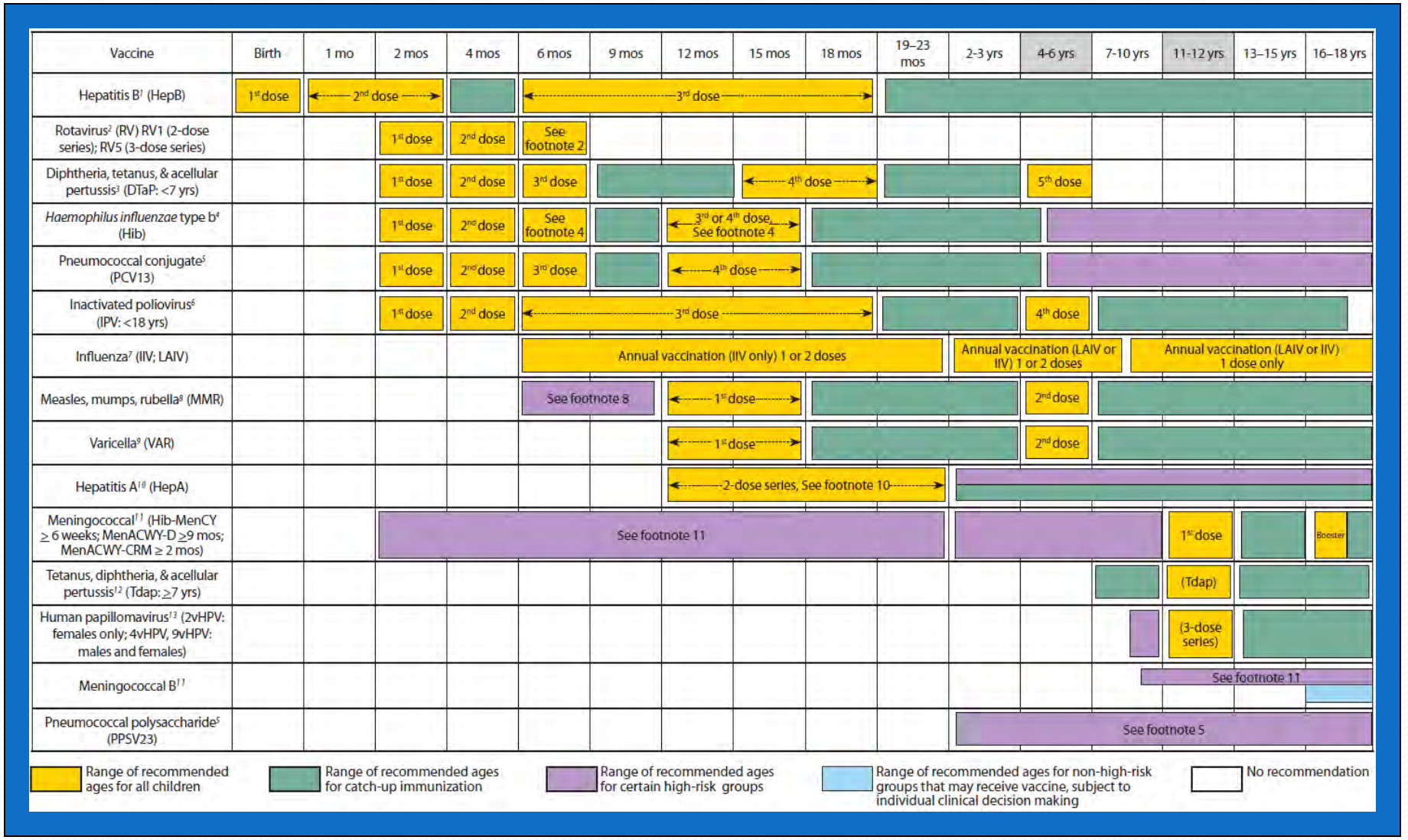
2014


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)
1st dose
2nd dose
3rd dose
Rotavirus[2] (RV) RV1 (2-dose series); RV5 (3-dose series)
1st dose
2nd dose
See footnote 2
Diphtheria, tetanus, & acellular pertussis[3] (DTaP: <7 yrs)
1st dose
2nd dose
3rd dose
4th dose
5th dose
Tetanus, diphtheria, & acellular pertussis[4] (Tdap: ≥7 yrs)
(Tdap)
Haemophilus influenzae type b[5] (Hib)
1st dose
2nd dose
See footnote 5
3rd or 4th dose, See footnote 5
Pneumococcal conjugate[6] (PCV13)
1st dose
2nd dose
3rd dose
4th dose
Pneumococcal polysaccharide[6] (PPSV23)
Inactivated poliovirus[7] (IPV) (<18 yrs)
1st dose
2nd dose
3rd dose
4th dose
Influenza[8] (IIV; LAIV) 2 doses for some: See footnote 8
Annual vaccination (IIV only)
Annual vaccination (IIV or LAIV)
Measles, mumps, rubella[9] (MMR)
1st dose
2nd dose
Varicella[10] (VAR)
1st dose
2nd dose
Hepatitis A[11] (HepA)
2-dose series, See footnote 11
Human papillomavirus[12] (HPV2: females only; HPV4: males and females)
(3-dose series)
Meningococcal[13] (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)
See footnote 13
1st dose
Booster
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

2015


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)
1st dose
2nd dose
3rd dose
Rotavirus[2] (RV) RV1 (2-dose series); RV5 (3-dose series)
1st dose
2nd dose
See footnote 2
Diphtheria, tetanus, & acellular pertussis[3] (DTaP: <7 yrs)
1st dose
2nd dose
3rd dose
4th dose
5th dose
Tetanus, diphtheria, & acellular pertussis[4] (Tdap: ≥7 yrs)
(Tdap)
Haemophilus influenzae type b[5] (Hib)
1st dose
2nd dose
See footnote 5
3rd or 4th dose, See footnote 5
Pneumococcal conjugate[6] (PCV13)
1st dose
2nd dose
3rd dose
4th dose
Pneumococcal polysaccharide[6] (PPSV23)
Inactivated poliovirus[7] (IPV: <18 yrs)
1st dose
2nd dose
3rd dose
4th dose
Influenza[8] (IIV; LAIV) 2 doses for some: See footnote 8
Annual vaccination (IIV only) 1 or 2 doses
Annual vaccination (LAIV or IIV) 1 or 2 doses
Annual vaccination (LAIV or IIV) 1 dose only
Measles, mumps, rubella[9] (MMR)
See footnote 9
1st dose
2nd dose
Varicella[10] (VAR)
1st dose
2nd dose
Hepatitis A[11] (HepA)
2-dose series, See footnote 11
Human papillomavirus[12] (HPV2: females only; HPV4: males and females)
(3-dose series)
Meningococcal[13] (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)
See footnote 13
1st dose
Booster
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

Recommended immunization schedule for persons aged 0 through 18 years – United States, 2016



2016 Catch-up Schedule

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, 2016.

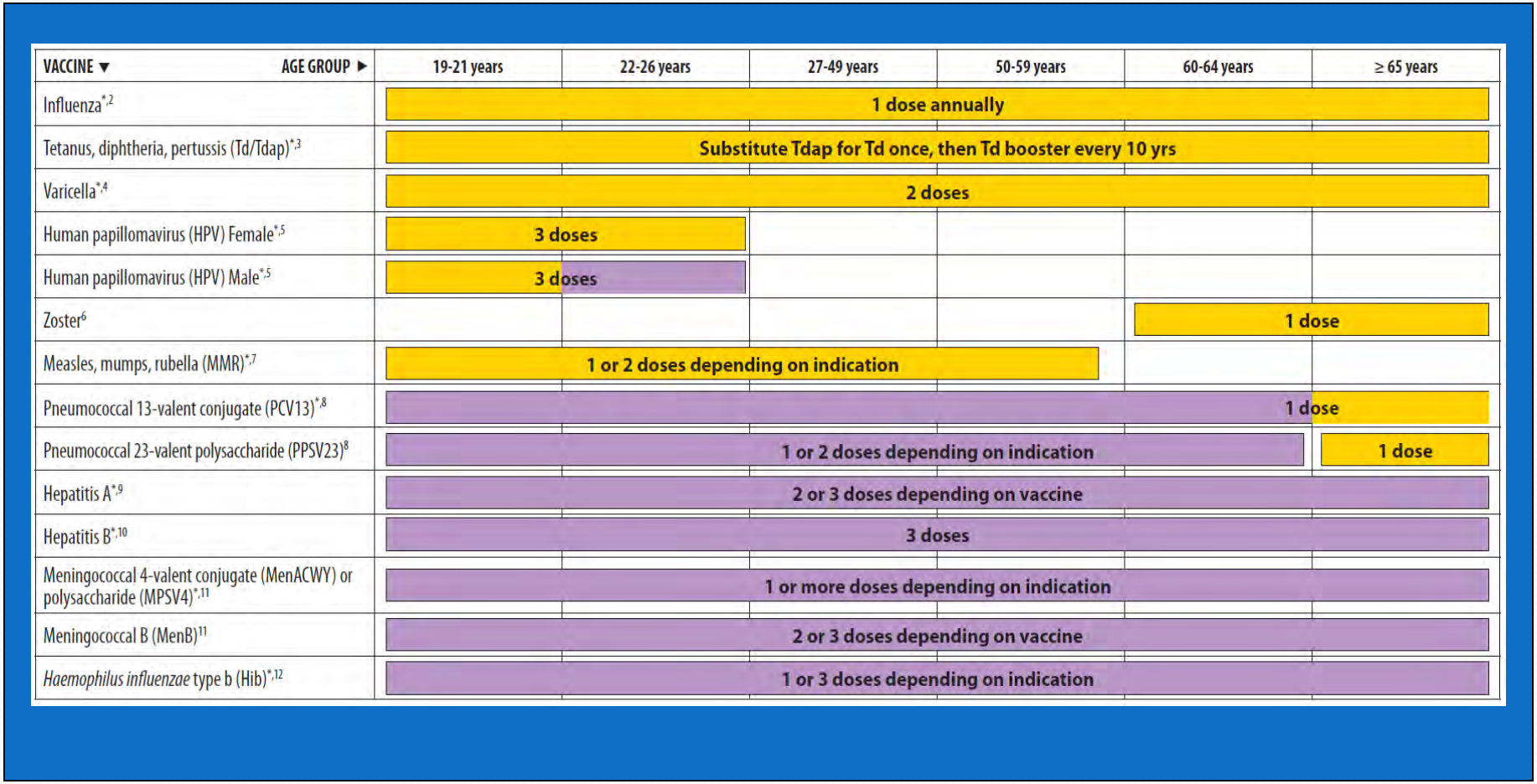
The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table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

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
Children age 4 months through 6 years					
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, and acellular pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[4]	6 weeks	4 weeks if first dose was administered before the 1st birthday. 8 weeks (as final dose) if first dose was administered at age 12 through 14 months. No further doses needed if first dose was administered at age 15 months or older.	4 weeks[4] if current age is younger than 12 months **and** first dose was administered at younger than age 7 months, **and** at least 1 previous dose was PRP-T (ActHib, Pentacel) or unknown. 8 weeks *and* age 12 through 59 months (as final dose for healthy children)[4] • if current age is younger than 12 months **and** first dose was administered at age 7 through 11 months (wait until at least 12 months old); OR • if current age is 12 through 59 months **and** first dose was administered before the 1st birthday, **and** second dose administered at younger than 15 months; OR • if both doses were PRP-OMP (PedvaxHIB; Comvax) **and** were administered before the 1st birthday (wait until at least 12 months old). No further doses needed if previous dose was administered at age 15 months or older.	8 weeks (as final dose) This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal[5]	6 weeks	4 weeks if first dose administered before the 1st birthday. 8 weeks (as final dose for healthy children) if first dose was administered at the 1st birthday or after. 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 and previous dose given at <7months old. 8 weeks (as final dose for healthy children) if previous dose given between 7-11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was given before age 12 months. 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[6]	6 weeks	4 weeks[6]	4 weeks[6]	6 months[6] (minimum age 4 years for final dose).	
Measles, mumps, rubella[8]	12 months	4 weeks			
Varicella[9]	12 months	3 months			
Hepatitis A[10]	12 months	6 months			
Meningococcal[11] (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)	6 weeks	8 weeks[11]	See footnote 11	See footnote 11	
Children and adolescents age 7 through 18 years					
Meningococcal[11] (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)	Not Applicable (N/A)	8 weeks[11]			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis[3]	7 years[12]	4 weeks	4 weeks if first dose of DTaP/DT was administered before the 1st birthday. 6 months (as final dose) if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday.	6 months if first dose of DTaP/DT was administered before the 1st birthday.	
Human papillomavirus[13]	9 years	Routine dosing intervals are recommended.[13]			
Hepatitis A[10]	N/A	6 months			
Hepatitis B[1]	N/A	4 weeks	8 weeks **and** at least 16 weeks after first dose.		
Inactivated poliovirus[6]	N/A	4 weeks	4 weeks[6]	6 months[6]	
Meningococcal[11]	N/A	8 weeks[11]			
Measles, mumps, rubella[8]	N/A	4 weeks			
Varicella[9]	N/A	3 months if younger than age 13 years. 4 weeks if age 13 years or older.			

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

http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

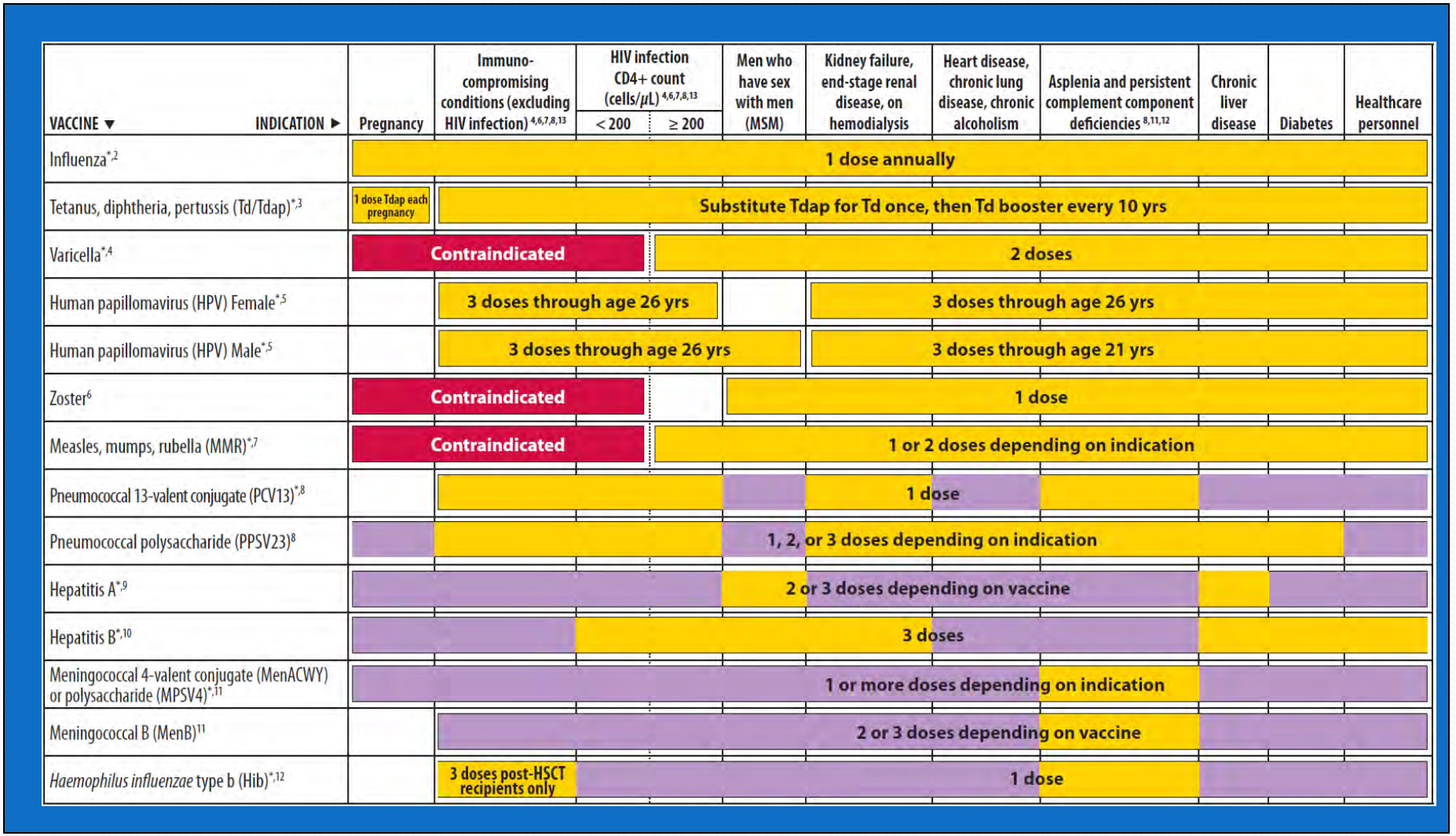
Adult Immunization Schedule by Vaccine and Age Group, 2016



VACCINE ▼ / AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza*,2	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap)*,3	Substitute Tdap for Td once, then Td booster every 10 yrs					
Varicella*,4	2 doses					
Human papillomavirus (HPV) Female*,5	3 doses					
Human papillomavirus (HPV) Male*,5	3 doses					
Zoster6					1 dose	
Measles, mumps, rubella (MMR)*,7	1 or 2 doses depending on indication					
Pneumococcal 13-valent conjugate (PCV13)*,8	1 dose					
Pneumococcal 23-valent polysaccharide (PPSV23)8	1 or 2 doses depending on indication					1 dose
Hepatitis A*,9	2 or 3 doses depending on vaccine					
Hepatitis B*,10	3 doses					
Meningococcal 4-valent conjugate (MenACWY) or polysaccharide (MPSV4)*,11	1 or more doses depending on indication					
Meningococcal B (MenB)11	2 or 3 doses depending on vaccine					
Haemophilus influenzae type b (Hib)*,12	1 or 3 doses depending on indication					

http://www.cdc.gov/vaccines/schedules/hcp/index.html

Vaccines that might be Indicated for Adults based on Medical and Other Indications



