Who Decides the Vaccine Schedule, How Did We Get Here, and Where are We Going

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1

Disclosures/Acknowledgments

- I have no financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.

2

Objectives

- By the end of this presentation, audience members should expect to:
  - Be able to explain the process by which vaccines are licensed and recommended
  - Be able to describe the history of vaccine recommendations in the US

3

Outline

- The history of vaccine recommendations in the US: How did we get here?
- Who decides the vaccine schedule?
- Where are we going?

4

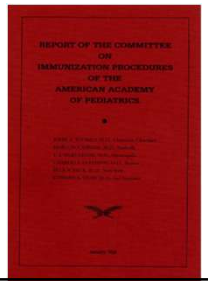
History of US Vaccine Recommendations: How Did We Get Here?

5

Vaccine Recommendations Started with AAP

- Prior to the creation of the Advisory Committee on Immunization Practices in 1964, the main body that made recommendations on vaccine use in the US was the Committee on Infectious Diseases of the AAP

First Red Book, 1938; 8 pages, 18 diseases



Pickering, Peter, Shulman, The Red Book Through the Ages, Pediatrics, Nov 2013

6

Timeline: Pre-ACIP Vaccine Recommendations

- 1930: AAP established in the library of Harber Hospital in Detroit
- 1933: AAP establishes "Special Committee on Prophylactic Procedures Against Communicable Diseases"
- 1935: Committee publishes forerunner of Red Book, the 6-page "Routine measures for the prophylaxis of communicable diseases"
  - Diphtheria, scarlet fever, typhoid fever, whooping cough, measles, smallpox, poliomyelitis, epidemic (meningococcal) meningitis, mumps, chickenpox, rabies, and tetanus

7

ROUTINE MEASURES FOR THE PROPHYLAXIS OF COMMUNICABLE DISEASES

REPORT OF SPECIAL COMMITTEE ON PROPHYLACTIC PROCEDURES AGAINST COMMUNICABLE DISEASES

- *"It is not unlikely that certain modifications may be necessary to suit varying conditions and modifications will of course be necessitated by advances in knowledge."*
- Diphtheria: *"Immunization should be routine at one year. It is a desirable practice for the physician to send an appropriate notice at the child's first birthday."*
  - First mention of reminder/recall in the medical literature?

Journal of Pediatrics, April 1935

8

Timeline: Pre-ACIP Vaccine Recommendations

- 1936: AAP Executive Board creates "Committee on Immunization Procedures" (name evolved to "Committee on Infectious Diseases" ~1969)
- 1938: First "Red Book" - 8 pages, 18 diseases
- 1939-1947: revised and published yearly reflecting the rapid pace of advances in medicine
  - "A great demand from physicians, medical students, health departments, and pharmaceutical houses ensued" (James Hughes)
- 1948-1964: Red Book is primary source for immunization recommendations

9

1948 Immunization Schedule

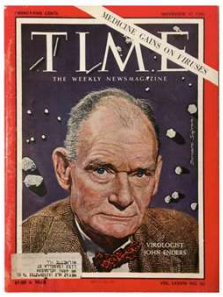
SCHEDULES OF IMMUNIZATION

	Author I	Author II	Miller	Fischer	Conventional procedure
1 mo.	Pert. Alum pptd.				
2 mo.	Pert. Alum pptd.				
3 mo.	Pert. Alum pptd.				Smallpox
4 mo.	Smallpox (1)	Smallpox		Smallpox (1)	
5 mo.	Typhoid			Pertussis	
6 mo.	Typhoid	DPT } Plain or	Pertussis	DPT	Pertussis
7 mo.	Typhoid	DPT } alum	Pertussis	DPT	Pertussis
8 mo.	Diph-Tet alum pptd.	DPT } Precipitated	DPT	Smallpox (2)	Pertussis
9 mo.	Diph-Tet. alum pptd.	Typhoid (3 weekly)		Diph-Tet.	
10 mo.	Smallpox (2)		Smallpox		Diph-Tet.
11 mo.					Diph-Tet.
1 yr.	Tuberculin Test DPT Booster	Tuberculin Test Schick Test	Diph-Tet.	S.hick Test	Diph-Tet
15 mo.	Schick Test		Schick-Tet.		
18 mo.			Pertussis		
2 yr.	Tet. booster (annually)	DPT	Tetanus	DPT	Typhoid-Schick
	Typhoid booster annually	Typhoid booster annually			Typhoid-Pert.-Tet.
3 yr.	Pertussis booster	Tet-typhoid booster annually	Tetanus	DPT	
4 yr.					
5 yr.					
6 yr.	Schick-smallpox Pertussis booster	Schick-smallpox DPT	Smallpox-Schick Pert.Tet every 2 years		Smallpox-Schick

10

Timeline: Pre-ACIP Vaccine Recommendations

- 1944: Public Health Service Act allowed US Surgeon General to recommend vaccines for licensure
- 1950s: Start of the "golden age" of vaccine development as the first viruses grown in tissue culture led to rapid proliferation of new vaccines
  - John Enders, Thomas Weller and Frederick Robbins won the Nobel Prize in Physiology or Medicine in 1954 for culturing poliovirus in a lab in 1949



11

Brief Tangent… Vaccine Scientists Who DID NOT win a Nobel Prize

Scientist	Vaccine	Notes
Jonas Salk	Inactivated polio vaccine (IPV)	Never awarded a Nobel, despite worldwide fame.
Albert Sabin	Oral polio vaccine (OPV)	His vaccine virtually eradicated polio in many regions. No Nobel.
Maurice Hilleman	Over 40 vaccines (MMR, hepatitis A and B, meningitis, pneumonia, etc.)	Arguably the most prolific vaccine developer in history. No Nobel.
Louis Pasteur	Rabies vaccine, anthrax vaccine	Pre-Nobel era (died before prizes were established).
Stanley Plotkin	Rubella vaccine	Key figure in vaccinology; no Nobel.
Ruth Bishop	Discovery of rotavirus (led to vaccines)	Huge impact on child mortality, no Nobel.

12

SCHEDULE OF ACTIVE IMMUNIZATION FOR INFANTS AND CHILDREN

Age	Preparation	
1½–2 mo.	D.P.T.*	Poliomyelitis vaccine†
3 mo.	D.P.T.	Poliomyelitis vaccine
4 mo.	D.P.T.	Poliomyelitis vaccine
10–12 mo.		Smallpox vaccine
12–18 mo.	D.P.T.	Poliomyelitis vaccine
3–4 yr.	D.P.T.	Poliomyelitis vaccine
5–6 yr.		Smallpox vaccine
8 yr.	D.T. (Adult type)	Poliomyelitis vaccine
12 yr.	D.T. (Adult type)	Poliomyelitis vaccine
16 yr.	D.T. (Adult type)	Poliomyelitis vaccine

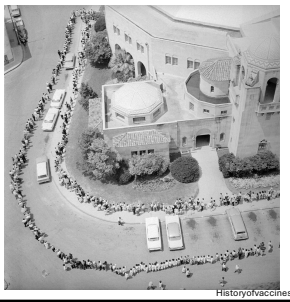
Pediatrics, 1960

13

Timeline: Pre-ACIP Vaccine Recommendations

- 1960: Public Health Service issued recommendations on use of oral polio vaccine and influenza vaccine
- 1962: Advisory Committee on Poliomyelitis Vaccine; Vaccination Assistance Act authorized CDC to support mass vaccination campaigns and provide vaccines directly to state and local health departments
- 1963: Advisory Committee on Measles Vaccine

Crowd waiting for 1962 oral polio vaccination



Historyofvaccines.org

14

Formation of ACIP: 1964

- Proliferation of new vaccines made ad hoc committee approach untenable
- ACIP charged with "the responsibility of advising the Surgeon General regarding the most effective application of public health practice of specific preventive agents, which may be applied in communicable disease control"
- Charter states that committee deliberations shall include consideration of "disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, economic analyses and implementation issues"
- First meeting held at CDC May 25-26, 1964, chaired by CDC director

