



Nova Scotia Immunization Manual

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[November 2019](#)

Chapter 1: Nova Scotia Immunization Program

History

Vaccination as a deliberate attempt to protect humans against disease has a long history; although only in the 20th century has the practice flowered into routine vaccination of large populations.

It is a well-established fact that vaccinations are probably the most cost-effective health measure that exists today. With the exception of safe water, no other modality, not even antibiotics, has had such a major effect on mortality reduction and population growth.

Providing immunization to people of Nova Scotia (NS) is a responsibility shared between the Department of Health and Wellness (DHW), Public Health Services within the Nova Scotia Health Authority and primary health-care practitioners. Nova Scotia Health and Wellness provides policies, standards and guidelines for each of the vaccine programs, in addition to providing vaccines to providers for immunization purposes. Physicians and other primary health-care practitioners play an important role in providing 80-85 percent of primary immunizations to infants and children up to age 5 and to adults. Public Health staff provides immunization to almost 100 per cent of school-aged children and other groups as needed.

The following provides a brief history of the introduction of vaccine in Nova Scotia.

- 1926 Diphtheria vaccine introduced
- 1930 Diphtheria vaccine routine
- 1930 Pertussis vaccine introduced (estimated date)
- 1940 Tetanus vaccine introduced
- 1943 Pertussis whole-cell vaccine introduced
- 1949 Tetanus vaccine routine
- 1952 Pertussis vaccine routine (estimated date)
- 1962 Sabin oral polio mass immunization
- 1962 Salk injection introduced/routine
- 1963 Measles vaccine licensed
- 1968 Live mumps vaccine available
- 1969 Measles vaccine provided to doctors (MR, not live vaccine)
- 1970 Community Health Nurses (public health staff start to administer vaccines)
- 1970 Live rubella vaccine available
- 1975 MMR routine up to 5 years of age
- 1976 Smallpox vaccine discontinued
- 1976 Live rubella vaccine routine for 11-year-old girls
- 1983 10-year-old booster DPT vaccine discontinued

- 1984 DTP absorbed vaccine introduced/routine
- 1986 MMR vaccine boosters if immunized prior to Jan. 1, 1975 (one time in school)
- 1986 Hepatitis B vaccine introduced for persons at risk
- 1988 Rubella vaccine for 11-year-old girls discontinued
- 1989 Influenza vaccine
- 1992 Act Hib started at 2 months
- 1992 Mass meningococcal immunization campaign (July–Sept, Northern Region excluded)
- 1994 Polyvalent introduced; DTP+Act Hib routine
- 1995 Hepatitis B routine in grade 4
- 1996 MMR 2nd dose introduced, routine (before starting school)
- 1997 Acellular pertussis introduced, routine
- 1997 Pneumococcal vaccine publicly funded for 65 years+
- 2001 Td only given to 15-year-olds (polio discontinued)
- 2003 Varicella introduced for routine immunization for those 1 year of age
- 2003 Varicella eligibility extended to children age4-6 and to non-immune health-care workers
- 2004 Tdap to 14- to 16-year-olds, in place of Td
- 2005 Meningococcal conjugate for 1-year-olds, catch up for Grade 4's and 14-to16-year-olds
- 2005 Pneumococcal conjugate vaccine (7) introduced
- 2005 Varicella, "catch-up" to grade 4
- 2007 School-based program moved to grade 7; HPV, meningococcal C, and Tdap given
- 2007 Tdap: one dose for adults
- 2010 Switched from Pneumococcal conjugate 7 (Pevnar 7) to Pevnar 13
- 2010 Influenza vaccine for all
- 2011 2 dose HBV (Adult) in School program (change from 3 dose Pediatric)
- 2012 3 dose Pneumococcal conjugate vaccine for healthy children
- 2012 2 dose Varicella vaccine for children-1 year and 4-6 years of age
- 2012 Switch to MMR-V product at 1 year and 4-6 years of age
- 2012 Tdap-IPV introduced to replace Quadracel
- 2012 MMR 2 doses for those born after 1970
- 2013 Meningococcal C two doses at 1 year of age and in Grade 7(not a catch-up program)
- 2015 Meningococcal B added for post exposure prophylaxis and specific high-risk groups
- 2015 HPV for females reduced from 3 doses to 2 doses for the school-based program
- 2015 HPV for males introduced as a 2 dose school based program for the 15-16 school year
- 2015 Meningococcal school program changed from Men C to Men-ACYW-135 for the 15-16 school year
- 2015 MMR or MMRV second dose to be given anytime between 18 months and 6 years

- 2015 Meningococcal B vaccine will be available to individuals with high risk conditions, close contacts of individuals with Meningococcal B disease and in outbreak situation as determined by Public Health
- 2015 Polysaccharide 23 pneumococcal vaccine available to those 2- 64 years at highest risk of invasive pneumococcal disease should receive one booster dose five years after the previous dose
- 2018 Tdap vaccine should be offered in every pregnancy irrespective of previous Tdap immunization
- 2018 Fluzone®High-Dose vaccine will be available to Long Term Care Facility (Nursing Home and Residential Care) residents 65 years of age and older (2018-2019 influenza season)
- 2018 HPV vaccine offered to both males and female in grade 7 will be Gardasil®9.
- 2019 HPV vaccine made available for individuals with HIV and for men who have sex with men, up to and including 45 years of age
- 2019 Haemophilus Influenzae Type B (Hib) vaccine no longer publicly funded for individuals with HIV (IDEG recommendation)
- 2019 Rotavirus vaccine will be available to children born on or after November 1, 2019, up to 8 months of age.

N.S. Immunization Program Goals and Objectives

- To offer protection against vaccine-preventable diseases in order to attain a high level of immunity that will eliminate or prevent outbreaks of vaccine-preventable diseases
- To protect at least 95 per cent of children against vaccine-preventable diseases by immunizing them at the earliest appropriate age
- To maintain the immunization status of children through reinforcement doses throughout their preschool and school-age years
- To offer immunization for adults as recommended and determined by individual circumstances
- To offer specific immunization programs to targeted high-risk groups

Immunization Schedules

Nova Scotia Provincial Schedule: <http://novascotia.ca/dhw/cdpc/immunization.asp>

Other Provincial Schedules: www.phac-aspc.gc.ca/im/is-vc-eng.php

Chapter 2: Professional Responsibilities

Professional Accountability

[Health Protection Act](#)

[Safer Needles in Healthcare Workplaces Act](#)

[Registered Nurses Act](#)

[College of Registered Nurses of Nova Scotia](#)

[RN Code of Ethics](#)

[Documentation Guidelines for Registered Nurses](#)

[Immunization Guidelines for Registered Nurses](#)

[Standards for Nursing Practice](#)

[Licensed Practical Nurses Act](#)

[College of Licensed Practical Nurses of Nova Scotia](#)

[LPN Documentation](#)

[LPN Code of Ethics, Standards of Practice](#)

[Canadian Immunization Guide](#)

Medical Directives

In Nova Scotia, the medical directive for immunizations for Registered Nurses takes the form of guidelines established by the Department of Health and Wellness as outlined in the [NS Immunization Schedule](#).

Public Health Nurses deliver immunization programs under policy/guidelines developed by the Chief Medical Officer of Health, Department of Health and Wellness (considered to be a Medical Directive).

Community health nurses (RN) employed by First Nations communities in Nova Scotia can follow the Nova Scotia Immunization Schedules for Adults and Children as a Care Directive in the provision of publicly funded immunizations to members of the First Nations Communities. The CRNNS joint position statement can be found at this location: <http://crnns.ca/>

Roles and Responsibilities

Public Health Services (PHS) in the Nova Scotia Health Authority (NSHA) are responsible for implementing policies, standards and guidelines developed by the Department of Health and Wellness and for providing data and information required to monitor and evaluate the immunization program.

These responsibilities include:

- providing immunization against vaccine-preventable diseases of a serious health consequence to targeted high-risk populations
- facilitating the delivery of immunization programs by health professionals who follow current standards of practice
- maintaining a health record of persons immunized in the community in order to assess community immunization rates; the record should include the following:
 - ✓ name of product administered
 - ✓ date given
 - ✓ dose
 - ✓ site and route
 - ✓ lot number
 - ✓ provider name
- providing an immunization record to the client
- submitting statistical information to Department of Health and Wellness as required
- reporting adverse events following immunization
- supplying provincially funded vaccines free to community vaccines providers who manage, monitor, report and deliver safe and effective immunization services
- determining who can provide immunization using publicly funded vaccine and in what circumstances

Documentation

As part of an immunizer's professional responsibility, the care or service they provide must be documented in the legal health record.

Regardless of the documentation system used, immunization providers are responsible and accountable to ensure that the information entered is accurate and timely and in accordance with their particular professional practice standard.

The health care provider must keep a permanent record of immunization history.

Ensure the documentation includes required information:

- Client's name
- Health Card Number (HCN)
- Vaccine Name
- Lot number
- Dose number in series
- Route administered
- Anatomic location of immunization
- Dose
- Signature of immunizer
- Date of immunization
- Adverse Events Following Immunization

Infant/Childhood and Adult Immunizations given by Public Health

- Record infant/childhood and adult immunizations on the legal documentation record defined in the Nova Scotia Health Authority e.g. consent form, a reciprocal notification form or an MCH9 card. This document containing the immunizer's signature will serve as the legal record of the immunization.
- Enter the immunization into the Application for Notifiable Disease Surveillance (ANDS).

