Supplemental Competencies on Injection for Canadian Pharmacists

November 2012
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INTRODUCTION

The current landscape of the scope of practice for Canadian pharmacists varies from jurisdiction to jurisdiction. Generally speaking, legislation to expand the scope of practice for pharmacists is changing across the country to include a greater range of activities and services performed by licensed pharmacists. One such activity is the administration of drugs including multiple routes both parenteral and non parenteral.

NAPRA’s members, the pharmacy regulatory authorities (PRAs), put forward that the establishment of a common set of competencies on injection for Canadian pharmacists that would allow consistent training of pharmacists across Canada and allow labor mobility for pharmacists trained in one province to move to another province and apply their training where the legislative framework exists to do so. In addition, the hope is that future training courses could be developed incorporating these common competencies without the necessity of a fulsome review of both competency as well as course requirements.

All PRAs and NAPRA explored how best to address the development a set of competencies for injection to meet the training needs of all. It was agreed by all NAPRA members that the Immunization Competencies for Health Professionals published by the Public Health Agency of Canada could be adopted. An additional competency was developed to specifically address injection of other substances thus completing the content for NAPRA’s Supplemental Competencies on Injection for Canadian Pharmacists.

NAPRA would like to thank all PRA representatives who contributed to the development of this document as well as all stakeholders who provided feedback on the draft document during the consultation period.

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Immunization Competencies for Health Professionals
Immunization Competencies for Health Professionals

Prepared by the Professional Education Working Group of the Canadian Immunization Committee

Approved by the Communicable Disease Control Expert Group and the Pan-Canadian Public Health Network

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As a starting point for *Immunization Competencies for Health Professionals*, the working group used a document prepared by the U.K. Health Protection Agency entitled *Core Curriculum for Immunisation Training* and adapted it to the Canadian context.

The levels of proficiency (aware, knowledgeable, or proficient) used to develop the Immunization Competencies Levelling Tool was adapted from a document prepared by the Northwest Center for Public Health Practice, University of Washington School of Public Health and Community Medicine entitled *Informatics Competencies for Public Health Professionals*. 
Preamble

The competencies contained in the handbook Immunization Competencies for Health Professionals were developed to support the application of the National Guidelines for Immunization Practices, published in the Canadian Immunization Guide. The aim of this handbook is to promote safe and competent practices to achieve higher vaccine coverage rates. This effort will enable and maintain the highest possible degree of community protection against vaccine-preventable diseases.

The competencies range from knowledge of the scientific basis of immunization to essential immunization practices and contextual issues relevant to immunization. Each competency is supported by a learning domain and a number of guiding learning objectives.

This handbook does not dictate how to teach or assess health professionals. Instead, it lays out the essential topics for effective immunization that are universal to a wide range of health professionals. These can be adapted and incorporated into all immunization training or performance evaluations. As such, the immunization competencies provide the framework stakeholders can use to tailor education programs to the needs of health professionals based on their level of experience, practice setting, and degree of involvement with immunization.

The competencies can be used by:

» Educational institutions and continuing education providers to conduct needs assessments, assess existing curricula, and incorporate the Immunization Competencies in undergraduate and continuing education training;

» Coordinators and managers of immunization programs to set practice standards and conduct employee performance evaluations;

» Front-line health professionals to identify their individual learning needs and select learning opportunities that address the Immunization Competencies; and

» Educators to assess curricula and adapt existing educational resources to support the Immunization Competencies.

Professional education is one of the initiatives undertaken by the Public Health Agency of Canada (PHAC) to support the National Immunization Strategy, launched in 2003. In 2005, PHAC formed the Professional Education Working Group (PEWG) with members representing front-line health professionals, immunization program planners, professional societies, and academics from across Canada. PEWG is a sub-group of the Canadian Immunization Committee, a federal, provincial, and territorial group of public health officials providing leadership, advice, and recommendations to PHAC on implementing the strategy and on issues affecting immunization in Canada.

PEWG is responsible for making recommendations regarding professional development strategies and learning opportunities for health professionals in the field of immunization. The Immunization Competencies were developed in consultation with immunization program planners from federal, provincial, and territorial jurisdictions; expert advisory committees on immunization; health professional educators; licensing bodies and professional societies; health education accreditors; vaccine regulators; and vaccine manufacturers (Appendix A).
As part of its supporting role, PHAC is involved in the development of learning opportunities and resources that can help health professionals achieve and maintain the immunization competencies. PHAC encourages provincial and territorial jurisdictions, educational institutions, health professional organizations, and other stakeholders to use and incorporate the Immunization Competencies into their respective activities. The desired result is an expanded and diverse set of immunization education resources to support a similarly diverse set of health professionals.

Appendix C includes a levelling tool to assist in identifying levels of proficiency based on the specific responsibilities and performance requirements of a given set of health professionals in a given work setting.
The Canadian Context

Vaccine Approval – Health Canada Biologics and Genetic Therapies Directorate
All vaccines authorized for sale in Canada are reviewed and approved by the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada. Like all medicines, vaccines must undergo rigorous review and testing before they are approved for use. Health Canada also supervises all aspects of vaccine production by the manufacturers to ensure safety, sterility, and quality.

Before a new vaccine can be submitted to Health Canada for approval, its manufacturer must collect sufficient scientific evidence from pre-clinical and clinical human trials (typically carried out over several years) that show the vaccine is safe, effective, and of high quality and that it produces the desired immune response. The manufacturer must then include this evidence along with information on how the vaccine was developed and manufactured, as well as how it will be routinely tested, in a New Drug Submission filed with the BGTD.

As part of the process for approving vaccines, members of the BGTD perform on-site inspections and evaluations of the vaccine manufacturer’s establishment(s) to assess the quality of the production process and ensure that the necessary quality controls and internationally recognized Good Manufacturing Practices are being used. The manufacturer must also provide at least three sample batches or “lots” of the vaccine to the BGTD for testing in its laboratories. The BGTD approves a vaccine only when its safety, effectiveness, and quality have been thoroughly proved and when the benefits of the vaccine greatly outweigh any risks associated with it. If the above requirements have been satisfied after thorough review of the New Drug Submission, the on-site evaluation(s), and the independent laboratory testing of samples, the vaccine is issued a Drug Identification Number and a Notice of Compliance indicating that it is approved for sale in Canada.

All vaccines sold in Canada undergo ongoing lot release evaluation even after they have been approved. The manufacturer must submit the results of testing for each lot of vaccine to be sold in Canada and lot samples for independent evaluation by the BGTD. In order to sell new lots of the vaccine, manufacturers must ensure that each new lot is the same in its specific characteristics as the ones tested before authorization was given. This method allows experts to reasonably determine that the new lots are as safe and effective as previous ones. If a vaccine lot meets all required specifications, a formal release letter is issued to approve the sale of that lot in Canada.

Optimal Use – The National Advisory Committee on Immunization
The National Advisory Committee on Immunization (NACI) is an independent committee of recognized experts (in the fields of paediatrics, infectious diseases, immunology, medical microbiology, internal medicine, and public health) that provides expert advice on vaccines to PHAC. After Health Canada authorizes a vaccine for sale in Canada, the NACI evaluates all available scientific information about that vaccine and then makes recommendations about its optimal use. For information on the list of immunizing agents and the companies that have received approval to market them in Canada, consult the Canadian Immunization Guide.

Immunization Programs – The Provinces and Territories
In Canada, provinces and territories are responsible for the development of publicly funded immunization programs, including the purchase of vaccines. Each provincial or territorial ministry of Health uses NACI’s recommendations to develop its program and schedules for children and adults. While the provinces and territories decide which vaccines to purchase, most of the vaccines used in publicly funded immunization programs in Canada are purchased through a bulk purchasing program coordinated by Public Works and
Government Services Canada. In some cases, provinces may purchase vaccines on their own behalf. All vaccine purchases must follow a process that is open, fair, and transparent and must respect Canada’s obligations under applicable national and international trade agreements. The vaccine procurement process is intended to ensure that equal consideration is given to all eligible vaccines that have met the stringent requirements for approval in Canada.

**Post-Marketing Surveillance – Public Health Agency of Canada**

After any vaccine is approved to be sold in Canada, mandatory and voluntary post-market surveillance and adverse event reporting occur. Vaccine manufacturers are required by law to report serious adverse events following immunization within 15 days of notification of the occurrence. Public health nurses, doctors, and other healthcare workers in Canada also report these events to the Centre for Immunization and Respiratory Infectious Diseases (CIRID) at PHAC. After removal of any identifying personal information, such events reported at the provincial or territorial level are then referred to the Canadian Adverse Events Following Immunization Surveillance System. Selected serious events, particularly those affecting children, are also reported by the Immunization Monitoring Program – Active (IMPACT). IMPACT is administered by the Canadian Paediatric Society with funding from the Centre for Immunization and Respiratory Infectious Diseases of the Public Health Agency of Canada.

The goal of this national vaccine safety surveillance is to monitor all vaccines used in Canada and to detect, as quickly as possible, any evidence of concern regarding safety. If unexpected or increased side effects due to vaccines occur, the BGTD and CIRID decide on the best course of action needed to resolve these situations.

**Effective, Competent Practice – The National Immunization Strategy**

The development of the National Immunization Strategy (NIS) was first endorsed by the federal/provincial/territorial deputy ministers of Health in June 1999, under the direction of the Advisory Committee on Population Health. In 2002, the deputy ministers agreed in principle to the concept of a strategy and endorsed the *National Immunization Strategy: Final Report* in June 2003.

The NIS stipulates the need for continued collaboration and partnerships with federal, provincial, and territorial partners and other stakeholders to improve the effectiveness and efficiency of immunization programs in Canada. In addition, a key activity of the NIS is the development of a national professional education component to support the achievements and maintenance of a safe and competent practice to better protect Canadians from vaccine-preventable diseases.
Application of Basic Biomedical Sciences to Immunization
1. The Immune System and Vaccines

**Competency:** Explains how vaccines work using basic knowledge of immune system.

**Learning Objectives**

The health professional will be able to perform the following:

1. Compare and contrast innate and adaptive immunity.
2. Differentiate between the primary and memory immune response to a vaccine.
3. Differentiate between passive and active immunity.
4. Explain why some vaccines induce a memory response while others do not.
5. Name some host- and vaccine-related factors that affect the immune response to vaccines.
6. Explain how the immunization schedule accommodates factors that affect the immune response to vaccines.
7. Respond to the concern that giving too many vaccines will overload the immune system.
8. Discuss the pros and cons of immunity gained through immunization as opposed to wild-type infection.

**Key Terms:** Active immunity, antibody, antigen, B-lymphocyte (B-cell), booster, cell-mediated immunity (CMI), herd/community immunity, humoral immunity, memory response, passive immunity, primary immune response, protective level, T-lymphocyte (T-cell).