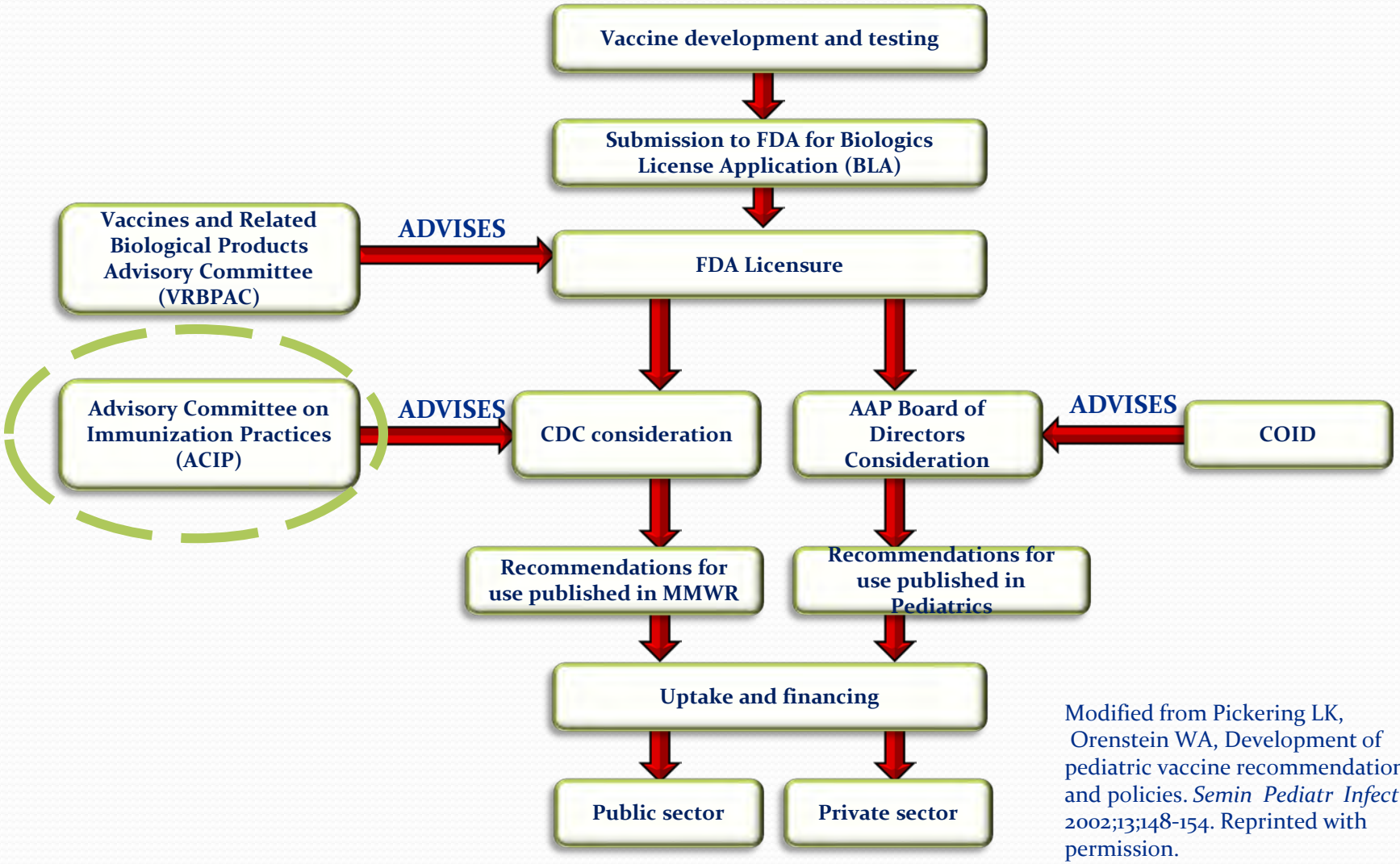
http://www.cdc.gov/vaccines/schedules/hcp/index.html

Immunization Policy Product: Two Immunization Schedules

- ACIP, AAP, and AAFP produce a "harmonized" child/ adolescent immunization schedule (0-18 years of age)
  - First harmonized in 1994
  - Before 1994, 2 different schedules existed
- ACIP, AAFP, ACOG and ACP produce a harmonized adult immunization schedule (≥19 years of age)
- Both schedules are updated annually and published in February in *MMWR* and liaison journals/websites

Vaccine Policy Development

Development of Vaccine Recommendations and Policies



Modified from Pickering LK, Orenstein WA, Development of pediatric vaccine recommendations and policies. *Semin Pediatr Infect Dis.* 2002;13;148-154. Reprinted with permission.

Example: BLA* Approval Letter from FDA (9vHPV)

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

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Vaccines, Blood & Biologics

Home > Vaccines, Blood & Biologics > Vaccines > Approved Products

Vaccines

Approved Products

Resources for You

- Gardasil 9

December 10, 2014 Approval Letter -GARDASIL 9

Our STN: BL 125508/0

Merck Sharp & Dohme Corp.
Attention: Alison Fisher, Ph.D.
P.O. Box 1000
UG2D-68
North Wales, PA 19454-1099

Dear Dr. Fisher:

We have approved your biologics license application for Human Papillomavirus 9-valent Vaccine, Recombinant effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Human Papillomavirus 9-valent Vaccine, Recombinant under your existing Department of Health and Human Services U.S. License No. 0002. Human Papillomavirus 9-valent Vaccine, Recombinant is indicated in girls and women 9 through 26 years of age for prevention of the following diseases:

Work Group Deliberations

- Meet monthly via telephone
- Gather information
  - In-depth data reviews
  - Clinical trials
  - Manufacturer Information
- Analyze Information
- Develop Recommendations
  - Reviewed by:
    - Other federal organizations
    - ACIP members
    - External Expert Consultants
- Prepare Information for ACIP meetings

Data Reviewed

- Disease epidemiology
  - Morbidity and mortality
- Vaccine efficacy and effectiveness
- Safety
- Program implementation
- Economic reviews/cost-effectiveness
- Recommendations of liaison organizations
- Surveys (parents, HCW)
- Public comments from previous meetings

Key Elements for Developing Evidence Based Recommendations

- Vaccine safety
- Vaccine efficacy/effectiveness
- Burden of disease
- Economic analysis and implementation issues (evidence not graded, but these are considered during policy development)

Evidence tables are used to summarize benefits and harms and strengths and limitations studies

Evidence Based Recommendations

- EBR approach approved by ACIP in October 2010
- System to be used: Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework
- GRADE tables linked to ACIP recommendations:
- http://www.cdc.gov/vaccines/acip/recs/GRADE/table-refs.html

GRADE Quality of Evidence

In the context of making recommendations:

- The quality of evidence reflects the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation.

Formulate question

Select outcomes

Rate importance

Outcomes across studies

Create evidence profile with GRADEpro

Rate quality of evidence for each outcome

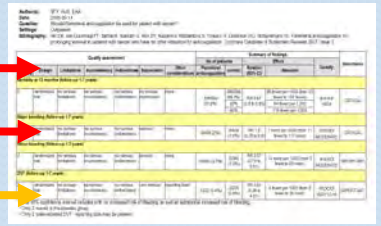
P
I
C
O

Outcome Critical

Outcome Critical

Outcome Important

Outcome Not important



Summary of findings & estimate of effect for each outcome

High
Moderate
Low
Very low

Randomization increases initial quality

Grade down

1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up

1. Large effect
2. Dose response
3. Confounders

Systematic review

Guideline development

Grade
overall quality of evidence across outcomes based on lowest quality of ***critical*** outcomes

Formulate recommendations:

- For or against (direction)
- Strong or conditional/weak (strength)

By considering:

- ❑ Quality of evidence
- ❑ Balance benefits/harms
- ❑ Values and preferences

Revise if necessary by considering:

- ❑ Resource use (cost)

- "We recommend using…"
- "We suggest using…"
- "We recommend against using…"
- "We suggest against using…"

Determinants of quality

- RCTs ⊕⊕⊕⊕
- observational studies ⊕⊕◯◯
- 5 factors that can lower quality
  1. limitations in design and execution *(risk of bias criteria)*
  2. Inconsistency *(or heterogeneity)*
  3. Indirectness *(PICO and applicability)*
  4. Imprecision *(number of events and confidence intervals)*
  5. Publication bias
- 3 factors can increase quality
  1. large magnitude of effect
  2. all plausible residual confounding may be working to reduce the demonstrated effect or increase the effect if no effect was observed
  3. dose-response gradient

GRADE: recommendation – quality of evidence

Clear separation between:

1) Quality of evidence
   - likelihood of bias
   - by outcome and across outcomes

And

2) Recommendation: Balance of benefits and downsides, values and preferences, resource use and quality of evidence

*www.GradeWorking-Group.org

ACIP Recommendation Categories

- Category A recommendations are made for all persons in an age- or risk-factor-based group.
  - Example: HPV4 vaccine in males http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm

- Category B recommendations are made for individual clinical decision making.
  - Example: hepatitis B vaccine in adults aged ≥60 years with diabetes mellitus http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm

CDC Resources for Learning More About GRADE

- Link to GRADE Working Group web site
  Full description and answers to frequently asked questions about GRADE
- Video: The GRADE Approach - An Introductory Workshop on Making Recommendations (held at CDC Sept 2011)
  - Video part 1: Overview of the GRADE Approach and the Process
  - Video part 2: Assessing the Quality of Evidence
- Slide presentations:
  - New Framework for Developing Evidence-Based Recommendations by the ACIP
- Publications:
  - Ahmed F et al. Methods for developing evidence-based recommendations by the ACIP. *Vaccine* 2011;29(49):9171-9176.
  - CDC. New Framework (GRADE) for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices. *MMWR.* 2012;61(18):327.
  - Ahmed F, Temte JL, Campos-Outcalt D, Schünemann HJ. Methods for developing evidence-based recommendations by the ACIP Of the CDC. *Vaccine* 2011;29(49):9171-9176.

http://www.cdc.gov/vaccines/acip/recs/GRADE/about-grade.html#resources
http://www.cdc.gov/vaccines/acip/recs/GRADE/table-refs.html

ACIP Meetings

- Topics solicited by:
  - Workgroups
  - CDC subject matter experts
  - ACIP members
- Topics may/may not require vote
- Topics include
  - Vaccine preventable disease epidemiology
  - Vaccine efficacy/effectiveness/safety
  - Vaccines in development
  - Newly licensed vaccines
  - Updates
  - Vaccine supply
  - Agency updates
- Public Comments

ACIP Meeting Agenda

Final - February 18, 2016

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Tom Harkin Global Communications Center, Kent "Oz" Nelson Auditorium
Atlanta, Georgia 30329
February 24, 2016 (1-day meeting)