CDC, Clifton Road Campus, 1960

stacks.cdc.gov

15

Vaccine Recommendations: 1960s to 1990s

- ACIP worked closely with AAP from its inception, often deferring to AAP Red Book for childhood immunization recommendations
- In general, although two schedules for children continued to be published (ACIP and AAP), recommendations were generally similar
  - AAP more directed to physicians and ACIP focused more on public health

Immunization Schedule, 1966 Red Book

Table 1.—*Recommended Schedule for Active Immunization and Tuberculin Testing of Normal Infants and Children*[1]

Age	Immunization or Test
2-3 Months	DTP*, type 1 OPV or trivalent OPV
3-4 Months	DTP, type 3 OPV or trivalent OPV
4-5 Months	DTP, type 2 OPV or trivalent OPV
9-11 Months	Tuberculine test
12 Months	Measles vaccine
15-18 Months	DTP, trivalent OPV, smallpox
2 Years	Tuberculine test
3 Years	DTP, tuberculin test
4 Years	Tuberculin test
6 Years	TD-smallpox vaccine, tuberculin test Trivalent OPV
8 Years	Tuberculin
10 Years	Tuberculin
12 Years	TD, smallpox vaccine, tuberculin test
14 Years	Tuberculin
16 Years	Tuberculin

* DTP indicates diphtheria and tetanus toxoids and pertussis vaccine combined; OPV, oral poliovaccine—if trivalent OPV is used, interval should be six weeks or longer; TD, tetanus and diphtheria toxoids, adult type.

16

Vaccine Recommendations: 1960s to 1990s

- 1972: ACIP designated as a Federal Advisory Committee by the Federal Advisory Committee Act
- Measles outbreaks in 1974 and 1977 led to President Carter's launch of the National Childhood Immunization Initiative
  - Goal of 90% measles iz coverage by 1979
- 1978-1988: great improvements in measles surveillance

17

Vaccine Recommendations: 1960s to 1990s

- Mid 1980's: CDC epidemiologists noted that infections were occurring primarily in 1) unvaccinated preschool children and 2) school aged children with a single dose of measles vaccine

1983 Immunization Schedule

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

18

MEASLES OUTBREAK IN A FULLY IMMUNIZED SECONDARY-SCHOOL POPULATION

Tracy L. Gustafson, M.D., Alan W. Lievens, M.D., Philip A. Brunell, M.D., Ronald G. Moellenberg, B.S., Christopher M.G. Buttery, M.D., and Lynne M. Sehulster, Ph.D.

Published March 26, 1987 | N Engl J Med 1987;316:771-774

- Corpus Christi, Texas (my hometown!); 157 total cases
- 99% (!) of students had record of MMR vaccination
- 4.1% lacked detectable antibody
- Seronegative rates: 0-3.3% for students with 2 doses and 3.6-6.8% for students with 1 dose

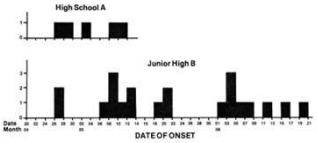


Figure 1. Measles Outbreaks at a Junior High and High School in Corpus Christi, Texas, 1985.

The NEW ENGLAND JOURNAL of MEDICINE

19

MEASLES OUTBREAK IN A FULLY IMMUNIZED SECONDARY-SCHOOL POPULATION

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We are indebted to Ray Falk, Melinda Gonzales, Gerry Heitkamp, and America Gonzales of the Corpus Christi School District; to Helen Reeves, Nancy Clary, and Carl Johnson of the health department; to Dr. Joe Oshman, Dr. Robert Bosquez, Dr. Patrick Brosnen, Mr. Wheeler Lipes, and all the other health professionals in both Corpus Christi and the Texas Department of Health for their help with the serologic survey; and to Judy Schwitzer for secretarial support.

Figure 1. Measles Outbreaks at a Junior High and High School in Corpus Christi, Texas, 1985.

The NEW ENGLAND JOURNAL of MEDICINE

20

Vaccine Recommendations: 1960s to 1990s

- 1989: both ACIP and AAP recommend a second dose of MMR for all children
- Large measles outbreaks in late 1980's/early 1990's
  - >10K hosp, >100 deaths
- Although AAP and ACIP worked closely, differences in schedules persisted
  - Biggest difference was timing of second MMR dose - ACIP, 4-6 years; AAP, 11-12 years

Sixth grader Ginger Taylor shows proof of Immunization against the measles in 1989.

PBS News; Photo By Glen Martin/The Denver Post

21

Vaccine Recommendations: 1960s to 1990s

- 1993: CDC convened summit with AAP and other professional societies to develop strategies to eliminate VPDs by vaccinating 90+% of US children by age 2
- One outcome of this summit - resolution to develop a single, easy-to-understand schedule and format for routine childhood vaccines
- Representatives from AAP, ACIP, AAFP, FDA and NIH formed core of work group dedicated to task
- First harmonized schedule published in January 1995 and approved by ACIP, AAP, and AAFP

Rosalynn Carter, Betty Bumpers and the babies celebrate the launch of Every Child By Two

Source: Vaccinate Your Family (formerly Every Child By Two)

22

1995: First Harmonized Immunization Schedule

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* 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[2]		Hib	Hib	Hib	Hib					
Polio		OPV	OPV	OPV				OPV		
Measles, Mumps, Rubella[4]					MMR			MMR or MMR		

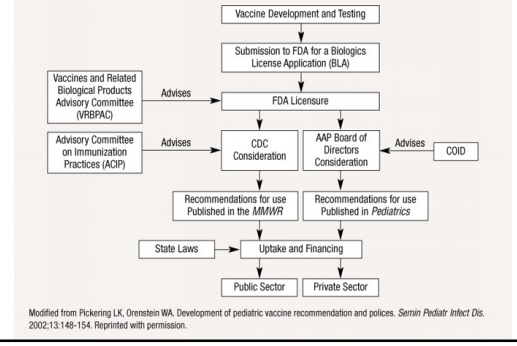
[1] Infants born to HBsAg-negative mothers should receive the second dose of hepatitis B vaccine between 1 and 2 months of age. Infants born to HBsAg-positive mothers should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth. The second dose should be administered at 1 month of age and the third dose at 6 months of age.

23

Who Decides the Vaccine Schedule?

1995 to present

24


Development of vaccine recommendations and policies
Vaccine Development and Testing
Submission to FDA for a Biologics License Application (BLA)
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Advises
FDA Licensure
Advisory Committee on Immunization Practices (ACIP)
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COID
Recommendations for use Published in the MMWR
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Uptake and Financing
Public Sector
Private Sector
Modified from Pickering LK, Orenstein WA. Development of pediatric vaccine recommendation and polices. Semin Pediatr Infect Dis. 2002;13:148-154. Reprinted with permission.

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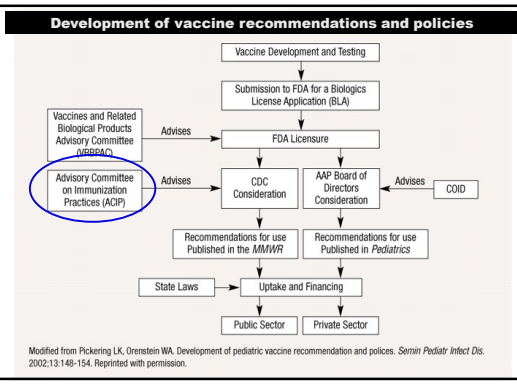
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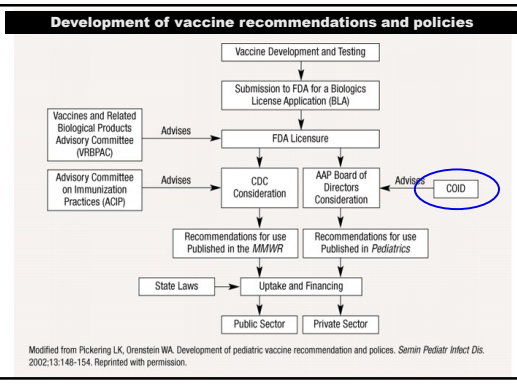
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27

ACIP Recommendations as HHS Policy

- ACIP recommendations become policy following approval by CDC Director and MMWR publication
- The Affordable Care Act (ACA) enacted in 2010 requires insurance coverage for immunizations included in ACIP's approved immunization schedules
- Health plans have one plan year from MMWR publication to implement recommendations according to CDC Immunization schedules

28

28

The FDA compared to ACIP

- FDA *licenses* vaccines
- ACIP *makes evidence-based recommendations* for vaccine use
- FDA licenses a vaccine based only on results of clinical studies and other data submitted by a vaccine manufacturer
- Manufacturers can only market vaccines based upon information in the package insert for that vaccine
- ACIP recommendations may differ from FDA licensure
- http/www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm

29

Composition of ACIP

- Up to 19 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
- 6 *ex officio members* – represent other government agencies involved in immunization. Non voting.
  - CMS, FDA, HRSA, IHS, NIH, Office of Infectious Diseases and HIV/AIDS Policy
- 31 liaison organizations –
  - representatives of professional societies and organizations involved with immunization programs (non-voting)
- Behind the scenes: ACIP Work Groups

30

ACIP Voting Members

- Medicine (Pediatrics, Internal Medicine, Family Medicine, Infectious Diseases, OB/GYN, others)
- State and Local health departments
- Public health and preventive medicine
- Nursing
- Immunology
- Vaccine research and policy
- Economics and cost-effectiveness
- Consumer perspective

31

Ex-Officio Members

- **Six** *ex-officio* members represent other government agencies involved in immunization

Thirty-one organizations with broad involvement in immunization
Professional organizations work with ACIP to develop the annual childhood and adult schedules

Liaison Organizations 32

32

ACIP Work Groups

ACIP voting members
≥2
Chair

CDC
Lead
+ Subject Matter Experts
+ Immunization Safety Office
+ Immunization Services Division

Ex-officio members

Liaison representatives

Consultants

- **Work Group** conducts in-depth review of topics to facilitate informed and efficient decision-making
- Responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by ACIP
- Unlike ACIP meetings, Work Group discussions are considered confidential

See ACIP Policies and Procedures guidance for abbreviations

33

ACIP Work Groups – ~~Current~~

PERMANENT WG	Combined Child/Adolescent and Adult Immunization Schedules
	Influenza
TASK-ORIENTED WG as of April 2025	Mpox Vaccines
	Human Papillomavirus Vaccine
	Chikungunya Vaccines
	Meningococcal Vaccines
	Pneumococcal Vaccines
	COVID-19 Vaccines
	Cytomegalovirus Vaccines
	RSV-Adult
	RSV-Pediatric/Maternal

34

Evidence to Recommendation

35

Process in "Normal" Times

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

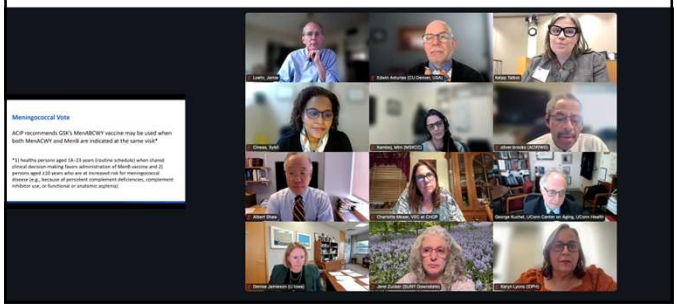
* Federal Advisory Committee Act

36

37

April 15-16, 2025 ACIP Meeting

Pandemic Times to the Present



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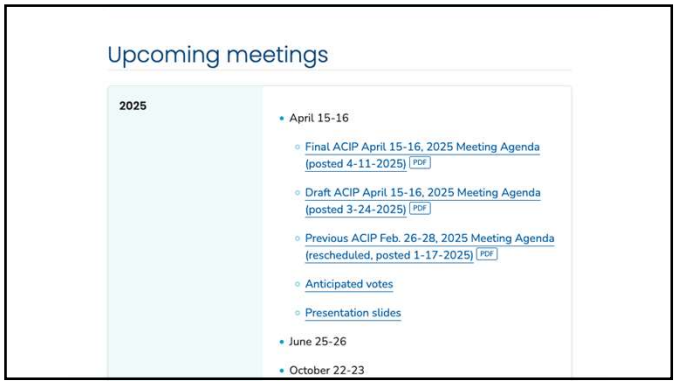
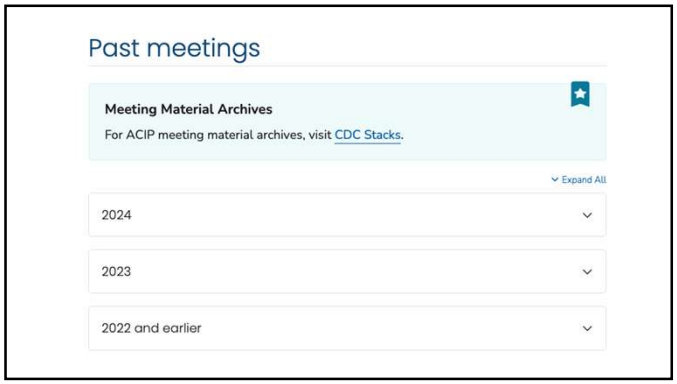
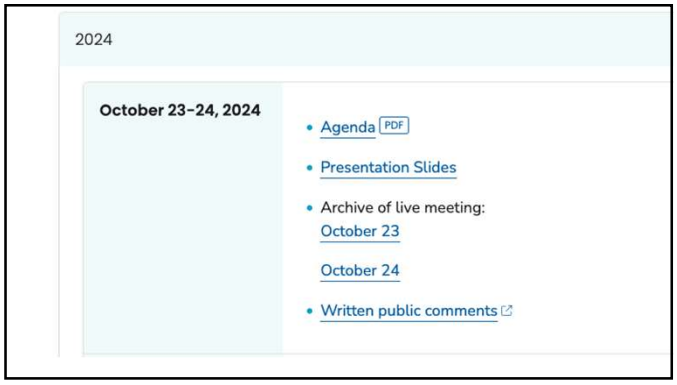
39


Upcoming meetings
2025
April 15-16
Final ACIP April 15-16, 2025 Meeting Agenda (posted 4-11-2025) PDF
Draft ACIP April 15-16, 2025 Meeting Agenda (posted 3-24-2025) PDF
Previous ACIP Feb. 26-28, 2025 Meeting Agenda (rescheduled, posted 1-17-2025) PDF
Anticipated votes
Presentation slides
June 25-26
October 22-23

40


Past meetings
Meeting Material Archives
For ACIP meeting material archives, visit CDC Stacks.
Expand All
2024
2023
2022 and earlier

41


2024
October 23-24, 2024
Agenda PDF
Presentation Slides
Archive of live meeting:
October 23
October 24
Written public comments

42

Human papillomavirus (HPV) Vaccines

Introduction PDF

Dr. O Brooks

Introduction to policy consideration: reduced number of doses PDF

Dr. L Markowitz

Introduction to policy consideration: wording of the age for routine vaccination PDF

Dr. R Stefanos

Review of the literature on HPV vaccination at ages 9-10 to increase coverage PDF

Dr. S Brewer

Work group - next steps PDF

Dr. C DeSisto

43

National Center for Immunization & Respiratory Diseases

Human papillomavirus vaccination at age 9 or 10 years to increase coverage – a systematic review and narrative review of the literature

Sarah Brewer, PhD, MPH

Division of Viral Diseases

Advisory Committee on Immunization Practices
October 24, 2024

44

...and Where Are We Going?

45

Medscape Internal Medicine > Medicine Matters

COMMENTARY

ACIP Meeting Rescheduled as HHS Rescinds Richardson Waiver: What's Next for Vaccine Policy?

Sandra Adamson Fryhofer, MD

DISCLOSURES | March 26, 2025

ACIP Meeting Postponed. Just a Delay or a Fortelling of Kennedy's Vaccine Agenda?

Managed Healthcare EXECUTIVE

February 21, 2025

By Peter Wehrwein, Managing Editor

Colorado lawmakers are quietly trying to RFK Jr.–proof school vaccination requirements

THE COLORADO SUN

An amendment slipped into a bill by Democrats would shift reliance away from a key federal committee in determining which vaccines Colorado schoolkids are required to get

CDC posts 'conflicts of interest' database on vaccine panel members

The list is part of Health Secretary Robert F. Kennedy Jr.'s push for "radical transparency." Experts say it could sow doubt about the agency's vaccine guidance.