School-based Immunizations given by Public Health

- Record immunizations provided within the school program on the [school immunization consent form](#). Ensure the documentation is complete. The consent form is part of the client record and is the legal record of the immunization.
- Enter the immunization into the Application for Notifiable Disease Surveillance (ANDS).

Competency

A vaccine provider must demonstrate the attitudes, knowledge and clinical skills necessary to provide safe and effective immunization programs.

To promote safe and competent immunization practice, registered nurses are expected to follow:

- Immunization Guidelines for Registered Nurses
- Standards of Practice for registered Nurses
- Code of Ethics
- Nova Scotia Immunization Schedule

It is recommended that all vaccine providers complete an Immunization Competency Program before administering vaccine and biological products. The purpose of this program is to assist health-care practitioners in fulfilling their roles as vaccine providers, educators and advocates for immunization. The Nova Scotia Public Health Immunization Competency Program can be found on the Provincial Learning Management System, an electronic learning aid, found at:

<https://elearning.nshealth.ca>.

To Sign in, enter your network User ID (username) and password in the spaces provided. This is likely the same user name and password you use for webmail. Be sure to include your DHA or domain and a backslash before your username. Use all lower case letters, no uppercase. Please note the direction of the backslash (\) e.g. ssdha\username.

N.S. Public Health Immunization Certification Program

Criteria for Certification:

1. Certifications to be coordinated by the designated person(s) in the DHA/SSA
2. Completion of NS/BCCDC Competency Modules
3. Pass mark for test – 90%. The coordinator can review the exam results on-line. Incorrect answers are discussed with the nurse. The nurse can be asked to find the reference for the correct answer or review certain material, etc. It is not necessary for the nurse to redo the exam after this discussion.
4. BCCDC Skills Demonstration Checklist to be completed
5. Review Immunization Guidelines from the RN or LPN professional association
6. Review Immunization Competencies for Health Professionals (PHAC)
7. Number of hours or clinics needed to maintain skills – minimum of 4 hours or 2 clinics, whichever is greater.
8. Recertification is required every 2 years.
9. Nurses have a professional accountability to attain and maintain their own competence in the provision of immunizations, in order to provide safe, competent and ethical care to their clients

Criteria for Recertification:

1. Recertification is to be coordinated by the designated Public Health Services person(s) in the DHA/SSA and is to be completed every 2 years.
2. Review of all the NS/BCCDC Competency Modules
3. Review Immunization Guidelines from the RN or LPN professional association
4. Review PHAC Immunization Competencies for Health Professionals (**Optional**)
5. Review of all relevant National Advisory Committee on Immunization (NACI) statements released since the initial certification
6. Administration of immunizations at the minimum number of hours or clinics/year (4 hours or 2 clinics, whichever is greater)
7. Nurses have a professional accountability to attain and maintain their own competence in the provision of immunizations, in order to provide safe, competent and ethical care to their client

Chapter 3: General Principles of Immunology and Immunization

Definition

- Active immunity is protection that is produced by a person's own immune system. This type of immunity is usually permanent.
- An antibody is a protein (an immune globulin molecule) produced by an organism in response to stimulation by an antigen. An antibody combines only with the specific antigen that induces its synthesis.
- An antigen is any substance that is capable of inducing an immune response when introduced into an organism. This immune response may be expressed by the production of certain antibodies, by the production of antigen-specific cells, or by the absence of any response (tolerance). In infectious disease, the antigen may be a complete infectious agent, one of its constituents, or one of its products.
- Inflammatory response is a non-specific defense mechanism elicited by tissue damage. It is generally characterized by four basic signs or symptoms: redness, pain, heat and swelling. It contributes to the elimination of micro-organisms, toxins and other foreign particles at the site of the injury, prevents their propagation to adjacent tissues and prepares the site for tissue repair.
- The immune system is a complex system of interacting cells whose primary purpose is to identify foreign (non-self) substances.
- Immunity is the ability of the human body to tolerate the presence of material indigenous to the body ("self") and to eliminate foreign ("not-self") material.
- Immunization is the process by which immunity is conferred, either by injection of antigens (active immunization) or by injection of serum containing specific antibodies (passive immunization).
- Immunogenicity is the capacity of an antigen to induce a specific immune response.
- Immunologic memory is the capacity of immunological cells (B and T lymphocytes) that have already been exposed to an antigen to recognize it and mount a faster and more heightened response (for example, after injection of a booster dose). Immunologic memory lasts a very long time, even when the concentration of antibodies in the serum is below the detection limit. This phenomenon allows for continuation of primary immunization regardless of the time elapsed between doses.
- Immunology can be defined as the branch of science concerned with the processes and consequences associated with the physiological recognition of

self and not-self. The human body is equipped with a system (the immune system) that recognizes and tolerates its genetically determined constituent elements and rejects anything that is foreign to it.

- Passive immunity is protection by products produced by an animal or human and transferred to another human, usually by injection. Passive immunity often provides effective protection, but this protection disappears with time, usually within a few weeks or months.
- Primary immunization is the number of doses of a single immunizing product that must be administered for a subject to develop adequate immunity.
- Seroconversion is the development of a specific antibody in the serum. The change of a serologic test from negative to positive indicates the presence of antibodies. Seroconversion may occur as a result of viral or bacterial infection or in response to vaccination. There is a varying lapse of time between the time of infection (or vaccination) and the time when the development of specific antibodies can be measured by serologic tests. The term “seroprotection” is sometimes used to indicate a high enough level of antibodies in the serum to protect a person against disease.
- Vaccination is a method of preventing certain infections. It consists of introducing preparations called vaccines into an organism for the purpose of inducing active immunity.
- A vaccine is an antigenic preparation which, when introduced into an organism, induces the production of antibodies capable of fighting off infection of that organism by a given micro-organism.
- Vaccine effectiveness is the protection a vaccine gives to a population. Vaccine effectiveness is measured by means of field observations, which are conducted in accordance with epidemiological methods to evaluate protection against clinical disease and include comparing the incidence of the disease in vaccinated subjects and non-vaccinated subjects.

Different Types of Immunity

Natural Immunity

Natural immunity, which is, by definition, innate, consists of a series of biological and physico-chemical mechanisms that act rapidly to protect an organism from penetration of a proliferation of infectious agents. This type of immunity is non-specific, in the sense that it does not distinguish among different infectious agents. It offers two lines of defense. The first is external and comprises the epithelial

tissues that cover the body (skin and mucous membranes) and the secretions produced by these tissues (mucous, tears, gastric juice, etc.) The second is internal and is triggered by chemical mediators that prompt various cells and proteins to launch an indiscriminate attack on invading antigens that have breached the organism's external barriers. These mechanisms make use of phagocytes (neutrophils, monocytes and macrophages), cells that produce inflammatory mediators (basophils, mast cells and end eosinophils) and natural "killer" cells. The components of immunity also include complement proteins and cytokines, such as interferon. Natural immunity is primarily called upon for the destruction of extracellular organisms, particularly bacteria. It is less effective against infection caused by intracellular organisms, such as viruses, mycobacteria, fungi, or parasites.

Acquired Immunity

Acquired immunity corresponds to the production (active immunity) or transmission (passive immunity) of a state of resistance to an antigen through the direct action of antibodies or cells specific to that antigen. This immunity improves with repeated exposure to a given antigen.

- Active acquired immunity is the result of activation of the organism's immune system through contact with an antigen.
 - Natural active acquired immunity results from an infection. The degree and duration of protection vary from one disease to another. This is why people must be vaccinated even when they have had certain infections in the past (e.g., typhoid fever, influenza).
 - Artificial active acquired immunity results from the immunization caused by vaccination, without involving the potential consequences and complications of the disease. This immunity takes advantage of the characteristics of the immune system for preventive purposes.
- Passive immunity results from the transfer of antibodies formed in another organism to a given individual.
 - This protection is of limited duration.
 - Natural passive acquired immunity is seen in babies during the first months of life as a result of antibodies transferred from the mother through the placenta or maternal milk. This immunity disappears during the first year of life.
 - Artificial passive acquired immunity occurs when an organism receives antibodies produced by another human or animal organism. The protection supplied by specific and non-specific immune globulins is an

- example of this kind of immunity.
- Humoral immunity results from the production of antibodies by the immune system's B lymphocytes. These antibodies may be found in many of the organism's biological fluids. Humoral immunity is primarily responsible for resistance to extracellular pathogens, such as bacteria. Antibodies are generally easy to measure in the laboratory and this measurement is used to determine the immune response to vaccines. However, antibodies represent only one part of the immune response.
 - Cell-mediated immunity primarily involves the lymphoid cells or the immune system's T lymphocytes. This immunity is primarily responsible for resistance to intracellular pathogens such as viruses, certain cancerous cells and transplants. It is much more difficult to measure in the laboratory. It may protect the individual even in the absence of detectable antibodies.

