Vaccine safety: Canada's system

Most parents know that vaccines are tested before they can be given to the general public. But they are probably less aware of the extensive monitoring, testing, information-sharing and decision-making that goes on behind the scenes.

Vaccines are among the most strictly regulated medical products in Canada. Like medicines, vaccines must go through a series of steps before they are approved for use. Before any vaccine is approved for use in Canada, it must be shown to be safe and effective in preventing the disease that it targets.

Vaccine recommendations

The Public Health Agency of Canada's National Advisory Committee on Immunization (NACI) makes recommendations on the use of vaccines in Canada. NACI members are non-governmental experts in infectious diseases, immunization, immunology, epidemiology and public health. The committee regularly reviews all the scientific information available on the safety and effectiveness of vaccines—new vaccines, as well as vaccines already in use.

Ensuring vaccine safety

Health authorities in Canada, including those in provincial and federal governments, take vaccine safety very seriously. Before a vaccine is licensed for use in Canada, the manufacturer must prove that their product is safe. This is done with studies to compare the immune response and other reactions of people who are given the vaccine with those in people who are given a placebo injection (saline solution that doesn't contain the vaccine). People taking part in these studies (or "trials") are volunteers. They understand that a vaccine is being studied and are informed about the possible side effects that may occur.

Monitoring vaccine safety is ongoing. Trials carried out before a vaccine is licensed can show that serious adverse (unpleasant) effects after getting the vaccine being tested are uncommon. But because of the limited number of participants, such trials may not pick up the possibility of rare adverse effects. Monitoring for possible but rare serious adverse events must continue after any vaccine has been licensed for use.

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD), which is part of Health Canada, regulates vaccines used in humans in Canada. They approve vaccines for use only if all acceptable standards of quality, safety and efficacy are met. The BRDD also supervises all aspects of production and quality control throughout the vaccine's life cycle, ensuring that the batches used to immunize children today are as safe and effective as the ones tested during original clinical trials. The factory where a vaccine is manufactured is inspected by government authorities regularly to ensure that facilities and all stages of production and quality control conform to the highest standards.

Each individual batch of vaccine must also be authorized for sale in Canada. Manufacturers have to submit an official document providing results from all the quality tests performed during the production process for that particular batch. Also, for most vaccines, the BRDD performs tests on samples from each batch in its own laboratory to monitor vaccine quality.

Monitoring vaccine safety

After the BRDD has approved a vaccine, Canada has advanced systems in place to monitor safety and to alert medical experts of unusual post-vaccine events. In the very rare event that a batch of vaccine results in an unexpected side effect, these systems can ensure that the rest of the batch is not used. Canada is a world leader in post-marketing surveillance of vaccine adverse events.

An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine. Some mild reactions are expected, such as a mild fever and redness, swelling and soreness at an injection site. An unexpected AEFI is one that was not recognized previously and was not listed in the information supplied by the manufacturer. A serious AEFI is one that is life-threatening and/or results in hospitalization, permanent disability, or death.

Reporting on AEFIs

In all provinces and territories, doctors and public health nurses are expected to report any *serious* or *unexpected* AEFI that occurs after vaccination to their local health department. Many less serious and expected events, such as fever or local reactions (e.g., redness, swelling) may also be reported, especially if these occur in clusters, more frequently than usual, or are more severe than usual.

- The local medical officer of health investigates all reports, and forwards them to the provincial or territorial ministry of health.
- The reports then go to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), a branch of the Public Health Agency of Canada. This federal agency keeps track of, and analyzes, all reports of adverse events after vaccination.

All vaccine manufacturers must quickly report any serious adverse events that they become aware of, in Canada or internationally, to Health Canada.

Canadian Immunization Research Network special immunization clinics (SICs)

Following an AEFI, not only must a cause be determined but an evaluation of the safety of further immunizations also has to be done. Not surprisingly, parents, patients and health care workers might be hesitant to continue administering a particular vaccine, especially if an AEFI required hospitalization.

To address this, the Canadian Immunization Research Network established special immunization clinics (SICs) in 2013, staffed by paediatric and adult infectious disease specialists and allergists that evaluate and advise individuals who have had AEFIs of particular concerns. Patients with conditions that may put them at higher risk of an AEFI (eg, compromised immunity) are also seen in SICs. Referred patients are assessed and managed using a standardized approach. With consent, these cases are entered into a central registry to allow review of other immunization outcomes for people with similar AEFIs, and to better evaluate management procedures.

IMPACT

Canada also has a unique program called IMPACT—the Canadian Immunization Monitoring Program, ACTive — to detect adverse events related to vaccination and monitor vaccine-preventable diseases. The program is funded by the Public Health

Agency of Canada and operated by the Canadian Paediatric Society.

The program works as follows:

- A nurse at each of the 12 children's hospitals across Canada reviews all admissions to the hospital for certain serious illnesses, including seizures, encephalitis, encephalopathy, loss of consciousness, meningitis, acute paralysis, bleeding or bruising, some types of rashes, and severe allergic reactions. Each year, these nurses screen more than 100,000 admissions at the 12 hospitals.
- If a child with any of these diagnoses has recently received a vaccine, a report is sent to the local health department and to CAEFISS for analysis.

Canadian Paediatric Surveillance Program

With the Canadian Paediatric Surveillance Program (CPSP), Canada has another valuable and unique surveillance tool for collecting active real-time data on rare diseases, including acute paralysis in children and some vaccine-preventable diseases.

The program involves thousands of paediatricians and paediatric subspecialists from all provinces and territories who monitor their practices for these conditions.

Public Health Agency of Canada

Experts with this government body review all reported cases of serious adverse events following vaccination that result in hospitalization, permanent damage or death.

Because such events are not necessarily caused by vaccination but may be linked in time by coincidence, careful review of the details of all cases on a regular basis is important to determine whether there are any vaccine safety concerns.

The results of these reviews are reported to the doctor or nurse who reported the event, and summaries are posted publicly.

Global Advisory Committee on Vaccine Safety

The World Health Organization established this committee to advise on vaccine safety issues of potential global importance. Committee members are experts from around the world in the fields of epidemiology (the study of disease incidence, control and

prevention), statistics, paediatrics, internal medicine, pharmacology and toxicology, infectious diseases, public health, immunology and autoimmunity, and drug regulation and safety.

Additional resources

- Vaccine Safety (Public Health Agency of Canada)
  (http://www.phac-aspc.gc.ca/im/safety-securite-eng.php)
- Immunize Canada
  (http://www.immunize.ca/en/publications-resources/questions.aspx)

Reviewed by the following CPS committees

- Infectious Diseases and Immunization Committee

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