March 7, 2025, 2:26 PM PST

OPINION — FIRST OPINION

Former chairs of the Advisory Committee on Immunization Practices on the panel's role

This committee's work is important to all Americans

By Grace Lee, José Romero, Nancy Bennett, Jonathan Temte, Carol Baker, and Myron Levin March 5, 2025

Lee, Romero, Bennett, Temte, Baker, and Levin are all past chairs of the U.S. Advisory Committee on Immunization Practices from 2003-2005 and 2009 to 2023.

ACIP postponement, shelving of CDC vaccine campaigns stir fears

CIDRAP

Chris Dall, MA, February 21, 2025

Topics: Public Health, Adult (non-flu) Vaccines, Influenza Vaccines, COVID-19

46

What happened since Apr-Dec 2025

- **Legitimate ACIP members fired and replaced with mostly unqualified individuals**
- **All liaison organizations were dismissed from ACIP work groups**
- **June 25-26 ACIP Meeting**

  The AAP did not participate in the ACIP meeting in its usual role as liaisons to ACIP
- **AAP and other medical organizations file a lawsuit against HHS**
  - So far, so good… stay tuned…
- **AAP continues to reinforce the critical role of the original ACIP**
- **AAP is now developing our own evidence-based recommendations**
  - Initial focus was on respiratory season viruses
  - Maintaining current schedule and consider other potential changes
- **AAP also did not participate in September or December ACIP meetings**
  - Fact checking with media and social media in real time
  - Press conference with large media presence both meetings

47

What Happened on January 5

48

"Aligning with Peer Nations"

- In an unprecedented move, politically appointed leadership of HHS announced major changes to the US childhood vaccination schedule
- Most closely aligned with schedule of Denmark, which is an outlier among developed nations in how few vaccines they recommend
- US schedule is similar to Canada, Ireland, Germany, Australia, New Zealand, etc
- Reasoning given was to "restore trust in vaccines"

49

Universal Opposition from Medical and Public Health Societies

- Many analogies given for how problematic this move was
  - "…like comparing a cruise ship to a kayak"
  - "…a jet engine to a toy plane"
  - "…square peg in a round hole"
  - "…outsourcing US policy to Denmark"
  - "…like setting our thermostat based on the weather in Denmark"
  - "…like comparing traffic laws without comparing roads"

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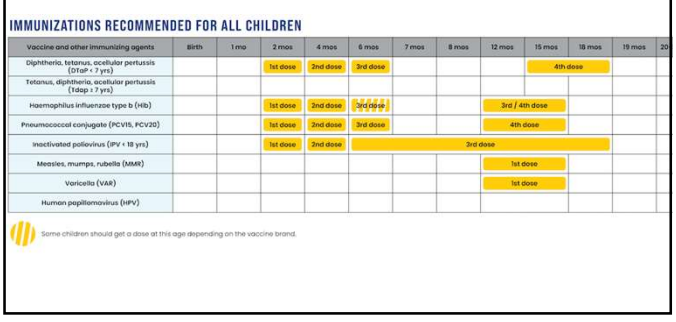

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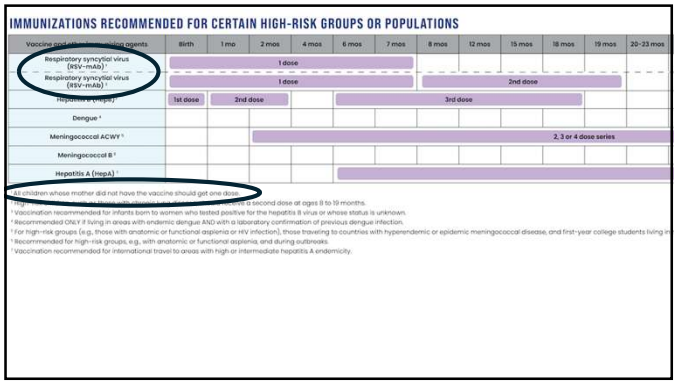
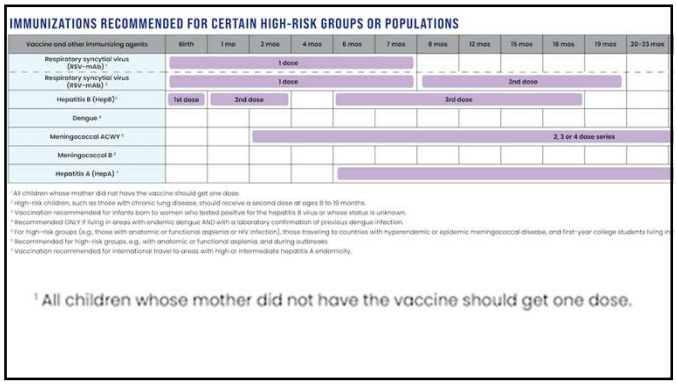

IMMUNIZATIONS RECOMMENDED FOR CERTAIN HIGH-RISK GROUPS OR POPULATIONS
Vaccine and other immunizing agents
Birth
1 mo
2 mos
4 mos
6 mos
7 mos
8 mos
12 mos
15 mos
18 mos
19 mos
20–23 mos
Respiratory syncytial virus (RSV–mAb) [1]
1 dose
Respiratory syncytial virus (RSV–mAb) [1]
1 dose
2nd dose
Hepatitis B (HepB) [2]
1st dose
2nd dose
3rd dose
Dengue [4]
Meningococcal ACWY [5]
2, 3 or 4 dose series
Meningococcal B [6]
Hepatitis A (HepA) [7]
All children whose mother did not have the vaccine should get one dose.
[2] High-risk children, such as those with chronic lung disease, should receive a second dose at ages 8 to 19 months.
[3] Vaccination recommended for infants born to women who tested positive for the hepatitis B virus or whose status is unknown.
[4] Recommended ONLY if living in areas with endemic dengue AND with a laboratory confirmation of previous dengue infection.
[5] For high-risk groups (e.g., those with anatomic or functional asplenia or HIV infection), those traveling to countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in
[6] Recommended for high-risk groups, e.g., with anatomic or functional asplenia, and during outbreaks.
[7] Vaccination recommended for international travel to areas with high or intermediate hepatitis A endemicity.

52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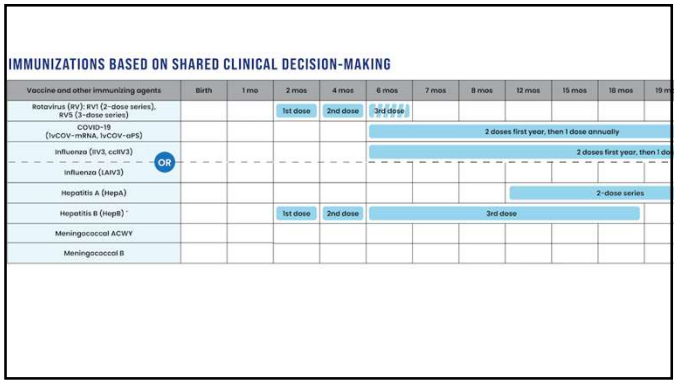
53


IMMUNIZATIONS BASED ON SHARED CLINICAL DECISION-MAKING
Vaccine and other immunizing agents
Birth
1 mo
2 mos
4 mos
6 mos
7 mos
8 mos
12 mos
15 mos
18 mos
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)
1st dose
2nd dose
3rd dose
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)
2 doses first year, then 1 dose annually
Influenza (IIV3, ccIIV3)
OR
Influenza (LAIV3)
Hepatitis A (HepA)
2-dose series
Hepatitis B (HepB) [1]
1st dose
2nd dose
3rd dose
Meningococcal ACWY
Meningococcal B

54

What's Wrong with This Picture?