Characteristics of the Immune System

The immune system has four principal characteristics:

- Specificity refers to the immune system's capacity to recognize and eliminate certain pathogens or foreign molecules called antigens. Each antigen has a unique molecular structure that triggers the production of specific cells or antibodies to fight it.
- Diversity corresponds to the immune system's capacity to fight off millions of types of attackers by recognizing each by its antigenic markers.
- Recognition of self and not self refers to the immune system's capacity to distinguish between the organism's own molecules (self) and foreign molecules (not self).
- Memory indicates the immune system's capacity to remember antigens that it has encountered and to react promptly and effectively to subsequent exposures.

Immune System Function

The organs of the immune system are known as lymphoid tissues. They are found almost everywhere in the human body. Bone marrow is where the lymphocytes, the smallest of the white blood cells, are produced. Lymphocytes that mature in the bone marrow become B lymphocytes, while those that migrate to the thymus differentiate into T lymphocytes. The lymph ducts and nodes are part of the circulatory system that transports the lymph, which consists primarily of lymphocytes. The spleen is a

lymphatic organ in which immune system cells attack pathogens. The tonsils, adenoids, Peyer's patches and appendix are also lymphoid tissues. Lymphoid cells and foreign molecules enter the lymph nodes through blood vessels and lymph ducts.

Lymphocytes have antigen receptors on their plasma membranes that recognize specific antigens. In the case of B lymphocytes, these receptors are actually antibodies, while the T lymphocytes have specific receptors.

When a pathogen breaches the non-specific natural defenses formed by the cutaneous and mucosal barriers and the phagocytic mechanisms, the immune system takes over. After partially digesting the microbial antigens, the macrophage becomes an antigen-presenting cell. Other cells, such as the dendritic cells, found primarily in the skin, are also very effective antigen-presenting cells. Antigen-presenting cells enable antigens to form a complex with the glycoproteins of the major histocompatibility complex (MHC) on the macrophage. These glycoproteins mark the macrophage as self. This complex will then be captured by a lymphocyte with the specific receptor able to bind to it. If the activated lymphocyte is a B lymphocyte, the effector lymphocytes become plasmocytes, which secrete specific antibodies to destroy the antigen. If the activated lymphocyte is a T lymphocyte, the effector lymphocytes will fall into two main categories: cytotoxic T lymphocytes (CD8+), which destroy infected and cancerous cells, and helper T cells (CD4+), which play a key role in stimulating humoral and cell-mediated immunity.

There are two types of helper T lymphocytes: Th1 and Th2 cells. Th1 cells are the regulatory cells in Th1 immunity. The main substance secreted by these cells is interferon, which, among other things, stimulates phagocytosis, promotes intracellular destruction of micro-organisms, facilitates presentation of the antigen to the T cells, and causes inflammatory reactions. Th1 immunity stimulates cell-mediated immunity, including the cytotoxic T cells, which are intensely phagocytic. Th1 immunity is usually associated with delayed hypersensitivity reactions. Th2 immunity stimulates the B cells, primarily through interleukins, and promotes the production of antibodies. This immunity is associated with allergic reactions, primarily because of the production of eosinophils, basophiles and IgE. Antigens that trigger humoral immune responses without the participation of T lymphocytes are called T-independent antigens; while those that cannot stimulate production of antibodies without helper T cells are called T-dependent antigens. The antibody response following stimulation by T-independent antigens is generally weaker.

Antibodies act primarily through neutralization, agglutination or activation of the complement system. Antibodies have a neutralizing effect when they bind to the sites that the micro-organism must use to attach to the host cell. The avidity of the antibodies is proportional to the strength of the bond between the antigen and the antibody. Phagocytes then destroy the antigen-antibody complex. Agglutination occurs through antibodies that have more than one antigen-binding site, allowing binding with adjacent antigens. Finally, antibodies may combine with the proteins of the complement system, prompting it to produce lesions in the membrane of the foreign cell and causing lysis of that cell. The principal antibodies are the IgG immune globulins found in the blood and tissues, IgM immune globulins, IgA immune globulins found in the mucous membranes, IgD immune globulins and IgE immune globulins.

In the majority of infections, Th1 immunity provides an initial defense, while Th2 immunity takes over when the inflammation generated by Th1 immunity resolves. The functioning of this system is complex, and the different components are closely interrelated and in constant balance. Several factors may lead to an inversion of the normal response process, such as a major stressor, immunosuppression, administration of glucocorticoids (cortisone or catecholamines), or a significant inoculation of antigens to induce the immune system to generate a Th2 response to an infection normally controlled by Th1 immunity.

After vaccination, some B lymphocytes rapidly differentiate into antibody-producing plasmocytes and others into memory B cells, with the help of Th 2 cells. After reaching the final stage of this differentiation, the antibody-producing plasmocytes stop dividing and naturally disappear over time. The maximum level of antibodies induced after vaccination directly reflects the number of plasmocytes generated by the vaccination. Similarly, the disappearance of antibodies reflects the disappearance of specific antibodies. The length of time for which the antibodies remain is directly related to the level reached after vaccination.

The memory cells are not reactivated unless they are again exposed to the antigen for which they are specific. In response to a vaccination (booster) or infectious exposure (disease), the memory cells proliferate very rapidly and differentiate, within three to five days, into plasmocytes producing high levels of antibodies or cytotoxic T lymphocytes capable of destroying the antigens or infected cells. In contrast to the plasmocytes, which do not divide any further and have a limited life span, the memory cells appear to persist for a long time, regardless of antigenic exposure.

Immunizing Products

Immunization gives the human body the means to defend itself against a biological attack before it occurs. In active immunization, the process consists of stimulating the immune system by means of a known and controlled immunizing product while avoiding the consequences associated with natural infection. In passive immunization, the process involves a transfer of antibodies, called immune globulins, from an immunized subject to a non-immunized one.

Vaccines

A vaccine is a biological product manufactured from a whole bacterium or virus, its constituents (polysaccharides or proteins), or its products (toxins), from which the capacity to produce the disease is destroyed by various means, while the capacity to induce an immune response (immunogenicity) is preserved. Vaccines may be inactivated or live attenuated.

The immunogenicity of a vaccine depends on a number of factors, including the antigen's foreign source, morphology, chemical makeup, molecular mass, route of administration, and use of adjuvants. Generally speaking, proteins are the most potent immunogenic substances. In addition, the greater the molecular mass, the more immunogenic the antigen will be. For this reason, some vaccines made of polysaccharides with low molecular mass are conjugated to a protein to make them more immunogenic at a younger age. The main proteins used for conjugation in current vaccine production are diphtheria antitoxin, tetanus antitoxin, the non-toxic variant of the diphtheria toxin (CRM197) and OMP protein from *Neisseria meningitidis* capsule.

Additional information on vaccine composition in Canada

Vaccines that are currently distributed in Canada contain many different components.

- **Antigens that induce active immunity**

A vaccine may be monovalent (containing only one antigen), polyvalent (containing more than one antigen from one infectious agent), or combination (containing more than one antigen from more than one infectious agent).

- **Culture media**

Vaccines are grown in various culture media. The ones used most frequently are bovine proteins, chick embryo cells, embryonated chicken eggs, human diploid cells and yeasts. The final product may contain trace proteins.

- **Suspending fluid**

Depending on the vaccine, the suspending fluid may vary from saline or sterile water to a

more complex protein liquid.

- **Preservatives or antibiotics**

These prevent the growth of bacteria in the vaccine. The most common preservatives are formaldehyde, phenol, 2-phenoxyethanol and thimerosal. The most common antibiotics are neomycin and polymyxin B.

- **Stabilizers**

The most common stabilizers are bovine albumin or bovine serum, human serum albumin, gelatin, glycine, lactose, sorbitol, sucrose, and saccharose. Polysorbates 20 or 80 (or Tween 20 or 80) are used as surfactants to make products homogeneous. Stabilizers are also found in some cake mixes and are used as emulsifiers in cosmetics and pharmaceutical products.

- **Adjuvants**

Adjuvants are used to boost the immunizing power of the vaccine in order to obtain a better serological response and ensure more lasting immunity with few antigens and fewer doses. Adjuvants act by prolonging the presence of antigens at the site of inoculation. This allows them to be released over a variable period of time and promotes activations of the antigen-presenting cells (i.e., dendritic cells and macrophages) as well as production of cytokines. When a vaccine contains aluminum salts (generally aluminum phosphate or aluminum hydroxide), it must be administered intramuscularly, because injecting aluminum salts into the subcutaneous tissues may cause a significant inflammatory reaction, subcutaneous nodules and sometimes even sterile abscesses. Other adjuvants may also be used, such as the MF59 water-in-oil emulsion. The components in the last three categories, also called excipients, do not by themselves play an active role in establishing the desired immune response, but they facilitate the preparation and administration of a vaccine. They also serve as vehicles for the active ingredients.

Immune Globulins

Immune globulin consists of protein extracted from the serum fraction of blood. It contains antibodies that recognize and attack specific pathogens. Immune globulin contains mainly IgG with small amounts of IgM and IgA. It can be of human or animal origin. In Canada, human immune globulins are used most frequently. However, in some developing countries, animal immune globulins are used instead.

