“Business as usual”:

Reinforcing Wisconsin’s commitment to evidence-based vaccine practices

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Ryan Westergaard, MD PHD
Infectious Disease Physician & Public Health Leader
May 14,2026

“Business as Usual”

(Not Really)

- What is unusual about the present moment?
- How are vaccine recommendations developed?
- Why transparent evidence review matters?
- Why (and how) Wisconsin remains committed to evidence-based immunization practices

Source:

Timeline of vaccine policy disruption

November 2024	President-elect Donald Trump announces Robert F. Kennedy Jr. as nominee for Secretary of Health & Human Services
February 20, 2025	Scheduled ACIP meeting postponed
June 9, 2025	Removal of all 17 ACIP Members
June 25-26, 2025	First meeting of newly constituted ACIP (8 new members)
September 18-19, 2025	New ACIP membership announced ahead of major policy votes → Modified COVID recommendations (“individual decision making”)
December 5, 2025	ACIP ended universal recommendation for hepatitis B vaccine birth dose (CDC adopted 12/16/25)

Timeline of vaccine policy disruption (cont.)

January 5, 2026	"Decision Memorandum" signed by Acting CDC Director Jim O'Neill following a presidential directive to review "international best practices" → Shifted from universal recommendations against 17 diseases to 11 → Affected influenza, HAV, HBV, rotavirus, Men A/B, RSV
January 19, 2026	Major medical associations file suit against HHS in federal court
March 16, 2026	Federal Judge issues preliminary injunction blocking ACIP membeship reconstitution and blocking overhaul of childhood schedule → Cited concern regarding procedural and advisory committee requirements → March 18-19 ACIP Meeting Canceled
April-May 2026	HHS rewrites ACIP charter US clinicians facing ongoing uncertainty Next ACIP meeting scheduled for June 24-26, 2026

What has *not changed?*

- Biology of measles = unchanged
- Vaccine safety data = unchanged
- Burden of vaccine-preventable disease = unchanged (now increasing)
- Pediatric infectious disease principles & practice = unchanged

The Trust Equation

$$T = \frac{C + R + I}{S}$$

T — Trustworthiness

C — Credibility

R — Reliability

I — Intimacy

S — Self-Orientation

Trust does not come from authority alone

Evidence → Review → Deliberation → Recommendation

VIEWPOINT

Advisory Committee on Immunization Practices Standards for Assessing Evidence

Doug Campos-Outcalt, MD, MPA; Jonathan Temte, MD, PhD

2008–2011: Institute of Medicine identifies widespread lack of systematic evidence review in guidelines

2011: IOM publishes *Clinical Practice Guidelines We Can Trust*, defining standards for rigor and transparency

2010: Advisory Committee on Immunization Practices adopts a modified GRADE approach aligned with IOM standards (Grading of Recommendations, Assessment, Development and Evaluation)

2010–2019: Systematic evidence tables and public documentation become routine for ACIP decisions

2019: ACIP adds Evidence-to-Recommendation (EtR) framework, incorporating equity, feasibility, values

Post-2019: IOM standards widely recognized as standard for credible, trustworthy recommendations

ANALYSIS

RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide

- Developed by a group of international guideline developers
- Clear separation between **quality** of evidence and **strength** of recommendations
- Explicit evaluation of the importance of outcomes of alternative management strategies
- Explicit criteria for downgrading and quality of evidence ratings
- Transparent process of moving from **evidence to recommendations**
- Clear, pragmatic interpretation of **strong vs. weak** recommendations
- Explicit acknowledgment of **values** and **preferences** for clinicians, patients, and policy makers

BMJ | 26 April 2008 | Vol 336

"I figure there's a 40% chance of showers, and a 10% chance we know what we're talking about."

GRADE – Core Concepts

1. Quality (certainty) of evidence

How confident are we that the estimated effect is true?

Factors that LOWER certainty of evidence

- Risk of bias
- Inconsistency
- Indirectness
- Impresicion
- Publication bias

Quality rated as:

- **High**
- **Moderate**
- **Low**
- **Very low**

GRADE – Core Concepts (cont.)

2. Strength of recommendation

Should clinicians/policymakers recommend the intervention?

Decisions to recommend depend on:

- Evidence certainty
- Benefits vs. harms
- Values/preferences
- Feasibility/resources

Strong recommendations can occasionally emerge from imperfect evidence if benefits clearly outweigh harms.

GRADE – Summary

- Systematic method for evaluating evidence quality
- Makes uncertainty explicit
- Disciplines experts from overstating conclusions

ELSEVIER
CrossMark
Journal of Clinical Epidemiology 76 (2016) 89–98
Journal of Clinical Epidemiology

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SERIES: GRADING OF RECOMMENDATIONS ASSESSMENT, DEVELOPMENT AND EVALUATION (GRADE)

GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health

Holger J. Schünemann[a,b,c,*], Reem Mustafa[a,c,d], Jan Brozek[a,b,c], Nancy Santesso[a,c], Pablo Alonso-Coello[a,c,e], Gordon Guyatt[a,b,c], Rob Scholten[f], Miranda Langendam[c,g], Mariska M. Leeflang[g], Elie A. Akl[a,c,h], Jasvinder A. Singh[c,i], Joerg Meerpohl[c,j], Monica Hultcrantz[k], Patrick Bossuyt[g], Andrew D. Oxman[l], GRADE Working Group

GRADE asks: “What does the evidence show?”

