

## 1 DEVELOPMENT



- Disease targeted for a vaccine. Research and development takes place.
- Pre-clinical tests in laboratory: *Can it work? Is it safe?*
- Researchers and manufacturer conduct clinical trials:

- PHASE**
- ① **Several volunteers:** *Is it safe?*
  - ② **Hundreds of volunteers:** *Is it safe? What's the ideal dose?*
  - ③ **Thousands of volunteers:** *Is it safe? How well does it work?*

- Ethical review is done on all vaccine research to ensure it meets the highest ethical standards and that the greatest protection is provided to participants who serve as research subjects.

## 2 TESTING & APPROVAL



- Health Canada examines results of clinical trials:

- Is the vaccine safe?
- Does it work?
- Which age groups?
- How many doses?
- Interval between doses?
- Side effects?
- Are the samples of consistent quality?
- Do the manufacturing facilities meet quality control standards?

- Health Canada approves the vaccine if it is determined to be safe, protective, and of high quality.

## 3 RECOMMENDATIONS



- National Advisory Committee on Immunization\* (NACI) reviews evidence on the best use of the vaccine:

### REVIEW

- Who would benefit most from the vaccine?
- How does it compare to similar vaccines?
- Are there additional and ongoing safety data available?
- How are other countries using it?
- What additional research questions need to be addressed?

- Following Public Health Agency of Canada (PHAC) approval, the recommendations are made available to healthcare providers.
- Each province/territory decides on vaccine's use:
  - Should it be publicly-funded (free)? If so, for whom?
  - Where will it be available - Schools? Pharmacies? Doctors' offices? Public Health Clinics?

\*The National Advisory Committee on Immunization (NACI) has been recognized for **over 50 years** and is comprised of experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health.

## 6 MONITORING



- For as long as a vaccine is used in Canada, it is monitored for adverse events following immunization (AEFI).
- AEFIs are reported by:
  - The general public
  - Health professionals
  - A network of pediatric hospitals
  - Local public health units
  - Provincial surveillance systems
  - Networks of vaccine researchers conducting studies
  - International monitoring
  - Manufacturers
- PHAC and Health Canada review all AEFIs and investigate safety concerns. Actions are taken as required.
- NACI\* updates its recommendations to incorporate new information as it becomes available.

**Note:** Together, all of these steps can take more than **10 years** to complete. Once available to Canadians, each vaccine is constantly monitored for safety and quality for as long as it is used.

## 5 VACCINATION



- A licensed health professional administers the vaccine and records details for the patient's record.
- Provincial, territorial and federal officials meet regularly to discuss vaccines and immunization programs:
  - Have there been any safety issues?
  - Has it reduced this disease in Canada?
  - Are there new recommendations or products available?
  - Do we have enough supply to meet the needs of Canadians?

## 4 MANUFACTURING, TRANSPORT & STORAGE



- Manufacturer tests each batch of the vaccine to ensure pre-set quality standards are met.
- Health Canada inspects the manufacturing facilities and reviews vaccine lots before they are sold in Canada to ensure consistency and quality.
- Packaged and labelled vaccines are carefully stored and transported from manufacturer, to destination site and final administration, under controlled temperature ("cold chain").

# VACCINE SAFETY IN CANADA

