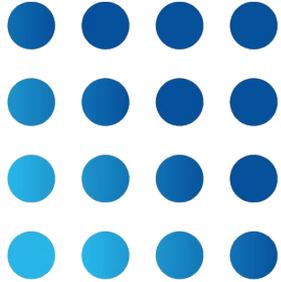


Vaccine Integrity Project Updates and Discussion

December 18, 2025



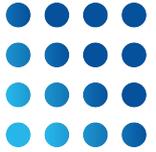


VACCINE INTEGRITY PROJECT

Background

Launched in April 2025, CIDRAP's Vaccine Integrity Project is dedicated to safeguarding vaccine use in the U.S. so that it remains grounded in the best available evidence.

To date, the Vaccine Integrity Project is supported by an unrestricted gift from Alumbra, a foundation established by philanthropist Christy Walton.



The Vaccine Integrity Project

Providing trusted, science-based information to empower individuals, families, communities, and clinicians to make informed vaccine choices.

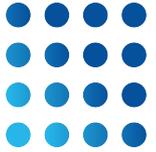
- **Focus:** Scientific evidence available to evaluate the safety and effectiveness of current (and new) immunizations
- **Purpose:** Communicate, both proactively and reactively, available evidence around immunizations and vaccine preventable diseases
- **Audience:** healthcare providers, professional medical societies, health systems, public health, insurers/payors, media, policy makers, and the public at large



Exploratory Phase

- 8 sessions conducted in May; total of 66 participants*
- Session questions focused on:
 - what activities can be done outside USG; prioritization
 - what should be the triggers to initiative activities
 - what are the benefits and risks of implementing the activities
- Additionally, more than 15 one-on-one conversations during May
- Data collection throughout May led to [Interim](#) findings published in June; [final](#) report published in July

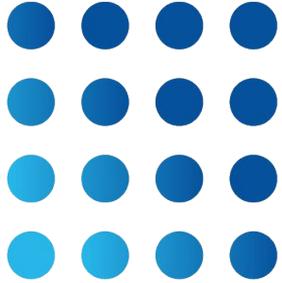
*Sectors included PH associations, academics, Pharma, payers, medical associations, state health officers, etc.



Opportunities for Action:

What we heard from the community

- Strengthening communication and improving information dissemination for today's environment
- Developing and disseminating clinical tools and guidelines
- Building an overarching coalition for strategy and alignment
- Maintaining the nation's vaccine infrastructure
- Stabilizing the vaccine safety system
- Providing assistance to state and local health departments
- Safeguarding insurance coverage
- Continuing the flow of data for decision-making



**VACCINE
INTEGRITY
PROJECT**

2025-2026

**Respiratory Virus
Evidence Review**



End Products

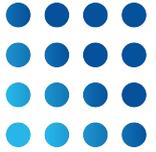
- [Webinar](#) held to share findings in August
- [Manuscript](#) and [executive summary](#) posted in October
- [Interactive tool](#) and data access launched in October
- [Viewpoints](#) posted between May and October, along with numerous OpEds
- Continued collaboration with medical societies, public health groups, etc.



Key Findings

Vaccines continue to deliver strong protection, and serious adverse safety events remain rare: A review of **511 recent studies** shows that COVID-19, RSV, and flu vaccines continue to **reduce hospitalizations and severe illness** across all age groups, with **safety findings consistent with previous reviews.**

Vaccination during pregnancy protects both mother and baby: Studies show that vaccination in pregnancy is **safe** and provides important protection, helping to **reduce preterm births** (for COVID-19) and **lower the risk of RSV hospitalization in infants.**



Key Findings

Kids benefit from strong and reliable protection: Immunizations continue to **keep children out of the hospital** for COVID-19, RSV, and flu. In countries where **nirsevimab** was introduced, **RSV hospitalizations among infants under six months dropped sharply**. Vaccine-related heart inflammation in teens remains **rare** and occurs **far less often** when doses are spaced farther apart.

Older adults and people with weakened immune systems also see real benefits: Updated COVID-19 vaccines cut adult hospitalizations by about **50%**, and **RSV vaccines** for adults 60 and older have led to **significant drops in hospital stays**. **High-dose and adjuvanted flu vaccines** remain the most effective options for seniors, with a strong record of safety.