EtR asks: “Given the evidence, what should we recommend?”

Domains that influence evidence-based decision making

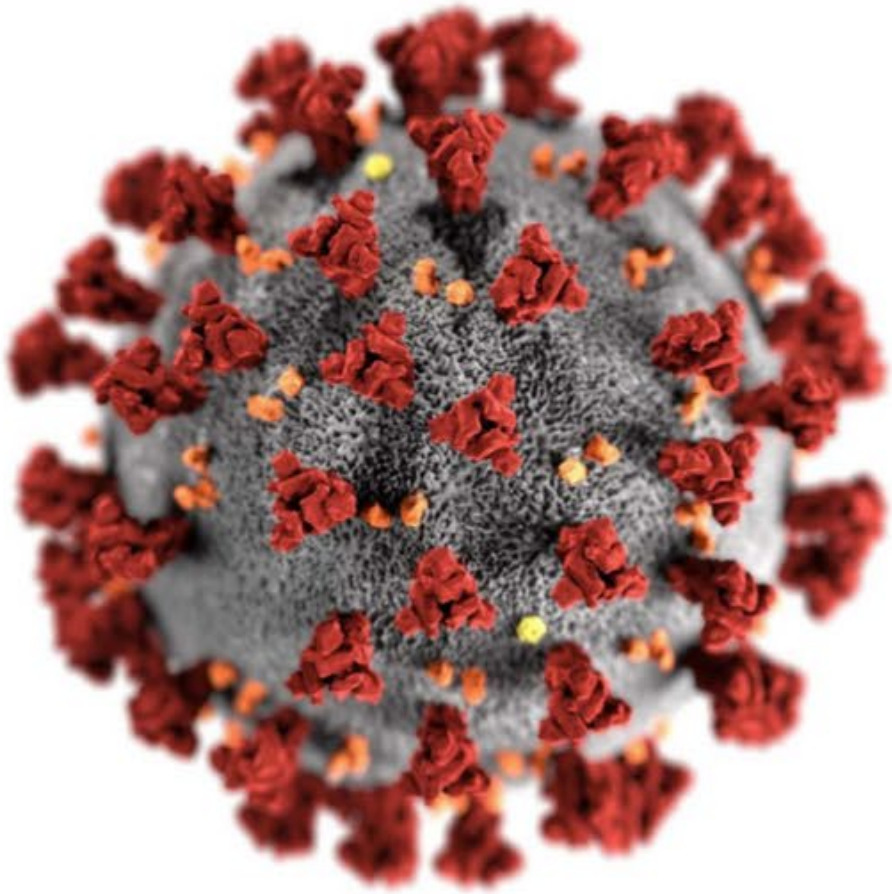
Milbank Q 2009;87(2):368-90

What does an EtR framework ask?

EtR Domain	Key Question
Public Health Problem	Is the disease an important public health problem?
Benefits & Harms	Do the desirable effects outweigh the undesirable effects?
Certainty of Evidence	What is the overall certainty of the evidence?
Values	Is there important uncertainty about how people value the outcomes?
Acceptability	Is the intervention acceptable to key stakeholders?
Resource Use	Is the intervention a reasonable and efficient use of resources?
Equity	“Would vulnerable groups be left behind?”
Feasibility	Is the intervention feasible to implement?

GRADE & EtR in Action

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer BioNTech COVID-19 Vaccine



Dr. Julia Gargano

ACIP Meeting

11 December 2020

CONFIDENTIAL DRAFT

Policy Question

- Should vaccination with Pfizer BioNTech COVID-19 vaccine (2-doses, IM) be recommended for persons 16 years of age and older under an emergency use authorization?

PICO Question

Population	Persons aged ≥16 years
Intervention	Pfizer-BioNTech COVID-19 vaccine BNT162b2 (30 µg, 2 doses IM, 21 days apart)
Comparison	No vaccine
Outcomes	Symptomatic lab-confirmed COVID-19 Hospitalization due to COVID-19 All-cause death SARS-CoV-2 seroconversion to a non-spike protein Asymptomatic SARS-CoV-2 infection Serious Adverse Events Reactogenicity

GRADE Criteria

- **Initial evidence type** (certainty level) determined by study design
  - Initial evidence type 1 (high certainty): A body of evidence from randomized controlled trials
  - Initial evidence type 3 (low certainty): A body of evidence from observational studies
- **Risk of bias:** Can include failure to conceal allocation, failure to blind, loss to follow-up. Risk of bias may vary across outcomes.
- **Inconsistency:** Criteria for evaluating include similarity of point estimates, extent of overlap of confidence intervals, and statistical criteria including tests of heterogeneity and I^2.
- **Indirectness:** Considers the generalizability of the evidence to the original PICO components (e.g., patients, intervention, comparison, or outcomes differ from those of interest[1]).
- **Imprecision:** Considers the fragility of the relative and absolute effect measures based on the interpretation of the 95% CIs and the optimal information size.
- **Other considerations:** Includes publication bias or indications of dose-response gradient, large or very large magnitude of effect, and opposing residual confounding.