	AGENDA ITEM	PURPOSE	PRESIDER/PRESENTER(s)
Wednesday, February 24			
8:00	**Welcome & Introductions**		Dr. Nancy Bennett (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary; CDC)
8:15	**Agency Updates**		
	CDC, CMS, DoD, DVA, FDA, HRSA, IHS, NIH, NVPO	Information	CDC and *ex officio* members
8:30	**Human Papillomavirus (HPV) Vaccines**		
	Introduction		Dr. Allison Kempe (ACIP, WG Chair)
	Background: 2-dose schedules		Dr. Lauri Markowitz (CDC/NCIRD)
	9-valent HPV vaccine 2- vs 3-dose trial data	Information & Discussion	Dr. Alain Luxembourg (Merck)
	Summary: 2-dose schedules, bivalent and quadrivalent HPV vaccines		Dr. Lauri Markowitz (CDC/NCIRD)
	Work Group plans		Dr. Elissa Meites (CDC/NCIRD)
9:50	***Break***		
10:20	**Meningococcal Vaccines**		
	Introduction		Dr. Lorry Rubin (ACIP, WG Chair)
	MenB-FHbp vaccine update		Dr. Laura York (Pfizer)
	Results of a mass immunization campaign with MenB-4C in Quebec, Canada	Information & Discussion	Dr. Gaston De Serres (Quebec, Canada)
	Considerations for use of MenACWY vaccines in HIV-infected persons		Ms. Jessica MacNeil (CDC/NCIRD)
	Meningococcal disease among men who have sex with men (MSM), United States, January 2012-June 2015		Dr. Temi Folaranmi (CDC/NCIRD)
	Considerations for use of MenACWY vaccines in MSM		Ms. Jessica MacNeil (CDC/NCIRD)
12:10	***Lunch***		
1:20	**Japanese Encephalitis (JE) Vaccine**		
	Introduction		Dr. Lorry Rubin (ACIP, WG Chair)
	Duration of protection following primary series and booster dose in adults	Information & Discussion	Dr. Katrin Dubischar (Valneva)
	Duration of protection and need for booster dose in children		Dr. Katrin Dubischar (Valneva)
	JE Vaccine Work Group summary and plans		Dr. Susan Hills (CDC/NCEZID)
2:10	**Influenza**		
	Introduction		Dr. Ruth Karron (ACIP, WG Chair)
	Influenza surveillance update		Ms. Lynnette Brammer (CDC/NCIRD)
	Quadrivalent Recombinant Influenza Vaccine	Information, Discussion	Dr. Wayne Hachey (Protein Sciences)
	Influenza Vaccination and Egg Allery		Dr. John Kelso (University of California, San Diego)
	Proposed Recommendations for 2016-17	**Vote**	Dr. Lisa Grohskopf (CDC/NCIRD)
3:10	***Break***		
3:30	**Update on Zika Virus**		Dr. Toby Merlin (CDC/NCEZID)

Final - February 18, 2016

3:40	**Cholera Vaccine**		
	Introduction	Information & Discussion	Dr. Art Reingold (ACIP, WG Chair)
	Vaxchora™ clinical data		Dr. Lisa Danzig (PaxVax)
	Cholera Vaccine GRADE evaluation and Work Group plans		Dr. Karen Wong (CDC/NCEZID)
4:50	**Vaccine Supply**		Dr. Jeanne Santoli (CDC/NCIRD)
4:55	**Public Comment**		
5:10	**Adjourn**		

Acronyms

CDC	Centers for Disease Control & Prevention
CMS	Centers for Medicare and Medicaid Services
DoD	Department of Defense
DVA	Department of Veterans Affairs
FDA	Food and Drug Administration
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
LAIV	Live Attenuated Influenza Vaccine
MSM	Men who have sex with men
NCHHSTP	National Center for HIV, Hepatitis, STD and TB Prevention [of CDC/OID]
NCIRD	CDC National Center for Immunization & Respiratory Diseases [of CDC/OID]
NCEZID	National Center for Emerging and Zoonotic Diseases [of CDC/OID]
NIH	National Institutes of Health
NVPO	National Vaccine Program Office
VFC	Vaccines for Children
WG	Work Group

Post-meeting Actions

- Recommendations are refined
  - Technical accuracy
  - clarity
- CDC clearance hierarchy
  - Acceptance through all related branches of CDC
  - Final review by Office of Director, CDC
    - Authority to adopt policy for HHS
    - May reject, revise, or return to ACIP
  - Office of MMWR
    - Edit
    - Publish – print and on-line
- Implementation by CDC (not ACIP)

CDC Approval Process Following an ACIP Vaccine Recommendation

If approved by CDC Director, adopted by agency:

Published in *MMWR Weekly* as a Policy Note within 2 months of an ACIP vote

Published in *MMWR Recommendations & Reports* within 6-8 months of an ACIP vote

Recommendation becomes official HHS/CDC policy upon publication in MMWR

Vaccine Safety


The Cow Pock — or — the Wonderful Effects of the New Inoculation!

Safety

- No Vaccine is 100% Safe
  - Everyone has different immune systems
- As disease incidence declines
  - People decrease concerns for disease and increase concerns for safety
- Decision to get vaccinated
  - Perceived susceptibility to the disease
  - Perceived seriousness of the disease
  - Perceived vaccine benefits
  - Perceived barriers
  - Social influence

Polio Vaccine 1955

- Cutter Labs – Berkley
  - 5 manufacturers total
- Inadequately attenuated
  - Did not follow Salk's protocol
- 200,000 vaccinated
  - 70,000 became ill
  - 200 permanently paralyzed
  - 10 died
- Major lawsuit followed

1970's

- More lawsuits
  - DPT
- Damages awards in spite of lack of scientific evidence
- Liability insurance skyrocketed
- Several manufacturers halted production
- Vaccine Shortage

1986

- National Childhood Vaccine Injury Act (NCVIA)
  - National Vaccine Program Office (NVPO)
  - Requires Vaccine Information Statements (VIS)
  - Vaccine Adverse Event Reporting System (VAERS)
  - National Vaccine Injury Compensation Program (NVICP)
  - Institute of Medicine (IOM) Committee to review

Institute of Medicine (IOM)

- Private, non-profit organization to provide health policy advice under a congressional charter
- U.S.P.H.S. contract with funding from CDC and NIH
- Immunization Safety Review Committee (ISRC)
- Reviews all vaccine adverse events

IOM Reports

- MMR and Autism (April 2001)
- Thimerosal and Neuro-developmental Disorders (Oct 1, 2001)
- Multiple Immunizations and Immune Dysfunction (Feb 20, 2002)
- Hepatitis B Vaccine and Neurological Disorders (May 30, 2002)
- SV-40 (Simian Virus from monkey cell culture) contaminated polio vaccines and Cancer (Oct. 22, 2002)
- Influenza Vaccine and Neurological Disorders (Oct. 6, 2003)
- Sudden Unexplained Death in Infancy (March 12, 2003)
- MMR and Autism / Thimersosal and Autism (February 9, 2004)
- Review of Adverse Effects of Vaccines (August 8, 2011)
- Childhood Immunization Schedule and Safety (January 16, 2013)
- And more!

Monitors - FDA

- Pre-licensing
  - 3 phases of clinical trials
    - 1 - Small Safety (20-100)
    - 2 – Larger safety, efficacy, dose, composition, ADE (several hundred)
    - 3 – placebo controlled (thousands)
  - 10 year or longer process
- Licensing
  - Vaccine
  - Production Plant
- Post-Licensing
  - Samples submitted of each lot
  - Surveillance

Vaccine Adverse Effects Reporting System (VAERS)

- Collection and Analysis of ADE
- Anyone can report to it
- 10,000 – 50,000 reports annually (44,012 in 2015)
- http://vaers.hhs.gov
- 800-822-7967

VAERS Reports

- Emerged in database
- Assigned number
- If serious – follow-up at 60 days & 1 year
- Monitored by FDA and CDC
- Data available to public

Pediatr Infect Dis J, 2004;23:287–94

Pediatr Infect Dis J, 2004;23:287–94
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Vol. 23, No. 4
Printed in U.S.A.

CENTERS FOR DISEASE CONTROL AND PREVENTION: CURRENT ISSUES IN PEDIATRICS.
EDITED BY LARRY K. PICKERING, M.D.

Understanding vaccine safety information from the Vaccine Adverse Event Reporting System

FREDERICK VARRICCHIO, MD, PHD, JOHN ISKANDER, MD, MPH, FRANK DESTEFANO, MD, MPH, ROBERT BALL, MD, MPH, SCM, ROBERT PLESS, MD, MSC, M. MILES BRAUN, MD, MPH AND ROBERT T. CHEN, MD, MA

The Vaccine Adverse Event Reporting System (VAERS) is administered by the Food and Drug Administration and CDC and is a key component of postlicensure vaccine safety surveillance. Its primary function is to detect early warning signals and generate hypotheses about possible new vaccine adverse events or changes in frequency of known ones. VAERS is a passive surveillance system that relies on physicians and others to voluntarily submit reports of illness after vaccination. Manufacturers are required to report all adverse events of which they become aware. There are a number of well-described limitations of such reporting systems. These include, for example, variability in report quality, biased reporting, underreporting and the inability to determine whether a vaccine caused the adverse event in any individual report. Strengths of VAERS are that it is national in scope and timely. The information in VAERS reports is not necessarily complete nor is it verified systematically. Reports are classified as serious or nonserious based on regulatory criteria. Reports are coded by VAERS in a uniform way with a limited number of terms using a terminology called COSTART. Coding is useful for search purposes but is necessarily imprecise. VAERS is useful in detecting adverse events related to vaccines and most recently was used for enhanced reporting of adverse events in the national smallpox immunization campaign. VAERS data have always been publicly available. However, it is essential for users of VAERS data to be fully aware of the strengths and weaknesses of the system. VAERS data contain strong biases. Incidence rates and relative risks of specific adverse events cannot be calculated. Statistical significance tests and confidence intervals should be used with great caution and not routinely. Signals detected in VAERS should be subjected to further clinical and descriptive epidemiologic analysis. Confirmation in a controlled study is usually required. An understanding of the system's defined objectives and inherent drawbacks is vital to the effective use of VAERS data in vaccine safety investigations.

