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**Viral Hepatitis Prevention Board
Meeting, Antwerp, Belgium**

**Hepatitis A prevention in
the USA depends on
routine universal
childhood vaccination -
The Lancet**

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Public Health



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CDC Decision Memorandum

“On **Jan 5, 2026**, the Acting Director of the US Centers for Disease Control and Prevention (CDC) signed a decision memorandum...which removed vaccines against meningococcal disease, influenza, COVID-19, **hepatitis A**, and **hepatitis B, including the birth dose**, as routinely recommended vaccines for all children.”



January 2026 – Childhood Immunization Schedule Change

- CDC cut the number of routinely recommended vaccines for children from 17 to 11
- The recommendations for the six diseases no longer routinely recommended were downgraded to **Shared Clinical Decision-Making (SCDM)**
- Decision based on a United States Health and Human Services (HHS) Assessment co-authored by two political appointees
 - HHS is the parent organization to the CDC



Five other Vaccines Recommended for Shared Clinical Decision Making

- **Hepatitis B**
- Rotavirus
- Meningococcal disease
- Influenza
- COVID-19



What is Shared Clinical- Decision Making? (United States)



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- An individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian.
- Often reserved for vaccines with weak or uncertain evidence among specific populations.
- U.S. Examples:
 - Meningococcal B (severe disease, low incidence, increased risk among college students in communal living situations, short vaccine duration of protection, limited population protection)
 - Hepatitis B (persons aged ≥ 60 years)



Why remove routine hepatitis A vaccine recommendations only 2-3 years after the end of 7 years of outbreaks?

- Three Reasons HHS Chose to Downgrade the hepatitis A recommendations:
 - 1) Low hepatitis A virus (HAV) incidence
 - 2) Safety - Concerns about how hepatitis A vaccine trials were conducted
 - 3) Peer Nations – Many other peer nations do not have a routine vaccination recommendation for protection against hepatitis A (e.g., Denmark)



Lancet Article

- Dr. John Ward and I refuted the US Department of Health and Human Services' claims against universal hepatitis A vaccination to support continued vaccination of all children to prevent hepatitis A among children and adults.

Viewpoint

Hepatitis A prevention in the USA depends on routine universal childhood vaccination

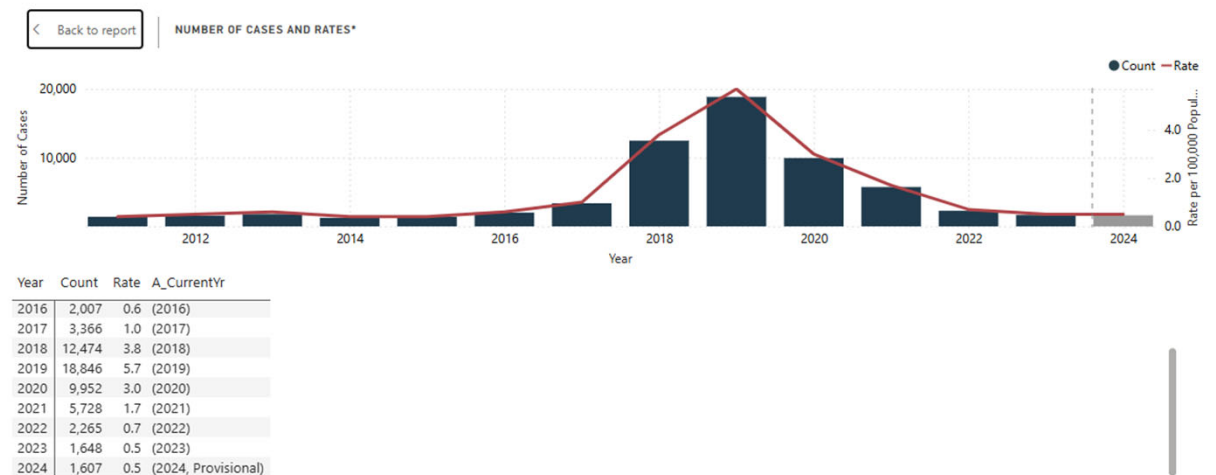


Noele P Nelson, John W Ward



Low Incidence – Result of Effective Vaccine Program

- Low hepatitis A incidence justifies continuing rather than discontinuing routine hepatitis A vaccination of children
- Low incidence is the result of an effective vaccine program