Guyatt GH, Oxman AD, Kunz R et al. GRADE guidelines: 8. Rating the quality of evidence--indirectness. *J Clin Epidemiol.* 2011. DOI:10.1016/j.jclinepi.2011.04.014

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Symptomatic lab-confirmed COVID-19	Critical	RCT (1)	Pfizer-BioNTech COVID-19 vaccine is effective in preventing symptomatic COVID-19	**1**
Hospitalization due to COVID-19	Critical	RCT (1)	Pfizer-BioNTech COVID-19 vaccine may prevent COVID-19-resulting in hospitalization, but the uncertainty is high because this is a rare outcome	**3**
All-cause Death	Important	RCT (1)	Pfizer-BioNTech COVID-19 vaccine may prevent death, but the uncertainty is high because this is a rare outcome	**4**
SARS-CoV-2 seroconversion	Important	No studies	Data not yet available from any studies	**ND**
Asymptomatic SARS-CoV-2 infection	Important	No studies	Data not available from any studies	**ND**
Harms				
Serious adverse events	Critical	RCT (2)	SAEs were balanced between vaccine and placebo arms. Two SAEs were judged to be related to vaccination.	**2**
Reactogenicity	Important	RCT (2)	Severe reactions were more common in vaccinated; any grade ≥3 reaction was reported by 8.8% of vaccinated vs. 2.1% of placebo group	**1**

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND, no data

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

Sara E. Oliver, MD[1]; Julia W. Gargano, PhD[1]; Mona Marin, MD[1]; Megan Wallace, DrPH[1,2]; Kathryn G. Curran, PhD[1]; Mary Chamberland, MD[1,3]; Nancy McClung, PhD[1]; Doug Campos-Outcalt, MD[4]; Rebecca L. Morgan, PhD[5]; Sarah Mbaeyi, MD[1]; José R. Romero, MD[6]; H. Keipp Talbot, MD[7]; Grace M. Lee, MD[8]; Beth P. Bell, MD[9]; Kathleen Dooling, MD[1]

Summary

What is already known about this topic?

On December 11, 2020, the Food and Drug Administration issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine.

What is added by this report?

On December 12, 2020, after an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19.

What are the implications for public health practice?

The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines.

infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients. Among vaccine recipients, reactogenicity symptoms, defined as solicited local injection site or systemic reactions during the 7 days after vaccination, were frequent and mostly mild to moderate. Systemic adverse

Evidence-based vaccine recommendations:

→ Necessary but insufficient

Annual child and adolescent vaccination data

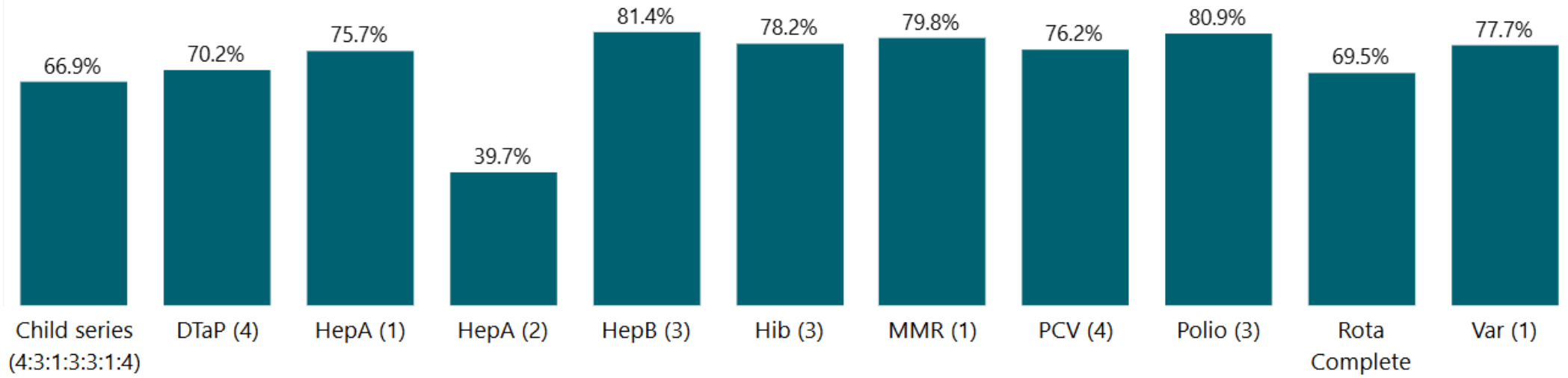
Vaccination Coverage of Wisconsin Children by 24 Months of Age