INTRODUCTION

The National Childhood Vaccine Injury Act of 1986 mandated physician reporting of certain vaccine adverse events to the Secretary of the Department of Health and Human Services. The Act also led to the creation of the Vaccine Adverse Events Reporting System (VAERS), a unified national system for reporting possible adverse reactions after any US-licensed vaccine.[1] VAERS became operational in July 1990 and is operated jointly by the CDC and the Food and Drug Administration (FDA). As part of postlicensure vaccine safety surveillance, VAERS accepts voluntary reports from health care providers, parents, patients or anyone else, as well as a smaller number of mandated reports of specific events.[2–4] Through the end of 2002, the VAERS database contains ~140 000 reports. In the 11-year period from 1991 to 2001, at least 1.9 billion doses of vaccines were distributed in the US.[5]

The primary function of VAERS is to detect early warning signals and generate hypotheses about possible new vaccine adverse events or changes in frequency of known ones. This is necessary once a vaccine is

Accepted for publication Dec. 3, 2003.
From the Division of Epidemiology, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration; the Immunization Safety Branch, Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention; and the Immunization Safety Unit, Immunization and Respiratory Infections Division, Centre for Infectious Disease Prevention and Control, Health Canada, Ottawa, Canada.
Key words: Adverse event, vaccine, Vaccine Adverse Event Reporting System (VAERS).
Reprints not available.

Vaccine Safety Datalink Project (VSD)

- CDC 1990
- Partnership with 8 Managed Care Organizations
- Large database (9 million members)
- Monitor medical records

National Vaccine Injury Compensation Program

- No fault compensation
  - Not required to prove negligence
- Vaccine Injury Table
- Compensation
  - Injury on VIT
  - Proof that vaccine caused
  - Demonstrates vaccine aggravates pre-existing condition

NVICP

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 04/01/2016

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DTaP-IPV	5	0	5	0	0
DT	69	9	78	26	51
DTP	3,286	696	3,982	1,273	2,706
DTP-HIB	20	8	28	7	21
DTaP	395	79	474	198	207
DTaP-Hep B-IPV	65	29	94	33	34
DTaP-HIB	11	1	12	5	3
DTaP-IPV-HIB	36	18	54	7	12
Td	189	3	192	115	66
Tdap	332	1	333	173	16
Tetanus	107	2	109	51	37
Hepatitis A (Hep A)	83	6	89	35	22
Hepatitis B (Hep B)	629	56	685	253	364
Hep A-Hep B	25	0	25	10	2
Hep B-HIB	8	0	8	4	3
HIB	33	3	36	13	15
HPV	300	14	314	92	92
Influenza	2,476	102	2,578	1,445	169
IPV	264	14	278	8	267
OPV	282	28	310	158	150
Measles	143	19	162	55	107
Meningococcal	49	2	51	31	4
MMR	916	57	973	378	506
MMR-Varicella	34	1	35	16	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	45	8	53	10	27
Rotavirus	73	1	74	44	17
Rubella	190	4	194	71	123
Varicella	83	9	92	55	20
Nonqualified1	92	9	101	2	87
Unspecified2	5,418	9	5,427	5	4,756
Grand Total	**15,687**	**1,191**	**16,878**	**4,582**	**9,915**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	232	294
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	123	205
FY 2008	147	132	279
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	166	537
FY 2015	512	79	591
FY 2016	242	2	244
Total	**4,582**	**9,915**	**14,497**

Federal Requirements for Documentation

- Must give VIS
- Required documentation for all vaccines covered by VICP
  - Date vaccine administered
  - Vaccine manufacturer
  - Vaccine lot number
  - Name, address, title of person administering the vaccine
  - Date printed on the VIS
  - Date the VIS is given to the vaccine recipient or the recipient's legal representative
- Signature is not required by federal law

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SEARCH

CDC A-Z INDEX

Vaccine Safety

The United States' long-standing vaccine safety program closely and constantly monitors the safety of vaccines.

A critical part of the program, CDC's Immunization Safety Office identifies possible vaccine side effects and conducts studies to determine whether health problems are caused by vaccines.

Data show that the current U.S. vaccine supply is the safest in history.

SAFETY INFORMATION ABOUT SPECIFIC VACCINES
See in-depth information about the safety of each FDA-approved vaccine in the U.S.

COMMON VACCINE SAFETY CONCERNS
Get answers to commonly asked questions about vaccine safety.

ENSURING VACCINE SAFETY
Learn how CDC works to ensure the safety of vaccines in the U.S.

VACCINE SAFETY RESEARCH
Read vaccine safety reports and published research.

Information For Parents And Caregivers

Information For Healthcare Providers

Related Links

- Immunization: Why is it Important?
- Immunization Schedules
- Vaccines for Travelers
- Understanding Side Effects and Adverse Events
- Who Should Not Get Vaccinated
- How to Report A Possible Vaccine Side Effect

http://www.cdc.gov/vaccinesafety

Standards for Adult Immunization Practices

1. Access Immunization Status of all of your patients at every clinical encounter
2. Strongly recommend vaccines the patients need
3. Administer needed vaccines or refer to a vaccination provider
4. Document vaccines received by your patients

Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice

Public Health Reports/ March-April 2014/Volume 129

Figure. Summary of 2013 National Vaccine Advisory Committee's standards for adult immunization practices

Audience	*Summary of standards*
All providers	• Incorporate immunization needs assessment into every clinical encounter. • Strongly recommend needed vaccine(s) and either administer vaccine(s) or refer patient to a provider who can immunize. • Stay up-to-date on, and educate patients about, vaccine recommendations. • Implement systems to incorporate vaccine assessment into routine clinical care. • Understand how to access immunization information systems (i.e., immunization registries).
Non-immunizing providers	• Routinely assess the immunization status of patients, recommend needed vaccine(s), and refer patient to an immunizing provider. • Establish referral relationships with immunizing providers. • Follow up to confirm patient receipt of recommended vaccine(s).
Immunizing providers	• Ensure professional competencies in immunizations. • Assess immunization status in every patient care and counseling encounter and strongly recommend needed vaccine(s). • Ensure that receipt of vaccination is documented in patient medical record and immunization registry.
Professional health-care-related organizations/ associations/health-care systems	• Provide immunization education and training of members, including trainees. • Provide resources and assistance to implement protocols and other systems to incorporate vaccine needs assessment and vaccination or referral into routine practice. • Encourage members to be up-to-date on their own immunizations. • Assist members in staying up-to-date on immunization information and recommendations. • Partner with other immunization stakeholders to educate the public. • Seek out collaboration opportunities with other immunization stakeholders. • Collect and share best practices for immunization. • Advocate policies that support adult immunization standards. • Insurers/payers/entities that cover adult immunization services should assure their network is adequate to provide timely immunization access and augment with additional vaccine providers if necessary.
Public health departments	• Determine community needs, vaccination capacity, and barriers to adult immunization. • Provide access to all ACIP-recommended vaccinations for insured and uninsured adults and work toward becoming an in-network provider for immunization services for insured adults. • Partner with immunization stakeholders and support activities and policies to improve awareness of adult vaccine recommendations, increase vaccination rates, and reduce barriers. • Ensure professional competencies in immunizations. • Collect, analyze, and disseminate immunization data. • Provide outreach and education to providers and the public. • Work to decrease disparities in immunization coverage and access. • Increase immunization registry access and use by vaccine providers for adult patients. • Develop capacity to bill for immunization of injured people. • Ensure preparedness for identifying and responding to outbreaks of vaccine-preventable diseases. • Promote adherence to applicable laws, regulations, and standards among adult immunization stakeholders.

http://www.publichealthreports.org/issueopen.cfm?articleID=3145

Standards for Child and Adolescent Immunization Practices, NVAC 2003

TABLE 1. Standards for Child and Adolescent Immunization Practices

Availability of vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other health care services and provided in a medical home[6] when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

Assessment of vaccination status

5. Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Health care professionals assess for and follow only medically accepted contraindications.

Effective communication about vaccine benefits and risks

7. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Proper storage and administration of vaccines and documentation of vaccinations

8. Health care professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. People who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
11. Health care professionals simultaneously administer as many indicated vaccine doses as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Health care professionals report adverse events after vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the Vaccine Injury Compensation Program (VICP).
14. All personnel who have contact with patients are appropriately vaccinated.

Implementation of strategies to improve vaccination coverage

15. Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
17. Health care professionals practice community-based approaches.

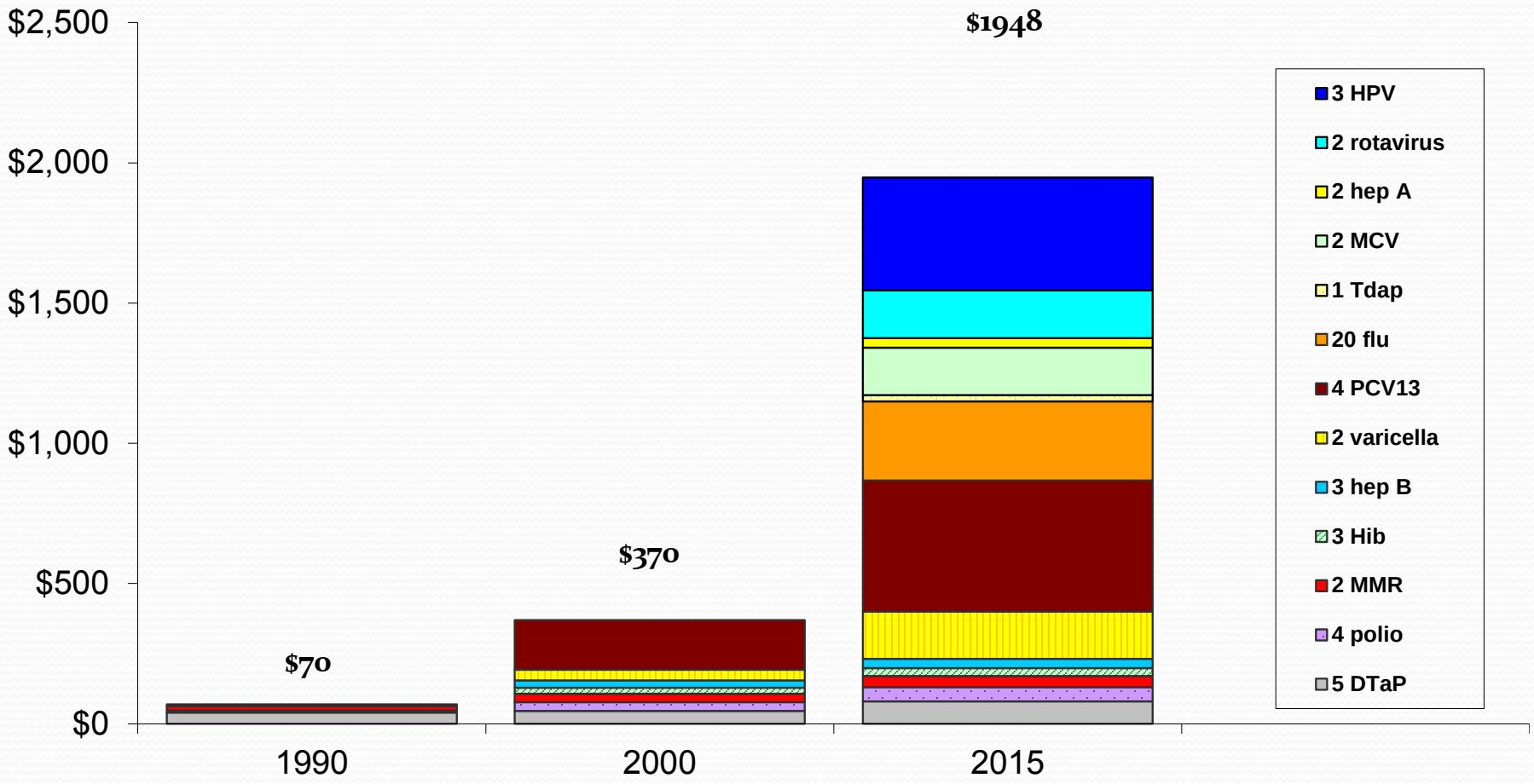
http://pediatrics.aappublications.org/content/112/4/958