Low Incidence – Depends on High Vaccine Coverage

- Pediatric vaccination and low incidence eliminates a reservoir of hepatitis A virus transmission to adults
 - In 2024, hepatitis A vaccination 2-dose coverage among adolescents aged 13–17 years was 87%; increased to 89% in 2025
 - In 2024, hepatitis A vaccine coverage was 87% (1-dose) and 79% (2-dose) among children aged 12–35 months
 - **Important to continue this trajectory of increasing coverage among children; weakening recommendations is likely to reduce coverage**
- Sustaining low incidence of HAV among children reduces the risk of infection among susceptible adults (outbreaks)
 - In 2020, self-report vaccine coverage was <33% among adults ≥40 years

US Centers for Disease Control and Prevention. Vaccination coverage among adolescents (13–17 years). Aug 22, 2024. <https://www.cdc.gov/teenvaxview/interactive/index.html> (accessed Jan 24, 2026). Hill HA, Yankey D, Elam-Evans LD, et al. Vaccination Coverage by Age 24 Months Among Children Born in 2021 and 2022 - National Immunization Survey-Child, United States, 2022-2024. *MMWR Morb Mortal Wkly Rep*. 2026 Mar 26;75(11):146-155. doi: 10.15585/mmwr.mm7511a2. Hofmeister MG, Yin S, Nelson NP, Weng MK, Gupta N. Trends and opportunities: hepatitis A virus infection, seroprevalence, and vaccination coverage—United States, 1976–2020. *Public Health Rep* 2023; published online July 21. <https://doi.org/10.1177/00333549231184007>.



Low Incidence and Routine Recommendation – Maintains Equity

- Removing the routine recommendation would likely increase incidence while also reducing equity in hepatitis A virus protection.
 - Private insurance
 - In 2021–23, vaccine coverage (≥ 1 dose) was 89% among children by age 24 months
 - Uninsured
 - In 2021–23 vaccine coverage was 75% among uninsured children
 - This gap could widen without a routine recommendation



Safety - Placebo-controlled Trials

- HHS Assessment claimed that “...without a proper placebo-controlled randomized trial, reliable safety data is limited”.
- Prelicensure studies for hepatitis A vaccines were appropriately conducted placebo-controlled trials.
- No safety concerns or serious adverse events were identified in prelicensure studies or the US Food and Drug Administration regulatory review for hepatitis A vaccines used in the United States.



Safety – Placebo-controlled Trials

- Werzberger et al. study - double-blind, placebo-controlled trial
 - Each dose of placebo, like the vaccine, contained aluminum hydroxide diluent (300µg of aluminum and thimerosal at a 1:20,000 dilution).
 - Approach preserves blinding, while helping determine whether any adverse effects are due to the antigen or to other ingredients in the vaccine.
- Innis et al. study - double-blind, randomized controlled trial with a crossover design stratified by community
 - Control vaccine was recombinant hepatitis B vaccine, 10µg of hepatitis B surface antigen per 0.5-mL dose, produced by the same manufacturer as the intervention vaccine.
 - Approach advantageous because all eligible children enrolled in the study received both vaccines, and surveillance for infection and safety can continue after crossover

Innis BL, Snitbhan R, Kunasol P, et al. Protection against hepatitis A by an inactivated vaccine. *JAMA* 1994; **271**: 1328–34.

Werzberger A, Mensch B, Kuter B, et al. A controlled trial of a formalin-inactivated hepatitis A vaccine in healthy children. *N Engl J Med* 1992; **327**: 453–57.



Safety – Post-licensure Studies

- From 1995 to 2005, ~188 million doses of hepatitis A vaccines were sold worldwide, including 50 million doses in the United States.
- From 2006 to 2018, an assessment using the post-licensure national passive surveillance system, Vaccine Adverse Events Reporting System, no serious adverse events were found.
- In 2022, WHO concluded that “based on the cumulative global experience gained from the use of several hundred million doses, the overall safety profile of all inactivated hepatitis A vaccines administered to children (aged 1 year to <15 years) and adults has been excellent, irrespective of schedule and manufacturer”.

Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of hepatitis A virus infection in the United States: recommendations of the advisory committee on immunization practices, 2020. *MMWR Recomm Rep* 2020; **69**: 1–38.

Fiore AE, Wasley A, Bell BP, and the Advisory Committee on Immunization Practices. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2006; **55**: 1–23.

WHO. Hepatitis A vaccines: WHO position paper, October 2022. <https://www.who.int/publications/i/item/who-wer9740-493-512> (accessed Feb 8, 2026).