Questions are frequently asked about the risk of transmitting infectious agents through the administration of immune globulin and this issue merits attention. First, all blood donors are required to complete a questionnaire designed to detect risk factors for infections transmissible by blood. They are also given a physical examination during which the examiner looks for evidence of injections inside the elbow and takes their temperature. A donor can also cancel his or her donation in complete confidence, even if it has been accepted. People who are at risk of developing Creutzfeldt-Jakob disease are not allowed to donate blood.

Every blood donation is then analyzed for hepatitis B, hepatitis C, HIV-1, HTLV-I and 2 lymphotropic virus, West Nile virus and syphilis. The diseases and the tests used to detect them may vary over time, as more effective tests become available. Any blood that tests positive for one of these diseases is rejected. Secondly, the processes used to extract immune globulin from the blood include the use of heat and alcohol, which are capable of inactivating HIV, HBV and HCV.

To date, the administration of the intramuscular immune globulin marketed in North America has never been associated with the transmission of an infectious agent, including HIV and hepatitis C. Furthermore, no human case of Creutzfeldt-Jakob disease has been causally linked to blood transfusions.

Two preparations are used to prevent and treat infectious diseases: non-specific (standard) immune globulin of human origin and immune globulin containing high titres of specific antibodies to a particular micro-organism or its toxin. The specific immune globulin may be of human or animal origin. Maximum plasma levels are reached between 48 and 72 hours after administration of these products.

Specific immune globulins

Human

- HBIG hepatitis b immune globulin
- RIG rabies immune globulin
- TIG tetanus immune globulin
- VZIG varicella-zoster immune globulin

Animal

- Botulism antitoxin
- Diphtheria antitoxin diphtheria immune globulin

More detail regarding information on Biological Products can be found <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>

Immunology of Vaccination

Like a natural infection, vaccination can induce either a humoral or a cell-mediated immune response. The response will vary according to two parameters: the type of vaccine administered (live or inactivated) and factors associated with the host.

Humoral Immune Response Induced by Different Types of Vaccines

Live vaccines

After the administration of a dose of live vaccine, an infection occurs, although no clinical signs are usually apparent. This infection induces immunity, which can be measured by a serum antibody determination. The humoral immune response and the protection conferred by the live vaccine appear to be similar in nature and intensity to those resulting from natural infection.

Inactivated whole-cell or inactivated purified protein vaccines

Two types of response correspond to the inactivated vaccine, depending on whether it is the organism's first contact with the protein antigen or subsequent contacts with the same antigen. The characteristics of the first response are the following:

- a relatively long latent period before the appearance of antibodies
- low intensity (usually insufficient to confer adequate protection)
- short duration
- primarily IgM

In comparison, the secondary, or anamnestic, response following another exposure is faster, stronger, and longer lasting; it primarily consists of IgG.

The quantity injected, number of doses, and intervals between doses are important factors in the success of an inactivated vaccine. For example, second antigenic stimulation too soon after the first may be ineffective because of elimination of the antigen by the high concentration of serum antibodies still present; it is therefore important to comply with the minimum interval between doses.

Polysaccharide vaccines

Polysaccharide vaccines directly stimulate B lymphocytes but not T lymphocytes (primarily stimulated by proteins), resulting in a production of antibodies, but not memory cells. This is a T-independent lymphocyte response.

Conjugate vaccines

Conjugation, which is the combining of polysaccharide with proteins, induces a T-dependent immune response very early in life. The antibodies produced are more effective than those induced by the unconjugated polysaccharide vaccine, and their affinity for the bacterial antigens improves with time. The immune response induced by a conjugate vaccine is therefore similar to the response induced by an inactivated whole-cell vaccine or an inactivated purified protein vaccine.

Host Factors

Age

During the first 2 or 3 months of life, the immune system is relatively immature. It is nevertheless capable of generating a relatively complete immune response, both humoral and cell-mediated. There is one exception: B lymphocytes in the infant are unable to respond to T-independent antigens such as polysaccharides until the age of about 2 years. Recent studies show that an infant's immune system can deliver a significant response: a calculation based on the number of lymphocytes available at that age show that an infant could receive up to 10,000 vaccines simultaneously without deleterious effects on the immune system, which has the capacity to regenerate up to two million CD4+T lymphocytes a day.

Maternal antibodies, passively transmitted to the child in utero or through breastfeeding, may have an inhibitory effect on the immune response.

- The quality and intensity of the humoral response in the infant is closely linked to the continuing presence of specific maternal antibodies and their protective efficacy, which is highly variable from one infection to another. Immunization schedules take these factors into account.
- The ability to generate a good immune response declines with age, since the pool of undifferentiated plasmocytes decreases over time. Nevertheless, elderly people respond relatively well to immunization.

Genetic factors

Some people respond better than others to immunization. This is partly because of genetic factors such as the ABO blood systems and the HLA histocompatibility antigens.

Immunodeficiency

Whether acquired or hereditary, immunodeficiency generally decreases the immune response, in the case of both humoral and cell-mediated immunity.

Malnutrition

This factor primarily results in a decline in cell-mediated immunity.

Impact of Acquired Immunity on the Individual and the Community

Immunity, whether acquired naturally or artificially through vaccination, plays an important role in the epidemiology of communicable diseases through an individual effect and a collective effect.

Individual Effect

Immunity protects the individual against reinfection, and this protection is specific. However, this protection is not necessarily permanent. People who have been vaccinated do not always develop a protective immunity.

Collective Effect

Transmission of a contagious disease is directly related to the proportion of susceptible subjects in the community. Transmission declines as the number of immune people rises. When this number is high enough, the infectious agent stops circulating among the population. This has a protective effect on the entire population, including non-immunized people. This effect is known as community or herd immunity. This is the basis for mass immunization programs.

In a population where only some individuals are protected, there is a critical threshold below which an epidemic may occur and another threshold beyond which the disease will disappear for lack of sufficient susceptible subjects who might pass it on.

These thresholds vary with the disease in question, its attack rate, and in the case of vaccine-preventable diseases, the immunization coverage rate in the population.

Immunization programs may have varying objectives, depending on such factors as the effectiveness of the available vaccines, the capacity to reach the target populations, and the epidemiology of the disease. The first objective may be eradication, or complete elimination of the disease world wide. The WHO declared smallpox officially eradicated in 1980. A second objective may be elimination of the disease, or the absence of sustained (endemic) transmission of the disease. Elimination has occurred if the epidemic potential is low enough that, on average, one case induces less than one other case. The third objective may be to control the rate of mortality or morbidity attributable to the disease.

General Recommendations for Effective Application of Immunization Concepts

Age at Which Immunizing Products Are Administered

Factors influencing the recommended ages for administration of vaccine include:

- potential antagonistic interference between immune system response and passive transfer of maternal antibodies
- the capacity of an individual of a given age to develop an immune response (immune system maturity)
- the age-related risk of developing a disease or its complications

Vaccination before the minimum recommended age may result in a suboptimal immune response and should not be counted as part of the primary immunization. The dose should therefore be readministered at the age initially recommended, provided the time between the dose given too early and revaccination complies with the minimum interval between two doses of the same vaccine.

Vaccination Intervals

Intervals between doses of the same vaccine

- Many vaccines require at least two doses to give effective protection, as well as periodic booster doses to maintain this level of protection.
- Unless otherwise indicated, doses given at less than the recommended interval may result in suboptimal antibody response and should not be counted as part of a primary series. These doses should therefore be readministered by calculating the minimum or recommended interval initially established from the

time of the dose that was administered too early. For example, if the third dose of DTaP-IPV-Hib was administered at the age of 6 months and the fourth dose at 11 months, the minimum interval was not observed, since 5 months had passed since the third dose rather than the minimum of 6 months. The fourth dose is considered invalid and must be readministered 6 to 12 months (minimum and recommended intervals) later, or at the age of at least 17 months. This dose will be considered the valid fourth dose of the primary immunization. Immunization should then continue in accordance with the recommended schedule.

- When the minimum interval between two doses of a vaccine is 1 month, this interval is generally considered equivalent to 4 weeks (28 days).
- As a general rule, interruption of a primary series of vaccinations does not require starting the series over again. Instead, the series should be continued where it was left off, regardless of the interval elapsed since the last dose, even if it is a matter of years.

Intervals between different vaccines

- Most of the commonly used antigens can be given simultaneously.
- Inactivated vaccines can be administered at the same time or at any time before or after a live vaccine or an inactivated vaccine.
- Different live vaccines should be administered simultaneously or at least 4 weeks (28 days) apart. A decrease in the effectiveness of the varicella vaccine has been shown when the interval between the MMR and varicella vaccines was too short.
- Since the MMR vaccine affects hypersensitivity to tuberculin (anergy or transient hypoallergy), the tuberculin skin test (TST) should be done before, at the same time as, or at least 4 weeks after administration of the MMR vaccine. It is possible that other injectable live vaccines, such as the varicella and yellow fever vaccines, may similarly falsify the TST results. If an injectable live vaccine must be administered and a TST is required, the test should be done before, at the same time as, or at least 4 weeks after the vaccination. Live vaccines administered orally probably do not have any effect on the response to TST.