**Suggested Content for Training**

» Antigens and antibodies
» Cell-mediated and humoral immunity
» Active and passive immunity
» Primary and secondary immune responses
» Conditions that affect immunity and the immune response to vaccines
2. Vaccine-Preventable Diseases

**Competency:** Demonstrates an understanding of the rationale and benefit of immunization, as relevant to the practice setting.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe the key clinical features, including acute and long-term complications, of each vaccine-preventable disease.
2. Describe the key epidemiologic features of each vaccine-preventable disease.
3. Describe the historical impact of immunization on the epidemiology of vaccine-preventable disease.
4. For each of the vaccines administered in the practice setting, formulate a response to the question “Why should I be immunized when vaccine-preventable diseases are so rare in Canada?”
5. Explain why accurate diagnosis of vaccine-preventable diseases is important.

**Key Terms:** Carriage, clinical features, communicability, complications, contagiousness, endemic, epidemic, epidemiology, incubation period, imported, natural infection, pandemic, reservoir, serotypes, serogroups, transmissibility, vaccine-preventable disease.

**Suggested Content for Training**

» Epidemiology, signs and symptoms, and mode of transmission of each disease
» Potential complications/long-term sequelae of vaccine-preventable diseases; the nature and rates of each
» Historical impact of immunization programs and the premature withdrawal of these programs, including reduced coverage
» Concepts of control, elimination, and eradication of vaccine-preventable diseases
3. Vaccine Development and Evaluation

**Competency:** Integrates into practice knowledge about the main steps in vaccine development and evaluation.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe, in general terms, the process to obtain marketing approval for vaccines in Canada.
2. Describe what can be learned about vaccines after they are approved for marketing, via surveillance activities and more formal post-marketing studies.
3. Characterize, in broad terms, the key roles and responsibilities for each of the following relative to the post-marketing assessment of vaccine safety and effectiveness:
   - Vaccine manufacturers
   - Canadian regulatory authority (Biologics and Genetic Therapies Directorate)
   - Public Health Agency of Canada
   - Provincial/territorial Health departments
   - Vaccine providers
   - Healthcare providers who don’t administer vaccines
   - Vaccine recipients or their parents/caregivers

**Key Terms:** Effectiveness, efficacy, immunogenicity, package insert, post-marketing, product monograph, reactogenicity, surveillance.

**Suggested Content for Training**

» Stages of vaccine trials before and after licensure

» Steps in the process of obtaining approval of vaccines for sale in Canada

» Post-marketing surveillance and immunization safety

» The role of surveillance in designing and monitoring immunization programs
4. **The Types of Immunizing Agents and Their Composition**

**Competency:** Applies the knowledge of the components and properties of immunizing agents as needed for safe and effective practice.

**Learning Objectives**

The health professional will be able to perform the following:

1. Classify each immunizing agent used in practice as live attenuated, inactivated, or subunit.
2. Demonstrate the ability to describe live attenuated, inactivated, and subunit immunizing agents to an audience with minimal or no science knowledge.
3. Compare the major advantages and disadvantages of live attenuated versus inactivated/subunit immunizing agents.
4. Identify key differences in the immune response to purified polysaccharide versus polysaccharide protein conjugate vaccines.
5. Describe, in general terms, the purpose, action and potential concerns of each of the following components that may be present in a given vaccine product: adjuvant, preservative, additives, glass vial, stopper, and pre-filled syringe.
6. Locate and utilize current information resources on the types and content of immunizing agents used in practice.

**Key Terms:** Active immunizing agent, additive, adjuvant, allergens, combination vaccine, inactivated vaccine, live attenuated vaccine, passive immunizing agent, polysaccharide, preservative, protein conjugate, purified protein, subunit vaccine, toxoid.

**Suggested Content for Training**

» Immunoglobulins, live and inactivated vaccines, polysaccharide and conjugate vaccines and combination vaccines

» Composition of a vaccine, use of adjuvants and other additives

» Efficacy, reactogenicity, compatibility
5. Population Health

**Competency:** Applies relevant principles of population health for improving immunization coverage rates.

**Learning Objectives**

The health professional will be able to perform the following:

1. Use specific examples to show how immunization is a population-based health strategy.
2. Explain the concept of herd immunity (also called community immunity) in non-scientific terms.
3. Explain, using examples, why vaccine-preventable diseases return when immunization coverage rates decrease.
4. Explain how immunization registries can benefit not only individuals but also populations.
5. Present the case for the importance of having a highly immunized healthcare workforce.
6. Use health promotion planning model to identify barriers (economic, educational, system-based, and social factors) to immunization uptake.
7. Use health promotion strategies to improve immunization coverage rates.

**Key Terms:** Community immunity, coverage rate, determinants of health, effectiveness, efficacy, endemic, epidemic, epidemiological triangle, herd immunity, incidence, mode of transmission, morbidity, mortality, pandemic, population health prevalence, prevention and health promotion, primary prevention, recall, reminder, sporadic.

**Suggested Content for Training**

» Concept of herd immunity and the effect of vaccination on the community as a whole
» How herd immunity protects individuals
» Identification of barriers and obstacles that may prevent uptake of vaccination
» Development of strategies to overcome barriers and improve immunization services
» Consideration of environmental factors such as the clinic environment, appointment timings, and length and attitudes of staff to immunization
Essential Immunization Practices
6. Communication

**Competency:** Communicates effectively about immunization, as relevant to the practice setting(s).

**Learning Objectives**

The health professional will be able to perform the following:

1. List the components of the evidence-based decision-making process.
2. Explain the importance of risk perception for immunization decision making.
3. Respond appropriately following an assessment of client knowledge, attitudes, and beliefs regarding immunization.
4. Deliver clear, concise messages about the risks of vaccine-preventable diseases and the benefits and risks of vaccines.
5. Provide appropriate evidence-based information and resources to clients regarding immunization and vaccines.
6. Provide guidance to clients so they can correctly identify credible sources of information on immunization and vaccines.
7. Apply, as appropriate to the practice setting, mass media strategies for public communication.

**Key Terms:** Credible sources, evidence-based decision making, informed decision making, risk communication, risk perception.

**Suggested Content for Training**

» Issues that affect and influence parents/caregivers in their vaccination decision making
» Responding to commonly asked questions and misconceptions
» Local and national sources of further information and advice for parents
» Importance of risk perception for immunization decision making
» Basic principles of risk communication
» The effect of media reporting on parental views and acceptance of vaccination
7. Storage and Handling of Immunization Agents

**Competency:** Implements Canadian guidelines when storing, handling, or transporting vaccines.

**Learning Objectives**

The health professional will be able to perform the following:

1. State where to access the most recent national guidelines dealing with vaccine storage, handling, and transportation.

2. Describe the national guideline requirements for vaccine storage, handling, and transportation and their importance in maximizing the potency and efficacy of each vaccine.

3. Outline the key steps for maintaining the cold chain in the practice setting.

4. Explain actions taken to report and manage breaks in the cold chain or other insults that compromise vaccine integrity.

**Key Terms:** Min-Max thermometers, National Vaccine Storage and Handling Guidelines for Immunization Providers, potency, efficacy, cold chain, stock rotation.

**Suggested Content for Training**

- Effects of temperature on potency, efficacy, and adverse events of vaccines
- Daily monitoring and written temperature records
- Correct use of designated purpose-built vaccine fridge
- Importance of regular checks for expired vaccine
- Ordering appropriate vaccine stock
- Management of breakdowns in the cold chain
- Disposal of heat- or cold-damaged vaccine
- Monitoring and maintaining the cold chain during vaccine transportation
- Maintenance of the cold chain during a clinic session
- Taking responsibility for ensuring that all vaccines administered have been stored correctly
- Importance of protocols/standard operating procedures in each practice setting
- Fulfillment of National Vaccine Storage and Handling Guidelines for Immunization Providers
8. Administration of Immunizing Agents

**Competency:** Prepares and administers immunization agents correctly.

**Learning Objectives**

The health professional will be able to perform the following:

1. Prepare a checklist for pre-immunization patient assessment, including precautions, contraindications, and indications for rescheduling.

2. Ensure the seven “Rights” of immunization: right drug, right client, right dose, right time, right route, right reason, and right documentation.

3. Demonstrate the steps involved in vaccine preparation, including reconstitution, if appropriate, administration, and disposal.

4. Name the resources that are used to guide the immunization administration process and decision making.

5. Develop a table listing the vaccine, age, dose, route, site, contraindications/precautions, and side effects for each vaccine used in the practice setting.

6. Demonstrate the age-appropriate injection sites and proper client positioning used for immunization.

7. Choose the correct needle length and gauge for the age and size of the client.

8. Describe actions taken to increase safety in immunization clinics related to the provider, the recipient, and the environment.

9. Demonstrate the appropriate technique for immunization.

10. Describe techniques to reduce the pain associated with immunization.

**Key Terms:** Aseptic technique, Canadian Immunization Guide (CIG), contraindications, expired stock, expiry date, immunization schedules (delayed, interrupted, etc.), injection error, injection site, medication error, minimum vaccine intervals, needle length and gauge, needle stick injury, precautions, reconstitution, rotation of stock, route of administration (intramuscular, subcutaneous, intradermal, intranasal, oral), routine practices, safety-engineered injection devices.

**Suggested Content for Training**

- Assessment of fitness for vaccination and identification of true contraindications to vaccination
- Route, needle size, and injection site for administration of vaccine based on research, current recommendations, and effects on efficacy and local reactions
- Dosage and reconstitution of each vaccine
- Preparation and disposal of vaccination equipment
9. Adverse Events Following Immunization

**Competency:** Anticipates, identifies, and manages adverse events following immunization, as appropriate to the practice setting.

**Learning Objectives**

The health professional will be able to perform the following:

1. Use reliable, evidence-based resources to list the frequencies of the common, uncommon, and rare adverse events associated with vaccines.

2. Inform recipients and/or their caregivers on what to expect and what to do regarding adverse events that could follow immunizations.


4. Document all adverse events following immunization on the appropriate form and submit it to the appropriate agencies.

5. Distinguish between reporting an adverse event following immunization and proving that immunization caused an adverse event.

**Key Terms:** Abscess, active surveillance, adverse event following immunization, adverse vaccine reaction, anaphylaxis, anxiety attack, causality, cellulitis, encephalitis, encephalopathy, Guillain-Barré syndrome, hypotonic hyporesponsive episode, induration, injection site reaction, local reaction, nodule at injection site, oculorespiratory syndrome, passive surveillance, serious adverse events, syndromic surveillance.