Challenges

Challenges

- Role of cost-effectiveness (economic) analyses
- ACIP recommendations may differ from FDA licensing indications
- Increasing number of vaccines in the routine child/adolescent immunization schedule (30 doses targeting 16 diseases)
- Vaccine hesitancy among some members of the public

Costs



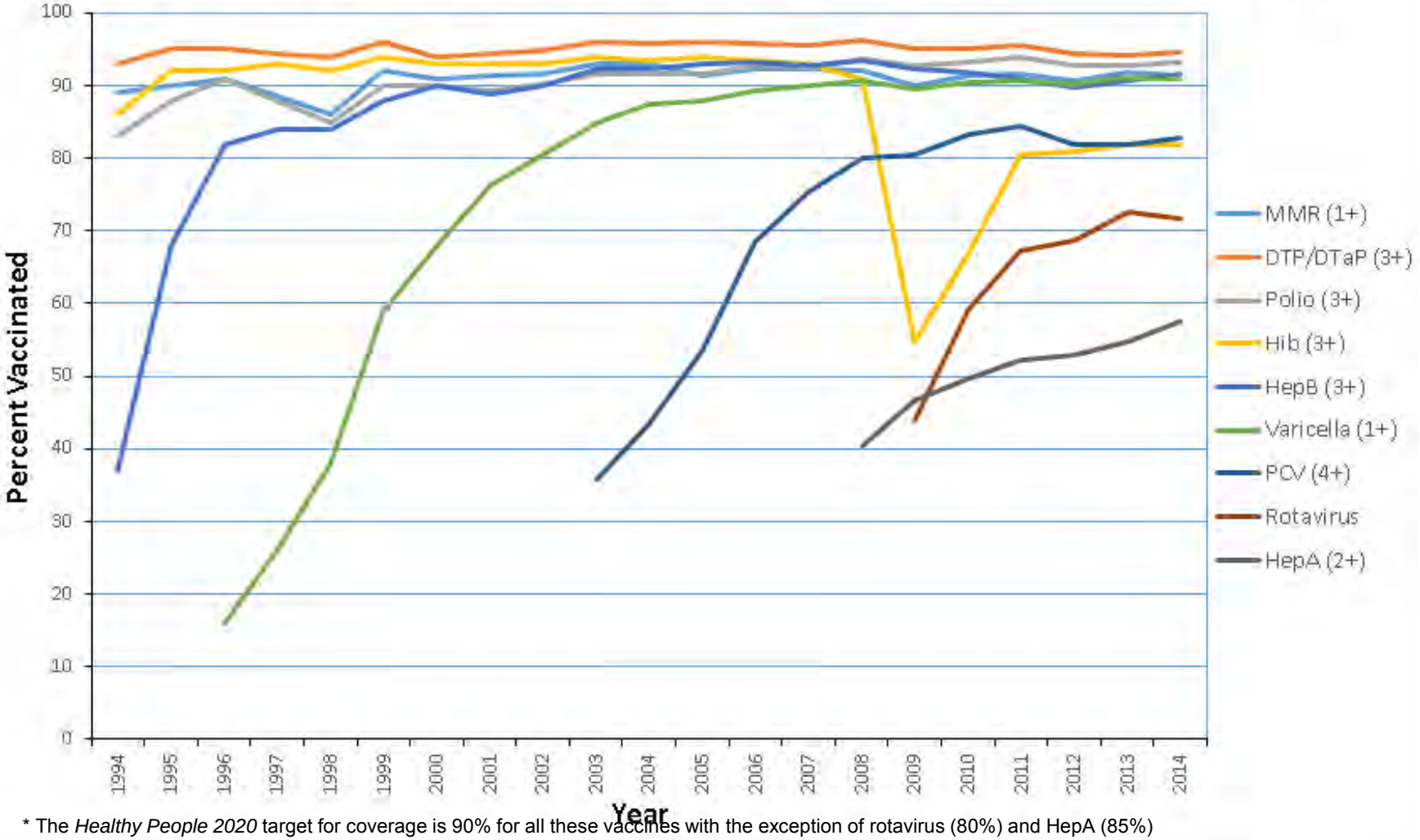
2015 represents minimum cost to vaccinate a child (birth through 18); exceptions are 1) no preservative pediatric influenza vaccine, and 2) HPV for males and females.

Federal contract prices as of February 1, 1990, September 27, 2000, and April 1, 2015.

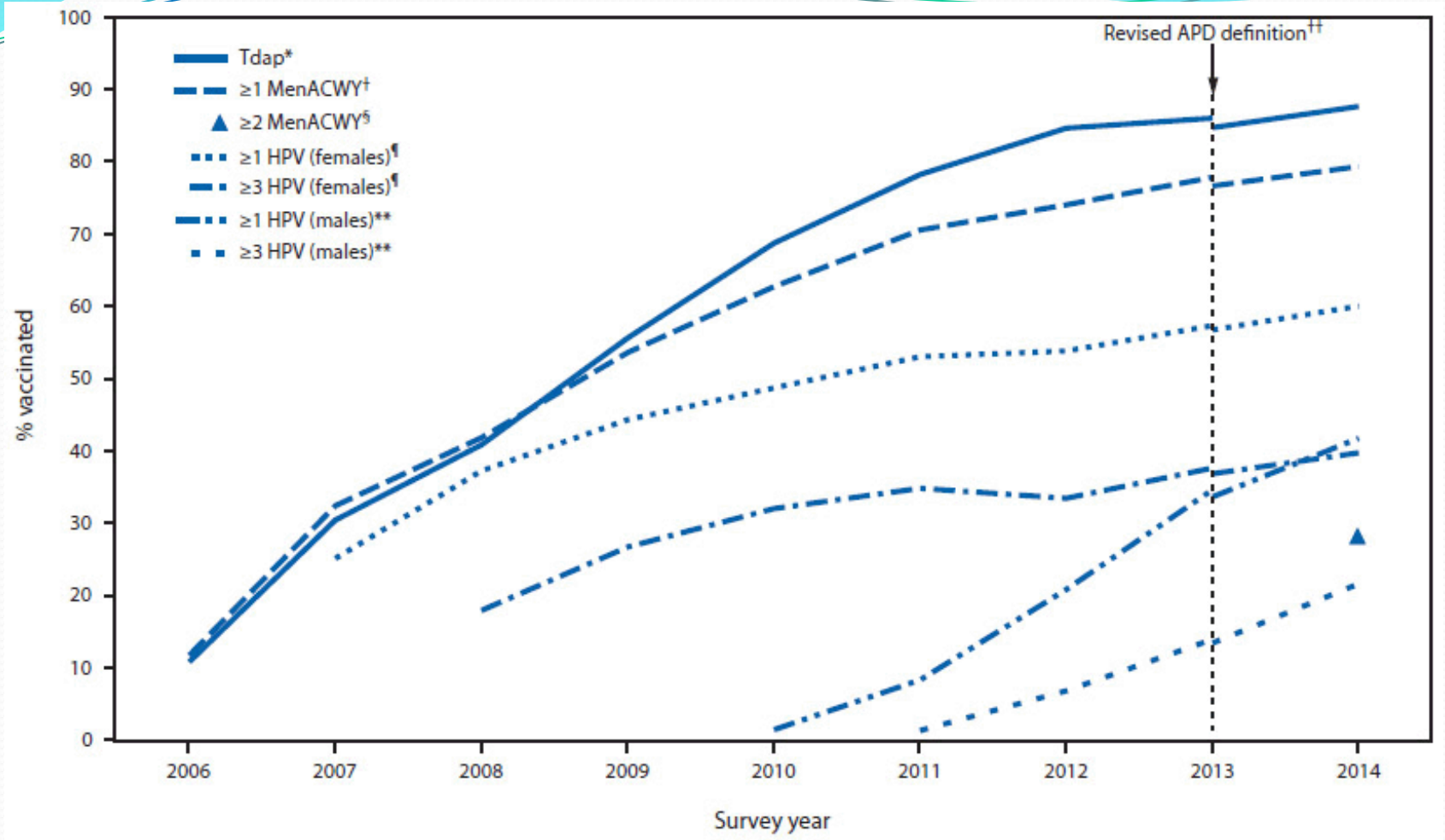
Examples of difficult issues

- PCV13 dose reduction in children (4 to 3 doses)
- PCV13 for adults - intervals
- HPV vaccine: transition from 4vHPV to 9vHPV
- Duration of protection of Tdap vaccine
- Meningococcal B-containing vaccines
- Several influenza vaccine preparations
- Upcoming: introduction of new herpes zoster vaccines, and phasing into program