Interval between immune globulin (IG), other blood products, and vaccines

Please refer to the [Canadian Immunization Guide: Part 1 – Key Immunization Information – Blood products, human immune globulin and timing of administration](#) for guidelines on the interval between administration of immune-globulin (Ig) preparations or blood products and vaccines.

Contraindications and Precautions to Vaccines

General Contraindications to Vaccines

A contraindication is a condition that significantly increases the chance that a serious adverse event will occur if the vaccine is given.

- Anaphylactic reaction to a constituent of vaccine or to a previous dose, either of the same vaccine or of another vaccine with the same constituent.
- Significant immunosuppression (live vaccines only)
 - immunodeficiency such as gammaglobulinemia, hypogammaglobulinemia, or dysgammaglobulinemia
 - leukemia, lymphoma, or other generalized neoplastic disorders capable of altering immune mechanisms
 - treatment with immunosuppressive agents (corticosteroids, antimetabolites, or other immunosuppressive agents)
 - HIV and AIDS infections (some live vaccines are contraindicated for people infected with AIDS)
 - pregnancy

General Precautions to Vaccines

A precaution is 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.

- Persons who have chronic underlying illness or who are immunocompromised, in whom there may be a reduced response to the vaccines
- Persons with a history of Guillain-Barre syndrome (GBS) with onset within 8 weeks of a previous immunization

Factors That Are Not Contraindications to Immunization

- significant local reactions to a previous dose of vaccine, for example, swelling of the entire limb, following administration of a previous dose of DTaP-IPV Hib
- minor illness without fever, such as a cold or mild diarrhea in an otherwise healthy person
- antibiotic treatment
- prematurity

- pregnancy of the subject's mother or any other woman in contact with the subject
- recent exposure to infectious disease
- breastfeeding: the only vaccinal virus that has been isolated in maternal milk is the rubella virus; however, it has not been shown that its presence in the milk presents a risk to the infant's health
- personal or family history of non-specific allergy
- history of allergy to antibiotics contained in the biological product, except in the case of an anaphylactic reaction
- history of allergy to chicken or chicken feathers
- family history of sudden infant death syndrome
- family history of convulsions associated with vaccination
- family history of adverse reactions to vaccination not associated with immunosuppression
- administration of an inactivated vaccine to immunocompromised people
- multiple sclerosis or any other auto immune disease
- evolving neurological conditions: there is no need to defer pertussis vaccination for children with such conditions
- hypotonic-hyporesponsive episodes: children experiencing such reactions to a previous dose of vaccine have not had problems with the administration of subsequent doses
- afebrile convulsions and encephalopathy temporally associated with administration of a vaccine including pertussis: it has not been shown that the a cellular vaccine was responsible
- febrile convulsions: these may be more likely in a susceptible child who develops high fever; parents should be advised of how to relieve post-vaccination fever
- persistent, inconsolable crying lasting 3 hours or more, within 48 hours of vaccination; it is believed that these reactions are caused by pain at the injection site
- thrombocytopenia

Adverse Events Following Immunization (AEFI)

Immunizing products are effective and safe. However, it is possible that reactions may occur after their administration, without a causal association to them. These reactions must be reported to public health for the appropriate follow-up. Please refer to [Chapter 8](#) for further details regarding AEFI reporting.

Immunization in Specific Clinical Circumstances

Moderate to Severe Acute Illness, With or Without Fever

Moderate to severe illness with or without fever is a valid reason to defer immunization. This precaution avoids superimposing adverse effects from the vaccine on the underlying illness or mistakenly identifying a manifestation of the underlying illness as a complication of vaccine use.

The following may be signs of a serious illness and should be taken into account when determining the severity of an illness:

- fever
- irritability or persistent crying
- lethargy or unusual sleepiness
- other symptoms of illness, such as vomiting, diarrhea, pallor or cyanosis, or diaphoresis
- inability to take part in usual activities

A minor illness (not affecting the person's general condition), even with fever, is not in itself a contraindication to vaccination. It is therefore not necessary to take subject's temperature before administering a vaccine.

Anaphylactic Hypersensitivity to a Vaccine Constituent

General principle

In general, a vaccine should not be administered to a person with a known anaphylactic hypersensitivity to a constituent of the vaccine or to a previous dose, either of the same vaccine or of another vaccine with the same constituent.

Anaphylactic reactions may be indicated by the following signs and symptoms:

- generalized urticaria
- swelling of the lips, mouth, and throat
- breathing difficulty
- hypotension
- shock

The person should be referred to a specialized clinic for reevaluation of the allergy, and if possible, the constituent of the vaccine responsible for the reaction should be determined, so that they may be immunized as completely as possible.

Hypersensitivity to a Combination Vaccine

When a person has an anaphylactic reaction associated with administration of a combination vaccine (e.g., Pediacel), no other dose of any of the vaccine components should be given, unless the antigen responsible for the reaction is determined.

Hypersensitivity to Eggs

“Anaphylactic egg allergy is rare. People with egg allergy may be immunized with MMR or MMRV vaccines in the routine manner. The amount of egg/chicken protein in these vaccines have been found to be insufficient to cause an allergic reaction in egg-allergic individuals. Egg-allergic individuals may be vaccinated against influenza using TIV, without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, with the following conditions. Those with mild reactions such as hives, or those who tolerate eggs in baked goods may be vaccinated in regular vaccination clinics. Those who have suffered from anaphylaxis with respiratory or cardiovascular symptoms should be vaccinated in a medical clinic, allergy office or hospital where appropriate expertise and equipment to manage respiratory or cardiovascular compromise is present. These individuals should always be kept under observation for 30 minutes. Referral to a specialist with expertise in allergies may be necessary in occasional circumstances where there is strong concern about proceeding with the recommendation above and the individual is at risk of complications from influenza. If the individual is not in a high-risk group, the need for vaccination may be reassessed. Data are not currently available to support these recommendations for LAIV”. (Public Health Agency of Canada, 2013)

Hypersensitivity to Vaccine Excipients

In rare cases, a person may have a known anaphylactic hypersensitivity to a vaccine excipient. These people should not be given vaccines containing these substances. Studies conducted in recent years suggest that an anaphylactic reaction to the measles-mumps-rubella vaccine may be associated with the gelatin in the vaccine. If a person has had an anaphylactic reaction to the administration of a vaccine containing gelatin, they should not be given a vaccine containing that substance until they have been assessed for such an allergy.

Allergic reactions to the thimerosal found in ophthalmic drops and contact lens solutions are not contraindications to vaccination, except in the case of an anaphylactic allergy. There is no contraindication to giving a vaccine containing neomycin to someone who develops contact dermatitis in reaction to neomycin,

since dermatitis is a delayed hypersensitivity rather than an immediate hypersensitivity.

Lactose intolerance is not a contraindication to vaccination. Lactose intolerance, characterized by digestive problems following the ingestion of a large amount of lactose, generally in the form of milk, is attributable to a lactase deficiency in the digestive system. The amount of lactose used as a stabilizer in some vaccines is extremely small and does not cause any problems.

Hypersensitivity to Latex

Vaccines as such do not contain latex. There may, however, be latex in the stoppers of vaccine vials and in syringe plungers and caps.

There is some confusion surrounding the terminology used to describe materials derived from rubber plants, products manufactured from intermediate forms of raw natural rubber, and synthetic rubber and latex products (which do not contain natural rubber). Natural latex is a milky liquid consisting of fine particles of rubber in a watery liquid, obtained primarily from the rubber tree, *Hevea brasiliensis*. This liquid also contains natural substances, such as plant proteins, that may be the cause of latex allergies. Synthetic latex does not contain any natural substances and, consequently, does not cause latex allergies.

The majority of allergic reactions to natural latex involve delayed hypersensitivity (contact dermatitis). This type of reaction does not constitute a contraindication to vaccination. However, some people or groups are at greater risk of developing an anaphylactic allergy because of their frequent and repeated exposure to latex. The example of people with myelodysplasia (particularly children with spin bifida), who are the subject of multiple urological procedures (such as urinary catheterizations), is well documented. The recommendation for these people is to avoid exposure to latex in all its forms, even in the absence of previous allergic reactions.

Rare cases of anaphylactic reactions have been reported following the use of injection materials containing latex, including a case following the administration of a hepatitis B vaccine. Anaphylactic reaction is a contraindication to the use of injection materials (including gloves) made of natural latex and administration of vaccines supplied in vials containing natural latex, unless the benefits of vaccination are clearly greater than the anticipated risk.

Immunization of People with Bleeding Disorders

People with bleeding disorders or severe thrombocytopenia may develop hematomas at the site of an injection. When a vaccine must be given, the following specific precautions should be taken: immunization should be carried out using a 23-gauge needle or smaller and firm pressure should be applied, without rubbing,

to the injection site for at least 5 minutes. In people receiving replacement factors, the risk of bleeding may be considerably reduced if vaccination is done immediately after treatment.

When the intramuscular route is recommended for administering a vaccine (e.g., the hepatitis A or B vaccines), it must be used even if the manufacturers suggest using the subcutaneous route for people with bleeding disorders. Since the subcutaneous route may be less immunogenic, it is preferable to use the recommended intramuscular route, with the above precautions.

Immunosuppression

Immunosuppression is the prevention or diminution of the organism's immune response to an antigen.