**Suggested Content for Training**

» Physiology of anaphylaxis and allergic reactions

» Potential causes of anaphylaxis and ways of decreasing the risks

» Signs and symptoms of and differences between anaphylaxis and fainting

» Treatment of anaphylaxis, equipment required, adrenaline dosages, and sites for its administration

» Definition and types of adverse events

» Where and how to report adverse events to vaccines – Canadian Adverse Events Following Immunization Surveillance System

» Recording of adverse events to vaccinations – Use of the Adverse Event Following Immunization Reporting Form
10. Documentation

**Competency:** Documents information relevant to each immunization encounter in accordance with national guidelines for immunization practices and jurisdictional health information processes.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe the role and importance of immunization records.
2. Identify the information to be documented on an immunization record.
3. Record an immunization encounter on the appropriate documentation instruments accurately and completely.
4. Facilitate the transfer of information in the vaccination record to other providers and to appropriate agencies in accordance with requirements.
5. Record the reason and planned follow-up action when a scheduled immunization is not given.

**Key Terms:** Bar coding, immunization coverage, immunization record professional chart, immunization record take-home, immunization registry, lot number.

**Suggested Content for Training**

- Requirements and importance of accurate documentation
- Where and why vaccinations should be recorded and reported
- Policy for reporting and recording vaccine errors
- Importance of and reasons for recording lot numbers
11. Populations Requiring Special Considerations

**Competency:** Recognizes and responds to the unique immunization needs of certain population groups.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe the unique immunization needs of certain populations, as relevant to the practice setting, including:
   - individuals who are off course of a recommended immunization schedule;
   - individuals who have had a serious adverse event following a prior immunization;
   - individuals with certain medical conditions, including transplant recipients;
   - pregnant women;
   - women who are breastfeeding;
   - occupational risk groups;
   - travellers;
   - new Canadians;
   - international students;
   - individuals with behaviours that put them at risk for vaccine-preventable diseases;
   - “hard-to-reach” individuals; and
   - outbreak populations.

2. Appropriately refer to expert professionals/resources when required to address the immunization needs of certain populations.

**Key Terms:** International students, medical conditions and pregnancy, new Canadians, occupational risk groups, risk behaviours, special populations, “hard-to-reach” individuals/populations/groups, travellers.

**Suggested Content for Training**

- Designing schedules for people with uncertain or incomplete vaccination status with the minimum number of visits
- National and provincial guidelines that guide travel immunization
- Expert advice available to consult regarding travel immunization and recommendations
- Citizenship and Immigration Canada’s policy – distinguish when newcomers are immunized before arrival and when they are not
Contextual Issues Relevant to Immunization
12. The Canadian Immunization System

**Competency:** Demonstrates an understanding of the immunization system in Canada and its impact on his/her own practice.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe how the National Immunization Strategy (NIS) is relevant to practice.
2. Distinguish between federal and provincial/territorial responsibilities as related to immunization programs in Canada.
3. List who can administer immunizations in Canada.
4. Describe the current status of immunization registries in the province or territory where practice is based.
5. Describe the process required to introduce a new publicly funded vaccine in a province or territory.
6. Explain the reasons for the variable immunization schedules among the provinces and territories.
7. Locate the current immunization schedule for the province or territory of practice.
8. Identify laws and regulations that may affect immunization delivery programs in provinces and territories.

**Key Terms:** *Canadian Immunization Guide* (CIG), immunization schedule.

**Suggested Content for Training**

» Goals of the NIS

» How the number, timing, and spacing of doses is decided upon

» The role of the National Advisory Committee on Immunization and how vaccine recommendation is decided upon

» Current published recommendations in the CIG

» The role and responsibilities of the federal, provincial, and territorial governments in publicly funded immunization programs and vaccine purchase

» Provincial and territorial resources available to consult about immunization issues
13. Immunization Issues

**Competency:** Addresses immunization issues using an evidence-based approach.

**Learning Objectives**

The health professional will be able to perform the following:

1. Describe factors which lead to scepticism regarding immunization for both health professionals and the general public.

2. Describe the impact that misperceptions regarding immunizing agents have on immunization programs and on the population.

3. Address misperceptions regarding immunizing agents using an evidence-based approach.

4. Locate evidence-based sources of information on current issues relating to immunization.

5. Use evidence-based scientific knowledge to develop clear, concise key messages regarding true immunization benefits and risks.

**Suggested Content for Training**

» Importance of keeping up to date

» Anti-immunization messages on social media

» Multiple injections

» Thimerosal

» How and where to find information (local and national sources of advice) and assessing the reliability of sources

» Media portrayal of vaccine news stories

» The critical importance of professional confidence in immunization
14. Legal and Ethical Aspects of Immunization

**Competency:** Acts in accordance with legal and high ethical standards in all aspects of immunization practice.

**Learning Objectives**

The health professional will be able to perform the following:

1. Discuss the implications of basic ethical principles, including individual’s right, confidentiality, privacy, informed consent, and informed refusal.
2. Describe the legal requirements relevant to immunization administration, documentation, recording, and reporting.
3. Describe the legal requirements in the province/territory of immunization practice that relate to immunization status and exclusion from daycare, school, workplace, or other settings.
4. Identify his/her own professional scope of practice as it relates to immunization (jurisdiction, organization, practice setting – institutions, etc.).
5. Discuss the ethical issues arising from:
   - mandatory versus voluntary immunization; and
   - targeted versus universal immunization.
6. Discuss the responsibility of health professionals to inform patients regarding the availability of all recommended vaccines regardless of whether they are publicly funded or not.
7. Describe the ethical implications when a provider’s beliefs conflict with evidence-based recommendations for immunization.

**Key Terms:** Assent, benefit, conflict of interest (real and perceived), disclosure, harm, informed consent for immunization, informed consent for registry, mandatory immunization, prejudices, risks, medicolegal, targeted immunization, universal immunization, voluntary immunization.

**Suggested Content for Training**

» Current legal requirements for informed consent

» Data protection

» Documentation

» Professional accountability
# List of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFMC</td>
<td>Association of Faculties of Medicine of Canada</td>
</tr>
<tr>
<td>AFPC</td>
<td>Association of Faculties of Pharmacy of Canada</td>
</tr>
<tr>
<td>BGTD</td>
<td>Biologics and Genetic Therapies Directorate</td>
</tr>
<tr>
<td>CAEFISS</td>
<td>Canadian Adverse Events Following Immunization Surveillance System</td>
</tr>
<tr>
<td>CAIRE</td>
<td>Canadian Association for Immunization Research and Evaluation</td>
</tr>
<tr>
<td>CASN</td>
<td>Canadian Association of Schools of Nursing</td>
</tr>
<tr>
<td>CIC</td>
<td>Canadian Immunization Committee</td>
</tr>
<tr>
<td>CIG</td>
<td>Canadian Immunization Guide</td>
</tr>
<tr>
<td>CMA</td>
<td>Canadian Medical Association</td>
</tr>
<tr>
<td>CNA</td>
<td>Canadian Nurses Association</td>
</tr>
<tr>
<td>CNCI</td>
<td>Canadian Nursing Coalition for Immunization</td>
</tr>
<tr>
<td>CPS</td>
<td>Canadian Paediatric Society</td>
</tr>
<tr>
<td>CPhA</td>
<td>Canadian Pharmacists Association</td>
</tr>
<tr>
<td>CPHA</td>
<td>Canadian Public Health Association</td>
</tr>
<tr>
<td>CIRID</td>
<td>Centre for Immunization and Respiratory Infectious Diseases</td>
</tr>
<tr>
<td>CFPC</td>
<td>College of Family Physicians of Canada</td>
</tr>
<tr>
<td>CIQ</td>
<td>Comité sur l’immunisation du Québec</td>
</tr>
<tr>
<td>CHNA</td>
<td>Community Health Nurses of Alberta</td>
</tr>
<tr>
<td>FNSSC</td>
<td>Federation of National Specialty Societies of Canada</td>
</tr>
<tr>
<td>FNIHB</td>
<td>First Nations and Inuit Health Branch</td>
</tr>
<tr>
<td>IMPACT</td>
<td>Immunization Monitoring Program – Active</td>
</tr>
<tr>
<td>MPhA</td>
<td>Manitoba Pharmaceutical Association</td>
</tr>
<tr>
<td>NACI</td>
<td>National Advisory Committee on Immunization</td>
</tr>
<tr>
<td>NIS</td>
<td>National Immunization Strategy</td>
</tr>
<tr>
<td>OPA</td>
<td>Ontario Pharmacists’ Association</td>
</tr>
<tr>
<td>PEWG</td>
<td>Professional Education Working Group</td>
</tr>
<tr>
<td>PHAC</td>
<td>Public Health Agency of Canada</td>
</tr>
<tr>
<td>VIC</td>
<td>Vaccine Industry Committee</td>
</tr>
<tr>
<td>VON</td>
<td>Victorian Order of Nurses</td>
</tr>
</tbody>
</table>
Resources

**Canadian Online Resources**

Canadian Adverse Events Following Immunization Surveillance System  

Canadian Immunization Guide  

Canadian Paediatric Society – Your Child’s Best Shot: A Parents Guide to Vaccination  
www.cps.ca/english/publications/bookstore/yourchildbestshot.htm


National Vaccine Storage and Handling Guidelines for Immunization Providers  

**Canadian Organizations**

Biologics and Genetics Therapies Directorate – Drugs and Health Products  
www.hc-sc.gc.ca/dhp-mps/brgtherap/index-eng.php

Canadian Immunization Committee – (not available on line)

Centre for Immunization and Respiratory Infectious Disease  

National Advisory Committee on Immunization  
www.phac-aspc.gc.ca/naci-ccni/index-eng.php

Public Health Agency of Canada  
www.phac-aspc.gc.ca/index-eng.php
Provincial and Territorial Immunization Manuals and Guidelines

Alberta
Alberta Immunization Strategy 2007–2017

Routine Immunization Schedule

British Columbia
Immunization Manual
www.bccdc.org/content.php?item=193

Manitoba
Manitoba Immunization Schedule

New Brunswick
Immunization Brochure
www.gnb.ca/0053/disprev/pdf/3680e.pdf

Newfoundland and Labrador
Immunization Manual

Northwest Territories
NWT Immunization Schedule

NWT Certification of Immunization Competence Self-Directed, Web-Based Learning Module
www.hlthss.gov.nt.ca/sites/immunization%5Fquiz/

Nova Scotia
Immunization Protects Children (Immunization Schedule)
www.gov.ns.ca/hpp/publichealth/content/pubs/13002_ImmunizationProtectsBrochure_Jun08_Eng.pdf

Nunavut
Routine Immunization Schedule

Ontario
Immunization: Your Best Protection
**Prince Edward Island**

Immunization Schedule  

**Québec**

Guide des normes et pratiques de gestion des vaccins à l’intention des vaccinateurs  
www.msss.gouv.qc.ca/sujets/santepub/vaccination/download.php?f=7a2d4cf9e5e619575bb5937accb0fc67