Updated: 03/09/2026

View child data

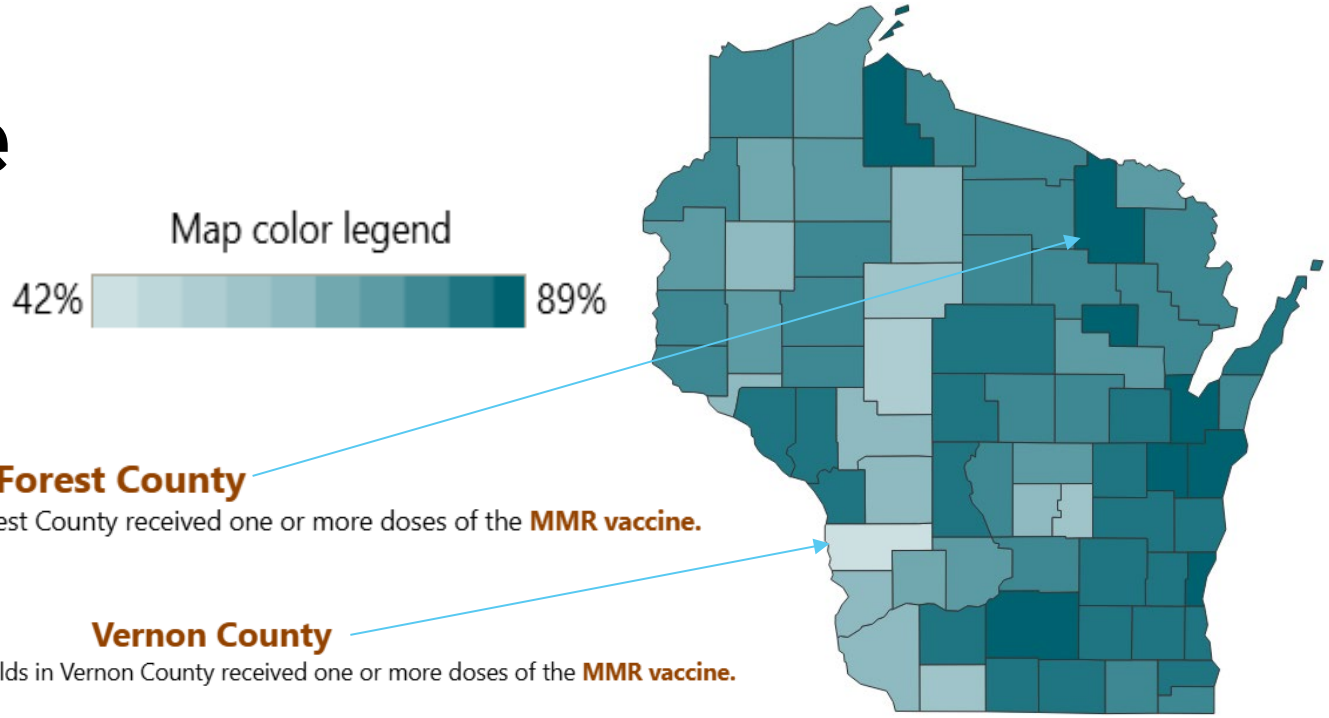
View adolescent data

Coverage Rates of Wisconsin 24-month olds, 2025



https://www.dhs.wisconsin.gov/immunization/child-adolescent-vaccine-data.htm

MMR Coverage



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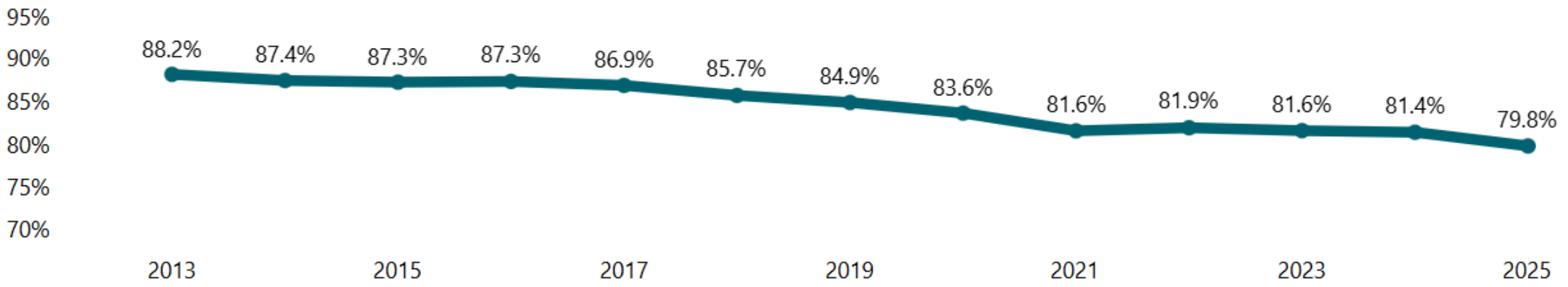
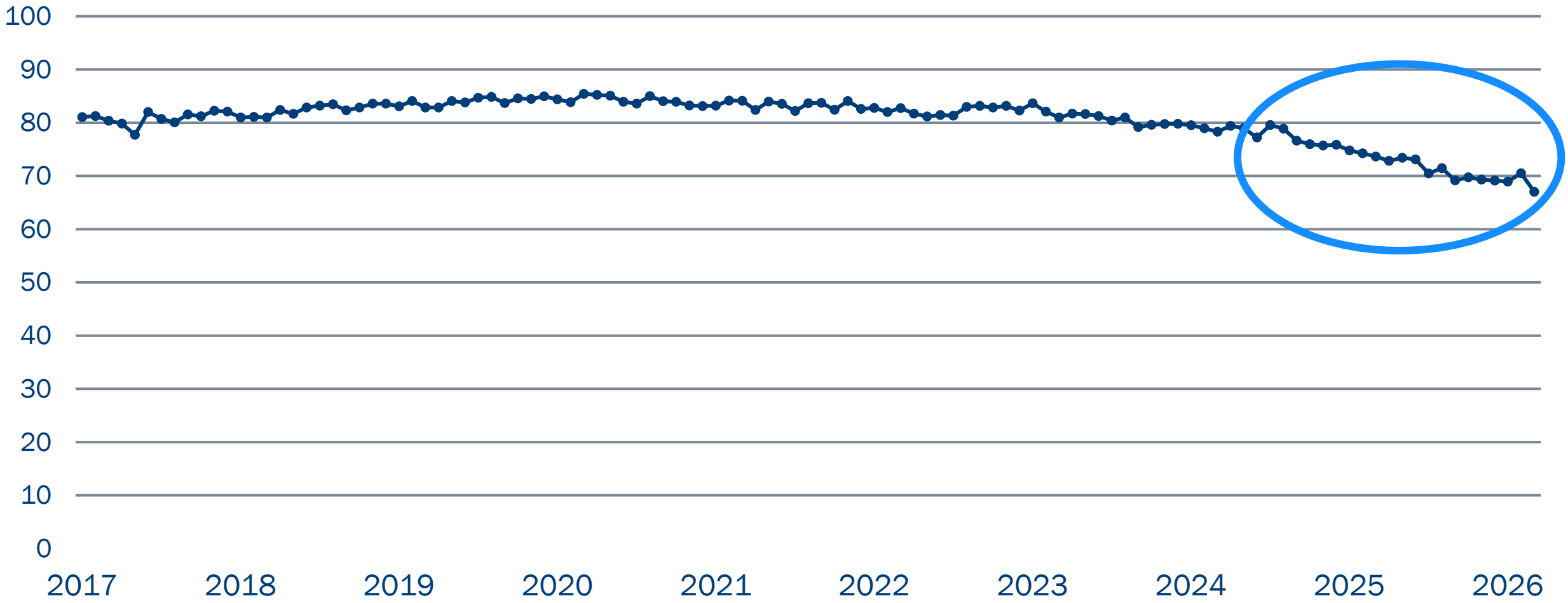
Trends in the percent of Wisconsin 24-month olds who received one or more doses of the MMR vaccine