Source: ChatGPT

55

Among the many problems with the change…

- **Process:** No disease-burden modeling, impact assessment, public comment, independent expert input
  - No transparency in decision; prioritizes perception over data
- **Health outcomes are what matter, not number of vaccines**:
  - illnesses, hospitalizations, deaths, and disabilities prevented
  - avoided financial costs, missed work and schools, costs to families and communities
- **Vaccine schedules aren't interchangeable lists**: You can't copy and paste public health
  - Different countries have different populations, health systems, size, cost considerations, etc

56

Among the many problems with the change…

- **The US is not actually an outlier**: Many "peer" high income countries use similar routine childhood vaccine schedules
  - Denmark is the outlier among peer countries; Denmark was chosen to make the US schedule look "bloated" compared to peer nations
  - US similar to Canada, Germany, Italy, Australia, S.Korea, Israel, etc
- **"Fewer vaccines against fewer diseases" is not a good thing**: preventing disease and suffering is a good thing
- **Clear recommendations matter**: clinicians already tailor conversations to individual needs and help patients make decisions based on the benefits and risks; having tiered recommendations creates confusion
  - Historically, SCDM vaccines have very low uptake

57

Let's talk about the details…

58

"Too many vaccines"

- "In the US, children get [insert a scary large number, like 80 or 96] doses of vaccine by the time they are 18 years old"
- Reality: By the time a child turns 18, they're recommended to receive vaccines that protect against 17 diseases
- If counting specific diseases, based on boosters:
  - 28 doses by 2 years (including flu)
  - 35 by 5 years (including flu)
  - 54 by 18 (one-third of these are annual flu)
- Total doses depends on combination vaccines used

59

The Facts: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?

- Infant has theoretical capacity to respond to about 100,000 vaccines at any one time!
  - (10^7 B cells per mL by 10^3 epitopes per vaccine)
  - Cohn and Langman, Immuno Rev 1990
- Most vaccines contain fewer than 100 antigens, therefore if 11 vaccines given at one time then 0.1% of the immune system would be "used up"

60

Children's immune systems regularly encounter thousands of antigens, and the antigens in vaccines are actually far less than they used to be

TABLE 2. Number of Immunogenic Proteins and Polysaccharides Contained in Vaccines Over the Past 100 Years

1900		1960		1980		2000	
Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins/ Polysaccharides
Smallpox*	~200	Smallpox	~200	Diphtheria	1	Diphtheria	1
Total	~200	Diphtheria†	1	Tetanus	1	Tetanus	1
		Tetanus‡	1	WC-Pertussis	~3000	AC-Pertussis¶¶	2–5
		WC-Pertussis§	~3000	Polio	15	Polio	15
		Polio‖	15	Measles¶	10	Measles	10
		Total	~3217	Mumps#	9	Mumps	9
				Rubella**	5	Rubella	5
				Total	~3041	Hib††	2
						Varicella‡‡	69
						Pneumococcus§§	8
						Hepatitis B‖‖	~1
						Total	123–126

Offit PA et al, *Pediatrics* (2002) 109:124-9

61

Most nurses and parents prefer multiple injections at once, and pain may be worse with spreading out

- Nurses prefer to give multiple injections at once to reduce pain and distress (Horn & McCarthy, Journal of Pediatric Health Care, 1999)
- Most parents prefer simultaneous (Bogin et al, Pediatric Resident, 2004)
- Salivary cortisol levels similar with simultaneous and sequential injections ("hurts with 1, hurts with 3"), and pain scores lower in simultaneous (Hanson et al, Infant Behavior and Development, 2010)

62

Vaccine Moved to SCDM

AKA Which diseases do we want to see children in the US needlessly suffer from?

63

Hepatitis A

- Prior to widespread vaccination, roughly 10.4 cases per 100K in US
  - ~20,000-30,000 cases/year
  - ~100 deaths/year
- Recent years: 0.5-0.6 cases per year (17-fold reduction)
- Community immunity achieved through widespread childhood vaccination, so circulation now is rare in children
- Low burden of disease currently in US is cited as a reason for the change, but the low burden IS BECAUSE OF VACCINATION!

64

Hepatitis B

- Highly transmissible pathogen
- Causes liver cancer, cirrhosis
- Prior to widespread vaccination, ~20,000 cases or hepatitis B in children every year
- Infants can be perinatally infected if mother has hep B (50% of cases)
- Infants and children can also acquire hep B from household or other casual contacts (the other 50%)
- ~1-2.4 million persons in US living with hep B
  - **50-66% are unaware they are infected**
- 90% of children who acquire hep B develop chronic disease
  - Of those, roughly 25% will die from the disease
- In 2023, there were seven perinatally acquired hep B cases in the US

65

Hepatitis B: Why does the birth dose matter?

- Routine vaccination is far more effective than identifying risk groups
- ~15% of pregnant women are not screened for hepatitis B
- Per CDC website (MMWR), from 2015-2017, 20,678-21,314 infant were born to women who were Hep B surface Ag+
  - Of those, **only 52.6%** were identified through prenatal screening
- Many documented cases of communication errors, transcription errors, acquisition of hep B late in pregnancy leading to infant infection
- **Vaccination in the first 24 hours can prevent hep B in the infant**
- One missed case is too many

66

Hepatitis B: So why do some countries not recommend a birth dose?

- Different systems, different burdens
- Denmark, for example, has nearly 100% screening for hep B in pregnancy
- Centralized medical records from birth to death
- Up to a year paid parental leave
- Very low burden of chronic hep B
- Systems with few gaps
  - The US health care system has many gaps

67

Rotavirus

- "Winter vomiting syndrome"
- Prior to widespread vaccination in the US, ~**50,000 hospitalizations per year**
  - 50-100 deaths per year
- Since routine vaccination, rarely see infants hospitalized for rotavirus, even in unvaccinated infants, because of high community levels of protection

68

Influenza

- Routine vaccination of everyone >6 months since 2010
- Per CDC website, in 2023-2024 season, influenza vaccination prevented 20,000 hospitalizations and 266 deaths in children 6 months through 17 years
- Vaccination is highly effective against severe outcomes in children, including ICU admission and death, including the present season
  - Many studies showing this now
- Vaccination rates steadily increased in children to >60% through 2021, sharp dropoff to high 40s since pandemic
- 280 pediatric deaths last year, 89% incompletely vaccinated (worst year in >15 years)
- Current season starting quite severe with high rates of ER visits and hospitalizations

69

MenACWY

- Severe disease with high morbidity and mortality
- Currently fairly rare in US
- ACIP was considering changing recommendations prior to dismissal of legitimate members because of two new pentavalent products
  - MenACWY (routine at 11 and 16) + Men B (SCDM at 16)--- MenABCWY
- ~35 states require for school

70

Single dose HPV and age at recommendation

- ACIP and AAP had been considering moving to this prior to dismissal of legitimate members
- WHO considers it an option, and several high-income countries have moved to single dose
- Unclear what the schedule change means for vaccinating at age 9-10 which was formerly an option with a growing evidence base
  - Recommended by ACS and AAP

71

What's wrong with a Shared Clinical Decision Making recommendation?

- Clinicians generally don't like this type of recommendation
- Not easily implemented
- Clinicians already do it… all day… every day…
- Almost certainly leads to lower vaccination coverage
  - Implies these vaccines are less important
- Confusing to have tiered recommendations for parents and clinicians
  - SCDM discussions take much more time than routine recs
- Documentation and consent concerns from clinicians
- Some clinicians may not stock vaccines under SCDM
- Potential for lawsuits against manufacturers

72

AAP Response

73

AAP and Immunizations

- AAP has led immunization recommendations for children and adolescents since 1935
- Immunization schedule published every year in Pediatrics
  - We will continue to do this as we have always done
- Evidence review for immunizations is an ongoing process led by the Committee on Infectious Diseases

74

≡ AAP Publications

AAP News

AAP: CDC plan to remove universal childhood vaccine recommendations 'dangerous and unnecessary'

January 5, 2026

Melissa Jenco, Senior News Editor; Steve Schering, Staff Writer; and Sean Stangland, Associate Editor

75

From the President

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Press Statement by Andrew D. Racine, MD, PhD, FAAP, AAP President:

January 5, 2026

AAP Opposes Federal Health Officials' Unprecedented Move to Remove Universal Childhood Immunization Recommendations

"Today's announcement by federal health officials to arbitrarily stop recommending numerous routine childhood immunizations is dangerous and unnecessary. The longstanding, evidence-based approach that has guided the U.S. immunization review and recommendation process remains the best way to keep children healthy and protect against health complications and hospitalizations.

