Canada has one of the best vaccine safety programs in the world. Vaccine safety is carefully monitored from the vaccine's early development and lasts for as long as the vaccine is being used. Here are some important things to know about vaccine safety and your role in keeping vaccines safe.

The journey of your child’s vaccine

Making a new vaccine takes many years. Vaccines must pass many safety tests before they are considered to be safe for people. It usually takes about 10 years of research and development before a vaccine is considered for approval by Health Canada. There is a strong system in place to monitor the safety of vaccines. Every single batch of vaccine is tested according to strict guidelines for safety and quality before it is used. Once it is in use, there are several systems in place to monitor the vaccine’s safety. Adverse events after immunization are reported in each province and territory of Canada; they are also reported to the federal government. Adverse events are studied carefully and every serious event is reviewed in detail.

What is an adverse event?

An adverse event following immunization (also known as an AEFI) is an unwanted or unexpected change in health that happens after someone receives a vaccine. An adverse event may or may not be caused by the vaccine.

Most people who receive vaccines have no side effects.

However, like any medicine, side effects can occur after vaccination. Most side effects are minor and don’t last very long; minor side effects include a sore arm or a mild fever.

Serious adverse events from vaccines are rare.

Some known rare events include anaphylaxis (a severe allergic reaction) which can occur in about one in every one million doses of vaccine given. Talk to your health care provider before your child receives the vaccine about both the benefits and risks of vaccination.

Vaccines protect us from serious diseases and save lives.

The risk of serious effects from vaccines is very small, compared to the risk of the diseases they prevent.

We all play a role in keeping vaccines safe.
You can play a role in keeping vaccines safe

Stay at your health care provider’s office for 15 minutes after a vaccine is given. Your health care provider is prepared to treat any reaction, if it should happen.

Pay attention to your child for a few days after vaccination. If you notice any change in your child’s health that concerns you, call your health care provider. You can also contact your public health unit to ask questions or to report an adverse event.

Report to your health care provider or public health unit any unusual symptoms or reactions. These may include:

- a fever higher than 40 °Celsius (104 °Fahrenheit)
- crying or fussing for more than a day
- worsening swelling where the needle went in
- an allergic reaction (for example, a rash or hives)
- unusual sleepiness
- severe vomiting or diarrhea
- any other unusual or unexpected event

What happens when I report an adverse event?

Your health care provider or public health unit will fill out an Ontario “Report of Adverse Event Following Immunization (AEFI)” reporting form. In order to complete the form, you will be asked about:

- your child’s medications and medical history
- all of the symptoms that you noticed in your child, when they started and how long they lasted

Once the form is completed, it is sent to the public health unit. After that, the adverse event will be reported to Public Health Ontario and the Public Health Agency of Canada.

Health officials take vaccine safety very seriously. By reporting adverse events, possible vaccine safety issues can be found early to lessen any health effects on people who need vaccines.

Contact your health care provider or your local public health unit to report an adverse event.

Contact information for the public health units in Ontario is available at ontario.ca/publichealth.

For information about vaccines, please visit the following websites:

- Government of Ontario: ontario.ca/vaccines
- Public Health Ontario: publichealthontario.ca/en/health-topics/immunization/vaccine-safety

It takes all of us to protect each of us.

Vaccines help keep you and your family healthy. Vaccine safety is constantly monitored in Canada.

You play an important role in keeping vaccines safe by reporting any adverse event after immunization.