The terms immunosuppression and immunodeficiency are often used interchangeably. Immunosuppression may be caused by congenital or acquired immunodeficiency, leukemia, lymphoma, or generalized neoplasia or by treatment with antineoplastic agents, radiotherapy, or certain corticosteroid therapies. The extent of immunosuppression must be assessed (clinically or in the laboratory) on a case-by-case basis by the treating physician.

General principles

Several general principles apply to the immunization of immuno compromised individuals:

- Maximize the benefits of immunization while minimizing the potential risks.
- Make no assumptions about the person's immune status with regard to a given disease, even with a previous history of infection or immunization.
- Immunize when maximum immune response can be anticipated, for example:
 - before the predictable deterioration of an irreversible condition
 - after a transient state of immunodeficiency
 - when the state of immunodeficiency has ended
- Consider the person's environment (for example, family members in the case of influenza or varicella).
- Avoid live vaccines as much as possible, unless
 - data support their use
 - the risk of disease greatly exceeds the risk of immunization
- Do not expect as strong an immune response when inactivated vaccines are administered.
- Frequently check the person's immune status and give booster doses if necessary.
- Use passive immunization when benefit is expected.

Immunosuppressive Therapy

Long-term immunosuppressive therapy is used for organ transplantation and a wide range of chronic infectious and inflammatory conditions (e.g., systemic lupus erythematosus). These therapies have their greatest impact on cell-mediated immunity, although antibody production can also be adversely affected.

Ideally, vaccines should be given at least 14 days before the initiation of immunosuppressive therapy and should be delayed until at least 3 months after the therapy is completed.

This recommendation stems from the fact that the immune response should be restored at least 3 months after the end of such therapy. The underlying illness must also be in remission or under control.

If it was not possible to observe these intervals, the vaccine should be readministered. In the case of people who require immunization against influenza and who are receiving cyclical immunosuppressive therapy that interferes with the recommended intervals, the vaccine should be given between two treatments, ideally 2 weeks before the next cycle begins.

No firm recommendation on the interval that should elapse after termination of immunosuppressive therapy for safe administration of a live vaccine is possible, since that interval may vary in each case depending on the type, intensity, and duration of the immunosuppressive treatment and the underlying disease among other factors. The treating physician should be consulted to determine the timing of immunization.

Corticosteroid Treatment

A person may be immunocompromised because of treatment with steroids. Generally speaking, the following corticosteroid therapies do not result in significant immunosuppression, and people receiving these types of therapy may receive a live vaccine:

- short-term systemic corticosteroid therapy (<2 weeks)
- low-or moderate-dose corticosteroids, taken daily or every 2 days (<2 mg/kg/day of prednisone or a maximum of 20 mg/day)
- physiological replacement or maintenance doses of corticosteroids in people with no underlying immunodeficiency
- topical corticosteroid therapy (nasal, bronchial, ocular, or skin) or intra-articular or tendonous injections

Immunization and Chronic Diseases

Individuals with chronic illness are not necessarily more susceptible to vaccine-preventable diseases but are more likely to suffer significant illness and death from these infections. Vaccination against influenza, pneumococcus, diphtheria, and tetanus are recommended. Hepatitis A and B immunization may be appropriate in people with chronic liver disease, since they are at risk of fulminant hepatitis if they become infected. The immune response to vaccines can be suboptimal in many of these people, or antibody levels may fall more rapidly.

Immunization and Asplenia

The spleen plays an essential role in the body's immunological defense mechanisms. It filters out the antigen and antibody complexes as well as bacteria. It also plays a role in eradicating poorly opsonized bacteria from circulation. In addition, it represents a significant source of IgM, presentation of antigens to T lymphocytes, and differentiation of B memory cells.

Asplenia may be congenital, surgical, or functional. The incidence of mortality as a result of septicemia is 50 times higher for children who have undergone splenectomy after trauma and approximately 350 times higher for those with hemoglobinopathy (functional asplenia) than for healthy children.

A number of conditions can lead to functional asplenia: sickle cell anemia, thalassemia major, systemic lupus erythematosus, essential thrombocytopenia (excess platelets), celiac disease, and inflammatory bowel disease. These individuals are highly susceptible to the invasive infections caused by encapsulated bacteria (*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Neisseria meningitidis*) and should be immunized against them. The conjugate meningococcal and pneumococcal vaccines should be given before the polysaccharide products whenever possible. These individuals should also receive annual influenza immunization.

When elective splenectomy is planned, vaccines should be delivered at least 10 to 14 days before the surgery.

Immunization during Pregnancy

Live vaccines

In general, live vaccines should not be administered to pregnant women because of potential danger to the fetus.

However, the vaccines against yellow fever and poliomyelitis (oral vaccine) may be administered to pregnant women in certain situations if the risks of the disease are greater than the theoretical risk from the vaccine for the fetus.

Live vaccines may be given to the pregnant woman's family, including her other children, without risk to the fetus.

Vaccines including the rubella or varicella components

Administration of the vaccine to a susceptible individual is generally followed by replication of the vaccine strain and viremia. Monitoring of hundreds of cases of inadvertent vaccination against rubella during pregnancy has shown that the virus may cross the placental barrier and infect the fetus, but no case of congenital rubella syndrome has ever been reported. Since it is impossible to rule out all possibility of a very slight teratogenic risk, caution is advised.

The current consensus is to avoid vaccinating a pregnant woman against rubella. Before vaccination, women should be asked if they are pregnant and should not receive the vaccine if the answer is yes. However, it is not necessary to order a pregnancy test or defer vaccination if a woman is not sure she is pregnant. Any woman who could become pregnant should be informed of the theoretical possibility of a teratogenic effect and be told to avoid pregnancy for 1 month after administration of the vaccine. However, vaccination of a pregnant woman or a woman who becomes pregnant in the month after vaccination does not justify considering termination of the pregnancy.

Data collected to date in the United States on 509 women who were inadvertently vaccinated against varicella during their pregnancies (a frequently given reason is that the vaccine was confused with the specific varicella immune globulin) does not indicate that this vaccine poses an increased risk of congenital defects for the fetus. Rare cases of transmission of the vaccine virus to the families of vaccinated people developing a varicelliform rash have been documented. This very slight risk does not justify postponing immunization of children from families with pregnant women.

Inactivated vaccines

A pregnant woman may receive a vaccine manufactured from killed bacteria, killed viruses, or their constituents (polysaccharides, proteins) if specifically indicated. In such cases, it is preferable to administer the vaccine in the second or third trimester. The diphtheria and tetanus vaccines may be administered at any time during the pregnancy. All pregnant women at 26 weeks of pregnancy or later, who have not received a dose of pertussis-containing vaccine in adulthood, should be encouraged to receive a Tdap Immunization. Inactivated influenza vaccine should be given to all pregnant women regardless of the stage of pregnancy. (Public Health Agency of Canada, 2013)

Immunization and Breastfeeding

There is evidence that breastfeeding enhances the active immune response in the first year. Infants who are breast-fed should receive all recommended vaccinations at the usual times. Mothers may breastfeed children who are going to receive or have just received a live vaccine without altering the response to the vaccine. Similarly, breastfeeding mothers may safely be given vaccines. Although the

vaccinal rubella virus may be excreted in the mother's milk, it does not generally infect the infant. If such an infection occurred, it would be benign because the virus is attenuated and cannot be transmitted.

Immunization of Premature and Low Birth-Weight Babies

Clinically stable premature and low birth-weight babies should receive their primary immunization in accordance with the recommended ages, intervals, and doses, regardless of degree of prematurity or birth weight. The immune response is a function of post-natal age rather than gestational age.

The response to hepatitis B vaccine may be diminished in infants with birth weights below 2000 grams. Nevertheless, vaccination of an infant born to a woman who is hepatitis B positive should be done immediately after birth in accordance with the protocol.

In other circumstances, hepatitis B vaccination, if appropriate, should be delayed until the infant reaches 2000 grams or 2 months of age.

Immunization of Health-Care Workers

A health-care worker is defined as follows: any person who gives health care or who works in a health-care establishment that provides care to patients, including a doctor, nurse, paramedic, pharmacist, dental worker, nursing student, medical student, laboratory technician, volunteer, or support or administrative worker in an establishment (this is not an exhaustive list). In addition to these workers, the term encompasses first responders who give health care and people providing health care in medical or dental clinics, doctors' offices, and community pharmacies.

These individuals risk exposure to micro-organisms circulating in health-care establishments. They are also at risk of transmitting them from one patient to another. Their immunization status must therefore be checked regularly and kept up to date.

Immunization Guidelines

The following guidelines are adapted from the national guidelines for childhood immunization practices, published in the Canadian Immunization Guide, 2006 edition.

