Standard for Vaccine Hesitancy

Alberta Health Services
Communicable Disease Control

Section 3	General Principles	**Standard # 03.150**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	June 30, 2025	**Revised**	June 30, 2025

Preamble

AHS Provincial Immunization Program Standards and Quality, Population and Public Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information related to provincial immunization program standards and quality. These standards are based on current evidence-based information, Alberta Health (AH) policy, and provincial and national guidelines.

Background

Immunization is a cornerstone to public health and researchers have estimated that 154 million lives worldwide have been saved since 1974. In the 1900s, infectious diseases were leading causes of death in Canada and the introduction of public immunization programs in the 20th century has significantly reduced the burden of vaccine-preventable diseases. Before the era of vaccines, many common infectious diseases such as smallpox, polio, diphtheria, measles and pertussis caused severe illness and even death especially among younger populations. In Canada, immunizations occur across the lifespan. However, immunization of children is a priority, and young children are routinely immunized against diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, *Haemophilus influenzae* type b (Hib), hepatitis B, rotavirus, measles, mumps, rubella, varicella (chickenpox), meningococcal and pneumococcal. High immunization coverage is of critical importance to prevent the transmission of vaccine preventable diseases and reduce the morbidity and mortality resulting from these diseases.

Informed vaccine decision-making is a complex array of factors and as a result influence whether vaccine uptake is low or high. Vaccine uptake, according to Health Canada is the most effective way to protect against vaccine-preventable diseases, prevent outbreaks, and keep communities healthy.

Key determinants of vaccine acceptance or refusal may be influenced by the following:

Contextual Influences

- Communication and media environment
- Influential leaders
- Religion/culture/gender identity/sexual orientation/socio-economic
- Politics/policies
- Geographic barriers/accessibility
- Perception of the pharmaceutical industry

Individual and Group Influences

- Personal, family and/or community members' experience with immunization, including pain and side effects
- Social network
- Beliefs, attitudes about health and prevention
- Perceived benefit vs risk
- Concerns regarding vaccine safety
- Distrust with institutions (political, healthcare, pharmaceutical)
- Information sources

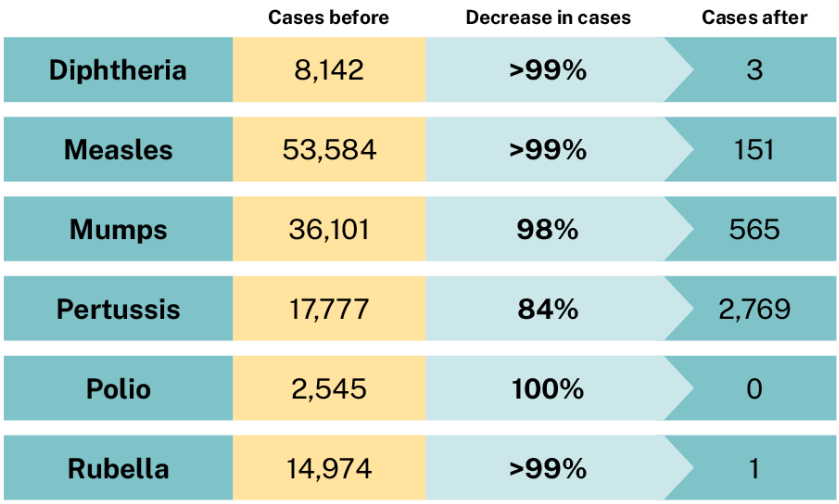
Immunization Specific Influences

- Introduction of a new vaccine or a new recommendation for an existing vaccine

- Concern with vaccine ingredients
- Mode of administration
- Immunization schedule or programs
- Scientific and epidemiological evidence
- Reliability and source of supply of vaccine

Science supports the efficacy of vaccines at reducing disease impact and that healthcare professionals remain the most trusted source of immunization related healthcare advice. Healthcare providers that can effectively communicate about vaccines may have the opportunity to improve vaccine uptake which will positively influence population health.

Figure 1. Vaccines Work: Decrease in disease following vaccine introduction



Cases before: Average number of disease cases reported yearly in Canada during the five years before routine vaccine use, or the closest possible five years where stable reporting was occuring.

Cases after: Average number of disease cases reported yearly in Canada from 2013 to 2017.