Protocole d’immunisation du Québec  
http://206.167.52.1/fr/document/publication.nsf/4b1768b3f849519c852568fd0061480d/a61341010d1b912885256e82006cc1bc?OpenDocument

**Saskatchewan**

Immunization Manual  
www.health.gov.sk.ca/immunization-manual

**Yukon**

Routine Immunization Schedule for Infants and Children  
**International Online Resources**

American Academy of Paediatrics – The Red Book
http://aapredbook.aappublications.org

The Children’s Hospital of Philadelphia – Vaccination Education Center
www.chop.edu/consumer/jsp/division/generic.jsp?id=75697

U.K. Department of Health – Immunisation Against Infectious Disease: The Green Book

U.K. National Health Service – Immunisation Information
www.immunisation.nhs.uk

U.S. Advisory Committee on Immunization Practices – Recommendations and Guidelines
www.cdc.gov/vaccines/recs/acip

U.S. Centers for Disease Control and Prevention
www.cdc.gov

World Health Organization – Information on Immunization and Vaccines
www.who.int/topics/immunization/en
www.who.int/topics/vaccines/en

World Health Organization – WHO Vaccine Preventable Diseases Monitoring System (Country Profiles)
www.who.int/vaccines/globalsummary/Immunization/CountryProfileSelect.cfm
Articles and Books


Appendix A: Organizations Consulted

Special thanks to the following organizations for providing feedback and comments during the consultation process that supported the development of *Immunization Competencies for Health Professionals.*

**Round 1 Consultation**
- Biologics and Genetic Therapies Directorate (BGTD)
- Canadian Immunization Committee (CIC)
- Canadian Nursing Coalition for Immunization (CNCI)
- Canadian Paediatric Society (CPS) – Infectious Disease and Immunization Committee
- Comité sur l’immunisation du Québec (CIQ)
- First Nations and Inuit Health Branch (FNIHB), Health Canada
- National Advisory Committee on Immunization (NACI)
- P/T immunization programs

**Round 2 Consultation**
- Association of Faculties of Medicine of Canada (AFMC)
- Association of Faculties of Pharmacy of Canada (AFPC)
- BIOTEC Canada Vaccine Industry Committee (VIC)
- Canadian Association for Immunization Research and Evaluation (CAIRE)
- Canadian Association of Schools of Nursing (CASN)
- Canadian Medical Association (CMA)
- Canadian Nurses Association (CNA)
- Canadian Paediatric Society (CPS)
- Canadian Pharmacists Association (CPhA)
- Canadian Public Health Association (CPHA)
- College of Family Physicians of Canada (CFPC)
- College of Nursing, University of Saskatchewan
- College of Registered Nurses of Nova Scotia
- Community Health Nurses of Alberta (CHNA)
- Dalhousie University
- Faculty of Pharmaceutical Sciences, University of British Columbia
- Faculty of Pharmacy, University of Manitoba
- Federation of National Specialty Societies of Canada (FNSSC)
- Manitoba Pharmaceutical Association (MPhA)
- Ontario Pharmacists’ Association (OPA)
- Victorian Order of Nurses (VON)
## Appendix B: Table of Vaccine-Preventable Diseases

<table>
<thead>
<tr>
<th>Microbial Agent</th>
<th>Disease</th>
<th>Medical term</th>
<th>Common Term</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bordetella pertussis</em></td>
<td>pertussis</td>
<td>whooping cough</td>
<td></td>
</tr>
<tr>
<td><em>Corynebacterium diphtheriae</em></td>
<td>diphtheria</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Clostridium tetani</em></td>
<td>tetanus</td>
<td>lockjaw</td>
<td></td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em> (multiple capsular serotypes)</td>
<td>invasive pneumococcal disease</td>
<td>pneumonia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>pneumococcal meningitis</td>
<td>meningitis</td>
<td></td>
</tr>
<tr>
<td><em>Neisseria meningitidis</em> (serotypes A, B, C, Y, W-135)</td>
<td>invasive meningococcal disease, meningococcal meningitis, meningococcemia</td>
<td>sepsis, blood poisoning, epiglottitis</td>
<td></td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> (serotype B)</td>
<td>hemophilus meningitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em> (disease agent)</td>
<td>tuberculosis</td>
<td>TB</td>
<td></td>
</tr>
<tr>
<td>Bacillus Calmette Guérin (vaccine agent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Salmonella typhi-murium</em></td>
<td>typhoid fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Vibrio cholerae</em></td>
<td>cholera</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poliovirus (types 1,2,3)</td>
<td>poliomyelitis</td>
<td>polio</td>
<td></td>
</tr>
<tr>
<td>Measles virus</td>
<td>measles</td>
<td>red measles</td>
<td></td>
</tr>
<tr>
<td>Mumps virus</td>
<td>mumps</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rubella virus</td>
<td>rubella, congenital rubella syndrome</td>
<td>German measles</td>
<td></td>
</tr>
<tr>
<td>Influenza virus (groups A, B)</td>
<td>influenza</td>
<td>flu</td>
<td></td>
</tr>
<tr>
<td>Rotavirus</td>
<td>gastroenteritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus</td>
<td>cancer (cervical, vaginal or vulval), genital warts, condyloma, recurrent respiratory papillomatosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A virus</td>
<td>hepatitis A</td>
<td>infectious hepatitis</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B virus</td>
<td>hepatitis B</td>
<td>serum hepatitis</td>
<td></td>
</tr>
<tr>
<td>Varicella Zoster Virus</td>
<td>varicella</td>
<td>chickenpox</td>
<td></td>
</tr>
<tr>
<td></td>
<td>herpes zoster</td>
<td>shingles, postherpetic neuralgia</td>
<td></td>
</tr>
<tr>
<td>Rabies virus</td>
<td>rabies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yellowfever virus</td>
<td>yellow fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japanese encephalitis virus</td>
<td>encephalitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variola virus (disease agent)</td>
<td>smallpox</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccinia virus (vaccine agent)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C: Immunization Competencies Levelling Tool

The Immunization Competencies Levelling Tool is intended to help assess various segments of the public health workforce in order to tailor training programs, practice standards, or performance assessment.

Because of the complexity of the health workforce and the settings in which immunization is provided, levels of proficiency should be adapted as appropriate to the specific performance requirements of a given set of professionals in a given work setting.

How to Use the Levelling Tool

Identify and define the specific segment of health professionals you will be assessing, and use the following scale to identify the level of proficiency for each learning objective:

» **Aware** indicates a basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a relatively limited ability to perform the skill.

» **Knowledgeable** indicates an intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

» **Proficient** indicates an advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
## 1. The Immune System and Vaccines

| Competency: Explain how vaccines work using basic knowledge of immune system. |
|-----------------------------|-----------------------------------|
| **1.** Compare and contrast innate and adaptive immunity. | Aware | Knowledgeable | Proficient |
| **2.** Differentiate between the primary and memory immune response to a vaccine. | Aware | Knowledgeable | Proficient |
| **3.** Differentiate between passive and active immunity. | Aware | Knowledgeable | Proficient |
| **4.** Explain why some vaccines induce a memory response while others do not. | Aware | Knowledgeable | Proficient |
| **5.** Name some host- and vaccine-related factors that affect the immune response to vaccines. | Aware | Knowledgeable | Proficient |
| **6.** Explain how the immunization schedule accommodates factors that affect the immune response to vaccines. | Aware | Knowledgeable | Proficient |
| **7.** Respond to the concern that giving too many vaccines will overload the immune system. | Aware | Knowledgeable | Proficient |
| **8.** Discuss the pros and cons of immunity gained through immunization as opposed to the wild-type infection. | Aware | Knowledgeable | Proficient |

**Targeted Health Professional:**

Aware = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.

Knowledgeable = Intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

Proficient = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
# 2. Vaccine-Preventable Diseases

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstrates an understanding of the rationale and benefit of immunization, as relevant to the practice setting.</td>
<td>Aware&lt;br&gt;Knowledgeable&lt;br&gt;Proficient</td>
</tr>
</tbody>
</table>

1. Describe the key clinical features, including acute and long-term complications, of each vaccine-preventable disease.

2. Describe the key epidemiologic features of each vaccine-preventable disease.

3. Describe the historical impact of immunization on the epidemiology of vaccine-preventable disease.

4. For each of the vaccines administered in the practice setting, formulate a response to the question “Why should I be immunized when vaccine-preventable diseases are so rare in Canada?”

5. Explain why accurate diagnosis of vaccine-preventable diseases is important.

Aware = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.

Knowledgeable = Intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

Proficient = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
### 3. Vaccine Development and Evaluation

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrates into practice knowledge about the main steps in vaccine development and evaluation.</td>
<td></td>
</tr>
</tbody>
</table>

1. Describe, in general terms, the process to obtain marketing approval for vaccines in Canada.

- Awareness
- Knowledgeable
- Proficient

2. Describe what can be learned about vaccines after they are approved for marketing, via surveillance activities and more formal post-marketing studies.

- Awareness
- Knowledgeable
- Proficient

3. Characterize, in broad terms, the key roles and responsibilities for each of the following relative to the post-marketing assessment of vaccine safety and effectiveness:
   - Vaccine manufacturers
   - Canadian regulatory authority (Biologics and Genetic Therapies Directorate)
   - Public Health Agency of Canada
   - Provincial/territorial Health departments
   - Vaccine providers
   - Healthcare providers who don’t administer vaccines
   - Vaccine recipients or their parents/caregivers

- Awareness
- Knowledgeable
- Proficient

---

**Aware** = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.

**Knowledgeable** = Intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

**Proficient** = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
4. The Types of Immunizing Agents and Their Composition

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applies the knowledge of the components and properties of immunizing agents as needed for safe and effective practice.</td>
<td>Aware</td>
</tr>
<tr>
<td>1. Classify each immunizing agent used in practice as live attenuated, inactivated, or subunit.</td>
<td>Aware</td>
</tr>
<tr>
<td>2. Demonstrate the ability to describe live attenuated, inactivated, and subunit immunizing agents to an audience with minimal or no science knowledge.</td>
<td>Aware</td>
</tr>
<tr>
<td>3. Compare the major advantages and disadvantages of live attenuated versus inactivated/subunit immunizing agents.</td>
<td>Aware</td>
</tr>
<tr>
<td>4. Identify key differences in the immune response to purified polysaccharide versus polysaccharide protein conjugate vaccines.</td>
<td>Aware</td>
</tr>
<tr>
<td>5. Describe, in general terms, the purpose, action, and potential concerns of each of the following components that may be present in a given vaccine product: adjuvant, preservative, additives, glass vial, stopper, and pre-filled syringe.</td>
<td>Aware</td>
</tr>
<tr>
<td>6. Locate and utilize current information resources on the types and content of immunizing agents used in practice.</td>
<td>Aware</td>
</tr>
</tbody>
</table>

Aware = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.