- Immunization services should be readily available.
- There should be no un-necessary barriers to the receipt of vaccines.
- Providers should use all clinical opportunities to screen for needed vaccines and, when indicated, to vaccinate.
- Providers should educate parents and adult vaccine recipients in general terms about immunization.
- Providers should inform patients and parents in specific terms about the risks and benefits of vaccines that they or their child are to receive.
- Providers should recommend deferral or withholding of vaccines for true contraindications only.
- Providers should administer all vaccine doses for which a recipient is eligible at the time of each visit.
- Providers should ensure all vaccinations are accurately and completely recorded.
- Providers should maintain easily retrievable summaries of the vaccination records to facilitate age-appropriate vaccination.
- Providers should report clinically significant adverse events following vaccination—promptly, accurately, and completely.
- Providers should report all cases of vaccine-preventable diseases as required under provincial and territorial legislation.
- Providers should adhere to appropriate procedures for vaccine management.
- Providers should maintain up-to-date, easily retrievable protocols at all locations where vaccines are administered.
- Providers should be properly trained and maintain ongoing education regarding current immunization recommendations.
- Immunization errors should be reported by providers to their local jurisdiction
- Providers should operate a tracking system.
- Audits should be conducted in all immunization clinics to assess the quality of immunization records and assess immunization coverage levels.

The Golden Rules of Immunization

- Be familiar with the immunizing products administered.
- Always remember that no vaccine is totally effective or safe. Observe storage and handling procedures to minimize the risks associated with vaccination and optimize its effectiveness.
- Remember that all immunizing products may be administered at the same time, except in the case of interaction.
- Do not use buttock muscle to administer a vaccine. Reserve its use for immune globulin.
- In general, follow the recommended schedule. The use of minimum intervals should be reserved for situations where it is important to establish protection quickly.
- Readminister the last dose when the minimum interval was not observed between two doses of vaccine.
- Always give full doses.
- Observe at least a 15-minute waiting period following the administration of one or more immunizing products.
- In general, do not reinitiate a primary vaccination, but continue from the dose at which it was interrupted, regardless of the time elapsed.
- Use every opportunity to update a person's immunization status.
- Make sure your own immunizations are up to date.

Chapter 4: Informed Consent

Consent can be either oral or written. However, written consent is usually preferred and is the normal practice. This is the preferred route because it can be used as evidence should a dispute arise in the future. It is important to note that the mere fact of a client's signature on a consent form does not constitute proof of consent. The consent form can provide an evidentiary basis for conclusions about the content of a dialogue between the health-care provider and the client.

Elements of Consent

There are four basic requirements of a valid consent:

- It must be voluntary.
- It must be given by a person with the capacity to consent.
- It must refer to both the treatment and the provider of the treatment.
- It must be informed.

What is informed consent?

Informed consent means the client must be provided with the information necessary to make a decision to have or to refuse treatment. This information must include:

- the nature and purpose of the treatment—what the treatment is and how it will be done
- the expected benefits of the treatment
- the risks and possible side effects of the treatment
- alternative courses of action—other things that the client can do to prevent the disease
- the risks of not having the treatment

The client must also have had the chance to ask for, and receive, further information or clarification about the proposed treatment. Some examples of treatment are immunization, dental screening, or counselling.

The consent must:

- state exactly what is going to be done
- be informative
- be freely given (voluntary) and not have been obtained through misrepresentation or fraud

Is consent needed for the school-based immunization program?

Mature Minor Consent: It is recommended that parents or guardians and their children discuss consent for immunization. Efforts are first made to seek

parental/guardian or representative consent prior to immunization. However, individuals who are able to understand the benefits and possible reactions for each vaccine and the risk of not getting immunized, can legally consent to or refuse immunizations. There is no minimum age for giving consent. Public Health staff must assess the student's situation and ability to understand the information given. If the student is assessed as being unable to give informed consent, a substitute decision maker must be involved, for example, a parent or guardian.

Who may give consent?

A person is capable of giving consent to be immunized, if they

- understand the information that is important
- understand the consequences of the decision to be immunized or not be immunized

What is the role of the parent or guardian?

Parents/guardians need to discuss immunization with their children. Their child needs to know about

- previous reactions to vaccines they may have had
- present health concerns, including medications they are taking and allergies to antibiotics or components of the vaccine
- their parents' views on health and immunization

What does this mean for the school-based immunization program?

Students can make informed decisions about immunization. Just as they are capable of understanding the issues and risks associated with certain diseases, they are able to understand the issues and risks of immunization.

A student can choose to receive an immunization or to refuse an immunization. Parents/guardians may sign the consent form—it is preferable that the parent/guardian signs the form after discussing immunization with their child. However, before the immunization is given, every student is asked if they understand, have any questions, and consent to be immunized. If the parent wishes the student to be immunized and the student refuses, the immunization will not be given. A student who is judged capable of giving informed consent may be immunized even if the parents do not consent.

The health-care system provides access to services where they can be delivered safely. Health-care services are not restricted to hospitals, doctors, offices, or clinics. When immunizations are administered in the school setting, they fall under the authority of the Health Protection Act.

Chapter 5: Vaccine Inventory Management

Cold Chain

The Effective Cold Chain

Three main elements combine to ensure proper vaccine transport, storage, and handling:

- trained personnel
- transportation and storage equipment
- efficient management procedures

Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and with administration of the vaccine. The optimum temperature for refrigerated vaccines is between 2°C and 8°C. For frozen vaccines the optimum temperature is –15°C or lower. In addition, protection from light is a necessary condition for some vaccines.

Proper storage temperatures must be maintained at every link in the chain.

Importance of Maintaining the Cold Chain

Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. Vaccines exposed to temperatures above or below the recommended temperature range experience some loss of potency with each episode of exposure. Cold-sensitive vaccines experience an immediate loss of potency following freezing. Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible. Information on vaccine degradation is sparse, and multi-point stability studies on vaccines are difficult to perform. Information from manufacturers is not always available, so it can be difficult to assess the potency of a mishandled vaccine.

Maintaining the potency of vaccines is important for several reasons:

- There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine-preventable disease.
- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccine may result in the cancellation of immunization clinics, resulting in lost opportunities to immunize.

- Revaccination of clients who received an ineffective vaccine is professionally uncomfortable and may cause loss of public confidence in vaccines and/or the health-care system.

An estimated 17–37 per cent of health-care providers expose vaccines to improper storage temperatures. Refrigeration temperatures are more commonly kept too cold rather than too warm.

When a cold chain break has been identified after a vaccine has been administered, the type of vaccine and the duration and temperature of the exposure will be taken into account when assessing the situation. Serological testing or revaccination may be suggested.

Immunization programs have had a major impact on the health status of the world's population by preventing many cases of infectious diseases through immunization. Vaccine storage and handling are key components in maintaining the efficacy of immunization programs. It is a shared responsibility from the time the vaccine is manufactured until it is administered.

The objective of these guidelines is to provide recommendations for vaccine storage and handling for all health-care providers. These guidelines are adapted from the national document National Vaccine Storage and Handling Guidelines for Immunization Providers.

These guidelines are based on feasibility and available evidence and are designed to create consistency in practice. They include recommendations for

- routine and urgent storage handling protocols
- vaccine storage and equipment maintenance
- temperature monitoring
- storage troubleshooting
- vaccine management
- vaccine shipment

Designated Biological Coordinators

Each site should have a staff person designated as primary biological coordinator and another designated as backup in the case the primary coordinator is unavailable. Designated biological coordinators should be fully trained in routine and urgent vaccine storage and handling protocols.

The designated person will be responsible for ensuring that all personnel receive appropriate cold chain training.

Training Personnel

All new staff that handle or administer vaccines should be trained in proper vaccine storage and handling. All other new staff should be trained to have an understanding of the importance of cold chain maintenance and basic practices so they are aware of their responsibilities for the cold chain. Staff who monitor and record vaccine storage unit temperatures should immediately report inappropriate storage conditions to the designated biological coordinator or designate.

Routine Protocols

The routine protocols should include

- up-to-date contact information
- designated biological coordinators responsible for routine vaccine storage and handling
- description of the roles and responsibilities of the designated biological coordinators and other staff members
- refrigerator and freezer maintenance and repair company(s)
- vaccine storage unit alarm company
- protocols for
 - vaccine storage unit temperature monitoring
 - vaccine storage equipment maintenance
 - placement of vaccine within storage units
 - responding to vaccine storage and handling problems
 - vaccine inventory management
 - packaging, transporting, and receiving vaccine shipments
 - disposal of vaccines and diluents as directed by jurisdictional guidelines

Avoid transporting vaccines as much as possible. The more often they are moved, the more likely it is that they might become spoiled. It is very important to maintain the cold chain when moving vaccines.

When transporting vaccines using a personal vehicle, do not place vaccines inside the trunk of the vehicle. Avoid placing the vaccine in direct sunlight or directly in line with air from the vehicle's heater and air conditioner. Never leave vaccine unattended.

Shipping vaccines from one Public Health office to another

1. Schedule a time with the receiving provider to ensure that someone will be available in the office to assist with the transfer.
2. Pack vaccine as detailed in the section titled Packing Biologicals for Transport and Clinics.
3. When you receive your vaccine shipment, open the cooler and immediately inspect the contents. Note the condition of the vaccine. Assure that the vaccines are cool to touch.
4. Pack only the amount of vaccine you expect to use during the immunization clinic.

Protecting Vaccines during Immunization Clinics

Maintain the vaccines at the required temperature (between 2°C and 8°C) during the immunization clinic. It is important to ensure that the administered vaccine retains its potency.