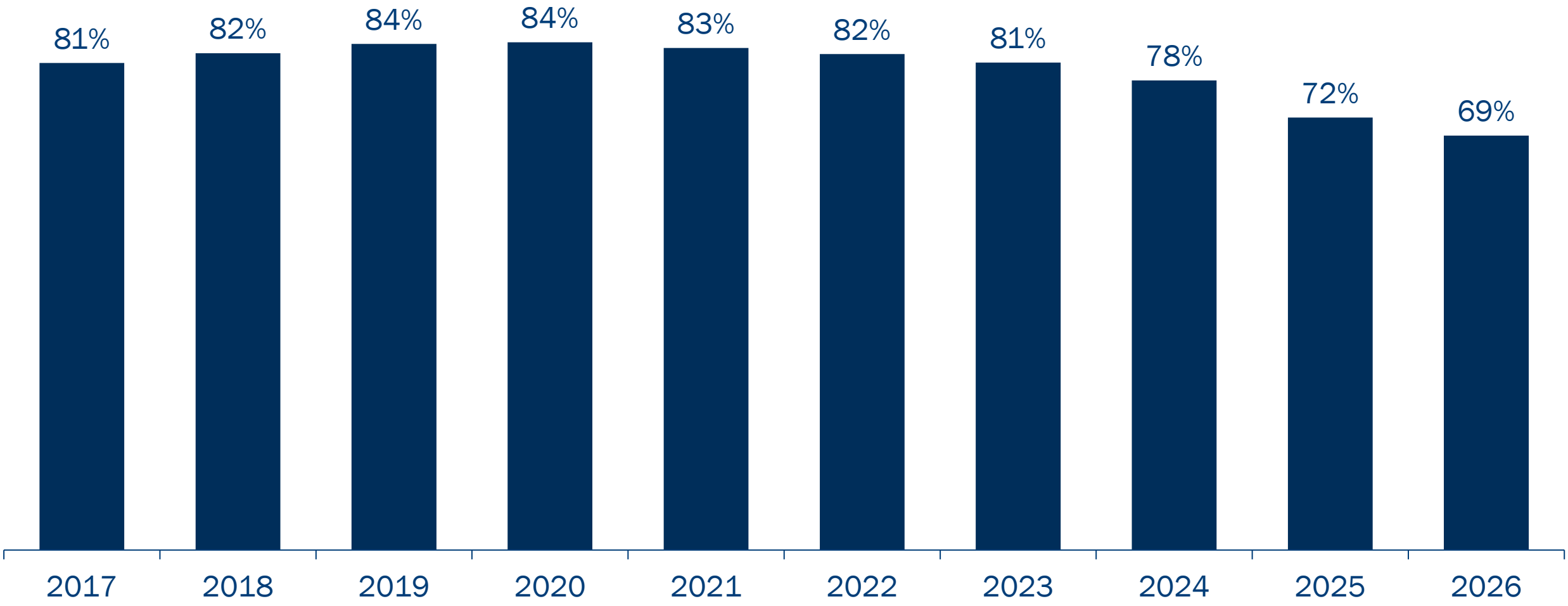


Percent of Infants That Received a Birth Dose of the Hepatitis B Vaccine by Month



Notes: Data is only for children born in Wisconsin who were over 2,000 grams at birth according to Vital Records. A birth dose of Hepatitis B is defined as a dose given within 3 days of birth.