Figure 1 data source: Public Health Agency of Canada. Large Data Extract – Notifiable diseases on-line https://diseases.canada.ca/notifiable/charts?c=ppd

Vaccine hesitancy is a key barrier to immunization success. Vaccine hesitancy has increased in scope and scale over time and has been described by the World Health Organization (WHO) as the reluctance or refusal to immunize despite the availability of vaccines. Vaccine hesitancy can lead to decreased immunization coverage and increased outbreaks of vaccine preventable diseases. According to WHO, vaccine hesitancy represents one of the top 10 global health threats and estimates 1.5 million deaths could be prevented, if vaccine coverage was improved globally. In 2012, the WHO established a Strategic Advisory Group of Experts (SAGE) with the mandate of defining and addressing vaccine hesitancy. Vaccine hesitancy can be demonstrated on a continuum, shown in Figure 2, ranging from “accept all with confidence” to “refuse all with conviction” emphasizing that vaccine hesitancy can present on a decision-making spectrum.

Figure 2. The vaccine acceptance continuum

Figure 2 adapted from: MacDonald and the SAGE Working Group on Vaccine Hesitancy. Vaccine hesitancy: Definition, scope and determinants - ScienceDirect

The COVID-19 pandemic, a key global event, was officially declared by the WHO on March 11, 2020 and has significantly influenced the context of vaccine hesitancy. Despite the availability of vaccines to reduce the spread of COVID-19, the critical milestone of herd immunity is difficult to achieve unless there is adequate uptake of vaccine. The introduction of new vaccines can trigger new questions about the safety, efficacy, and importance of vaccines amidst a landscape of misinformation that can lead to a declining trust of expertise and authority. Research studies have emphasized the unintended consequences in the context of COVID-19 such as lack of trust in government and scientific institutions, reduced vaccine uptake not only for COVID-19 vaccine, but also routine immunizations. Given today's communication landscape that can include the rapid spread of myths or facts related to vaccine information, health care providers that are confident about the safety, effectiveness, and importance of immunization are strategically positioned to enhance vaccine uptake among the population.

Purpose

This standard is an important resource for immunizers to understand what it means to be vaccine hesitant and to support the series of prevention, management, communication and promotion activities aimed at reducing the vaccine hesitancy rate in the population.

Applicability

This standard applies to all immunizers providing provincially funded vaccines and biologicals.

Definitions:

Vaccine Hesitancy

- Defined as the reluctance or refusal to immunize despite the availability of vaccines.
- Has also been defined by the WHO SAGE working group as "a complex behavioral phenomenon specific to vaccines, context, time, and place and influenced by factors of complacency, convenience, and confidence."

Vaccine Acceptance

- Is the willingness or intent to receive a vaccine

Vaccine Confidence

- Is the belief that vaccines are effective, safe, and part of a trustworthy medical system.

Vaccine Literacy

- Is the degree to which people have the capacity to obtain, process, and understand basic information about vaccines and immunization services to make informed decisions.

Cultural Safety

- Cultural safety is an outcome based on respectful engagement that recognizes and strives to address power imbalances inherent in the healthcare system. It results in an environment free of racism and discrimination, where people feel safe when receiving health care.

Competency

The Public Health Agency of Canada has published the Immunization Competencies for Health Professionals with the goal of promoting safe and competent practices for immunization providers. The following competencies outlined in that document are applicable for this standard:

- Describe factors which lead to skepticism regarding immunization for both health professionals and the public.
- Describe the impact that misperceptions regarding immunizing agents have on immunization programs and on the population.
- Address misperceptions regarding immunizing agents using an evidence-based approach.
- Locate evidence-based sources of information on current issues relating to immunization.
- Use evidence-based scientific knowledge to develop clear, concise key messages regarding true immunization benefits and risk.

Section 1: Vaccine Hesitancy Framework

The reasons for vaccine hesitancy are complex and can be demonstrated through a primary framework such as the 5C Psychological Antecedents of Vaccination Model. Although there have been several models and/or approaches to explain vaccine hesitancy previously noted in the literature, the 5C model assesses all relevant concepts identified in the literature regarding vaccine hesitancy. Thus, the 5C model presents a comprehensive overview to understand the psychological foundations of vaccine uptake and demonstrates that addressing vaccine hesitancy is not a one size fits all approach.

The following 5C Model summarizes the key factors that can influence vaccine hesitancy:

Confidence: Level of trust in the effectiveness and safety of vaccines, the systems that deliver vaccines including competence of the health services and health professionals and the motives of those who establish vaccine policies.

Calculation: Individual engagement in extensive information searching and evaluation of risks of infections vs immunizations. Depending on the information sources that are used and due to vast amounts of anti-immunization sources available, increased calculation can result in non-immunization.

