IMMUNIZATION SAFETY

PUBLIC HEALTH ISSUE

As a leader in immunization safety surveillance and research, CDC's Office of Immunization Safety (ISO) plays a vital role in assuring vaccine safety. Sound immunization policies affecting our nation's health depend upon continuous monitoring of vaccines and ongoing assessment of immunization benefits and risks. Using a multifaceted approach, CDC identifies possible vaccine side effects, conducts epidemiological studies to determine whether a particular adverse event is caused by a specific vaccine, helps determine the appropriate public health response to vaccine safety concerns and communicates the benefits and risks of vaccines to the public, media, and healthcare communities. A robust and transparent immunization safety monitoring and research system must exist to ensure safe and effective vaccines and maintain public confidence in immunizations.

CDC ACCOMPLISHMENTS

Vaccine Adverse Event Reporting System (VAERS): VAERS is a public health activity authorized by the National Childhood Vaccine Injury Act of 1986 and administered by CDC in collaboration with the U.S. Food and Drug Administration. VAERS serves as an early-warning system to detect problems that may be related to vaccines. VAERS provides postmarketing surveillance on childhood and adolescent vaccines that protect against 16 diseases and adult vaccines that protect against 13 diseases. In 2005, VAERS reports indicated a possible association between Guillain-Barre syndrome (GBS) and receipt of meningococcal conjugate vaccine (MCV4, Menactra®).

By October 2006, ISO had led an investigation of 18 confirmed cases of GBS following Menactra® immunization to prevent meningococcal disease and published three MMWR articles on this issue. Initial investigations suggested there may be a small increased risk of GBS following Menactra® immunization, but CDC is unable to determine whether Menactra® increases the risk of GBS in persons who receive the vaccine. CDC continues to recommend routine vaccination with Menactra® for those at increased risk.

Vaccine Safety Datalink Project (VSD): Through the VSD Project, ISO staff collaborates with eight managed care organizations (MCOs) to collect vaccination data on more than 5.5 million people annually. This collaboration resulted in 10 journal articles published in 2006.

The Brighton Collaboration: ISO staff works with scientists from 71 countries to develop standardized case definitions and guidelines for vaccine adverse events. Through The Brighton Collaboration, 16 case definitions were completed in 2006.

Clinical Immunization Safety Assessment (CISA): ISO staff collaborates with six academic centers to investigate pathophysiologic mechanisms and biologic risks of adverse events following immunization. CISA established an IRB-approved registry and repository to enroll people experiencing adverse events following immunization and store specimens for future studies. CISA enrolled and evaluated new cases of GBS following Menactra ®and new cases of illness following yellow fever vaccine.

NEXT STEPS

Research Planned on Potential Association of Vaccine Adverse Events and Human Genetic Variations
In 2006, ISO received $1.5 million additional funding from Congress to study risk factors for serious adverse reactions, develop screening tools to identify children at high risk for developing serious vaccine adverse reactions and develop effective treatments and interventions for children experiencing severe adverse reactions. CDC is finalizing the request for proposals that will be issued through this new extramural immunization safety research activity.