Vaccine-specific coverage* among children 19-35 months, National Immunization Survey, 1994-2014



- * The *Healthy People 2020* target for coverage is 90% for all these vaccines with the exception of rotavirus (80%) and HepA (85%)
- Abbreviations: MMR = measles, mumps, and rubella vaccine; DTP/DTaP = diphtheria, tetanus toxoids, and pertussis vaccine / diphtheria, tetanus toxoids, and acellular pertussis vaccine; Hib = *Haemophilus influenzae* type b vaccine; HepB = hepatitis B vaccine; PCV = pneumococcal conjugate vaccine; HepA = hepatitis A vaccine



•**Abbreviations:** Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; MenACWY = meningococcal conjugate; HPV = human papillomavirus; ACIP = Advisory Committee on Immunization Practices; APD = adequate provider data.
•* ≥1 dose Tdap vaccine at or after age 10 years.
• ≥1 dose MenACWY or meningococcal-unknown type vaccine.
• ≥2 doses MenACWY or meningococcal-unknown type vaccine, calculated only among adolescents aged 17 years at time of interview. Does not include adolescents who received their first and only dose of MenACWY at age 16 years or later.
• HPV vaccine, either bivalent (2vHPV) or quadrivalent (4vHPV), among females. ACIP recommends 2vHPV, 4vHPV, or nine-valent (9vHPV) vaccine for females. Although the 9vHPV vaccine was licensed in December 2014 and recommended by ACIP in February 2015, it was not distributed until 2015 and thus was not administered to adolescents in 2014.
•** HPV vaccine, either 2vHPV or 4vHPV, among males. ACIP recommends the 4vHPV or 9vHPV vaccines for males; however, some males might have received the 2vHPV vaccine. Although the 9vHPV vaccine was licensed in December 2014 and recommended by ACIP in February 2015, it was not distributed until 2015 and thus was not administered to adolescents in 2014.
• NIS-Teen implemented a revised APD definition in 2014 and retrospectively applied the revised APD definition to 2013 data. Estimates using different APD definitions might not be directly comparable.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 60 / No. 2
January 28, 2011

General Recommendations on Immunization

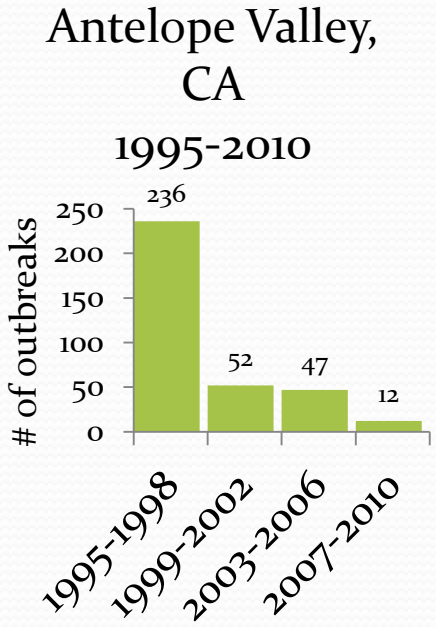
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

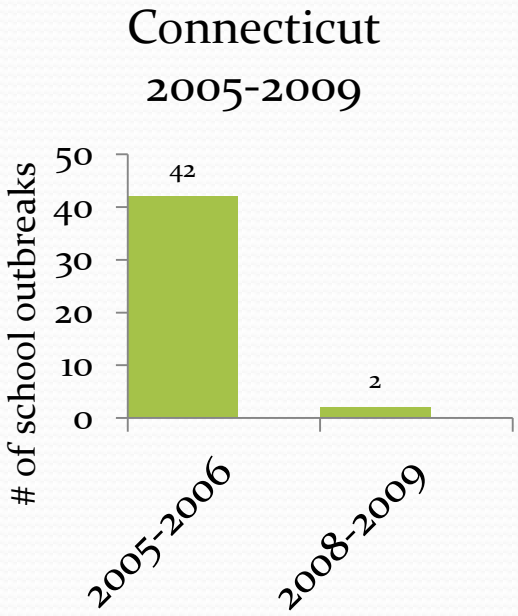
Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html