"For decades, leading health experts, immunologists, and pediatricians have carefully reviewed new data and evidence as part of the immunization recommendation process, helping to keep newborns, infants, and children protected from diseases they could be exposed to in the United States as they develop and grow. Today's decision, which was based on a brief review of other countries' practices, upends this deliberate scientific process.

76

"Said to be modeled in part after Denmark's approach, the new recommendations issued today by the U.S. Centers for Disease Control and Prevention no longer recommend routine immunization for many diseases with known impacts on America's children, such as hepatitis A and B, rotavirus, respiratory syncytial virus (RSV), flu, and meningococcal disease. AAP continues to recommend that children be immunized against these diseases, and for good reason; thanks to widespread childhood immunizations, the United States has fewer pediatric hospitalizations and fewer children facing serious health challenges than we would without this community protection.

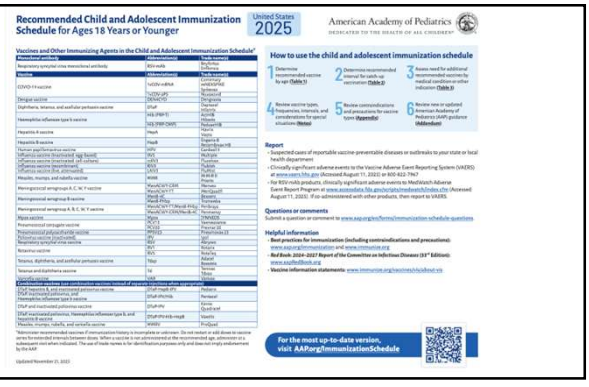
"The United States is not Denmark, and there is no reason to impose the Danish immunization schedule on America's families. America is a unique country, and Denmark's population, public health infrastructure, and disease-risk differ greatly from our own.

"At a time when parents, pediatricians and the public are looking for clear guidance and accurate information, this ill-considered decision will sow further chaos and confusion and erode confidence in immunizations. This is no way to make our country healthier.

"During this uncertain time, the AAP will continue to publish our own childhood vaccine recommendations. My message for parents today is this: As a parent, you know your child and what they need to thrive. Your child's pediatrician has the medical training, special knowledge, and scientific evidence about how to support children's health, safety and wellbeing. Working together, you can make informed decisions about what's best for your child. If you have questions about vaccines or anything else, your child's pediatrician is there to help.

"The Academy's mission has never been more vital. The AAP and our pediatrician members will continue to stand up for children, just as we have done for the past 95 years."

77



Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger

United States 2025

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Vaccine [and other immunizing agents]	Abbreviations	Trade names
Respiratory syncytial virus monoclonal antibody	RSV-mAb	Beyfortus
Vaccine	Abbreviation(s)	Trade name(s)
COVID-19 vaccine	1vCOV-mRNA	Comirnaty, Comirnaty JN.1
	1vCOV-aPS	Spikevax
	1vCOV-PS	Nuvaxovid
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel, Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB
	Hib (PRP-OMP)	Hiberix, PedvaxHIB
Hepatitis A vaccine	HepA	Havrix, Vaqta
Hepatitis B vaccine	HepB	Engerix-B, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (quadrivalent, egg-based)	IIV4	Fluzone
Influenza vaccine (trivalent, all cohorts)	aIIV3	Fluzone
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV4	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II, Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	Menquadfi
Meningococcal serogroup B vaccine	MenB-4CMP	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/MenB-FHbp	Penbraya
	MenACWY-CRM/MenB-4CMP	Pentacel
Mpox vaccine	JYNNEOS	JYNNEOS
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Respiratory syncytial virus vaccine	RSV	Abrysvo
	RSV	Arexvy
Rotavirus vaccine	RV1	Rotarix
	RV5	RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac
Tick-borne encephalitis vaccine	TBE	TicoVac
Combination vaccines (use combination vaccines instead of separate injections when appropriate)		
DTaP-hepatitis B-and-inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP-inactivated poliovirus vaccine	DTaP-IPV/Hib	Pentacel
Haemophilus influenzae type b vaccine		
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix, Quadracel
DTaP-inactivated poliovirus, Haemophilus influenzae type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series forrecommended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit when indicated. The use of trade names is for identification purposes only and does not imply endorsement by the AAP.

Updated November 21, 2025

How to use the child and adolescent immunization schedule

1 Determine recommended vaccine by age (Table 1)
2 Determine recommended interval for catch-up vaccination (Table 2)
3 Assess need for additional recommended vaccines by medical condition or other indication (Table 3)
4 Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)
5 Review contraindications and precautions for vaccine types (Appendix)
6 Review new or updated American Academy of Pediatrics (AAP) guidance (Addendum)

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov (Accessed August 11, 2025) or 800-822-7967
- For RSV mAb products, clinically significant adverse events to MedWatch Adverse Event Report Program at www.accessdata.fda.gov/scripts/medwatch/index.cfm (Accessed August 11, 2025). If co-administered with other products, then report to VAERS.

Questions or comments

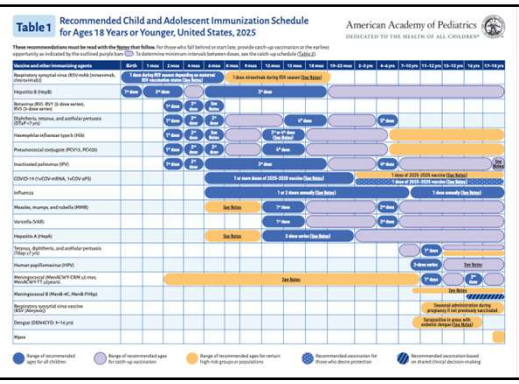
Submit a question or comment to www.aap.org/en/forms/immunization-schedule-questions

Helpful information

- **Best practices for immunization (including contraindications and precautions):** www.aap.org/immunization and www.immunize.org
- **Red Book: 2024–2027 Report of the Committee on Infectious Diseases (31st Edition):** www.aapRedBook.org
- **Vaccine information statements:** www.immunize.org/vaccines/viss/#vis-vis

For the most up-to-date version, visit AAP.org/ImmunizationSchedule

78



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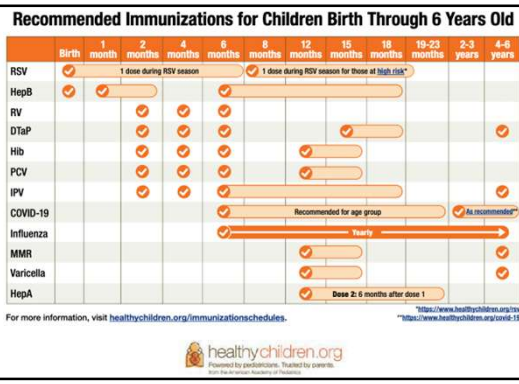

80

What's Likely Coming Next…

81

Sowing Fear about Aluminum

- Al+ used as vaccine adjuvant 80+ years;
  - Remarkable safety record
- Adverse reactions: sterile abscesses, granulomatous inflammation, contact hypersensitivity
- Vaccines that include Al+ adjuvant:
  - DTP, DTaP, some HIB, Hepatitis A & B, HPV, anthrax, rabies
- No aluminum: IPV, influenza

82

So what about aluminum?

- Found in numerous foods and beverages, baby formulas, honey
  - Typical adults ingest 7-9 milligrams of aluminum per day
- Aluminum contained in vaccines is similar to that found in a liter of infant formula
- We ingest orders of magnitude more aluminum than the amount contained in vaccines

83

"But it's injected into my baby!"