Data Visualization Tool

Filter by virus, population, study design, and risk of bias ranking

Export datasets as CSV or Excel formats

CIDRAP

VACCINE INTEGRITY PROJECT

Landing page **Studies** Meta-analysis

	COVID	RSV	Influenza
Pregnancy	12	7	9
Pediatrics	121	31	71
Adults	258	30	108
Immunocomp.	30	7	17

Search: _____

article	virus	population	journal	Risk of bias	pmid
Otsuki 2024	RSV	Pediatrics	Vaccine	Low	38853036
Otsuki 2024	RSV	Pregnancy	Vaccine	Low	38853036
Simoes 2025	RSV	Pregnancy	Obstet Gynecol	Low	39746212
Fell 2024	Influenza	Pediatrics	J Infect Dis	Low	39052720

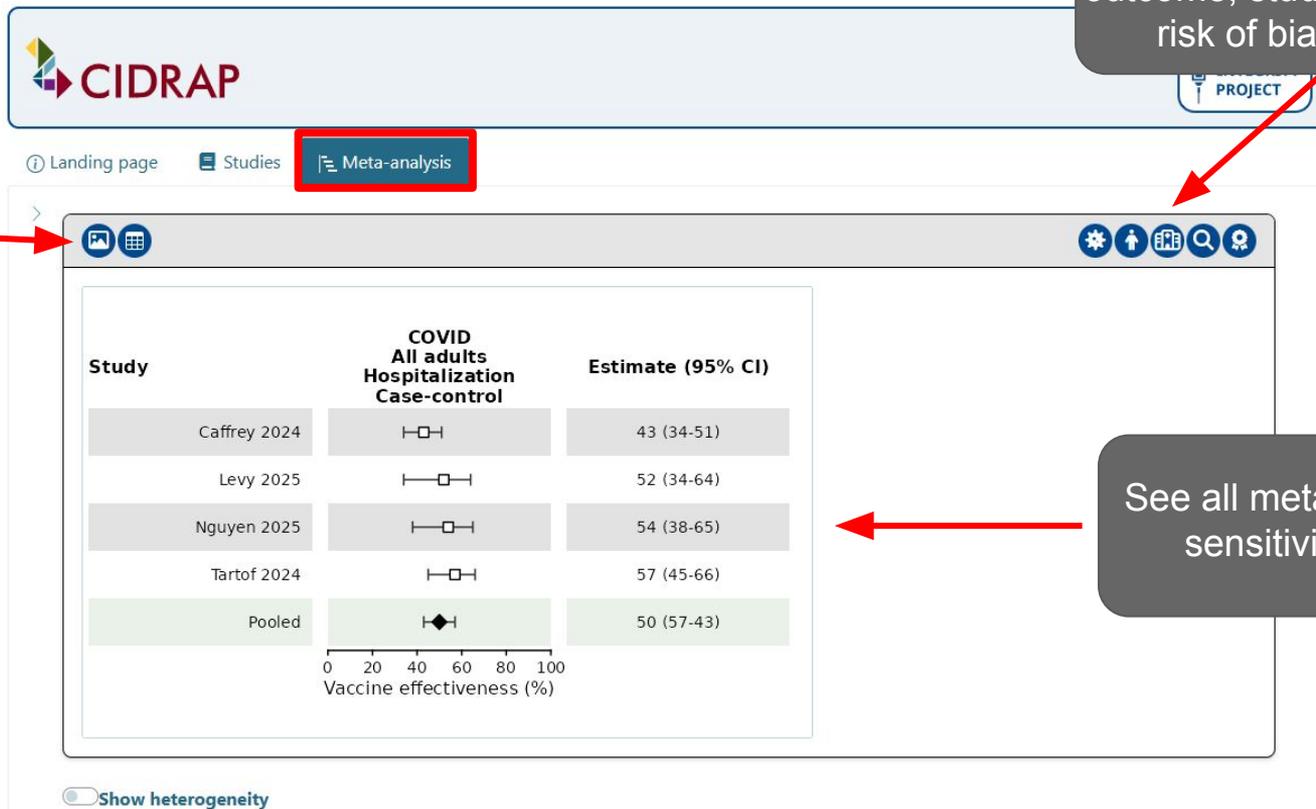
This heat map displays a summary overview of the domains of included studies

