IMMUNIZATION SAFETY

WHAT IS THE PUBLIC HEALTH ISSUE?

No vaccine is 100% safe. As more and more people receive vaccinations and the risk of disease decreases, both real and perceived vaccine side effects increase. The end result is heightened public concern about the safety of vaccines and loss of public confidence in vaccines, which could result in decreased vaccination levels, followed by epidemics of disease. A credible immunization safety monitoring system to determine which illnesses are caused by vaccines, and which are not, must exist to maintain public confidence in immunizations and prevent the return of disease epidemics.

WHAT HAS CDC ACCOMPLISHED?

CDC has implemented a multi-faceted strategy to address immunization safety issues, which includes various programs and partnerships. The Vaccine Adverse Event Reporting System (VAERS) is operating in collaboration with the Food and Drug Administration and serves as an early-warning system to detect problems that may be related to vaccines. CDC is adding Web-based reporting to improve the timeliness, accuracy, and efficiency of VAERS. Work is also under way to ensure vaccine safety through continued research and enhancements to the Vaccine Safety Datalink (VSD) project. VSD is a linked database containing comprehensive medical and immunization histories of over 7.5 million people. VSD enables researchers to compare the incidence of health problems between vaccinated and unvaccinated people. CDC has established a vaccine safety data sharing process so that external researchers can access final datasets created through VSD.

Other programs aimed at improving immunization safety include the Clinical Immunization Safety Assessment (CISA) Network, which provides in-depth, standardized clinical evaluations for individuals with unusual or severe vaccine adverse events, and the Safe Injection Global Network, a global consortium working to solve the problem of unsafe injections as a major means of transmitting diseases like hepatitis B, C, and HIV/AIDS.

CDC is also working with the Institute of Medicine to increase outside participation in evaluating safety concerns and guiding research efforts. CDC is continuing its efforts to determine how best to disseminate information on the benefits and risks of vaccinations; develop safer vaccines and delivery methods (especially needle-free jet injectors for mass immunization campaigns); and establish a global collaboration to standardize case definitions for study of vaccine reactions, thereby creating a common "vocabulary" for vaccine safety research.

Example of Program in Action

VSD provided valuable information regarding the safety of influenza vaccine in children to the Advisory Committee on Immunization Practices,' which led to the formulation of the committee's policy recommendation for routine influenza vaccination of children to 23 months of age in the United States.

WHAT ARE THE NEXT STEPS?

To enhance the current immunization safety program, CDC plans to

- Increase the knowledge of genetic risk factors for vaccine reactions.
- Enhance analysis of VAERS data and increase research of immunization safety concerns through VSD and CISA.
- Conduct research regarding how the public perceives and accepts the risks and benefits of vaccines.
- Improve vaccine benefit-risk communication to parents and healthcare professionals through partnerships.