Convenience: Extent to which vaccines are available, affordable, accessible, and individuals' ability to understand (as a reflection of language and health literacy) the need for immunizations.

Complacency: Perception that risks of vaccine-preventable disease are low and vaccines are not deemed a necessary preventative action.

Collective responsibility: Extent to which one is willing to protect others by one's own immunization by means of herd immunity.

Figure 3. The 5C Model of Vaccine Hesitancy

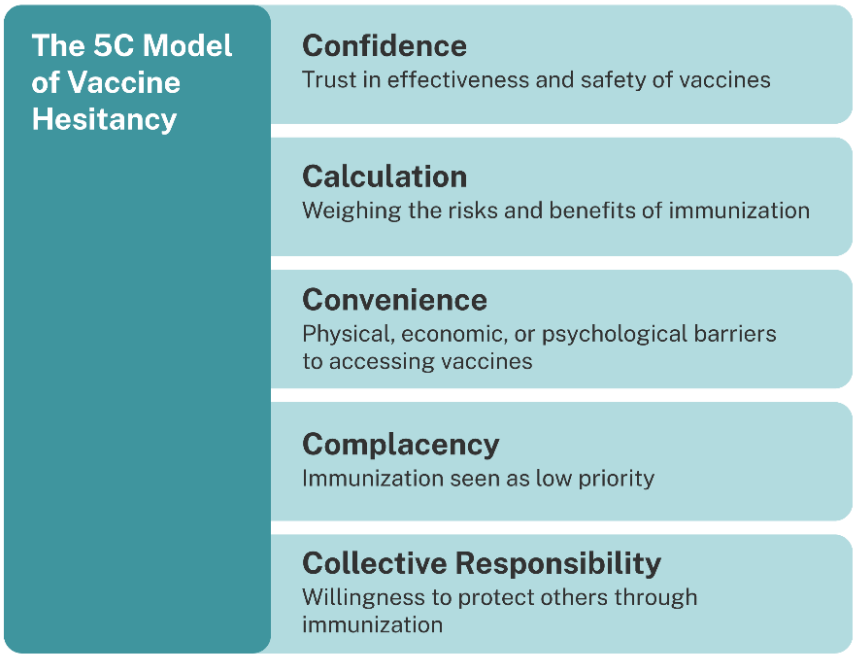


Figure 3 adapted from: Understanding COVID-19 Vaccine Hesitancy in the United States: A Systematic Review. https://doi.org/10.3390/vaccines12070747

Responding to Vaccine Hesitancy through the "5C Model"

Individual	Health care provider
Confidence	
"There is a lot that worries me about these vaccines. I don't know if they are actually safe, and I don't trust these vaccines".	"Thank you for sharing your thoughts with me. I can say with confidence that Health Canada has very high standards for vaccine safety. Decisions to authorize vaccines for use in Canada are based on scientific and medical evidence showing that vaccines are safe and effective".
Complacency	
"I do a lot of things to protect myself from getting sick. I eat well, wash my hands, and exercise regularly. I feel like I am healthy and don't think I need to get immunized".	"It's great to hear you are doing things to keep yourself healthy! However, unfortunately, even healthy people can become sick from vaccine-preventable diseases. For some, symptoms may be mild, but others can experience long-term complications or even death after getting disease. Vaccines make your immune system stronger and more capable at preventing or minimizing the effects of certain diseases".

Convenience	
"I must get multiple doses of some of these vaccines, and I don't drive, and I have to take the bus everywhere. On top of that I also have a job where I work various shifts. It just seems it might be hard for me to get the vaccine, so I don't know if it is worth it"	"You're right, some vaccines require multiple doses and that there's a recommended spacing required. That said, there is some flexibility to accommodate your schedule. I know your job is important to you. We offer evening and weekend appointments so that you can find something that works with your schedule. Getting immunized will keep you healthy so you can continue working and protect you from some diseases when you're on the bus or at work."
Calculation	
"I have done a lot of reading online about vaccines and I think getting immunized is a scare tactic used by governments so pharmaceutical companies can make money. The government is not going to force me to get one of those vaccines."	"Thanks for sharing this with me. I wish it was true that vaccine-preventable diseases aren't real or harmless, but unfortunately, that's just not the case. Here's what we know for sure: since the introduction of vaccine programs, cases of vaccine preventable diseases have seen an 84%-100% decrease in disease cases. This is a part of why vaccines are so key for limiting the spread and number of deaths caused by vaccine preventable diseases. The government is not going to force anyone to get vaccines. That said, as your healthcare provider, I absolutely recommend you get all recommended vaccines for your yourself and for your loved ones".
Collective responsibility	
"I know that with 'community (herd) immunity', it's not necessary for everyone to get immunized. Since most people get immunized, I should be safe, even if I don't get a vaccine myself."	"Thank you for sharing your thoughts. With community (herd) immunity, the more people in a community who are immunized, the harder it is for a disease to spread, and the chance of an outbreak greatly decreases. Immunization rates need to be high for community immunity to work. Depending on several factors and the specific disease, immunization levels must reach 75% or greater to achieve community immunity. In addition, community immunity does not protect against all vaccine-preventable diseases. For example, tetanus bacteria can be found in dirt, dust, and soil and does not spread from person to person. Any unimmunized person is at risk of getting tetanus as they are not protected by community immunity".

