

Keeping Vaccines Safe for Everyone

In the United States, we expect to be safe and healthy. We expect our drinking water to be clean, the kitchens in our restaurants to be sanitary, and airplane cabins to be free of cigarette smoke. But most of us rarely ask ourselves how these things actually happen. They happen because every day, public health professionals work to protect the safety and health of individuals, families, and communities.

One of the key responsibilities of public health professionals is to ensure the safety of vaccines that protect us from serious diseases. They develop and manage systems that closely monitor how well vaccines work and about any side effects reported by people who get the vaccines. That information helps public health professionals detect possible safety problems and take action if needed.

Vaccine monitoring actually starts during the development of the vaccine itself. The U.S. Food and Drug Administration (FDA) ensures the safety and effectiveness of vaccines for the United States. Before FDA approves a vaccine, it is tested extensively. FDA scientists and medical professionals then carefully evaluate all the information to determine a vaccine's safety and efficacy. Once a vaccine is licensed, FDA regularly inspects vaccine manufacturing facilities to make sure they are following strict regulations. Vaccines are manufactured in lots, and vaccine manufacturers must test each and every lot of a vaccine to make sure they are safe, pure, and potent. Vaccine lots cannot be marketed and distributed until licensed by the FDA.

Once vaccines are licensed and approved, FDA works with the Centers for Disease Control and Prevention (CDC) to monitor their safety. At CDC, the Immunization Safety Office (ISO) is responsible for multiple vaccine safety activities, including monitoring and research.

Through the Vaccine Adverse Event Reporting System (VAERS), anyone – including parents, patients, and healthcare professionals – can report any health problem that may happen after getting vaccines, whether they believe the problem was caused by a vaccine or not. CDC also utilizes the Vaccine Safety Datalink (VSD) to look for potential safety problems. The VSD uses electronic health records of millions of people to monitor for possible vaccine safety problems and to conduct research. The VSD data allow CDC scientists to determine how often certain side effects occur, and whether or not certain groups of people (for example, young children or pregnant women) are affected by them.

In addition, CDC partners with medical research centers on the Clinical Immunization Safety Assessment (CISA) Project to conduct clinical research on vaccine safety. The CISA Project also allows U.S. healthcare providers to consult with vaccine safety experts when they have patients with complex health issues following vaccination. Finally, in the event of a disease outbreak where a mass vaccination campaign is needed, CDC can activate emergency preparedness activities that include vaccine safety monitoring, to ensure that potential vaccine safety problems are rapidly detected and assessed.

As part of vaccine safety efforts in the United States, CDC's Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts external to the federal government, carefully reviews safety and effectiveness data on vaccines and makes recommendations for their use. When needed, ACIP can modify existing recommendations, based on ongoing safety monitoring.

If vaccine safety monitoring identifies a potential problem with a vaccine, CDC and FDA take action to inform the public, health officials, and healthcare providers. Public health officials, including those on the ACIP, weigh the benefits of a vaccine against any known risks to determine if recommendations for using the vaccine should change.

For example, RotaShield® vaccine was the first vaccine approved for use in the United States to prevent rotavirus gastroenteritis. Some infants developed intussusception (a rare type of bowel obstruction most common among young children) soon after the vaccine was licensed in August 1998. CDC quickly recommended that use of the vaccine be suspended and immediately started two emergency investigations in collaboration with the FDA and state and local health departments to find out if receiving the vaccine was causing some of the cases of intussusception. When the results of these investigations linked the vaccine to intussusception, the ACIP withdrew its recommendation to vaccinate infants with RotaShield® vaccine, and the manufacturer voluntarily withdrew the vaccine from the market in October 1999.

Vaccine safety efforts in the United States are extensive, and supported by multiple monitoring and research systems. These efforts are ongoing, and help ensure the U.S. vaccine supply is as safe as possible.