Peer Nations – One Size Doesn't Fit All

- HHS assessment noted the scarcity of peer nations with a routine childhood vaccine recommendation, with Greece being identified as the sole example.
 - We argued that nations (e.g., Israel, South Korea, Argentina, Cyprus) and others that could be considered “peer” recommend routine childhood vaccination for hepatitis A.
- HHS assessment proposed Denmark’s absence of a routine hepatitis A vaccination recommendation as a model for the United States
 - Did not account for differences across countries (e.g., epidemiology, population size and demographics, access to health care, economics, and other factors) that WHO recommends be considered when developing national vaccination guidelines.

WHO. Hepatitis A vaccines: WHO position paper, October 2022. <https://www.who.int/publications/i/item/who-wer9740-493-512> (accessed Feb 8, 2026).

WHO. Introduction of hepatitis A vaccine. <https://immunizationdata.who.int/global/wiise-detail-page/introductionof-hepatitis-a-vaccine> (accessed Jan 24, 2026).

European Centre for Disease Prevention and Control. Surveillance report: hepatitis A, annual epidemiological report for 2022.

February, 2024. https://www.ecdc.europa.eu/sites/default/files/documents/HEPA_AER_2022_Report.pdf (accessed March 1, 2026).



Peer Nations – Comparison to Europe

- Recent rates of hepatitis A in most European Union countries exceed the lowest rate achieved in the U.S. after universal hepatitis A vaccination (0.4 cases per 100 000 population).
- Rates are low in the U.S. due to routine vaccination
- As outbreaks persist in the European region, more countries may consider routine hepatitis A recommendations in the future



Conclusion

- Three decades of hepatitis A vaccination in the U.S. have firmly established the effectiveness, long-term immunity, and safety of the hepatitis A vaccine.
 - Removal of a routine recommendation will not sustain these gains in disease prevention.
- The loss of protection among unvaccinated children will increase the reservoir of hepatitis A virus in communities, leading to:
 - Widespread outbreaks
 - Associated costs and burden on public health and health-care professionals
 - Preventable morbidity and mortality among unvaccinated people



Conclusion

- In the U.S., continuation of routine vaccination of children remains prudent given the documented safety and effectiveness of hepatitis A vaccination, the high levels of global hepatitis A virus circulation, and the potential for large-scale outbreaks among unvaccinated cohorts.

Hofmeister MG, et al.. Epidemiology and control of widespread community hepatitis A outbreaks in 37 US States, 2016–2023. *J Viral Hepat* 2026; **33**: e70137.

Hofmeister MG, et al. Hepatitis A person-to person outbreaks: epidemiology, morbidity burden, and factors associated with hospitalization-multiple states, 2016–2019. *J Infect Dis* 2021; **223**: 426–34.

Hofmeister MG, et al. Trends and opportunities: hepatitis A virus infection, seroprevalence, and vaccination coverage—United States, 1976–2020. *Public Health Rep* 2023; published online July 21. <https://doi.org/10.1177/00333549231184007>.

WHO. Hepatitis A vaccines: WHO position paper, October 2022. <https://www.who.int/publications/i/item/who-wer9740-493-512> (accessed Feb 8, 2026).



What happened? – non-government schedule American Academy of Pediatrics (AAP) Schedule

AAP's 2026 immunization schedule keeps routine recommendations intact after overhaul of federal schedule

<https://publications.aap.org/aapnews/news/34141/AAP-s-2026-immunization-schedule-keeps-routine?autologincheck=redirected>