Individual studies are linked here with additional detail

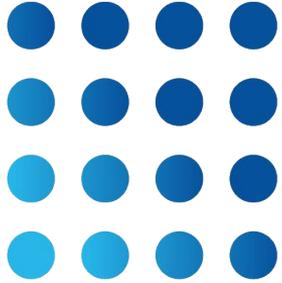
Data Visualization Tool

Generate forest plots and summary tables, available for download

Filter by virus, population, outcome, study design, and risk of bias ranking



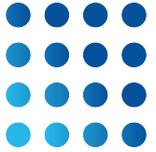
See all meta-analyses and sensitivity analyses



**VACCINE
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PROJECT**

Hep B Birth Dose Evidence Review

Hep B Birth Dose Evidence Review



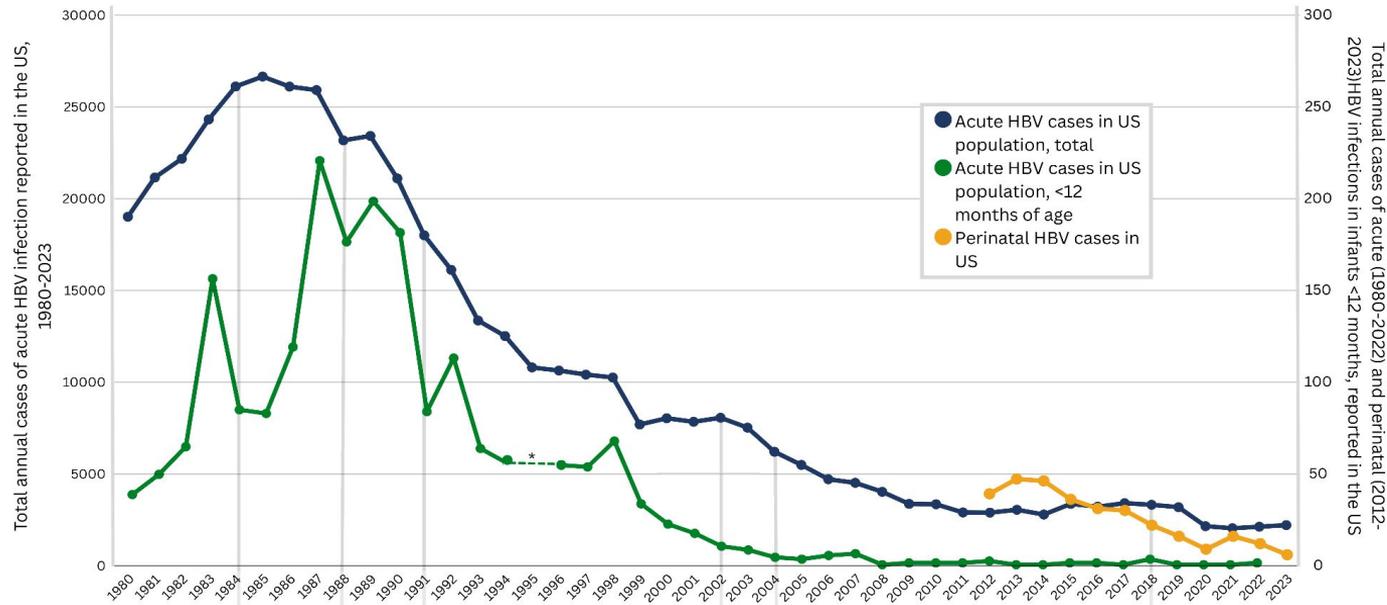
Introduction

- In place since 1991, universal hepatitis B vaccination for all medically stable newborns at birth are critical safety nets prevent pediatric HBV transmission and eliminate hepatitis B nationwide.
- Without prophylaxis at birth, approximately **90%** of newborns infected perinatally will develop chronic hepatitis B infection, and **25%** of those with chronic infection will die prematurely from chronic liver disease.
- The Vaccine Integrity Project conducted an independent review of the evidence and compared current recommendations with delayed administration of the first hepatitis B vaccine dose.

Hep B Birth Dose Evidence Review



Reported number of acute hepatitis B cases in the United States by year, 1980-2023 and related policy milestones



A series of evidence-based adjustments to policies and recommendations for universal maternal HBsAg screening and hepatitis B vaccination within 24 hours of birth resulted in a **99% decline in pediatric HBV infections since the early 1990s.**

- 1984**
ACIP recommends testing high-risk pregnant women for HBsAg; infants of positive mothers should receive HepB vaccine + HBIG.
- 1988**
ACIP recommends universal HBsAg screening for all pregnant women.
- 1991**
ACIP recommends universal HepB vaccine birth dose for all infants.
- 2002**
ACIP establishes a preference for HepB vaccination within 24 hours of birth.
- 2004**
USPSTF reviews HBV screening in pregnancy finding that benefits outweigh harms.
- 2018**
ACIP recommends universal HepB vaccination for all infants ≥2000 g within 24 hours of birth.