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

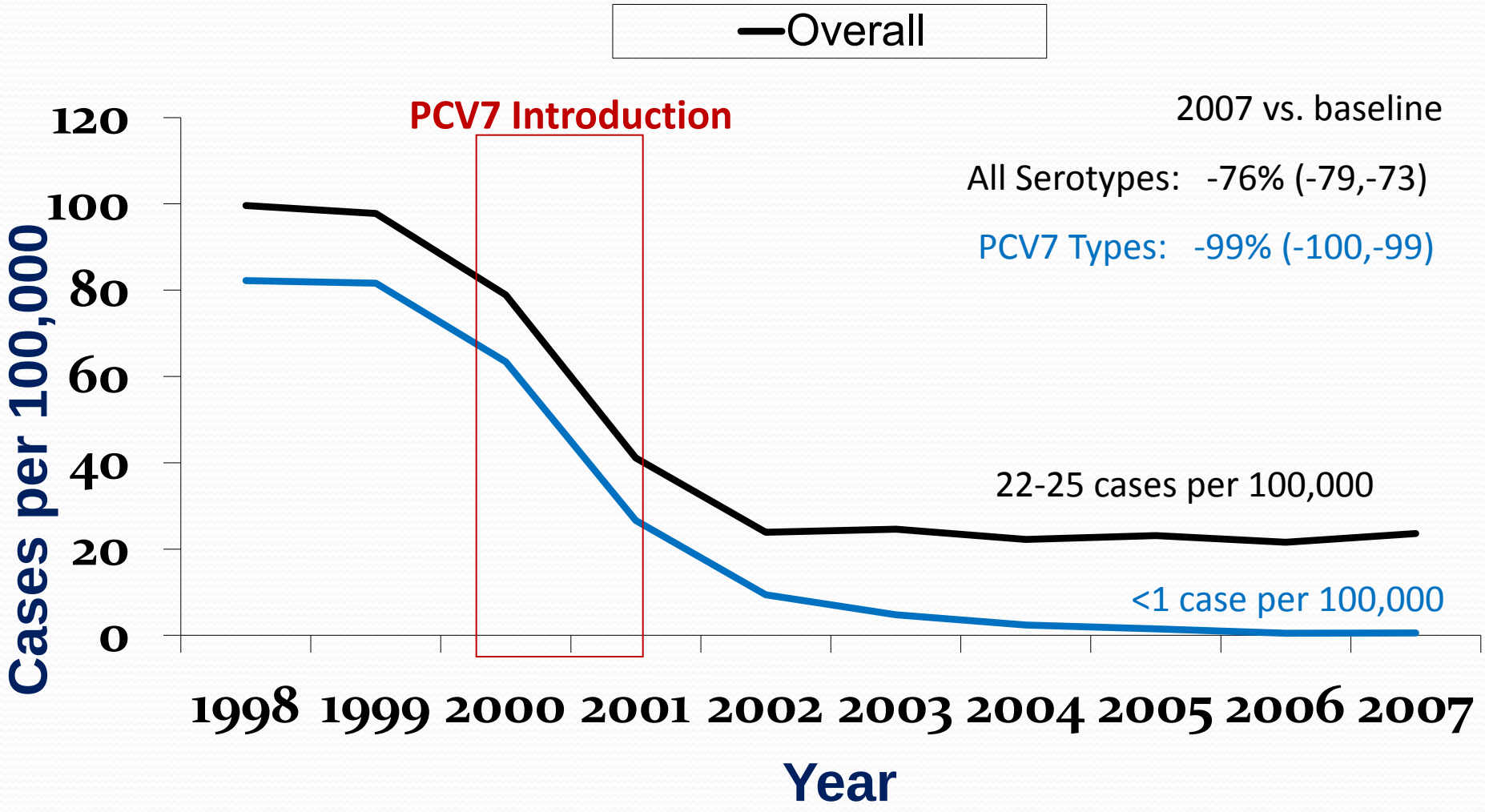
From Policy to Public Health Impact

Declining Numbers of Varicella Outbreaks in the 2-Dose Varicella Vaccination Era



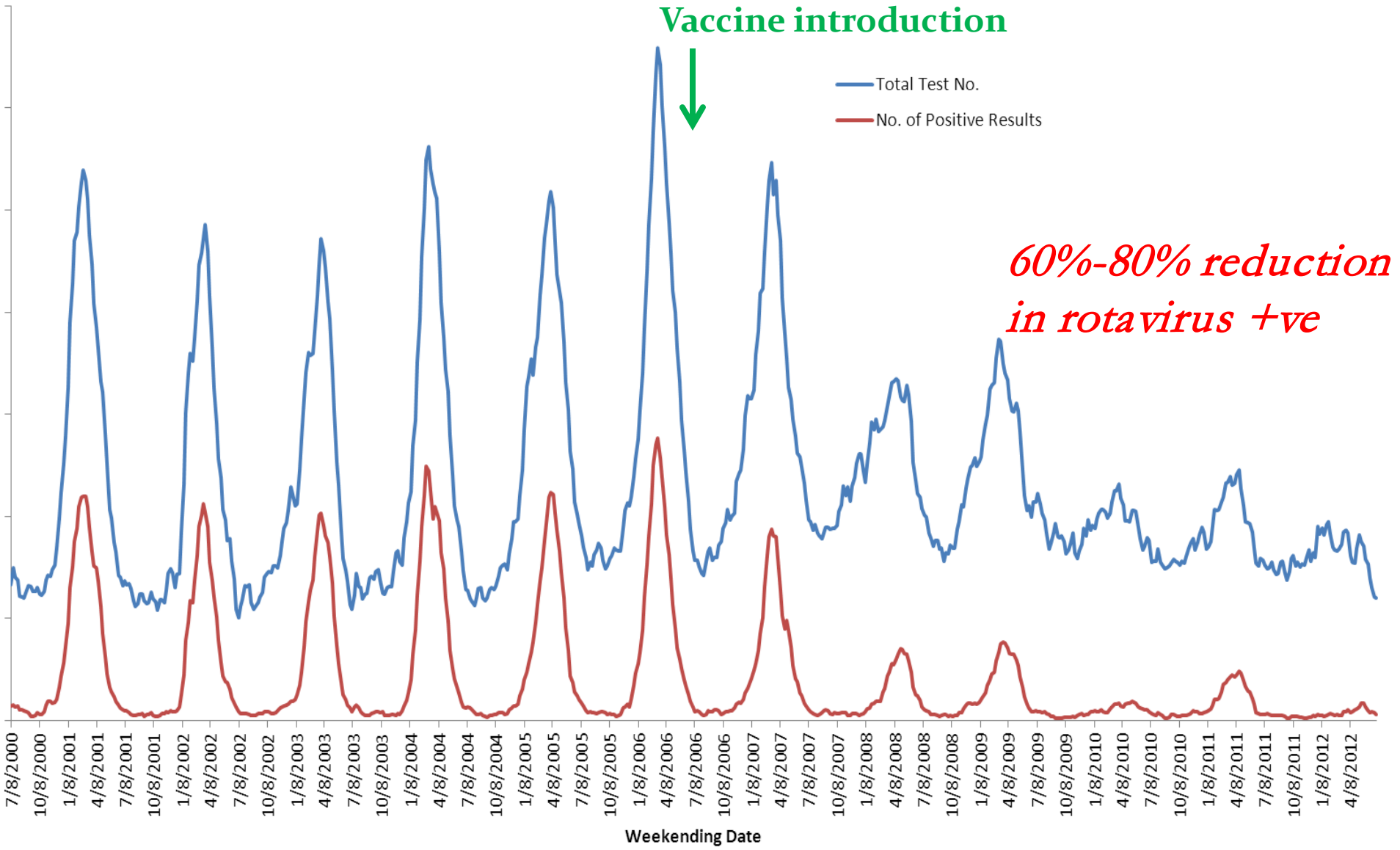


Incidence of IPD among Children Aged <5 Years, U.S., 1998–2007



CDC, ABCs, unpublished 2008

Total number of rotavirus tests and positive results* from 24 continuously reporting laboratories - National Respiratory and Enteric Virus Surveillance System, United States, July 8, 2000 - June 30, 2012



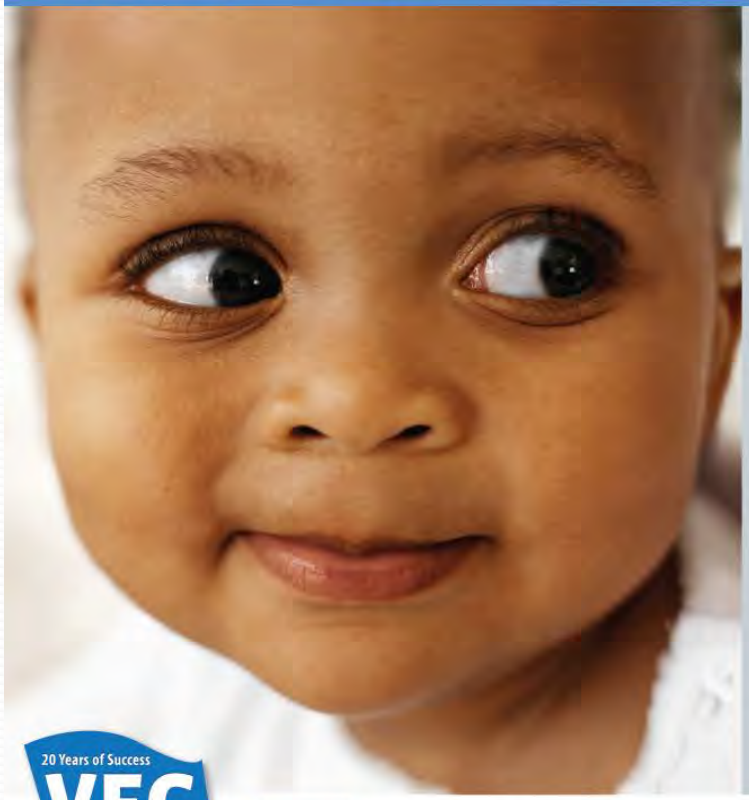
Tate et al. Pediatrics 2009 and unpublished CDC data

*3-week moving average

Vaccines for Children

20 years of protecting America's children

The Vaccines for Children program was established in 1994 to make vaccines available to uninsured children. VFC has helped prevent disease and save lives...big time!



CDC estimates that vaccination of children born between 1994 and 2013 will:

prevent **322 million** illnesses → more than the current population of the entire U.S.A.

help avoid **732,000** deaths → greater than the population of Boston, MA.

save nearly **$1.4 trillion** in total societal costs *(that includes $295 billion in direct costs)* → or $4,473 for each American

MMWR: Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013 NCIRD-404 | 04.23.2014

20 Years of Success VFC Vaccines for Children Program

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

www.cdc.gov/features/vfcprogram

ACIP Web Site

http://www.cdc.gov/vaccines/acip/

Immunizations

Immunization Schedules

Instant Childhood Immunization Schedule

WHO IVB vaccines and diseases

VFC Resolutions

Status of Licensure and Recommendations for New Vaccines

Register for upcoming June ACIP meeting

June 22-23, 2016

Deadline for registration:

Non-US Citizens: May 18, 2016

US Citizens: June 6, 2016

Meeting Webcast Instructions

Registration is NOT required to watch the live meeting webcast or to listen via telephone.

FINAL AGENDA [2 pages] (as of February 19)

Public Comment Instructions [1 page]

- New MenB recommendations

9-valent HPV Vaccine

Additional guidance [4 pages] for providers regarding 9-vHPV vaccine use among persons who previously received 2vHPV or 4vHPV vaccine.

FDA extends age indication for males [1 page]

Get Email

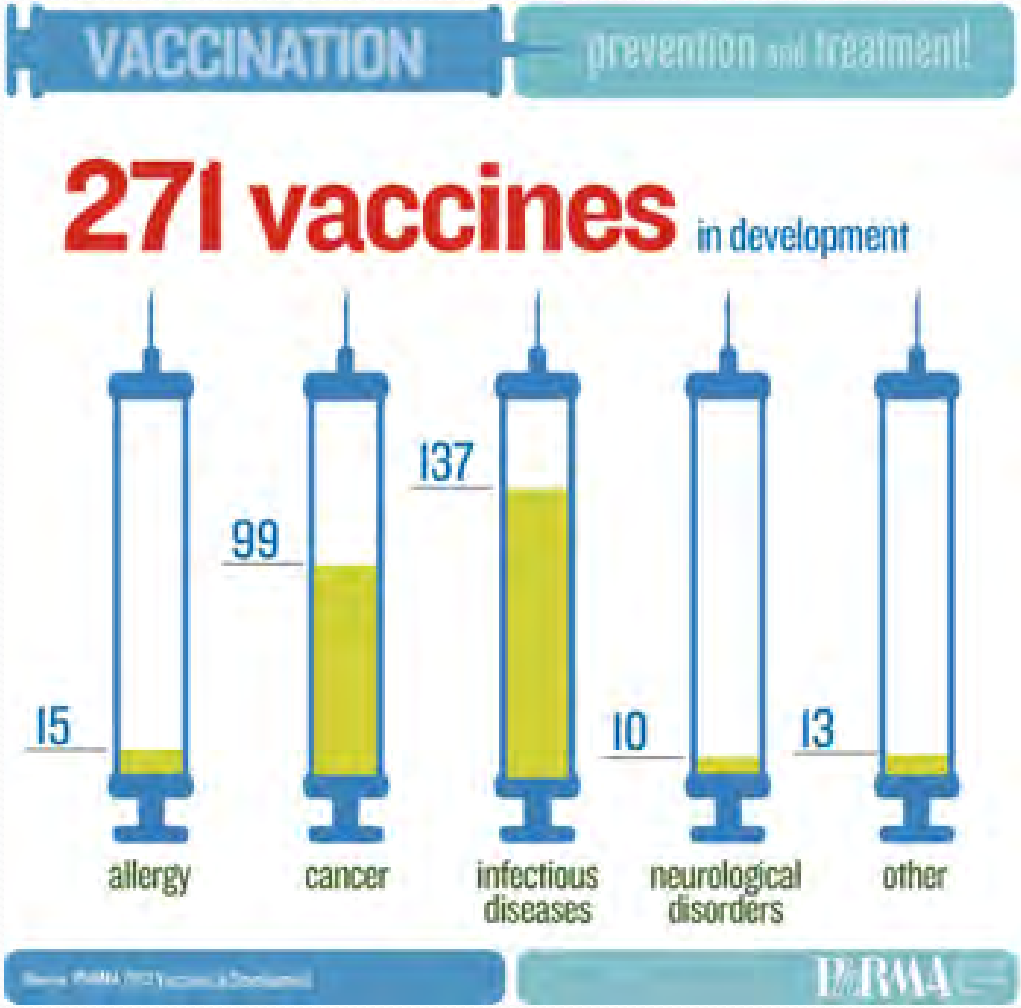
ACIP Recommendations

ACIP Meetings

Immunization Resources

- Immunization Action Coalition
  - http://www.immunize.org
- Centers for Disease Control and Prevention
  - http://www.cdc.gov/vaccines/
  - http://www.cdc.gov/vaccinesafety
  - http://wwwnc.cdc.gov/travel/
- Advisory Committee on Immunization Practices
  - http://www.cdc.gov/vaccines/recs/acip/default.htm
- Epidemiology and Prevention of Vaccine Preventable Diseases ("The Pink Book") (Centers for Disease Control and Prevention) http://www.cdc.gov/vaccines/pubs/pinkbook/pink-chapters.htm

Investigational Vaccines



Questions?