- About 1% of ingested aluminum reaches the bloodstream (all injected aluminum does)
- Once in bloodstream, though, processed exactly the same whether injected or ingested
  - Most eliminated by the kidney quickly
  - Small amounts retained in tissues
  - By adulthood, 50-100 milligrams have accumulated, almost all of which comes from food
- Levels of aluminum in tissues no different when comparing vaccinated and unvaccinated subjects (Goulle et al, 2020)
- Blood and hair aluminum levels have no association with vaccine history or development (Karwowski et al, Acad Peds, 2018)
- Burden of aluminum from diet and vaccines well within levels considered safe (Mitkus et al, Vaccine, 2011)

84

Sowing Fear of the HPV vaccine

- Some ACIP members and HHS secretary have been involved in lawsuits against HPV vaccine manufacturer
- HPV work group planned with a chair whose public comments are deeply antivaccine

85

Reworking the Vaccine Injury Compensation Program

- Goal: Rig it to make manufacturers liable
- Goal: Add autism to the injury table
- Antivaccine "researchers" have been hired by HHS to "study" this
  - Bogus studies likely coming
- Two members of ACCV recently fired
  - Committee that advises HHS on VICP
- Potentially the biggest threat because manufacturers could leave US market

86

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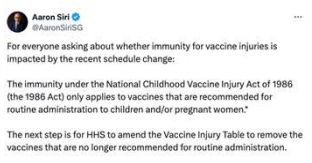


87

Conclusions

- Vaccine recommendations have evolved over the last 90 years guided by burden of disease, vaccine development, and scientific consensus among experts across many disciplines
  - Vaccine safety is always a top consideration in any recommendation
- AAP, AAFP, ACOG, ACP will be leading evidence-based vaccine recommendations for the foreseeable future, with support from the Vaccine Integrity Project and similar groups
- We must unfortunately ignore vaccine guidance from the federal government at this time
- Vaccine recommendations must continue to follow the science

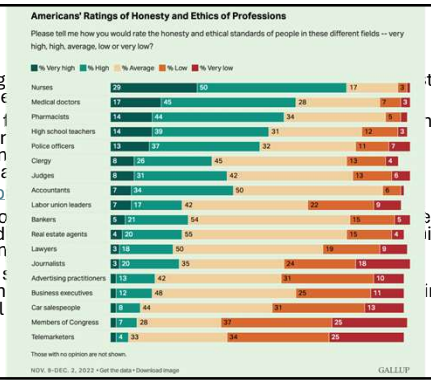
88

And Finally…

- Recognize that you are parents' and patients' most trusted source of information
- Don't forget about tried-and-true evidence-based techniques to increase vaccination uptake, like standing orders for vaccination, reminder/recall, provider assessment and feedback, etc
  - https://www.thecommunityguide.org/
- The combination of multiple evidence-based techniques, including communication techniques, will lead to the highest vaccination uptake
- Make sure your entire staff, including the front desk, administrative staff, medical assistants, nurses, and clinicians are all on the same page about vaccination

89

- Recog … ted source
- Don't f … niques to incr … vaccin … feedba …
  - http …
- The co … es, includ … ighest vaccin …
- Make s … admin … inicians are all …



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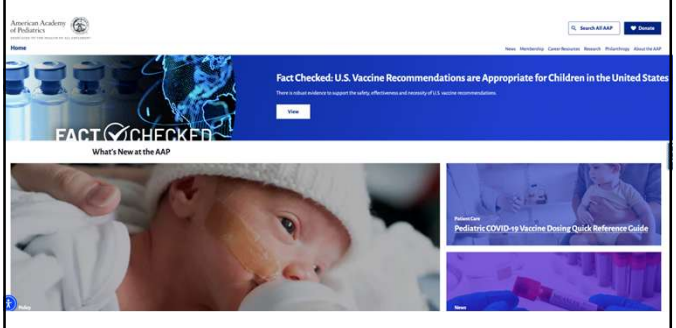
91

Resources

92



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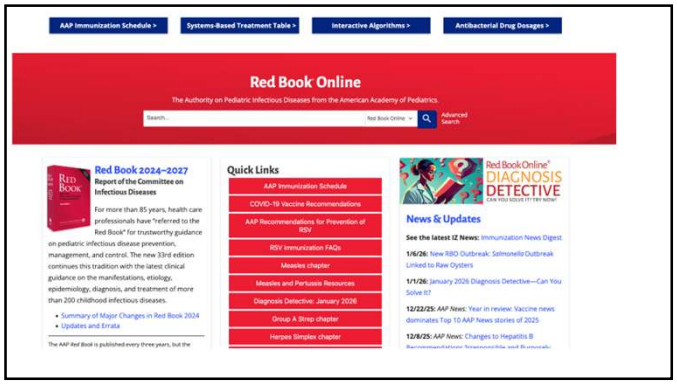
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The Authority on Pediatric Infectious Diseases from the American Academy of Pediatrics
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Report of the Committee on Infectious Diseases
For more than 85 years, health care professionals have "referred to the Red Book" for trustworthy guidance on pediatric infectious disease prevention, management, and control. The new 33rd edition continues this tradition with the latest clinical guidance on the manifestations, etiology, epidemiology, diagnosis, and treatment of more than 200 childhood infectious diseases.
Summary of Major Changes in Red Book 2024
Updates and Errata
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COVID-19 Vaccine Recommendations
AAP Recommendations for Prevention of RSV
RSV Immunization FAQs
Measles chapter
Measles and Pertussis Resources
Diagnosis Detective: January 2026
Group A Strep chapter
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DIAGNOSIS DETECTIVE
CAN YOU SOLVE IT? TRY NOW!
News & Updates
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1/6/26: New RBO Outbreak: Salmonella Outbreak Linked to Raw Oysters
1/1/26: January 2026 Diagnosis Detective—Can You Solve It?
12/22/25: AAP News: Year in review: Vaccine news dominates Top 10 AAP News stories of 2025
12/8/25: AAP News: Changes to Hepatitis B

94


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Immunizations
Today, most children in the United States lead much healthier lives and parents live with much less anxiety and worry over infections during childhood. Immunizations are one of the success stories of modern medicine.
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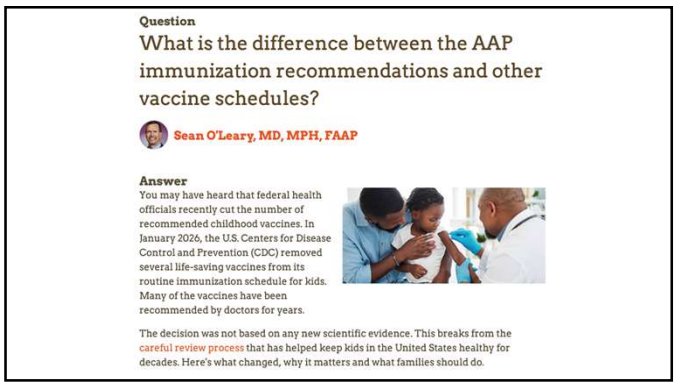
How to Protect Your Children During a Measles Outbreak
Multiple Vaccines at One Time
Vaccines Your Child Needs by Age 6

95


Question
What is the difference between the AAP immunization recommendations and other vaccine schedules?
Sean O'Leary, MD, MPH, FAAP
Answer
You may have heard that federal health officials recently cut the number of recommended childhood vaccines. In January 2026, the U.S. Centers for Disease Control and Prevention (CDC) removed several life-saving vaccines from its routine immunization schedule for kids. Many of the vaccines have been recommended by doctors for years.
The decision was not based on any new scientific evidence. This breaks from the careful review process that has helped keep kids in the United States healthy for decades. Here's what changed, why it matters and what families should do.

96

The American Academy of Pediatrics (AAP) continues to **strongly recommend** the full set of immunizations to keep your child healthy and will keep publishing its own evidence-based vaccine guidance. Other doctors and health specialists across U.S. agree with **AAP evidence-based vaccine recommendations**.