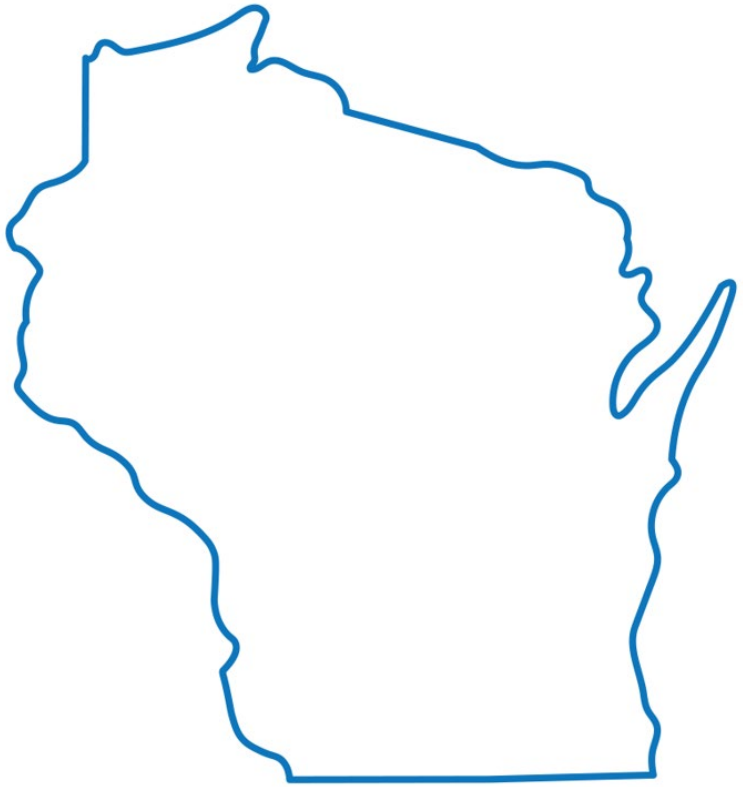
Percent of Infants That Received a Birth Dose of the Hepatitis B Vaccine by Year



Notes: Data is only for children born in Wisconsin who were over 2,000 grams at birth according to Vital Records. A birth dose of Hepatitis B is defined as a dose given within 3 days of birth.

Wisconsin DHS Remains Committed to Evidence-based Vaccine Recommendations

Wisconsin Guidance



STATE OF WISCONSIN
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1 West Wilson Street
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Madison WI 53701-2659

Telephone: 608-267-9003
Fax: 608-261-4976
TTY: 888-701-1253

Date: December 11, 2025

BCD 2025-05

To: Wisconsin Vaccinators

From: Ryan Westergaard, MD, Ph.D. Chief Medical Officer and State Epidemiologist for Communicable Disease

Hepatitis B Vaccine Recommendations

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Summary

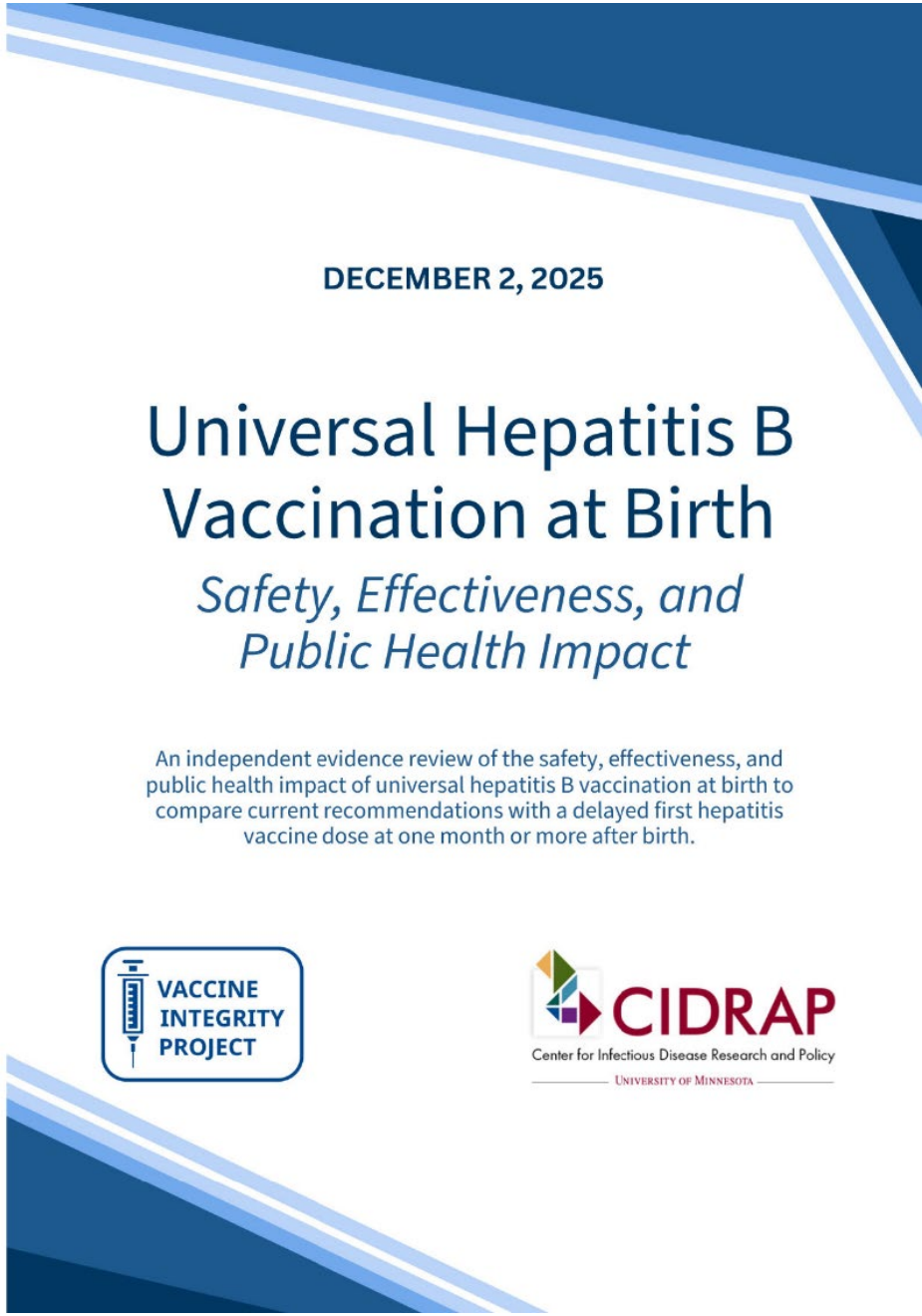
- The Wisconsin Department of Health Services (DHS) continues to recommend routine administration of the hepatitis B vaccine within 24 hours after birth for all newborns and the full 3-dose vaccine series for all children by 18 months.
- Serologic testing has no demonstrated role for guiding the schedule of doses in children born to hepatitis B–negative mothers, and is not recommended.
- No new clinical data, on either safety or effectiveness, were presented at the recent CDC ACIP meeting that would justify changes to this longstanding and successful public health practice. Wisconsin recommendations align with the American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule.