Section 2: Practical Evidence-Based Communication Strategies for Reducing Vaccine Hesitancy

Start early	Prenatal appointments and/or postpartum visits can be a strategic opportunity to introduce the importance of immunizations as well as offer individuals the chance to ask questions and be provided with credible resources.
Build trust with parents	Time spent discussing vaccines and addressing concerns, as well as tailoring information helps providers build trust to promote vaccine uptake. Providers that are knowledgeable, respectful, and provide culturally safe care will demonstrate the communication competence to positively influence parental attitudes.

Present both the risks and benefits of vaccines fairly and accurately	Studies in other countries have found presenting both the benefits and risks of vaccines to be a promising approach for increasing vaccine acceptance. Describe the benefits and risks in an understandable way using simple vocabulary and avoiding medical jargon.
Address injection pain	Studies have shown that fear of needles or pain related to immunization can cause people to be vaccine-hesitant or to refuse vaccines altogether. Research has shown that parents are more comfortable with their baby's immunizations when pain is controlled. Commitment to Comfort | Alberta Health Services
Use presumptive approach	How immunization is presented to the individual matters. A presumptive approach such as "John needs to be immunized today" is more likely to result in vaccine acceptance vs "How would you like to proceed with John's immunizations today?".
Use motivational interviewing techniques to understand an individual's vaccine concerns	Motivational interviewing [MI] is a communication technique that involves the exploration of ambivalences and promoting internal motivation for attitudinal change. Using open ended questions, affirming what has been heard, listening reflectively and then summarizing are all key components. PACES 2 – Change and Motivational Interviewing Examples of motivational interviewing scripts are included in the Motivational Interviewing Scripts.
Keep messages short and simple	Research has shown that for parents who are already vaccine hesitant, messaging that too strongly advocates immunization can be counterproductive and providing too much information can increase hesitancy. Choose clear vocabulary to describe disease or vaccine risks. The Immunization Tool for Health Care Providers is an excellent resource for answering individual's questions.
Focus on the protection of the child and the community	Remind parents that choosing not to immunize puts their child at risk and others too, including those most vulnerable. Be sure to emphasize the importance of protecting each other. Stories from parents of children who cannot be immunized (for example, children with cancer) can be powerful and can help parents connect to the importance of immunization.
Remind parents that community immunity does not guarantee personal protection	Remind parents that for protection from community immunity (herd immunity) to work, immunization levels for some diseases need to be very high. For example, measles requires an immunization rate of at least 95% to achieve community immunity. Also, remind parents that protection through community immunity does not exist for some diseases (for example, tetanus).
Use Visual Aids	Visual aids can help people understand complex concepts, especially those with low literacy or English as a second language. Examples of visual aids are included in Visual Graphics that Providers Can Use to Explain More Complex Information.

Section 3: Canada's Vaccine Safety System

Vaccines in Canada go through extensive monitoring, testing, and decision making at different levels before they are available to the public. Perceived vaccine safety risks can present as a barrier to vaccine uptake. Health care providers with a comprehensive understanding of Canada's vaccine safety system are better able to effectively communicate on vaccine safety to gain public confidence.

Vaccine Product Life Cycle

Table 1 and Table 2 describe the phases of the vaccine life cycle along with associated studies and regulatory requirements as appropriate, and what each contributes to knowledge about and/or assurance of vaccine product safety. The pharmacovigilance activities shown in the tables are global in scope and information is shared so that new evidence can be applied to ensure the ongoing safe use of vaccines.