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## 5. Population Health

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applies relevant principles of population health for improving immunization coverage rates.</td>
<td></td>
</tr>
<tr>
<td>1. Use specific examples to show how immunization is a population-based health strategy.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>2. Explain the concept of herd immunity (also called community immunity) in non-scientific terms.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>3. Explain, using examples, why vaccine-preventable diseases return when immunization coverage rates decrease.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>4. Explain how immunization registries can benefit not only individuals but also populations.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>5. Present the case for the importance of having a highly immunized healthcare workforce.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>6. Use health promotion planning model to identify barriers (economic, educational, system-based, and social factors) to immunization uptake.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
<tr>
<td>7. Use health promotion strategies to improve immunization coverage rates.</td>
<td>Aware</td>
</tr>
<tr>
<td></td>
<td>Knowledgeable</td>
</tr>
<tr>
<td></td>
<td>Proficient</td>
</tr>
</tbody>
</table>

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Knowledgeable = Intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

Proficient = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
## 6. Communication

### Competency:
Communicates effectively about immunization as relevant to the practice setting(s).

### Targeted Health Professional:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. List the components of the evidence-based decision-making process.</td>
<td>Aware</td>
</tr>
<tr>
<td>2. Explain the importance of risk perception for immunization decision making.</td>
<td>Aware</td>
</tr>
<tr>
<td>3. Respond appropriately following an assessment of client knowledge, attitudes, and beliefs regarding immunization.</td>
<td>Aware</td>
</tr>
<tr>
<td>4. Deliver clear, concise messages about the risks of vaccine-preventable diseases and the benefits and risks of vaccines.</td>
<td>Aware</td>
</tr>
<tr>
<td>5. Provide appropriate evidence-based information and resources to clients regarding immunization and vaccines.</td>
<td>Aware</td>
</tr>
<tr>
<td>6. Provide guidance to clients so they can correctly identify credible sources of information on immunization and vaccines.</td>
<td>Aware</td>
</tr>
<tr>
<td>7. Apply, as appropriate to the practice setting, mass media strategies for public communication.</td>
<td>Aware</td>
</tr>
</tbody>
</table>

**Aware** = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.

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**Proficient** = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
## Appendix C: Immunization Competencies Levelling Tool

### 7. Storage and Handling of Immunization Agents

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implements Canadian guidelines when storing, handling, or transporting vaccines.</td>
<td>Aware</td>
</tr>
</tbody>
</table>

1. State where to access the most recent national guidelines dealing with vaccine storage, handling, and transportation.

   | Aware | Knowledgeable | Proficient |

2. Describe the national guideline requirements for vaccine storage, handling, and transportation and their importance in maximizing the potency and efficacy of each vaccine.

   | Aware | Knowledgeable | Proficient |

3. Outline the key steps for maintaining the cold chain in the practice setting.

   | Aware | Knowledgeable | Proficient |

4. Explain actions taken to report and manage breaks in the cold chain or other insults that compromise vaccine integrity.

   | Aware | Knowledgeable | Proficient |

---

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**Proficient** = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
8. **Administration of Immunizing Agents**

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepares and administers immunization agents correctly.</td>
<td></td>
</tr>
<tr>
<td>1. Prepare a checklist for pre-immunization patient assessment,</td>
<td>Aware</td>
</tr>
<tr>
<td>including precautions, contraindications, and indications for rescheduling.</td>
<td>Knowledgeable</td>
</tr>
<tr>
<td>2. Ensure the seven “Rights” of immunization: right drug, right client,</td>
<td>Aware</td>
</tr>
<tr>
<td>right dose, right time, right route, right reason, and right documentation.</td>
<td>Knowledgeable</td>
</tr>
<tr>
<td>3. Demonstrate the steps involved in vaccine preparation, including</td>
<td>Aware</td>
</tr>
<tr>
<td>reconstitution, if appropriate, administration, and disposal.</td>
<td>Knowledgeable</td>
</tr>
<tr>
<td>4. Name the resources that are used to guide the immunization administration process and decision making.</td>
<td>Aware</td>
</tr>
<tr>
<td>5. Develop a table listing the vaccine, age, dose, route, site, contraindications/precautions, and side effects for each vaccine used in the practice setting.</td>
<td>Aware</td>
</tr>
<tr>
<td>6. Demonstrate the age-appropriate injection sites and proper client</td>
<td>Aware</td>
</tr>
<tr>
<td>positioning used for immunization.</td>
<td>Knowledgeable</td>
</tr>
<tr>
<td>7. Choose the correct needle length and gauge for the age and size of the client.</td>
<td>Aware</td>
</tr>
<tr>
<td>8. Describe actions taken to increase safety in immunization clinics related to the provider, the recipient, and the environment.</td>
<td>Aware</td>
</tr>
<tr>
<td>9. Demonstrate the appropriate technique for immunization.</td>
<td>Aware</td>
</tr>
<tr>
<td>10. Describe techniques to reduce the pain associated with immunization.</td>
<td>Aware</td>
</tr>
</tbody>
</table>

Aware = Basic level of mastery of the competency, in which individuals are able to identify the concept or skill but have a limited ability to perform the skill.
Knowledgeable = Intermediate level of mastery of the competency, in which individuals are able to apply and describe the skill.

Proficient = Advanced level of mastery of the competency, in which individuals are able to synthesize, critique, or teach the skill.
### 9. Adverse Events Following Immunization

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipates, identifies, and manages adverse events following immunization.</td>
<td>Aware</td>
</tr>
<tr>
<td>1. Use reliable, evidence-based resources to list the frequencies of the common, uncommon, and rare adverse events associated with vaccines.</td>
<td>Aware</td>
</tr>
<tr>
<td>2. Inform recipients and/or their caregivers on what to expect and what to do regarding adverse events that could follow immunizations.</td>
<td>Aware</td>
</tr>
<tr>
<td>4. Document all adverse events following immunization on the appropriate form and submit it to the appropriate agencies.</td>
<td>Aware</td>
</tr>
<tr>
<td>5. Distinguish between reporting an adverse event following immunization and proving that immunization caused an adverse event.</td>
<td>Aware</td>
</tr>
</tbody>
</table>

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## 10. Documentation

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documents information relevant to each immunization encounter in accordance with national guidelines for immunization practices and jurisdictional health information processes.</td>
<td><img src="false" alt="AWARE" /> <img src="false" alt="KNOWLEDGEABLE" /> <img src="false" alt="PROFICIENT" /></td>
</tr>
</tbody>
</table>

1. **Describe the role and importance of immunization records.**

2. **Identify the information to be documented on an immunization record.**

3. **Record an immunization encounter on the appropriate documentation instruments accurately and completely.**

4. **Facilitate the transfer of information in the vaccination record to other providers and to appropriate agencies in accordance with requirements.**

5. **Record the reason and planned follow-up action when a scheduled immunization is not given.**

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## 11. Populations Requiring Special Considerations

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognizes and responds to the unique immunization needs of certain population groups.</td>
<td></td>
</tr>
</tbody>
</table>

1. Describe the unique immunization needs of certain populations, as relevant to the practice setting, including
   - individuals who are off course of a recommended immunization schedule;
   - individuals who have had a serious adverse event following a prior immunization;
   - individuals with certain medical conditions, including transplant recipients;
   - pregnant women;
   - women who are breastfeeding;
   - occupational risk groups;
   - travellers;
   - new Canadians;
   - international students;
   - individuals with behaviours that put them at risk for vaccine-preventable infections;
   - “hard-to-reach” individuals; and
   - outbreak populations.

<table>
<thead>
<tr>
<th>Aware</th>
<th>Knowledgeable</th>
<th>Proficient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Appropriately refer to expert professionals/resources when required to address the immunization needs of certain populations.

<table>
<thead>
<tr>
<th>Aware</th>
<th>Knowledgeable</th>
<th>Proficient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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## 12. The Canadian Immunization System

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstrates an understanding of the immunization system in Canada and its impact on his/her own practice.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>1. Describe how the National Immunization Strategy is relevant to practice.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>2. Distinguish between federal and provincial/territorial responsibilities as related to immunization programs in Canada.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>3. List who can administer immunizations in Canada.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>4. Describe the current status of immunization registries in the province or territory where practice is based.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>5. Describe the process required to introduce a new publicly funded vaccine in a province or territory.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>6. Explain the reasons for the variable immunization schedules among the provinces and territories.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>7. Locate the current immunization schedule for the province or territory of practice.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
<tr>
<td>8. Identify laws and regulations that may affect immunization delivery programs in provinces and territories.</td>
<td>☐ Aware ☐ Knowledgeable ☐ Proficient</td>
</tr>
</tbody>
</table>

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## 13. Immunization Issues

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addresses immunization issues using an evidence-based approach.</td>
<td></td>
</tr>
<tr>
<td>1. Describe factors which lead to scepticism regarding immunization for both healthcare providers and the general public.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
<tr>
<td>2. Describe the impact that misperceptions regarding immunizing agents have on immunization programs and on the population.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
<tr>
<td>3. Address misperceptions regarding immunizing agents using an evidence-based approach.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
<tr>
<td>4. Locate evidence-based sources of information on current issues relating to immunization.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
<tr>
<td>5. Use evidence-based scientific knowledge to develop clear, concise key messages regarding true immunization benefits and risks.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
</tbody>
</table>

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### 14. Legal and Ethical Aspects of Immunization

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Targeted Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acts in accordance with legal and high ethical standards in all aspects of immunization practice.</td>
<td>Aware, Knowledgeable, Proficient</td>
</tr>
</tbody>
</table>

1. **Discuss the implications of basic ethical principles, including individual’s right, confidentiality, privacy, informed consent, and informed refusal.**

2. **Describe the legal requirements relevant to immunization administration, documentation, recording, and reporting.**

3. **Describe the legal requirements in the province/territory of immunization practice that relate to immunization status and exclusion from daycare, school, workplace, or other settings.**

4. **Identify his/her own professional scope of practice as it relates to immunization (jurisdiction, organization, practice setting – institutions, etc.).**

5. **Discuss the ethical issues arising from: **
   - mandatory versus voluntary immunization; and
   - targeted versus universal immunization.