https://www.dhs.wisconsin.gov/dph/memos/communicable-diseases/bcd-2025-05.pdf

Evidence to Support Universal Vaccination

- An independent analysis conducted in late 2025 of more than 400 studies continues t support routine vaccination of all infants at birth.
- Professional organizations, like the American Academy of Pediatrics (AAP), continue to recommend the universal birth

Removal of hepatitis B vaccine birth dose will increase the incidence of childhood chronic illness at a rate of approximately 18,000 cases per year in the U.S.



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Date: January 8, 2026

Enter Memo No.
BCD 2026-01

To: Wisconsin Vaccinators

From: Ryan Westergaard, MD, Ph.D. Chief Medical Officer and State Epidemiologist for Communicable Disease

Routine Childhood Vaccine Schedule Recommendations

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Summary

- The federal government issued a modified childhood vaccine schedule on January 5, 2026. No new clinical data on either safety or effectiveness were presented that would justify these changes.
- The Wisconsin Department of Health Services (DHS) stands by our current clinical guidance regarding vaccines in Wisconsin, and will not be making any changes to Wisconsin's school or child care recommendations.
- DHS recommends that clinicians refer to the standard immunization schedule published by the American Academy of Pediatrics (AAP) when consulting with parents and caregivers regarding childhood vaccines.
- DHS will continue to monitor national guidance and emerging evidence, and communicate any future updates to providers, health systems, and the public.

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HEALTH CARE

Wisconsin rejects CDC vaccine changes, recommends guidance from pediatrics group

BY: **ERIK GUNN** - JANUARY 8, 2026 12:37 PM

HEALTH, NEWS

Wisconsin reaffirms support of hepatitis B vaccine for newborns, defying federal advisers

CDC advisory committee voted last week to end recommendation of a universal birth dose. But state health officials are directing Wisconsin doctors to carry on with the 30-year standard of care.

BY HOPE KIRWAN • DECEMBER 11, 2025

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PRESS RELEASE

DHS Continues to Endorse Childhood Vaccine Recommendations of American Academy of Pediatrics

No changes will be made to vaccine recommendations that protect the health of Wisconsinites from preventable diseases, following best available scientific and safety data

By Wisconsin Department of Health Services - Jan 8th, 2026 11:01 am

HEALTH, NEWS

DHS: Wisconsin kids should continue to get recommended vaccines despite federal change

State Department of Health Services backs current childhood vaccine schedule, rejecting Trump administration move to reduce recommended shots

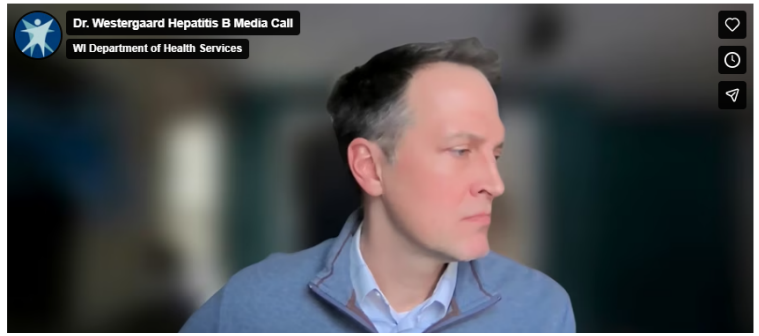
BY HOPE KIRWAN • JANUARY 8, 2026 • UPDATED JANUARY 8, 2026 at 3:52 PM

Wisconsin Radio Network

HOME | WRN DEEP DIVES

Despite a change from a federal advisory panel, Wisconsin health officials recommend all newborns should be **vaccinated against hepatitis B**.

"DHS continues to recommend that all newborns receive the Hepatitis B vaccine within 24 hours of birth, and then go on to complete the standard three dose series within the first 18 months of life," said Dr. Ryan Westergaard, chief medical officer in the Department of Health Services Bureau of Communicable Diseases. "This recommendation is grounded in decades of research showing that the vaccine is safe and effective, and it aligns with guidance of the American Academy of Pediatrics and other leading medical groups."



