

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:
 - 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.

VACCINE SAFETY IN CANADA

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.



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").



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?



Note:

Once available to Canadians, each vaccine is constantly monitored for safety and quality as long as it is used.