6. **Discuss the responsibility of health professionals to inform patients regarding the availability of all recommended vaccines regardless of whether they are publicly funded or not.**

7. **Describe the ethical implications when a provider’s beliefs conflict with evidence-based recommendations for immunization.**

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### Appendix D: Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abscess</td>
<td>A localized collection of pus caused by infection.</td>
</tr>
<tr>
<td>Active immunity</td>
<td>The production of antibodies against a specific disease by the immune system, acquired by either contracting the disease or through vaccination.</td>
</tr>
<tr>
<td>Active immunizing agent</td>
<td>Any substance or organism that provokes an immune response (produces immunity) when introduced into the body.</td>
</tr>
<tr>
<td>Active surveillance</td>
<td>An active case-finding based on a regular review of hospital admission records. Canada’s pediatric active surveillance system for serious adverse events following immunization, vaccination failures, and selected infectious diseases is called Immunization Monitoring Program – Active (IMPACT).</td>
</tr>
<tr>
<td>Adaptive immunity</td>
<td>The body’s second line of defense, which becomes active when innate immune defenses are overcome; it has three key features: specificity, memory and diversity; its mechanisms depend on the ability of the immune system to recognize “non-self” material, to respond to its presence and to dispose of it appropriately.</td>
</tr>
<tr>
<td>Additive</td>
<td>The substances added to vaccines to inactivate a virus or bacteria, stabilize the vaccine, or preserve the vaccine so that it remains potent over time. Examples of vaccine additives include albumin, aluminum hydroxide, and aluminum phosphate.</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>A substance (i.e. aluminum salt) that is added during production to increase the body's immune response to a vaccine. The adjuvant slow the release of antigens, stimulate local inflammation that attracts immune cells to the site, and enlarge the physical size of the antigen for more efficient uptake by antigen processing cells.</td>
</tr>
<tr>
<td>Adverse event following immunization (AEFI)</td>
<td>An undesirable experience or any unexpected medical occurrence in a patient occurring after immunization. Although a temporal relationship exists, a causal relationship is not necessarily established with the treatment or vaccine. The AEFIs are classified as being rare, uncommon, common, or very common. See Serious adverse event.</td>
</tr>
<tr>
<td>Adverse vaccine reaction</td>
<td>Any unexpected or dangerous reaction or unwanted effect caused by the administration of a vaccine. The adverse reaction may occur suddenly, or develop over time. See Serious adverse event.</td>
</tr>
<tr>
<td>Allergens</td>
<td>An antigen causing an allergic or hypersensitive response. Allergens induce the formation of IgE antibodies, a class of antibodies involved in all types of allergic reactions.</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>An immediate and severe allergic response. The cardinal features of anaphylaxis as outlined in the Canadian Immunization Guide (pp. 80-84, 7th ed.) are: itchy urticarial rash in 90% of cases; angioedema (progressive painful swelling) of face and mouth; respiratory symptoms (sneeze, cough, wheeze, dyspnea, laboured breathing); hypotension (can progress to collapse and shock).</td>
</tr>
</tbody>
</table>
Antibody  A protein found in the blood that is produced in response to foreign substances, (i.e. bacteria or viruses invading the body). Antibodies protect the body from disease by binding to these organisms and destroying them.

Antigen  Any substance, usually a protein that is capable of inducing an adaptive immune response.

Anxiety (or panic) attack  A sudden, unexpected period of intense anxiety often accompanied by symptoms such as heart palpitations, dizziness, trouble breathing, and intense fear of dying.

Aseptic technique  A set of practices and procedures performed under sterile conditions in order to prevent the introduction of micro-organisms, such as fungi, bacteria, and viruses.

Assent  The agreement of a person to allow diagnosis or treatment when the client does not have the capacity or legal empowerment to give informed consent, such as a child or cognitively impaired adult.

Bar coding  A method for encoding data using narrow and wide bars and spaces that represent a number or alphanumeric character. Bar coding allows for fast and accurate electronic readability. Bar codes are printed or stamped on products, labels, or other media.

Benefit  The advantage or improvement in condition provided to an individual or a population.

B-lymphocyte (B-cell)  A class of lymphocyte so called because they originate and mature in the bone marrow before being released into the bloodstream. B-cells are involved primarily in antibody-mediated immunity and produce antibodies.

Booster  A second, third, or greater immunization with a specific vaccine that may be necessary to insure that the individual is protected against the infectious disease.

Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)  The main function of this system is to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization.

Canadian Immunization Guide (CIG)  A guide containing information on the immunizing agents available in Canada and their use in the prevention of communicable diseases. Recommendations on routine immunizations are discussed in some detail, and an attempt is made to answer most of the day-to-day queries from providers.

Carriage  The presence of a potentially disease-causing micro-organism in an individual’s body that does not cause the disease in the carrier but may cause others to become infected.

Causality  The relationship between a cause and its effects. An effect, such as a disease, may have one or many causes, such as risk factors, predisposing factors, or precipitating factors (e.g. heart disease is caused by a combination of factors including genetic and behavioral factors).

Cell-mediated immunity (CMI)  The immune reactions that are mediated by cells, cytotoxic T lymphocytes (CTL cells) rather than by antibody or other humoral factors (e.g. complement proteins).
<table>
<thead>
<tr>
<th><strong>Cellulitis</strong></th>
<th>An infection of the skin and connective tissue characterized by redness, swelling, warmth, and tenderness. May also cause fever or chills.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client</strong></td>
<td>A person in the client index or registry. May be a contact, case, control, immunization recipient or other (e.g. guardian of a client).</td>
</tr>
<tr>
<td><strong>Clinical features</strong></td>
<td>The symptoms that are based on direct observation of the patient.</td>
</tr>
<tr>
<td><strong>Cold chain</strong></td>
<td>An unbroken series of storage and distribution activities that maintains a proper temperature range during storage and handling in order to preserve the potency of the vaccine.</td>
</tr>
<tr>
<td><strong>Combination vaccine</strong></td>
<td>A single vaccine that includes antigens for the prevention of several different diseases, or that protects against several strains of a single infectious agent that causes the same disease such as the measles, mumps, and rubella (MMR) vaccine.</td>
</tr>
<tr>
<td><strong>Communicability</strong></td>
<td>The capability to spread disease from person to person, or from species to species. Also referred to as being infectious.</td>
</tr>
<tr>
<td><strong>Community/herd immunity</strong></td>
<td>A large percentage of the population is vaccinated in order to prevent the spread of certain infectious diseases. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community. Also known as “herd immunity.”</td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td>A new disease or medical condition that develops during the treatment or course of an existing disease or medical condition.</td>
</tr>
<tr>
<td><strong>Confidentiality</strong></td>
<td>In medicine, confidentiality refers to the right of the patient to have personal identifiable, medical information revealed to a healthcare professional remain private. Limits are placed on how and when such information may be disclosed to a third party.</td>
</tr>
<tr>
<td><strong>Conflict of interest (real or perceived)</strong></td>
<td>A situation where an individual or the organization that they represent has competing professional or personal interest that may make it difficult for them to fulfill their duties in an impartial manner. A conflict of interest may be real or perceived.</td>
</tr>
<tr>
<td><strong>Contagiousness</strong></td>
<td>The degree of transmissibility - ability for a disease to be transmitted from person to person through direct or indirect contact with a bodily discharge of such a patient, or with an object touched by such a patient or by bodily discharges.</td>
</tr>
<tr>
<td><strong>Contraindication</strong></td>
<td>A symptom or condition that makes it likely a life-threatening problem would occur if a vaccine is given.</td>
</tr>
<tr>
<td><strong>Coverage rate (immunization coverage)</strong></td>
<td>The proportion of the target populations that has been vaccinated through the publicly funded programs that provides certain vaccines at little or no cost.</td>
</tr>
<tr>
<td><strong>Credible sources</strong></td>
<td>The clinical trials, academic studies, or other health-related sources of information that are based on scientific evidence. Credible studies or trials should be conducted by qualified scientists or other health professionals.</td>
</tr>
<tr>
<td><strong>Determinants of health</strong></td>
<td>The various factors that when combined together contribute to the overall health status of an individual or population. These include income, educational level, healthcare access, genetics, and lifestyle.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Disclosure</td>
<td>The release, transfer, or provision of access to, or divulging of individually identifiable health information outside of the entity holding that information.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>The ability of a vaccine to produce the desired beneficial effect(s) under real-world circumstances.</td>
</tr>
<tr>
<td>Efficacy</td>
<td>The maximum ability of a vaccine to produce a desired effect.</td>
</tr>
<tr>
<td>Encephalitis</td>
<td>The inflammation of the brain caused by a virus; encephalitis can result in permanent brain damage or death.</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>A general term describing brain dysfunction such as encephalitis, meningitis, seizures and head trauma.</td>
</tr>
<tr>
<td>Encounter</td>
<td>A point of service for any type of subject that is defined by date, time, location and the type of activity (e.g. immunization, disease screening or lab results). An encounter may or may not be associated with and investigation/control record within a subject record. An encounter may or may not be associated with other encounters through an episode.</td>
</tr>
<tr>
<td>Endemic</td>
<td>The continual, low-level presence of disease in a community.</td>
</tr>
<tr>
<td>Epidemic</td>
<td>The occurrence of disease within a specific geographical area or population that is in excess of what is normally expected.</td>
</tr>
<tr>
<td>Epidemiology</td>
<td>A branch of medical science that deals with the incidence, distribution, and control of disease in a population. The sum of the factors controlling the presence or absence of a disease or pathogen.</td>
</tr>
<tr>
<td>Epidemiological triangle</td>
<td>A model for the causation of disease that involves three elements: agent, host, and environment.</td>
</tr>
<tr>
<td>Episode</td>
<td>A descriptive group of one or more encounters. An investigation may have zero to many episodes. Encounters not associated to an investigation or control can also be grouped into one or more episodes. An episode is named by the user or the system and is defined by a start date and (optionally) and end date.</td>
</tr>
<tr>
<td>Evidence-based decision making</td>
<td>The decisions that are based on a careful analysis of accurate data and proven research findings.</td>
</tr>
<tr>
<td>Expired stock</td>
<td>All vaccines and diluents have an expiration date by which they should be used printed on their vials and boxes. Products that are passed their expiration dates are considered expired stock and should not be administered.</td>
</tr>
<tr>
<td>Expiry date</td>
<td>The date by which a vaccine or a diluent should be used.</td>
</tr>
<tr>
<td>Guillain-Barré syndrome</td>
<td>A rare neurological disease that occurs when the body's immune system attacks the peripheral nerves in the body, causing loss of reflexes and temporary paralysis. Symptoms include weakness, numbness, tingling and increased sensitivity that spreads over the body.</td>
</tr>
<tr>
<td>Hard-to-reach (individuals, groups, populations)</td>
<td>The individuals, groups, or populations that have the greatest difficulty accessing services (e.g. the disadvantaged, minorities, residents in remote communities).</td>
</tr>
<tr>
<td>Harm</td>
<td>The nature and extent of damage that could be caused by a vaccine.</td>
</tr>
</tbody>
</table>
**Host**

A person or other living organism that can be infected by an infectious agent under natural conditions.

