



# Vaccine safety updates

## Advisory Committee on Immunization Practices (ACIP) meeting

June 23, 2023

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# Session topics

- Background on the CDC Immunization Safety Office (ISO) and ISO efforts to evaluate studying the safety of the childhood immunization schedule (Dr. Tom Shimabukuro)
- The childhood immunization schedule and safety: Studies in the Vaccine Safety Datalink (Dr. Matthew Daley)
- Preliminary evaluation of aluminum content in childhood vaccines and risk of asthma in a Danish nationwide cohort (Dr. Anders Hviid)
- Discussion

# CDC Immunization Safety Office (ISO) mission

- Monitor the safety of vaccines given to children and adults

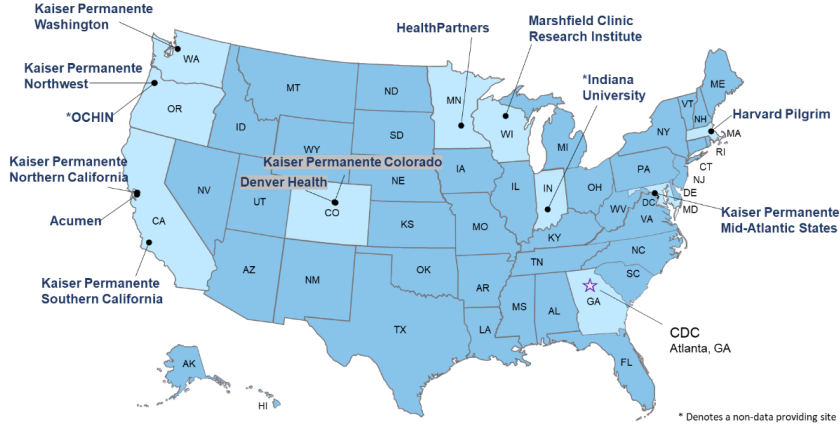
## ISO key activities

- Monitor newly recommended vaccines and new recommendations for existing vaccines
- Monitor CDC priority vaccines, including seasonal influenza and COVID-19 vaccines
- Conduct planned safety studies
- Support data needs of the Advisory Committee on Immunization Practices (ACIP)
- Assess individual risk factors for adverse events, conduct clinical case reviews, and provide clinical consultation to U.S. healthcare providers and health departments about vaccine safety questions for individual patients
- Respond to vaccine safety inquiries
- Conduct vaccine safety communication and education
- Coordinate with state health departments
- Prepare for pandemic and emergency responses

## Participating VSD Healthcare Organizations

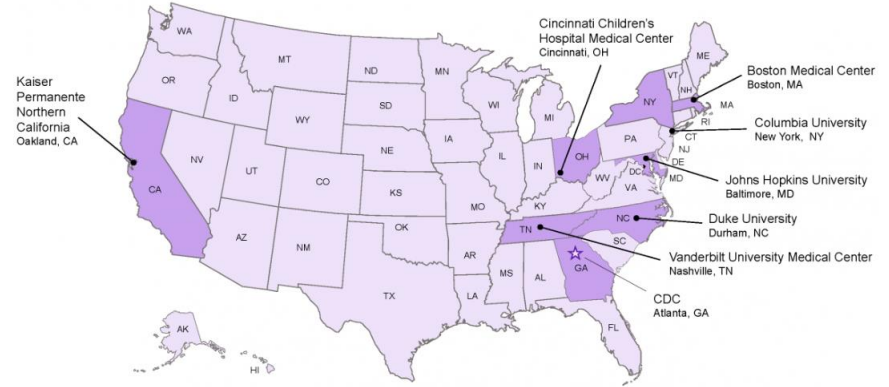
# VSD

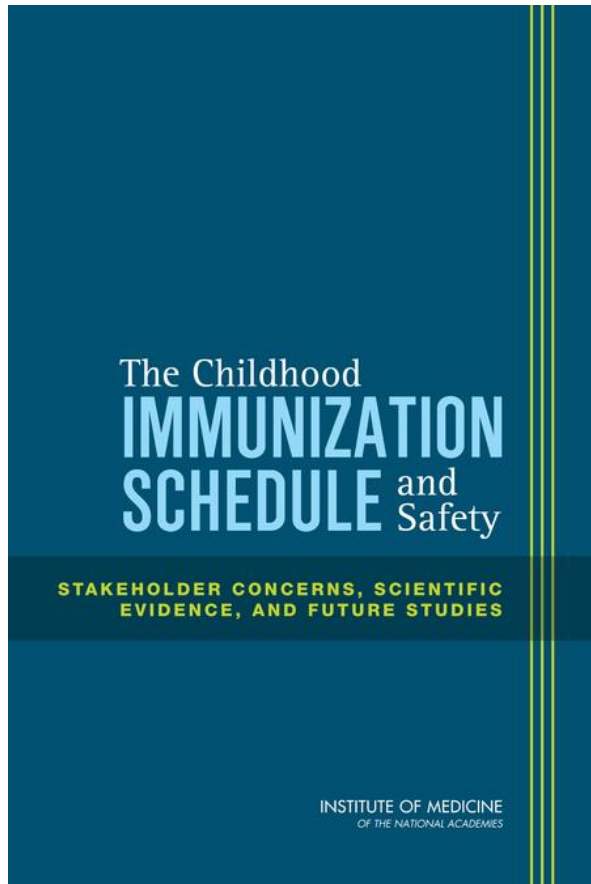
Sites that do not provide data are denoted with an asterisk(\*).



## Current CISA Project Sites

# CISA





Institute of Medicine. The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington (DC): National Academies Press (US); 2013.

- The lack of conclusive evidence linking adverse events to multiple immunizations or other “schedule” exposures suggests that the recommended schedule is safe.
- The risks to participants' health, the cost and time involved, and the ethical challenges all make the conduct of an [randomized controlled trial] RCT unsuitable for addressing the research questions, at least until further work with secondary data has been conducted.
- Although each new vaccine is evaluated in the context of the overall immunization schedule that existed at the time of review of that vaccine, elements of the schedule are not evaluated once it is adjusted to accommodate a new vaccine. Thus, key elements of the entire schedule—the number, frequency, timing, order, and age at administration of vaccines—have not been systematically examined in research studies.
- The most feasible approach to studying the safety of the childhood immunization schedule is through analyses of data obtained by [the Vaccine Safety Datalink] VSD.

## White Paper on Studying the Safety of the Childhood Immunization Schedule

For the Vaccine Safety Datalink



National Center for Emerging and Zoonotic Infectious Diseases  
Immunization Safety Office



## Four objectives of White Paper

1. Define types of alternative immunization schedules and patterns of undervaccination that could be evaluated, focusing on the first 24 months of age
2. Identify plausible adverse event outcomes that could be related to the childhood immunization schedule, with an emphasis on long-term adverse events
3. Suggest methodological approaches that could be used to assess the safety of the recommended schedule as a whole
4. Propose next steps for studying the safety of the childhood immunization schedule within the VSD



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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(<https://phil.cdc.gov/Details.aspx?pid=8876>)