ACIP = Advisory Committee on Immunization Practices; HBV = hepatitis B virus; HBsAg = hepatitis B surface antigen

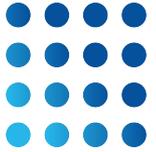
Hep B Birth Dose Evidence Review

Safety and effectiveness of the hepatitis B birth dose



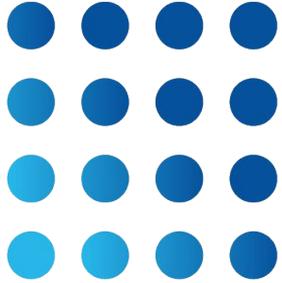
- RCTs, case series using routine safety monitoring systems, and large cohort studies have consistently demonstrated that hepatitis B vaccine administered at birth is safe.
- No increased incidence of vaccine-related serious or long-term adverse events. Predominantly mild-to-moderate, short-term reactions and acute reactogenicity.
- No difference in safety profile between administration at birth and 1 month post-birth.
- Vaccination at birth or delayed vaccination confer a similar and long-lasting protective immune response.

Hep B Birth Dose Evidence Review



Conclusions

- 40 years of evidence-based recommendations have driven major reductions in HBV infection among U.S. infants and children, linked to reduction of chronic liver disease, cancer, and death.
- Safety and effectiveness were confirmed in our review, no differences in short- or long-term adverse events between birth dose and delayed vaccination; delaying offers no efficacy or protection benefits.
- **This review found no evidence of any health benefit with delaying the birth dose among medically stable newborns born to HBsAg-negative mothers and identified only risks related to changing current US recommendations for universal hepatitis B vaccination.**



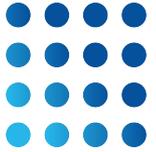
**VACCINE
INTEGRITY
PROJECT**

Next Steps



Priority Focus Areas

- **Summarizing and Disseminating Scientific Evidence:** Continue to summarize and broadly share available science to support evidence-based immunization recommendations.
- **Rapidly Communicating:** Increase frequency, breadth, and depth of the communication around the safety and effectiveness of immunizations.
- **Enhancing Collaboration and Visibility:** Continue informal outreach to wide variety of organizations to improve coordination, reduce duplication, and identify and address emerging issues.



Launching Public Health Alerts

- CIDRAP and NEJM Evidence launched a joint effort to publish timely alerts about emerging health threats and information.
- Public Health Alerts will be short, expert-reviewed dispatches that give state and local health departments, clinicians, researchers, and the public early insight into unusual outbreaks and other urgent health events.

Public Health Alerts



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PUBLIC HEALTH ALERTS | IN PARTNERSHIP WITH CIDRAP



Influenza Virus Characteristics in Department of Defense Populations, 2024–2025

Authors: Anthony C. Fries, Ph.D., Kayla M. Septor, Ph.D., William E. Gruner, M.S., Zhaodong Liang, M.S., Angelia A. Eick-Cost, Ph.D., Jeffrey W. Thervil, M.P.H., Dara A. Russell, M.P.H., [47](#), and M. Shayne Gallaway, Ph.D. [Author Info & Affiliations](#)



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PUBLIC HEALTH ALERTS | IN PARTNERSHIP WITH CIDRAP

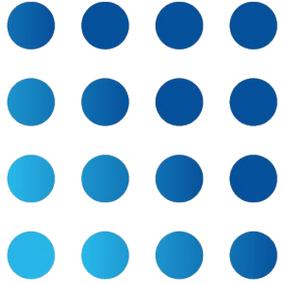


Detection of Community Transmission of Clade Ib Mpox Virus in the United States

Authors: Eric C. Tang, M.D., M.P.H., Monica Haw, M.P.H., Sonali Kulkarni, M.D., M.P.H., Emily Johnson, M.P.H., Crystal M. Gigante, Ph.D., Nora Balanji, M.P.H., Ricardo Berumen, III, B.S., [415](#), and Kathleen Jacobson, M.D. [Author Info & Affiliations](#)



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THANK YOU!