**Humoral immunity**

The term humoral refers to the extracellular fluids such as serum and lymph; in this case the immune response is mediated by antibodies produced by B-cells as effector molecules. Both B- and T-cells may be involved in this response.

**Hypotonic-hyporesponsive episode (HHE)**

A serious adverse reaction to immunization that results in a decrease in level of responsiveness, muscle tone and activity, and pallor. HHE is most commonly reported in response to administration of the whole-cell pertussis vaccine, but also occur with a lower frequency after diphtheria-tetanus (DT) and acellular pertussis-DT (DPT) immunization.

**Immunity**

The protection against a disease. There are several types of immunity: passive, active and humoral. The immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.

**Immunization record (professional chart and take-home)**

A record of all immunization a person has received. A record is kept by the healthcare provider who gave the immunization (professional chart), and in a local or provincial registry and by the individual or their parent or guardian (take-home record).

**Immunization registry**

A tool to consolidate immunization records from multiple sources, including any reports of adverse events, into one confidential record.

**Immunization schedules (delay, interruption, etc.)**

They outline the optimum timing of primary and secondary immunizations. A delayed immunization schedule may be used when a child receives his or her primary or secondary immunizations after the recommended ages of their regional immunization schedule. When a child’s vaccinations are interrupted by more than a month, an accelerated or catch-up immunization schedule should be used.

**Immunization status**

A client’s immunization status conveys whether they are eligible, due or overdue for a specified vaccine.

- **Eligible:** the earliest acceptable time period during which an immunization is considered a valid dose for immunization coverage reporting.
- **Due:** the time period during which an immunization is considered up to date according to the NACI schedule.
- **Overdue:** this time period is one month after an individual is due for an immunization, unless otherwise specified.

**Immunizing agent**

The term used to describe the different agent combinations used for immunization. These agents can be monovalent (single antigen) or multivalent (multiple antigens e.g. MMR) vaccines. The term “vaccine” can be used interchangeably with immunizing agent.

**Immunogenicity**

The inherent ability of an antigen to induce a humoral and/or cell-mediated immune response; for practical purposes the antibody-mediated response is most often used to measure the immunogenicity of vaccines.

**Imported**

To bring or carry in micro-organisms, such as viruses and bacteria, from an outside source.
Inactivated vaccine: A vaccine made from an infectious agent that has been inactivated or killed (without affecting the antigenicity) that allows for an active immunization.

Incidence: The number of new disease cases reported in a population over a certain period of time.

Incubation period: The period between the first exposure to a pathogen and the appearance of signs or symptoms of disease; normally bacterial incubation periods are short (hours to days) compared to virus incubation periods (weeks to months).

Induration: A hardening of soft tissue caused by inflammation. It is often a sign of infection; affected skin and other soft tissue may be red, thickened, and tender.

Informed decision making (consent) for immunization and registry: A legal term related to educating patients about the benefits, risks, and alternatives of therapeutic treatment. The patient, or a parent or guardian, must understand the potential risks and benefits of the treatment (or refusing treatment) before making a decision. The informed consent insures that the patient also understands the importance and benefit of the immunization registries.

Injection error: An error made either in the substance injected into a patient or in the location of the injection into the patient resulting in harm.

Injection site: The anatomical location of injection (e.g. left deltoid, right leg).

Injection site reaction: The inflammation or damage to the tissue surrounding the injection site.

International students: The students, from countries other than Canada, for whom the immunization status is unknown.

Live attenuated vaccine: A vaccine containing live, weakened bacteria or viruses that induce active immunity.

Local reaction: A limited reaction that occurs at the point of entrance of an infecting organism or of an injection. Also known as an injection site reaction.

Lot number: The number specific to a particular lot of a vaccine that allows it to be identified.

Mandatory immunization: The immunizations that are required by law in some provinces or territories.

Medical conditions and pregnancy: A usually defective state of health or unusual condition.

Medication error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional or patient. May also be referred to as a preventable adverse drug event.

Medicolegal: This term pertains to the legal aspects of practicing medicine (e.g. informed consent and malpractice).

Memory response (secondary immune response): The capacity of the body's immune system to remember an encounter with a specific antigen and to react more swiftly to the antigen in a later encounter.
<table>
<thead>
<tr>
<th>Glossary Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum vaccine intervals</td>
<td>The minimum amount of time that must pass before the next dose of the same vaccine is administered in order to ensure that the immune system has time to respond effectively to the first dose.</td>
</tr>
<tr>
<td>Min-Max thermometers</td>
<td>A thermometer that displays the current temperature and the minimum and maximum temperatures reached since the reset. It may include an alarm to indicate when a certain temperature threshold has been exceeded.</td>
</tr>
<tr>
<td>Mode of transmission</td>
<td>The mechanisms by which an infectious agent is spread to humans, including direct (skin-to-skin) and indirect (airborne, vector-borne, etc) methods.</td>
</tr>
<tr>
<td>Morbidity</td>
<td>A diseased state or symptom - the incidence of disease; the rate of sickness (as in a specified community or group).</td>
</tr>
<tr>
<td>Mortality</td>
<td>The level (rate) of death in a community. Usually the cause (a specific disease, a condition or an injury) is stated.</td>
</tr>
<tr>
<td>National Immunization Strategy</td>
<td>A comprehensive strategy to enable collaboration among levels of government to improve the effectiveness and efficiency of immunization programs across Canada.</td>
</tr>
<tr>
<td>National Vaccine Storage and Handling Guidelines for Immunization Providers</td>
<td>These recommendations on vaccine storage and handling for healthcare providers were developed in collaboration with the Canadian Nursing Coalition for Immunization and published by the Public Health Agency of Canada.</td>
</tr>
<tr>
<td>Natural infection</td>
<td>An infection or disease caused by bacteria or viruses found in the natural environment, such as measles or chicken pox.</td>
</tr>
<tr>
<td>Needle length and gauge</td>
<td>The needle length refers to the length of the needle’s barrel, while the needle gauge refers to the width or barrel size of the needle.</td>
</tr>
<tr>
<td>Needle stick injury</td>
<td>The injury caused by a needle puncture to the skin. The needle stick injuries can transmit infectious diseases, especially blood-borne viruses. They are a hazard for people who work with hypodermic needles and other needle equipment.</td>
</tr>
<tr>
<td>New Canadians</td>
<td>The people that have recently arrived to Canada and for whom the immunization status is unknown.</td>
</tr>
<tr>
<td>Nodule at injection site</td>
<td>A lump, swelling, or mass at the injection site.</td>
</tr>
<tr>
<td>Notice of compliance (NOC)</td>
<td>The Notices of Compliance are issued to a manufacturer following the satisfactory review of a submission to Health Canada. NOCs indicate that a manufacturer has complied with sections C.08.002 or C.08.003 and C.08.005.1 of the Food and Drug Regulations.</td>
</tr>
<tr>
<td>Occupational risk groups</td>
<td>The people who work in specific careers that expose them to a greater proportion of risk or harm.</td>
</tr>
<tr>
<td>Oculorespiratory syndrome</td>
<td>A syndrome of bilateral red eyes and upper respiratory symptoms, including coughing, wheezing, chest discomfort, sore throat, and, occasionally, facial swelling, following influenza vaccination. It is usually transient.</td>
</tr>
</tbody>
</table>
Package insert

The information that comes with the vaccine and is written in simple language intended for the public. The insert may contain, among other things, information on the proper use of the vaccine, a short description of the disease(s) it protects from, and storage and dosage instructions. It may also list warnings, precautions, interactions and possible side effects. Instructions and contact information on what to do if serious suspected side effects occur may also be provided.

Pandemic

This term denotes a disease affecting or attacking the population of an extensive region, as when the distribution of an epidemic disease spreads around the world (e.g. flu pandemics).

Passive immunity

The protection against disease through antibodies produced by another human being or animal. Passive immunity is effective, but protection is generally limited and diminishes over time (usually a few weeks or months). For example, maternal antibodies are passed to the infant prior to birth. These antibodies protect the baby for the first 4-6 months of life.

Passive immunizing agent

A substance or organism that provides immunity for the period of time it remains within the body. A passive immunizing agent may be acquired through the transfer of antibodies from another person or animal, from mother to fetus, or through inoculation.

Passive surveillance

A system of surveillance where the responsible agency relies on mandatory reporting by front-line healthcare providers or agencies, and the responsible agency does not carry out activities designed to stimulate reporting, such as inspections of facilities or telephone calls to healthcare providers.

Polysaccharide

The long chains of sugar molecules that resemble the surface of certain types of bacteria. Polysaccharide vaccines are available for pneumococcal disease, meningococcal disease and Haemophilus Influenzae type B. They are recommended for outbreak control, for the protection of persons travelling to locations with epidemic disease attributable to vaccine serogroups, and for persons who may be at increased risk of meningococcal disease. Polysaccharide vaccines are not recommended for routine childhood immunization.

Population health prevalence

The measure of disease presence which can vary depending on the interval of time studied. “Point prevalence” refers to the presence of the disease at a given point in time (i.e. a “snapshot”). It is the number of existing cases found in a cross-sectional survey. “Period prevalence,” a less common term, refers to the number of disease cases (new and existing) within a population over a given time period.

Post-marketing surveillance

The surveillance of a vaccine that is carried out after the vaccine has been approved for sale to the general public. Post-marketing surveillance allows for the identification of rare adverse events that may only occur at a rate of 1:10,000, or 1:1,000,000 of vaccine doses given. It also allows regulators to ensure that the vaccine retains its characteristics from one lot to the next over time.

Potency

The power of medicinal agents to produce the desired effects.
| **Precautions** | It refers to a condition that may increase the chance of an adverse reaction following immunization or that may compromise the ability of the vaccine to produce immunity. Depending on the circumstances, the vaccine may still be administered after careful consideration as to whether the potential benefits outweigh the potential harm. |
| **Prejudice** | Injury or damage resulting from some judgment or action in disregard of one’s rights. |
| **Preservatives** | They are chemical additives used to prevent bacterial and fungal contamination in vaccines. |
| **Prevention and Health promotion** | The actions and measures that reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse. |
| **Primary immune response** | The response by the immune system when it encounters an antigen for the first time. Primary immune responses are primarily composed of IgM antibodies and produce immunologic memory. |
| **Primary prevention** | The prevention that is focused on encouraging good nutrition, physical fitness, and immunization among the general population. It promotes good health, which reduces the likelihood of disease occurring. |
| **Privacy** | The right of the individual to keep their personal and health information free from unauthorized disclosure by healthcare providers. |
| **Product monograph** | A description of the name, chemical formula, and uniform method for determining the strength and purity of a drug. |
| **Protective level or Protective efficacy** | It represents the percentage of vaccinated individuals protected against disease when compared to an unvaccinated group (absolute efficacy) having the same risk of disease exposure over the same period of time, or a group that has received a comparative vaccine (relative efficacy). |
| **Protein conjugate** | A compound that is composed of a protein molecule and a non-protein prosthetic group. |
| **Protocol** | A predefined set of drugs (and the associated standard Rx data) used to treat a subject as part of a complete treatment plan. Predetermined drug protocols prevent the user from having to enter multiple drugs, and all of their associated details, when creating a prescription by pre-populating this information when selected. A drug protocol may be made up of a number of standard Rx records (previously called “regimen”). |
| **Provider** | A professional who provides health services (e.g. a public health nurse). |
| **Public health nurse (PHN)** | A healthcare provider that works with individuals, groups, and communities to address health issues. Also called “community health nurse.” |
| **Purified protein** | A protein that has been isolated from a complex mixture, such as a tissue culture. |
| **Range** | In statistics, the difference between the largest and smallest values in a distribution. In common use, the span of values from smallest to largest. |
| **Reactogenicity (reaction)** | The local and systemic adverse experiences that follow immediately after or in a short period after vaccination. See Local reactogenicity and Systemic reactogenicity. |
Appendix D: Glossary

Recall
The removal of a product from market. Recalls may be voluntary or mandatory.

