

## Background

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The Alberta Immunization Policy (AIP) outlines guidelines and recommendations for the provision of immunization services in Alberta. These guidelines and recommendations have been developed through consultation, literature review and jurisdictional scans. The Canadian Immunization Guide<sup>1</sup> ([www.phacaspc.gc.ca/publicat/cig-gci/index-eng.php](http://www.phacaspc.gc.ca/publicat/cig-gci/index-eng.php)), National Advisory Committee on Immunization (NACI) statements ([www.phac-aspc.gc.ca/naci-ccni/index-eng.php](http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php)), and vaccine product monographs (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) are the primary sources of immunization information.

Provision of immunization services within Alberta is directed by the policies, guidelines and standards contained within the AIP, which take precedence over those found in the Canadian Immunization Guide. This policy document is available as a reference for immunizers in Alberta and will be updated on an ongoing basis. Questions regarding interpretation of the AIP should be directed to Alberta Health, Public Health and Compliance Division, Immunization Program or the regional (Alberta Health Services Zone) Medical Officer of Health (MOH)/designate. In addition, providers of vaccines should be aware of the contents of the relevant biological product monographs. Vaccine components and dosage differ between manufacturers. Vaccine specific recommendations for each vaccine are included in the Biological Products section.

While immunization may not protect 100% of susceptible healthy individuals and immunocompromised persons may have suboptimal immune response to immunization<sup>1</sup>, immunization is one of the most effective medical interventions to prevent disease.<sup>1</sup> Immunization recommendations are based on scientific knowledge about the vaccine and immune system, epidemiology and burden of disease, vaccine safety, and a cost analysis of preventive measures. The benefits of immunization far outweigh any risks to a vaccine preventable disease. Benefits of vaccines include complete or partial protection against vaccine-preventable diseases for the individual, society as a whole through herd immunity and prevention of outbreaks. Vaccines reduce health-related costs associated with vaccine preventable diseases including visits to health care providers, antibiotic/antiviral use, hospitalizations, premature deaths, and parents lost time from work to care for sick children.<sup>1</sup> Recommendations for immunization balance the individual and societal benefits against the potential costs and risks of the vaccine.

Immunization schedules are designed to achieve the best levels of immunity and to increase individual compliance. The timing should be adhered to as closely as possible. If changes are necessary, the vaccine provider should record the rationale for the departure from the schedule.

## Federal Leadership

### Vaccine Production and Regulation

The Health Products and Food Branch, Biologics and Genetic Therapies Directorate ([www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php)) (BGTD) of Health Canada regulates vaccines for humans in Canada. Like all medicines, vaccines must undergo several stages of rigorous testing before they are approved for use. Before a vaccine is licensed for use by the BGTD, there must be evidence (clinical trials) to support the safety, efficacy and quality of the vaccine.<sup>1</sup> Vaccine efficacy is the ability of the vaccine to confer protection against the target diseases, either directly in terms of disease reduction or indirectly in terms of elicitation of protective antibodies. Once the efficacy of a vaccine is proven, its effectiveness in public health practice is determined. This measure reflects the direct and indirect effects of immunization in a population under possibly suboptimal “real-life” conditions.

The BGTD also supervises all aspects of vaccine production by manufacturers. Before any vaccine is licensed and approved for use in Canada, the factory where it is manufactured must be inspected to ensure that all stages of production meet the requirements for safety, sterility and quality control. Before release by the manufacturer, each batch of vaccines is tested for safety and potency. Most safety tests are carried out both by the manufacturer and independently by the laboratory of the BGTD.

Public Health Agency of Canada, National Advisory Committee on Immunization (NACI), and Canadian Immunization Committee (CIC)

The Public Health Agency of Canada ([www.phac-aspc.gc.ca/index-eng.php](http://www.phac-aspc.gc.ca/index-eng.php)) (PHAC) is primarily responsible for policies, programs and systems related to prevention, health promotion, disease surveillance, community action and disease control.

The National Advisory Committee on Immunization (NACI) is composed of experts from across the country in areas such as public health, infectious diseases and pediatrics. This committee provides the PHAC with ongoing and timely medical and scientific advice related to immunization. Recommendations from the NACI on the use of vaccines in Canada are published in the *Canadian Immunization Guide*.<sup>1</sup> Regular supplementary statements by the NACI are published in the *Canada Communicable Disease Report* ([www.phac-aspc.gc.ca/publicat/ccdr-rmtc/](http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/)) (CCDR). Adjustments to vaccine schedules and selection of vaccines are based on NACI recommendations.

The Canadian Immunization Committee (CIC) is a Federal, Provincial and Territorial (F/P/T) committee reporting to the Communicable Disease Control Expert Group operating within the Public Health Network of PHAC. The mandate of CIC is to provide a national forum for public health to implement the objectives of the National Immunization Strategy, provide policy guidance on immunization programs, address emerging immunization issues, and foster F/P/T cooperation, collaboration and engagement of non-governmental stakeholders.

The *National Guidelines for Immunization Practices*<sup>1</sup> were developed to provide a standard of practice that will ensure vaccines are handled properly and administered by competent immunizers delivered to all children as recommended by provincial and territorial programs. These guidelines are recommended for use by all health practitioners who administer vaccines or manage immunization services for infants and children. Some of the guidelines will be more applicable to particular settings or situations, but all should be considered in reviewing current practices. Health practitioners and local health officials should cooperate in their efforts to assure high coverage rates in the community to achieve and maintain the highest possible degree of community protection against vaccine-preventable diseases.

Adverse Events Following Immunization (AEFI) Monitoring

Adverse events following immunization (AEFI) are monitored by the Vaccine Safety Section of PHAC. The Canadian Adverse Events Following Immunization Surveillance System ([www.phac-aspc.gc.ca/im/vs-sv/index-eng.php](http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php)) (CAEFISS) was developed to provide a national monitoring system for the reporting of adverse events and suspected adverse events following immunization. Non-nominal case reports of events temporally related to the administration of a vaccine are submitted voluntarily by health care providers through their provincial/territorial public health authorities. The reports are reviewed to detect vaccine safety signals including any unexpected or unusual AEFI.

The Vaccine Vigilance Working Group (VWVG) includes representatives from all federal, Provincial/Territorial immunization programs, Health Canada regulators and Immunization Monitoring Program, ACTive (IMPACT) and whose activities include providing a national vaccine safety sentinel network that can rapidly share and disseminate information to appropriate stakeholders regarding vaccine safety issues or signals.

Additional surveillance to supplement the passive reporting system is also in place. Since 1990, IMPACT, an active, pediatric hospital-based surveillance program ([www.cps.ca/impact](http://www.cps.ca/impact)) has searched admissions for events that may be related to severe vaccine-associated adverse events, vaccination failures and vaccine preventable infections. The pediatric centres involved encompass 90% of all pediatric admissions to Canadian academic centres.

Alberta guidelines pertaining to the management and reporting of adverse events following immunization are provided separately in *Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers*.<sup>2</sup>

**References**

<sup>1</sup> National Advisory Committee on Immunization. *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.canada.ca/en/public-health/services/canadian-immunization-guide.html](http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html)

<sup>2</sup> Alberta Health. (2015, February). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. [www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf](http://www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf)