

# Improving the Evaluation, Management and Understanding of Adverse Events Possibly Related to Immunizations

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Vaccines are among the most widely used and effective public health interventions for preventing disease, and among the safest medical products available. But as the incidence of life-threatening, vaccine preventable diseases has decreased, rare adverse events following immunization have received increased attention by both parents and health care providers, leading some parents to withhold vaccinations for their children. Close monitoring and timely assessment of suspected vaccine adverse events are critical to prevent loss of confidence, decreased vaccine coverage and the return of epidemic disease.

Clinical Immunization Safety Assessment (CISA) centers are a new initiative designed to improve the scientific understanding of vaccine safety at the individual “patient” level. A network comprised of clinical academic centers in partnership with the Centers for Disease Control and Prevention (CDC) serves as a source of clinical expertise in evaluating and treating adverse events following immunization. Data from the CISA centers are expected to provide insight into preventing the occurrence of vaccine-related adverse events.

Prior to the creation of the CISA network, no coordinated facilities existed in the U.S. that investigated and managed adverse events on an individual level for the purpose of systematically collecting and evaluating those incidents. This void has previously left parents, patients and health care providers on their own to find answers and/or treatments for adverse events.

Clinically significant adverse events occur rarely, but CISA centers are working to improve the understanding of these events. Through participation in the CISA

network and with the CDC, medical and professional staff with expertise in vaccine safety will systematically evaluate cases of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is the national passive surveillance system for adverse events following immunization, which receives reports from health care providers and the public. Selected cases will undergo enhanced follow up and targeted clinical evaluation to better understand the mechanism(s) and risk factors for the event. Health care providers will also be able to refer patients to a CISA center for a consultation, either by filing a VAERS report and including a specific request, or through usual consultation mechanisms already in place at the institutions with which a center is affiliated. The results of these evaluations will be used to develop clinical evaluation protocols or patient management guidelines that can be used by all health care providers.

The network’s goals are to:

- Develop clinical protocols for the evaluation and management of adverse events possibly related to immunization, and disseminate them through professional publications or other appropriate mechanisms.
- Evaluate groups of patients with similar adverse events, using a standard protocol, in order to elucidate the mechanism(s) by which these unusual or severe adverse reactions occur. Through evaluation, genetic or other risk factors that predispose to these reactions may be determined.
- Provide immunization guidelines and clinical management protocols for patients who have had an adverse

reaction that may not contraindicate further vaccination but where there is concern regarding continuation of the particular vaccine series.

- Serve as a public and provider regional referral center for clinical vaccine safety inquiries.

In the U.S. immunization safety system, CISA centers will serve as an intermediate step between passive reporting of individual cases of adverse events with no or minimal follow-up, and more rigorous epidemiological investigations into vaccine safety, such as the use of large linked databases, clinical trials and case-control or cohort studies. These goals will help to better define the level of risk of an adverse event for the individual patient, identify areas for additional scientific investigation to keep vaccines safe and help maintain the public’s confidence in immunization.

The first group of CISA centers was funded in October 2001, and has begun the process of coordinating their activities and establishing mechanisms by which adverse event cases reported to VAERS will be reviewed, and clinical evaluations defined and performed. They include Johns Hopkins University partnering with specialists at the University of Maryland, in Baltimore; Northern California Kaiser with collaborators at Stanford University in San Francisco, California; Vanderbilt University in Nashville, Tennessee; Boston University Medical Center in Boston, Massachusetts; and Columbia Presbyterian Hospital in New York City, New York.

*For more information on CISA centers and other vaccine safety activities, please contact the Vaccine Safety and Development Activity Desk at (404) 639-8256.*