

The Centers for Disease Control and Prevention (CDC) continuously monitors vaccines to create sound immunization policies that improve the health of children and adults in the United States. CDC's Immunization Safety Office (ISO) assesses vaccine safety to identify health problems possibly related to vaccines and conducts studies that help determine whether a health problem is caused by a specific vaccine. CDC also works with the Food and Drug Administration (FDA) and other stakeholders to determine the appropriate public health response to vaccine safety concerns and to communicate the benefits and risks of vaccines.

CDC ISO conducts four primary vaccine safety activities:

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment (CISA)
- Public Inquiries and Partnerships

Vaccine Adverse Event Reporting System (VAERS)

VAERS, managed in collaboration with FDA, is a national reporting system that receives about 30,000 reports annually of adverse events following immunizations (AEFIs) from a variety of sources. VAERS serves as an early-warning system to detect vaccine safety concerns that may need further study using other systems. Generally, VAERS cannot determine if a vaccine caused an adverse event.

Vaccine Safety Datalink (VSD) Project

The VSD Project is a collaborative effort between ISO and nine large managed care organizations (MCOs). The project monitors the medical records of over 9 million MCO members to address gaps in scientific knowledge about AEFIs, including those that are rare and serious. The VSD Project complements VAERS by conducting formal epidemiologic studies of AEFIs, including those potentially associated with new vaccines or changes in immunization schedules.

VSD Project researchers investigate vaccine safety issues by analyzing data collected from the large administrative databases maintained by the MCOs. The databases contain detailed records of vaccine administration, data from medical care visits, and birth and census data on millions of children and adults. Scientists use this information to study short and long-term health problems that may occur in vaccinated people.

Clinical Immunization Safety Assessment (CISA) Project

The CISA Project is a national network of vaccine safety experts from the CDC ISO, seven medical research centers, and other partners. CISA provides a comprehensive vaccine safety public health service to the nation, and its goals are:

- To provide consultation and serve as a resource for clinical vaccine safety issues, including individual case reviews
- To assist with immunization decision making



- To develop strategies to assess individuals who may be at increased risk for AEFIs
- To conduct studies that identify risk factors and preventive strategies for AEFIs, particularly in special populations

CISA conducts research studies (registered at ClinicalTrials.gov) in the following areas:

- Maternal, infant, and child health
- Special populations
- Adverse event prevention
- Advancing technologies to improve understanding, detection, and reporting of adverse events

US healthcare providers who have a vaccine safety question (about a specific patient residing in the United States) that cannot be readily answered by the Advisory Committee on Immunization Practices (ACIP) guidelines (<http://www.cdc.gov/vaccines/acip/index.html>) can request a CISA evaluation at CISAEval@cdc.gov. This service is provided free of charge. Clinically experienced CDC ISO staff will review requests for clinical consultations and determine whether an inquiry is appropriate for a CISA evaluation.

Public Inquiries and Partnerships

ISO answers vaccine safety-related inquiries from healthcare providers and the general public.

- Call 800-CDC-INFO or 800-232-4636
- Visit <https://wwwn.cdc.gov/dcs/ContactUs/Form>
- Email nipinfo@cdc.gov

ISO works closely with other federal, state and local agencies, private entities, healthcare providers and the public to monitor and communicate information about U.S. vaccine safety. Current partnerships and collaborations include the FDA, the National Vaccine Program Office, state health departments, the Department of Defense, the World Health Organization, the Immunization Action Coalition, and the Institute for Safe Medication Practices.