Table 1: Pre-marketing evaluation of safety and quality

Vaccine life cycle phase	Type of study	Regulatory requirement/guidance	What it provides regarding vaccine safety
Non-clinical testing	Laboratory and animal testing	• Food and Drugs Act and Regulations • Good Laboratory Practice	Information on possible safety concerns
Clinical trials 1. Phase I 2. Phase II 3. Phase III	Human subjects: 1. 1-10 2. 100-1,000 3. 1,000-30,000	• Food and Drugs Act and Regulations • Good Clinical Practice	Type of vaccine adverse reactions that are: 1. very common 2. common 3. uncommon +/- rare
Validation of manufacturing process	Validation of each step in the manufacturing process, from seed lot or cell bank production to delivery and related quality control tests	• Food and Drug Act and Regulations • Good Manufacturing Practice • Other international quality guidance documents (ICH, WHO, other regulators)	Documents needed for regulatory review of: • Production processes and quality control • Production facilities
On-site evaluation of manufacturing process	Site visit by Health Canada product specialists to evaluate production processes and facilities	• Food and Drug Act and Regulations • Good Manufacturing Practice • Other international quality guidance documents (ICH, WHO, other regulators)	Ensures that the manufacturing process is capable of consistently delivering quality product
Lot release program: Consistency testing	Health Canada laboratories test samples from 3 or more consecutive lots	Food and Drug Act and Regulations	Quality of vaccine
Drug Establishment licensing	• Site visit by Health Canada specialist to evaluate the drug establishment	• Food and Drug Act and Regulations	• Ensures facilities in which the product is manufactured are appropriate to the

Vaccine life cycle phase	Type of study	Regulatory requirement/guidance	What it provides regarding vaccine safety
	• Sample analysis • Review of new and annual license applications	• Good Manufacturing Practice	specifications that apply to that product • Quality of vaccines

Table 2: Post-marketing regulatory oversight and pharmacovigilance activities

Vaccine life cycle phase	Type of study	Regulatory requirement/guidance	What it provides regarding vaccine safety
Lot release program	Health Canada bases the level of regulatory oversight (testing and/or protocol review) on the degree of risk linked to the product	Food and Drug Act and Regulations	Lot release risk-based approach to testing and oversight allows for enhanced post-market surveillance of vaccines
Establishment inspections	Regulator inspections of production facilities, usually every 2-3 years	• Food and Drug Act and Regulations • Good Manufacturing Practice	Ensures ongoing quality of vaccine production
Expanded vaccine safety data collection in target and special populations	Scientific and/or epidemiological studies of human populations involving hundreds to many thousands	Food and Drug Act and Regulations	• Safety profile in special populations not studied as part of pre-marketing clinical trials (for example, diabetics) • Possible interaction with other vaccines
Adverse events following immunization (AEFI) surveillance systems	Spontaneous, enhanced and/or active AEFI reporting systems	• Food and Drug Act and Regulations: for Market Authorization Holders • Public health legislation in some provinces and territories makes AEFI reporting mandatory	Detection of vaccine safety signals which are them investigated to determine root cause
Post-marketing studies	• Population-based epidemiological studies • Randomized control trials • Individual case clinical investigation	May be requested by regulators in response to new vaccine safety signals	• Rare and very rare vaccine product-related reactions • Vaccine attributable risk • Evidence that certain AEFI are coincidental events.

Authorization for marketing a vaccine in Canada

Health Canada's Biologics and Genetic Therapies Directorate (BGTD) is responsible for the Regulatory roadmap for biologic (Schedule D) drugs in Canada, including vaccines. Before manufacturers or sponsors are eligible to market a product in Canada, they must submit a "New Drug Submission". This submission contains extensive information and data about the vaccine's safety, efficacy and quality, including the results of the non-clinical and clinical studies, details regarding the production of the vaccine, packaging and labeling details, and information regarding therapeutic claims and side effects. The quality evaluation of the submission includes an onsite evaluation of the production facilities as well as laboratory testing of samples from three to five consecutive lots (or batches of vaccine production) to verify manufacturing consistency.

After BGTD determines that the vaccine is compliant with the Canada's Food and Drugs Act and Regulations, Health Canada will issue a Notice of Compliance and a Drug Identification Number (DIN) for market authorization.

Compliance with Good Manufacturing Practices (GMP) is an additional Health Canada requirement for selling vaccines in Canada. The Health Canada Regulatory Operations and Enforcement Branch ensures this compliance through issuance of Establishment Licenses for manufacturing sites in Canada via its own GMP inspections or through Mutual Recognition Agreements with international regulatory bodies, such as the European Medicines Agency, for manufacturing sites outside of Canada.