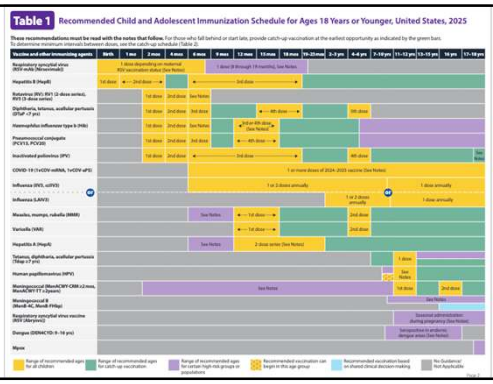
97

"Vaccines don't save lives; Vaccination saves lives"

98

EXTRA SLIDES

99



100

IOM report from 2013

- Hypotheses on how vaccines might cause asthma
  - Might stimulate a harmful immune response
  - Might suppress a beneficial immune response
- IOM, 2013:
  - "In summary, research examining the association between the cumulative number of vaccines received and the timing of vaccination and asthma, atopy, and allergy has been limited; **the findings from the research that has been conducted are reassuring**, however. No data have demonstrated harm (an increased risk of atopy) from immunizations. Indeed, the opposite may be the case."

101

Asthma

- Several studies have shown that it is extremely unlikely that vaccines play any role in the development of asthma
- A meta-analysis from 2007 of all the studies that looked at DTP vaccine showed no association
  - Is childhood vaccination associated with asthma? A meta-analysis of observational studies. Balicer RD, Grotto I, Mimouni M, Mimouni D. Pediatrics. 2007 Nov;120(5):e1269-77.

102

Asthma

- Conclusion: the available scientific evidence shows that it is **very unlikely** that multiple vaccines contribute to asthma
- Caveat: there are some data that LAIV (the live intranasal influenza vaccine) may trigger episodes of wheezing in children 6-23 months of age
  - Safety and efficacy of live attenuated influenza vaccine in children 2-7 years of age. Belshe RB, Ambrose CS, Yi T. Vaccine. 2008 Sep 12;26 Suppl 4:D10-6.
  - Emerging data on the safety and efficacy of influenza vaccines in children. Vesikari T. Pediatr Infect Dis J. 2008 Nov;27(11 Suppl):S159-61.

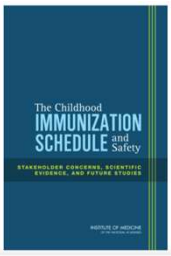
103

Association Between Aluminum Exposure From Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months

Matthew F. Daley, MD; Liza M. Reifler, MPH; Jason M. Glanz, PhD; Simon J. Hambidge, MD, PhD; Darios Getahun, MD, PhD; Stephanie A. Irving, MHS; James D. Nordin, MD, MPH; David L. McClure, PhD; Nicola P. Klein, MD, PhD; Michael L. Jackson, PhD, MPH; Satoshi Kamidani, MD; Jonathan Duffy, MD, MPH; Frank DeStefano, MD

104

How did we get here?



105

The Committee and Its Charge

- The 14-member committee was charged with:
- Reviewing existing literature and stakeholders' concerns related to the safety of the recommended immunization schedule
- Identifying appropriate methodological approaches for determining the safety of said schedule
- Issuing a summary report

106

How did we get here?

- "How do child health outcomes compare between those who receive no vaccinations and those who receive the full currently recommended immunization schedule?"
- "How do child health outcomes compare between (a) those who receive the full currently recommended immunization schedule and (b) those who omit specific vaccines?"
- "For children who receive the currently recommended immunization schedule, do short- or long-term health outcomes differ for those who receive fewer immunizations per visit (e.g., when immunizations are spread out over multiple occasions)?"
- "Do potentially susceptible subpopulations (for example, children from families with a history of allergies or autoimmune diseases) who may experience adverse health consequences in association with immunization with the currently recommended immunization schedule exist?"

107

Association Between Aluminum Exposure From Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months

Q1 *Matthew F. Daley, MD; Liza M. Reifler, MPH; Jason M. Glanz, PhD; Simon J. Hambidge, MD, PhD; Darios Getahun, MD, PhD; Stephanie A. Irving, MHS; James D. Nordin, MD, MPH; David L. McClure, PhD; Nicola P. Klein, MD, PhD; Michael L. Jackson, PhD, MPH; Satoshi Kamidani, MD; Jonathan Duffy, MD, MPH; Frank DeStefano, MD*

108

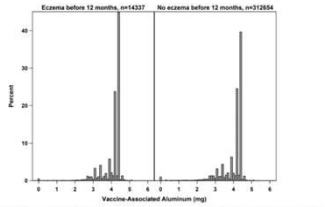


Figure 1. *Distribution of cumulative vaccine-associated aluminum received birth through 23 months of age, stratified by eczema status, Vaccine Safety Datalink.*

109

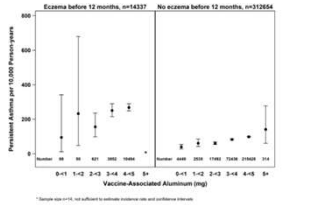


Figure 2. *Crude incidence rate of persistent asthma at 24 through 59 months of age by quantity of vaccine-associated aluminum in milligrams (mg), stratified by eczema status, Vaccine Safety Datalink.*

110

Table 3. Results for Primary Analyses, Secondary Analyses, and Negative Control Outcome, With Separate Models for the Eczema and No Eczema Cohorts, Vaccine Safety Datalink

	Eczema		No Eczema	
Model	Sample Size, n	Adjusted Hazard Ratio (95% CI) for Persistent Asthma	Sample Size, n	Adjusted Hazard Ratio (95% CI) for Persistent Asthma
Primary analyses (also shown in Table 2)	14,337	1.26 (1.07, 1.49)	312,654	1.19 (1.14, 1.25)
Secondary analyses				
Aluminum exposure as dichotomous (>3.00 mg vs ≤3.00 mg)†	14,337	1.61 (1.04, 2.48)	312,654	1.36 (1.21, 1.53)
Excluding those with aluminum exposure at the extremes (<1 mg or ≥5 mg)‡,†	14,225	1.27 (1.05, 1.53)	307,891	1.18 (1.11, 1.26)
Limited to those fully vaccinated with no delays‡,†	9477	1.08 (0.82, 1.43)	188,593	1.12 (1.01, 1.24)
Limited to those with breast-feeding data available‡,§	1913	1.38 (0.53, 3.60)	42,909	1.26 (0.99, 1.61)
Outcome defined as persistent asthma at 36–59 mos.*,†	12,967	1.22 (1.01, 1.47)	280,205	1.15 (1.09, 1.22)
Negative control outcome				
Outcome defined as all-cause injury at 24–59 mos.‖,¶	13,804	1.03 (0.94, 1.14)	298,276	1.01 (0.99, 1.03)

ED indicates emergency department; CI, confidence interval; mos., months; and VSD, Vaccine Safety Datalink.
*Adjusted for birth month and year, VSD site, sex, race/ethnicity, prematurity, medical complexity, food allergy, early-life severe bronchiolitis, utilization (outpatient, ED).
†Vaccine-associated aluminum treated as continuous linear exposure variable.
‡Adjusted for breast-feeding at 6 months (exclusive, some, or none), birth month and year, VSD site, sex, race/ethnicity, prematurity, medical complexity, food allergy, early-life severe bronchiolitis, utilization (outpatient, ED).
§Adjusted for birth month and year, VSD site, sex, race/ethnicity, prematurity, medical complexity, food allergy, early-life severe bronchiolitis, utilization (outpatient, ED, inpatient).

111

Limitations acknowledged by the authors

- Misclassification of vaccine-associated aluminum exposure
- Multiple different forms of aluminum adjuvants
- Case misclassification of asthma diagnosis
- "As with any observational study…" **unmeasured confounding** could have influenced results
  - Fraction had info on breastfeeding
  - No info on second hand smoke, SES, maternal education, etc

112

Unmeasured Confounding

- What Do We Know About Causes of Asthma?
  - Second-hand smoke
  - Air pollution
  - Breastfeeding
  - Etc
- Is there reason to believe these may have been different in those with the highest exposure to aluminum compared to those with less exposure?
  - Hard to say, but there certainly could be!

113

Principles of Causality Assessment (WHO)

- Temporal relationship
- Strength of association
- Dose-response relationship
- Consistency of evidence
- Specificity
- Biologic plausibility

114

Bottom Line: Based on this study, should we be worried about vaccines and asthma?

- Was this study poorly done?
  - No, but did they have all the information to do this study properly? NO
  - Should the study have been done in the first place? IOM asked for it
- My conclusion: I really doubt it, but more studies are needed, and even if real, benefits would still outweigh risk

115