Vaccine Safety

Post Licensure Monitoring of Vaccines

◊ Once FDA approval has been granted, there are a number of databases[3] that collect information on any vaccine side effects.

◊ Some side effects are not related to the vaccines, but occur at around the same time, but others may be related to the vaccine.

◊ Each report is therefore carefully reviewed by a health care professional. A more extensive follow-up is conducted on reports which suggest a new side effect.

◊ The Vaccine Adverse Events Reporting System (VAERS)[4] is the national vaccine safety surveillance system.

◊ Other vaccine safety surveillance systems include the Vaccine Safety Datalink (VSD)[5] which involves health care organizations and the Clinical Immunization Safety Assessment Project (CISA)[6] which involves medical centers around the country.

◊ Many other countries also have similar systems such as Canada[7]and England[8].

National Vaccine Injury Compensation Program

⇒ In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction.

⇒ In these instances, the National Vaccine Injury Compensation Program (VICP)[9] may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine.

- It is very important that vaccines are as safe as we can make them. Indeed, because we are putting them into healthy people, vaccines are held to a higher standard than medicines used to treat illness, when side effects may be more acceptable.
- Historically vaccines were crude preparations of bacteria or viruses that would often lead to considerable pain at the injection site and fever. In spite of this, vaccines provided protection against even more serious infections, and so people continued to use them. But vaccine purification methods have improved and today's vaccines are purer and safer than they have ever been.
- Before a vaccine is licensed by the US Food and Drug Administration (FDA) it must undergo extensive safety and efficacy trials [1,2]. A new vaccine or a new formulation of a vaccine must pass all the clinical trials before the vaccine can be licensed and used by the public.
- The basic questions that the trials must answer are:
  - Is the vaccine safe?
  - Is the vaccine effective—does it lead to protection from the disease?
  - What are the side effects and are they serious?
- Only after these questions have been answered and the vaccine found to be safe and effective will the vaccine be licensed.
- Even after the vaccine has been licensed, the safety of the vaccine is monitored, because there may be rare side effects that occur, even after testing in thousands of people (see side bar on Post-licensure monitoring)
- Manufacturers make their vaccine in large batches called lots. Each lot must be thoroughly tested for safety, purity and potency before the FDA will approve it for distribution.
- Some side effects are very rare, only occurring a few times after millions of people have received the vaccine. As vaccine trials involve thousands, but not millions of people, these rare events are unlikely to have been recognized before licensure. For this reason, monitoring for serious side effects continues even after licensure.

Vaccine Information Statements

* It is important for vaccine recipients to understand the vaccine they are being given.
* Vaccine Information Statements (VIS)[10] are information sheets explaining the vaccine and its benefits and risks.
* A VIS must be given to each vaccine recipient (or their parent) before the vaccine is administered and for them to keep.

When a Safety Issue is Suspected

⇒ A good example of how post-licensing monitoring of vaccines can pick up rare, but possibly serious side effects of a vaccine can be seen with the 1st rotavirus vaccine licensed in the US.

⇒ Rotavirus infections can be a very serious, gastrointestinal infection, usually seen in newborns and infants.

⇒ RotaShield, a vaccine against rotavirus infection was introduced in the US in 1999 and soon after cases of a bowel obstruction, called intussusception, following vaccination began to be reported.

⇒ A very extensive investigation was conducted by public health . They found that the risk of this condition was higher in infants who received the vaccine than in children who had not received it.

⇒ After weighing the risks and benefits of the vaccine, the vaccine was then taken off the market[11].

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11. Delage Rotavirus vaccine withdrawal in the United States. The role of postmarketing surveillance. Canadian J of Infectious Diseases 2000 Jan-Feb 11(1). 10-12. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2094741/

Additional Information:

Institute for Vaccine Safety, Bloomberg School of Public Health, Johns Hopkins University: http://www.vaccinesafety.edu/

American Academy of pediatrics: https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Studies-Examine-the-Evidence.aspx

iVaccinate: https://ivaccinate.org/about-vaccines/vaccines-are-safe/

Children's Hospital of Philadelphia. https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety