Vaccine Safety

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Vaccine Safety and Human Genetic Variations

Serious health problems following vaccination are rare, even though millions of people are vaccinated every year in the United States. Why do only a small number of people develop these health problems called vaccine-associated adverse events (VAEs)? Do they have genetically determined differences in their immune responses to vaccination, compared to those who do not experience adverse events?

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Few studies have been published on the genetic risk factors for VAEs. CDC has lead responsibility for monitoring the safety of vaccines licensed for use in the U.S., and for performing research to inform safe vaccination practices. So CDC is working with partners to study the relationship between human genetics and vaccine safety.

Identifying genetic associations and risk of serious VAEs eventually may allow–

- Screening for makers of susceptibility.
- Improved guidance for vaccination.
- Development of safer vaccines.

ISO's Genomics Initiative

CDC's Immunization Safety Office (ISO) is developing a genomics initiative to–

- Develop a scientific approach to understanding the genetic basis for VAEs and their proper public applications.
- Increase cooperation between federal agencies, academia, and industry.
- Perform studies to identify genes that may be associated with an increased risk for VAEs.
- Identify strategies for integrating genomics into vaccine safety.

This initiative's long-term goal is to identify genetic features that can be determined before vaccination, so doctors can tailor vaccine schedules to the patient's personal risk.

On January 30 and 31, 2008, ISO held a conference titled "Understanding the Genomic Basis of Vaccine Safety" that brought together representatives of CDC, the Food and Drug Administration, the Department of Defense's Vaccine Healthcare Centers Network, research universities, and vaccine manufacturers. The conference discussed a systematic approach to research into the genetics of immunization safety.

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Studies

There is increasing appreciation for how human genetic variation may affect the risk for medication-related and vaccine-related adverse events. While substantial research has been done on the genetic basis of medication safety, relatively little research has been done on the genetic basis of vaccine safety. ISO has sponsored five projects on this issue:

- **Evaluation of Genetic Risk Factors for Guillain-Barré Syndrome (GBS) After Vaccination.** GBS has been associated with 1976 swine influenza vaccine and the trivalent inactivated influenza vaccine in some seasons. Since GBS is rare, genetic predisposition may be an important contributing factor. This study will identify genes that may be associated with an increased risk of GBS after vaccination.
- **A Genome-Wide Association Study to Examine Genes Associated with an Increased Risk of Febrile Seizure in Children Following Measles-Containing Vaccines.** The objective of this case-control study is to evaluate the human genome of individuals who experienced a febrile seizure 7 to 10 days after Measles-Mumps-Rubella (MMR)or Measles-Mumps-Rubella-Varicella (MMRV) vaccines in order to identify genetic risk factors associated with febrile seizures.
- **Genetic Polymorphisms and Hypersensitivity Reactions to Vaccines.** The aims of this case-control study include evaluating the role of gelatin and other components in hypersensitivity reactions to vaccines and to identify the genetic basis of hypersensitivity reactions.
- **Atopy History and the Genomics of Wheezing after Influenza Vaccination in Children 6-59 Months of Age** Miller EK, Dumitrescu L, Cupp C, Dorris S, Taylor S, Sparks R, Fawkes D, Frontiero V, Rezendes AM, Marchant C, Edwards KM, Crawford DC. *Vaccine.* 2011 Apr 18;29(18):3431-7 http://www.ncbi.nlm.nih.gov/pubmed/21396408
- **Post-Vaccine Adverse Events: Establishment of a Centralized Repository of Biological Specimens.** CISA created a registry of clinically significant adverse events and related clinical data, and a repository of biological specimens from patients who experienced serious VAEs.

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