Wisconsin DHS vaccine schedule Watch >

HEALTH

Dr. Ryan Westergaard on hepatitis B vaccination for newborns

Wisconsin Department of Health Services state epidemiologist Dr. Ryan Westergaard describes continuing guidance to vaccinate newborns for hepatitis B after a federal panel changed its recommendations.

By FREDERICA FREYBERG | Here & Now
December 12, 2025

Wisconsin Health Leaders Affirm Childhood Immunization as Standard of Care

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Organizations represented reconfirmed their commitment to:

- Recommend routine childhood vaccines according to the AAP schedule;
- Engage in open, respectful conversations with families; and
- Support timely vaccination to protect children and communities.

ACP Wisconsin Chapter
American College of Physicians
Children's Wisconsin
Kids deserve the best.
Froedtert & Medical College of Wisconsin
+Health Connections
IMMUNIZE WISCONSIN
Pharmacy Society of Wisconsin
RWHC
Your partner. Your source.
ThedaCare
UWHealth
School of Medicine and Public Health
University of Wisconsin-Madison
WAFP
Wisconsin Academy of Family Physicians
WALHDAB
Public Health In Action
Wisconsin Chapter
American Academy of Pediatrics
Dedicated to the health of all children
Wisconsin Department of Health Services
Wisconsin Medical Society
WPHCA
Wisconsin Primary Health Care Association
WphA
Wisconsin Public Health Association

Summary

- Trustworthy vaccine policy depends on rigorous and transparent evidence review.
- GRADE and EtR frameworks were developed to make vaccine recommendations more systematic, reproducible, and accountable.
- Evidence-based recommendations only protect communities when they are trusted, implemented, and maintained at high uptake.
- Wisconsin remains committed to evidence-based immunization practices and protecting communities from vaccine-preventable diseases.

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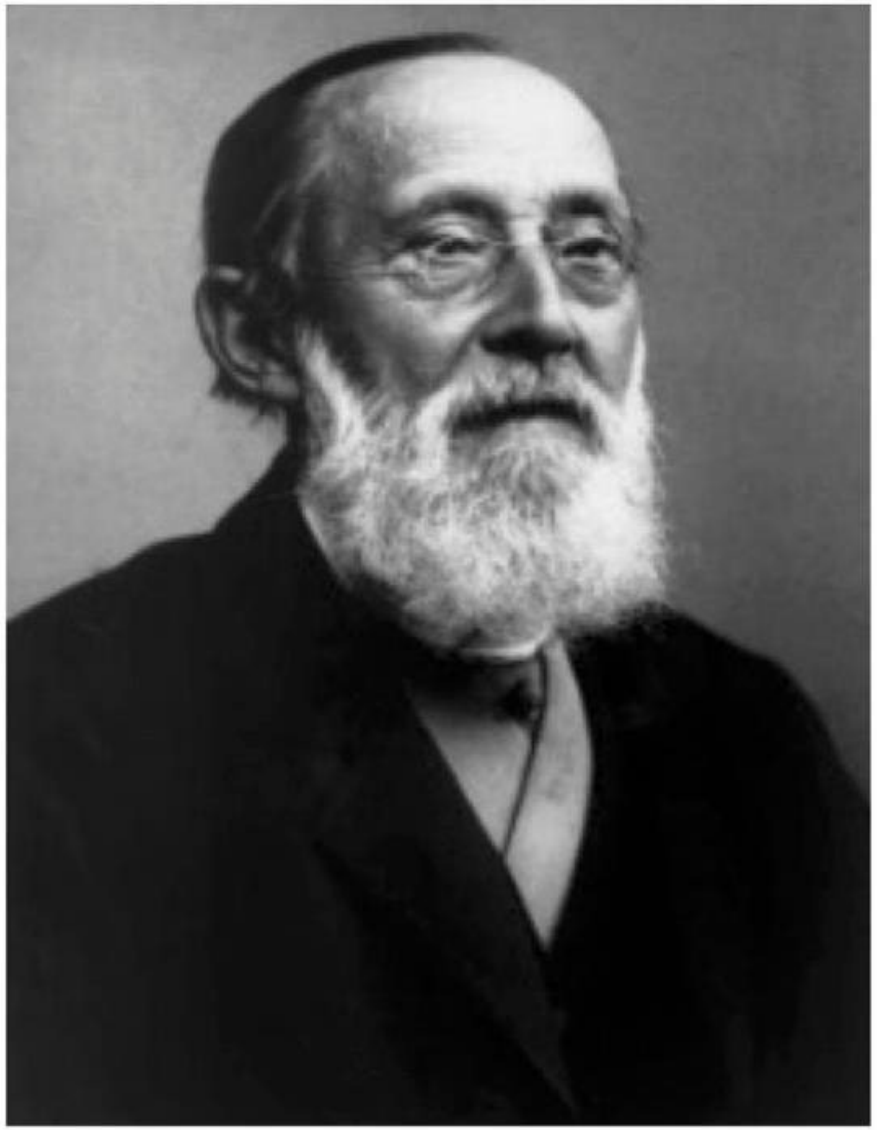
“ Medicine is a social science and politics is nothing else but medicine on a large scale.

Rudolf Virchow



QUESTIONS?