Reconstitution
The process of adding a liquid to a powder. Some prescription drugs and vaccines are provided as a dry powder requiring reconstitution before use.

Reminder systems
The systems to help inform those who administer vaccines that an individual patient is due for specific vaccinations.

Reservoir
Any living or non-living substance in or on which an infectious agent can live and multiply, serving as a source of infection. The reservoir is not usually injured by the presence of infectious agent.

Risk
The probability of harm being caused.

Risk behaviours
The behaviours that increase the likelihood that an individual will experience a certain event or may be harmed.

Risk communication
An exchange of information aimed at increasing the understanding of health risks.

Risk perception
The subjective judgment that an individual makes about the characteristics and severity of a risk. An individual’s perception of risk may not accurately reflect their actual level of risk.

Route of administration
The method by which a vaccine is introduced into the body. There are five routes of administration:

- Intramuscular, where the vaccine enters through the muscle;
- Subcutaneous, where the vaccine is injected under the skin;
- Intradermal, where the vaccine is placed on the skin and absorbed;
- Intranasal, where the vaccine is introduced through the nose; and
- Oral, where the vaccine is swallowed in pill, capsule, or liquid form.

Routine practices
The activities that are done to help reduce the risk of being exposed to blood, body fluids, or non-intact (broken) skin of other people. Proper hand hygiene, use of face protection (i.e. masks or shields) and gloves, safe sharps handling, and environmental cleaning are examples of routine practices.

Safety-engineered injection devices
The injective devices that are designed to help prevent needle stick injuries and reduce exposure to bloodborne pathogens. Examples of safety-engineered injection devices include hypodermic needles and syringes, pre-filled syringes, insulin-injection needles, and jet injectors.

Sequelae
A pathological condition resulting from a prior disease, injury, or attack (i.e. a sequela of polio). Verbatim from the Latin “sequela” (meaning sequel). Plural: sequelae.

Serious Adverse Event (SAE)
An adverse event that is fatal or life-threatening that results in hospitalization or prolongation of hospitalization; can also result in significant disability or incapacity, in a congenital anomaly or birth defect. SAEs must be reported to authorities and are not necessarily due to vaccination.

Serogroups
A group of micro-organisms containing a common antigen that may include more than one serotype.
### Serotypes
A group of micro-organisms containing a similar set of antigens.

### Special considerations
An umbrella term used to encompass contraindications, exemptions, precautions and adverse events following immunization.

**Contraindications:** Specific immunizations are intentionally not administered because the health risk outweighs the benefit to the recipient.

**Exemptions:** Clients are exempted because of prior immunity (e.g. had the immunization before or had the disease) or refusal (e.g. medical, religious, or philosophical).

**Precautions:** Indication that the recipient may be at an increased risk of an adverse event following immunization. If the benefit of immunization outweighs the risk, the vaccination will be administered, likely under special recommendations.

### Special populations
The classifications used to identify target groups such as children, women, and travelers.

### Sporadic
A disease or event that occurs infrequently and irregularly.

### Stock rotation (rotation of stock)
The placement and rearrangement of vaccine vials and boxes so that those with the earliest expiration date are the most accessible, allowing them to be used first.

### Subunit vaccine
The vaccines consisting of surface antigens only. Purified subunit vaccines contain purified bacterial or viral protein factions. They are generally better tolerated than whole bacteria or virus vaccines.

### Surveillance
The monitoring of vaccine safety to maintain public confidence in vaccines and immunization programs. See Passive surveillance, active surveillance, and syndromic surveillance.

### Syndromic surveillance
The surveillance of health data to detect epidemics, monitor their impact on public health, characterize affected populations, and monitor the effectiveness of response to the epidemic.

### Systemic reaction
The general adverse effects such as fever, irritability, fatigue, anorexia, vomiting, or periods of excessive or inconsolable crying following vaccination. These reactions may cause concern to parents and physicians, but most are completely reversible with no permanent consequences.

### Targeted immunization
The immunization program aimed at a specific group(s) or population(s).

### Thimerosal
A mercury-based preservative used in the manufacturing process of multi-dose vaccines to prevent infections at the vaccination site.

### T-lymphocyte (T-cell)
A class of lymphocytes so called because they originate in the bone marrow but mature in the thymus before being released into the bloodstream. T-cells are important in controlling cell-mediated immune reactions and B-cell development.

### Toxoid
A toxin that has been treated to destroy its toxic property, but retains its capability to stimulate the production of antitoxin antibodies.
Transmissibility

The ability of a disease to be passed from an infected individual or group to a previously uninfected individual or group. An infectious disease may be transmitted by:

- droplet contact through coughing and sneezing;
- direct physical contact;
- indirect contact, usually by coming into contact with contaminated surface or soil;
- airborne transmission;
- fecal-oral transmission, usually from contaminated food or water sources; or
- vector-born transmission, where infection is carried by an insect or other animal and transmitted to humans.

Travelers

The people travelling or who have travelled to areas where high disease endemicity is possible and for whom the immunization status is unknown.

Universal immunization

The attempt to achieve maximum immunization coverage of the population or a segment of the world’s population, usually by designating a goal in which efforts will be made to ensure that a specific percentage of the population (e.g. 80 – 90%) is immunized by a specific year.

Vaccine-preventable disease (VPD)

Any infectious disease for which vaccines exist.

Voluntary immunization

The immunizations that are not required by law in some provinces or territories.

Wild type

The original parent strain of a virus, bacteria, fruit fly, mouse, or other laboratory test organism. Often refers to how organisms are found naturally, in the wild, before mutations were induced by researchers.

Wild type infection

The infection caused by the original parent strain of a virus, bacteria, fruit fly, mouse or other laboratory test organism.
15. **Essential Competencies for Injection of Other Substances**\(^1\)

**Competency:** Safely and effectively administers substances by injection

**Learning Objectives**

The pharmacist will be able to perform the following:

1. Demonstrate the necessary technical skills required to prepare and administer injections (subcutaneously, intramuscularly, intradermally, intravenously to already established central or peripheral venous access devices where regulations permit)

2. Describe and comply with legal and regulatory requirements for administering substances by injection, including federal and provincial legislation and applicable standards and policies

3. Conduct a Therapeutic Review:
   - Locate and interpret evidenced-based information relating to current therapeutic information of the specific substance to be injected including indications, contraindications, approved routes of administration, pharmacokinetics, dosage, injection protocol, precautions, adverse effects, client monitoring parameters, and information pertaining to specific client factors (e.g., renal dysfunction, hepatic dysfunction, pregnancy etc.)
   - Prepare a checklist to assess and determine preferred route of administration
     - Appropriate for the substance/solution
     - Appropriate for the client
     - Appropriate for the facility or regional protocol

4. Perform all necessary steps for administering substances by injection:
   - **Assess the Client, including:**
     - Age, weight, current and previous relevant medical conditions and medications, current client status (e.g. fever/signs of infection, pregnancy), allergies, relevant lab values, relevant client adherence issues, past experience or reactions with injections, medications and/or immunizations

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\(^1\) In the context of this document, *substance* should be read as the definition of a drug under the *Food and Drug Act (FDA)* which includes among other things all drugs in Schedule D (e.g. blood products). According to the FDA, a drug includes any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal
- restoring, correcting or modifying organic functions in man or animal, or
disinfection in premises in which food is manufactured, prepared or kept.
(continued)

◊ Special population considerations (e.g. renal dysfunction, hepatic dysfunction, pregnancy etc.)

- **Provide Client Education and Obtain Consent:**
  ◊ Explain reason for the injection and outline risks and benefits, including common and serious potential side effects and management
  ◊ Obtain and record informed consent for administration of injection
  ◊ Provide teaching on self-administration, if appropriate

- **Ensure Medication Appropriateness**, including the ‘Seven rights of medication administration’:
  ◊ Right Product
  ◊ Right Client
  ◊ Right Dose
  ◊ Right Time
  ◊ Right Route
  ◊ Right Reason
  ◊ Right Documentation

- **Ensure Safe Medication Preparation, Administration, Storage and Disposal:**
  ◊ Ensure a clean, safe, private and comfortable environment for the client
  ◊ Demonstrate appropriate infection control procedures and aseptic reconstitution technique
  ◊ Choose appropriate needle gauge and size for the client
  ◊ Take precautions for clients and health care workers with latex allergies
  ◊ Demonstrate correct administration technique appropriate for route of injection, including techniques for reducing pain associated with injection
  ◊ Determine and locate appropriate site for injection, taking into account client characteristics, product considerations, and anatomical landmarks (bones, muscles, blood vessels, nerves)
  ◊ Perform universal precautions in addition to preventing and managing needle-stick injuries
  ◊ Monitor and maintain temperature-appropriate storage conditions of injectable medications following product specific storage guidelines
  ◊ Ensure safe disposal of injectable medications and supplies
(continued)

- **Monitor the Client After Injection:**
  - Maintain currency in CPR and First Aid
  - Anticipate, identify, manage and report adverse effects following medication injection
  - Respond to anaphylactic reactions, with appropriate use of emergency kits and following established step-by-step protocols
  - Describe and perform therapeutic monitoring of client with respect to goals of medication therapy

- **Document Information Relevant to Each Injection:**
  - Describe the role and importance of injection records
  - Document client assessment and therapeutic decision(s) in client’s care plan
  - Document client education and consultation provided, including informed consent
  - Document administration of substance on client’s record, including product name, lot number and expiry date; dose given, route and time of administration
  - Document any reaction client has to the injection and monitoring parameters
  - Facilitate transfer of relevant documentation to client’s other health care providers

**References:**