Quality monitoring activities

These strategies allow Health Canada to assess how well the manufacturing process is controlled and that the quality control tests remain suitable.

Lot Release Program

Each vaccine lot is subject to the Lot Release Program for Schedule D (Biologic) Drugs before sale in Canada. The results of key quality control tests performed throughout the manufacturing process of each individual vaccine lot must be submitted to Health Canada for review before a release letter is issued to allow the sale of the lot on the Canadian market. The purpose of the Lot Release Program is to ensure to the extent possible that each newly manufactured batch of vaccine matches the lots used to generate the safety and efficacy data for market authorization. As part of its Lot Release Program, Health Canada performs testing of most vaccine lots as per its Lot Release Guidelines.

Vaccine manufacturers may be requested to submit a Yearly Biological Product Report. This report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

In addition, regular Good Manufacturing Practice inspections are conducted to ensure continued compliance and renewal of establishment licenses for vaccine manufacturing facilities.

Safety monitoring activities

Canada Vigilance Program

Market authorization holders such as the sponsors or manufacturers that have the legal authority to market their drug in Canada are required to report serious adverse reactions to the Canada Vigilance Program, as mandated by the Food and Drugs Act and Regulations. The Canada Vigilance Program also accepts reports from health professionals and consumers. This information enables Health Canada to monitor the safety profile of vaccines to determine if their benefits continue to outweigh their risks.

Safety reports

The Food and Drugs Act and Regulations require market authorization holders to analyze adverse drug reaction data for safety concerns and prepare an annual summary report which represents a comprehensive assessment of the worldwide safety data of the vaccine. Market authorization holders must also notify Health Canada if they become aware of a significant change in the product benefit-risk profile.

Safety reports are assessed by Health Canada and, if specific safety issues are identified, additional safety information may be requested.

Risk management plans

Health Canada reviews the Risk Management Plan when the market authorization holder is seeking authorization to market a new vaccine in Canada but can also request for one to be submitted at other times.

Product risk/benefit assessments

Health Canada can ask the market authorization holder to submit a benefit-risk assessment of a therapeutic health product when the benefit-risk profile of a product has changed. Health Canada evaluators reviewing benefit-risk assessments use science-based procedures to determine whether the benefits outweigh the risks or whether the product needs regulatory intervention.

Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)

The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is a collaborative post-marketing federal/provincial/territorial (F/P/T) passive surveillance system with the following objectives:

- Continuously monitor the safety of marketed vaccines in Canada.
- Identify increases in the frequency or severity of previously identified vaccine-related reactions.
- Identify previously unknown Adverse Event Following Immunization (AEFI) that could possibly be related to a vaccine (unexpected AEFI).
- Identify areas that require further investigation and/or research. Provides timely information on AEFI reporting profiles for vaccines marketed in Canada that can help inform immunization-related decisions.

CAEFISS includes spontaneous, enhanced and active AEFI reporting processes. Each province and territory have their own reporting system that includes activities at the local/regional as well as the provincial/territorial levels. All provincial and territorial systems are part of CAEFISS.

Spontaneous AEFI reports may come from health care professionals and the public. F/P/T immunization program authorities encourage vaccine providers and others to report AEFI of public health importance and sometimes conduct enhanced AEFI surveillance as part of new publicly funded immunization programs or as a response to possible emerging vaccine safety signals. In most jurisdictions (Ontario, Quebec, Nova Scotia, Manitoba, New Brunswick, Saskatchewan, Prince Edward Island and Northwest Territories, British Columbia, Alberta and Nunavut) AEFI reporting is a legislated requirement.

In Alberta, the Public Health Act mandates that any health care practitioner (HCP) who becomes aware of an adverse event following immunization must report the event to the AHS provincial AEFI team.

Vaccine Vigilance Working Group

The Vaccine Vigilance Working Group (VVWG) includes members representing all federal (First Nations and Inuit Health Branch/Indigenous Services Canada, National Defence and the Canadian Armed Forces, Royal Canadian Mounted Police, Correctional Services of Canada) and P/T immunization programs as well as Health Canada regulators and Canadian Immunization Monitoring Program ACTive (IMPACT). The working group reports to the Canadian Immunization Committee and its activities include:

- Preparing national guidelines and procedures for monitoring AEFIs in Canada
- Providing a national forum to identify, share and promote best practices regarding vaccine pharmacovigilance
- Providing a national vaccine safety surveillance network that can rapidly share and disseminate information to appropriate stakeholders regarding vaccine safety signals or other relevant issues.

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