<https://downloads.aap.org/AAP/PDF/AAP-Immunization-Schedule.pdf>

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2026

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the outlined purple bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mos	2 mos	4 mos	6 mos	8 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 yrs	17–18 yrs
Respiratory syncytial virus (RSV-mAb [nirsevimab, clesrovimab])	1 dose during RSV season depending on maternal RSV vaccination status (See Notes)					1 dose nirsevimab during RSV season (See Notes)												
Hepatitis B (HepB)	1 st dose	2 nd dose				3 rd dose												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1 st dose	2 nd dose	See Notes													
Diphtheria, tetanus, and acellular pertussis (DTaP <7 yrs)			1 st dose	2 nd dose	3 rd dose				4 th dose				5 th dose					
Haemophilus influenzae type b (Hib)			1 st dose	2 nd dose	See Notes				3 rd or 4 th dose (See Notes)									
Pneumococcal conjugate (PCV15, PCV20)			1 st dose	2 nd dose	3 rd dose				4 th dose									
Inactivated poliovirus (IPV)			1 st dose	2 nd dose				3 rd dose					4 th dose					See Notes
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)						1 or more doses of 2025–2026 vaccine (See Notes)					1 or more doses of 2025–2026 vaccine (See Notes)							
Influenza						1 or 2 doses annually (See Notes)					1 dose annually (See Notes)							
Measles, mumps, and rubella (MMR)						See Notes		1 st dose					2 nd dose					
Varicella (VAR)								1 st dose					2 nd dose					
Hepatitis A (HepA)						See Notes		2-dose series (See Notes)										
Tetanus, diphtheria, and acellular pertussis (Tdap ≥7 yrs)															1 dose			
Human papillomavirus (HPV)															2-dose series	See Notes		
Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2 years)						See Notes									1 st dose		2 nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)																See Notes		
Respiratory syncytial virus vaccine (RSV [Abrysvo])																Seasonal administration during pregnancy if not previously vaccinated		
Dengue (DEN4CYD: 9–16 yrs)																Seropositive in areas with endemic dengue (See Notes)		
Mpox																		

Range of recommended ages for all children

Range of recommended ages for catch-up vaccination

Range of recommended ages for certain high-risk groups or populations

Recommended vaccination for those who desire protection

Recommended vaccination based on shared clinical decision-making

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Court Decision – AAP et al. v. Kennedy et al.

- U.S. District Judge Brian Murphy in Boston
 - Blocked the current 13 Advisory Committee on Immunization Practices (ACIP) appointees from continuing to serve in their positions and invalidated most votes they had previously taken
 - Preliminary ruling
- Ruling
 - Trump administration likely broke the law
 - CDC lacked authority to unilaterally change the immunization schedule in January without consulting ACIP
 - ACIP disregarded scientific methods
 - ACIP committee itself was unlawfully constituted and no longer complied with the Federal Advisory Committee Act's requirements for balance
 - "A committee of non-experts cannot be said to embody 'fairly balanced... points of view' within the relevant scientific community," Murphy wrote, citing the regulations governing advisory panels.

Federal health agencies failed to observe required procedures and acted arbitrarily and capriciously.



Executive Order: Delivering Gold Standard Childhood Vaccine Recommendations for Americans (8/10/2026)

- After a blocked attempt in January 2026, on August 10, 2026, Executive Order was issued
- Sec. 2. Recommendations for Childhood and Adolescent Vaccines. (a) Based on consultation with my advisors and review of available scientific evidence, it is hereby declared that the United States recognizes Gold Standard Childhood Vaccine Recommendations informed by the three distinct categories of childhood immunization recommendations identified in the scientific assessment, as specified below:
 - **Recommended (no change from 2025 ACIP schedule)**
 - (i) immunizations **recommended** for all children: measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B, pneumococcal disease, human papillomavirus, and varicella;
 - **Other vaccines recommended based on risk (perceived or disclosed) or shared clinical decision-making only (optional) [some changes from 2025 ACIP schedule]**
 - (ii) immunizations recommended for certain high-risk groups or populations: respiratory syncytial virus monoclonal antibodies, **hepatitis A, hepatitis B**, meningococcal B, meningococcal ACWY, and dengue; and
 - (iii) immunizations based on **shared clinical decision-making: hepatitis A, hepatitis B**, rotavirus, meningococcal disease, influenza, and COVID-19

Decision Memo. Adopting Revised Childhood and Adolescent Immunization Schedule. <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf>. Accessed January 24, 2026.
<https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans/>



Disruption in Vaccine Policy

- What is not happening?
 - No measles outbreak updates at the ACIP meetings
 - No recent presentations at ACIP on new post-licensure safety and effectiveness data
 - No discussion at ACIP of new vaccine recommendations
 - Preparations (delayed) for the current respiratory season (flu, RSV, COVID)
- What's at stake?
 - Loss of vaccine confidence; increased vaccine hesitancy
 - Health care personnel and public confusion
 - Loss of trust in vaccine policy among the public and global public health community
 - Threat of increases in vaccine preventable diseases due to decreasing vaccine uptake, and decreasing vaccine coverage
 - Numerous states considering legal changes that would relax vaccine requirements for school enrollment (e.g., non-medical exemptions)
 - Insurance coverage of vaccines uncertain for the future



Current Status

- Continue to follow AAP vaccine schedule
- Lack of U.S. authority for making vaccine recommendations
 - For how long?
- Continued uncertainty and disruption in U.S. vaccine policy



Thank you!

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