1. Minimize the number of times that the cooler is opened during the immunization.
2. Record temperature readings in the insulated cooler
 - before leaving the office with the cooler
 - upon arrival at the clinic location, but prior to the immunization clinic
 - every 3 hours during the clinic
 - upon completion of the clinic, but before transport back to the office
 - after return to the office, but before the vaccines are placed back in the refrigerator

Following these steps will ensure that the vaccines are maintained at the required temperature throughout the process and that the vaccines that are returned to the refrigerator have not been exposed to temperatures below 2°C or above 8°C.

Materials Required for Transportation of Vaccine and Biological Products

Equipment Required for Summer Packing Protocol: Small Igloo Container (16 Quart)

- 1-36 oz frozen Gel
- 3- (min) refrigerated 12ml flexible insulated blankets
- 1-96 oz refrigerated Gel
- 1-16 quart Vaccine Cooler
- 1-Vaccine Package (max 30 x 5 ml vials)
- 1-Temperature device

Equipment Required for Winter Packing Protocol: Small Igloo Container (16 Quart)

- 1-96 oz refrigerated Gel
- 1-24 oz frozen Gel
- 2- refrigerated 12ml flexible insulated blanket with additional for every 5°C below -15°C
- 2- 12ml 12x4 flexible insulated blanket 22C
- 1-16 quart Vaccine Cooler
- 1-Vaccine Package
- 1-Temperature device

Equipment Required for Summer Packing Protocol: 38 Qt Cooler

- 1-38 Quart Cooler
- 1-Temperature device
- 1- 48 oz frozen gel
- 6- refrigerated flexible insulating blankets
- 2- 36 oz refrigerated gel
- 3-Vaccine Packages

Equipment Required for Winter Packing Protocol: 38 Qt Cooler

- 1-38 Quart Cooler
- 1-Temperature device
- 1- 36 oz frozen gel
- 1-36 oz refrigerated gel
- 6- refrigerated flexible insulating blankets
- 2- flexible insulating blankets 22C
- 1-Vaccine Package

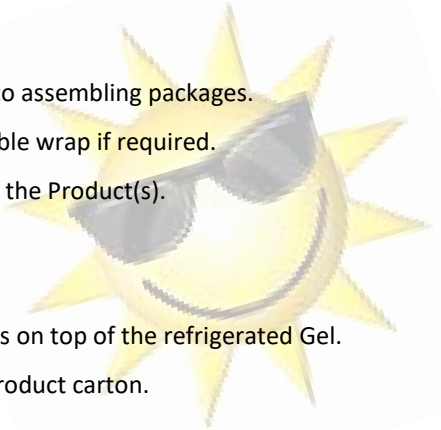
Packing Biological Products for Transport and Clinics

Packing Biologicals for Transport and Clinics

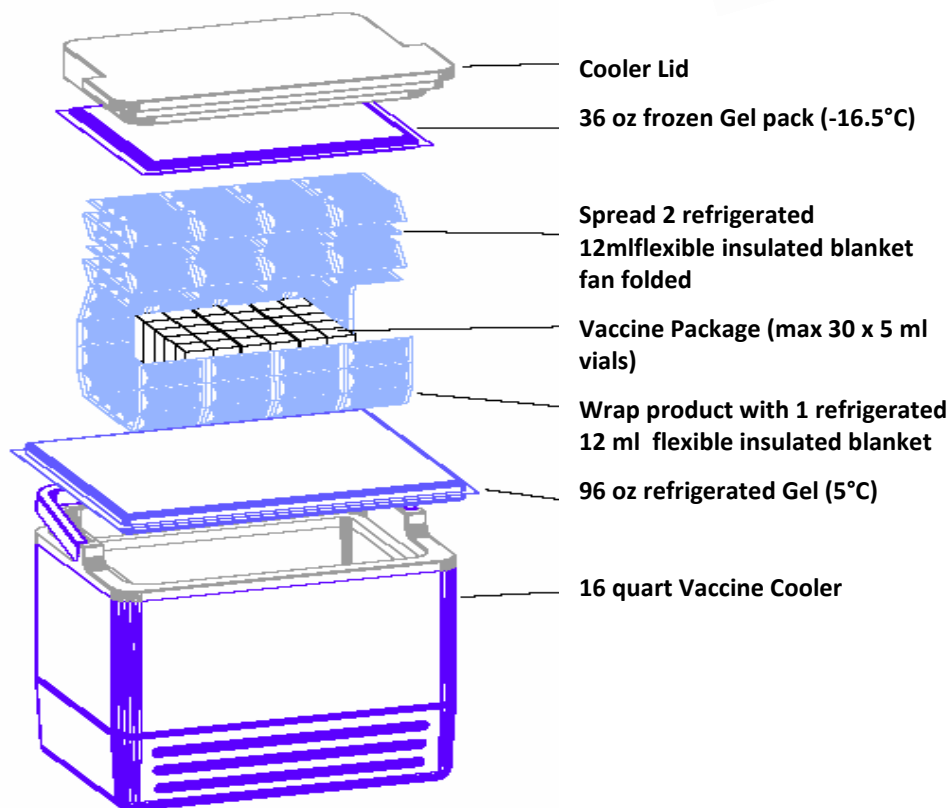
Vaccine Cooler Packing for School-Based & Community Mass Immunization Clinics

16 Quart Igloo Vaccine Cooler (Summer Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated **temperature monitoring device(s)** inside the carton with the Product(s).
4. Obtain one 16 quart vaccine cooler.
5. Spread one 96 oz refrigerated gel on the bottom of the container.
7. Wrap product carton with one layer of refrigerated flexible insulating blankets on top of the refrigerated Gel.
7. Fan fold two layers of refrigerated flexible insulating blankets on top of the product carton.
8. Place one 36 oz frozen Gel on top.



Packing Diagram for Vaccine Shipment – 16 Quart Cooler (Summer – April 2 to Nov 14)

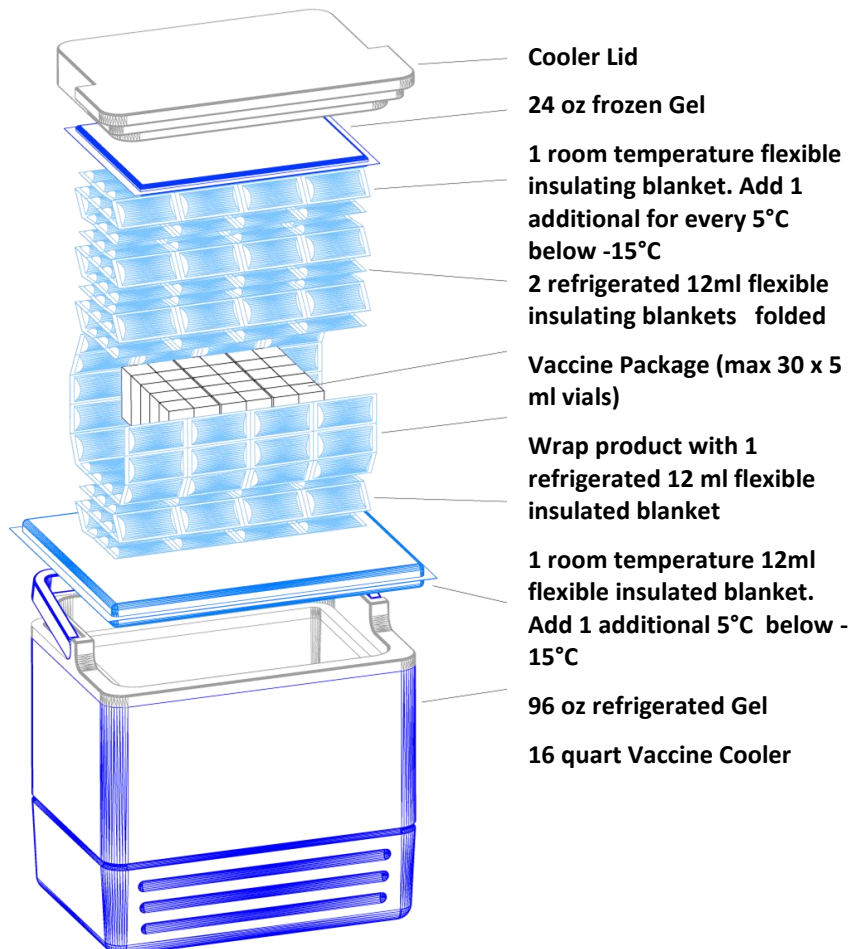


Vaccine Cooler Packing for School-Based & Community Mass Immunization Clinics

16 Quart Igloo Vaccine Cooler (Winter Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated **temperature monitoring device(s)** inside the carton with the Product(s).
4. Obtain one 16 quart vaccine cooler.
5. Spread one 96 oz refrigerated (5°C) gel on the bottom of the container.
6. Place one layer of room temperature (22°C) flexible insulating blanket on top of the refrigerated gel. Add one additional blanket for every 5°C below -15°C
7. Wrap product carton with one layer of refrigerated flexible insulating blanket.
8. Fan fold two layers of refrigerated (5°C) flexible insulating blankets on top of the product carton.
9. Place one layer of room temperature (22°C) flexible insulating blanket on top of the product carton. Add one additional blanket for every 5°C below -15°C.
10. Place one 24 oz frozen Gel on top.

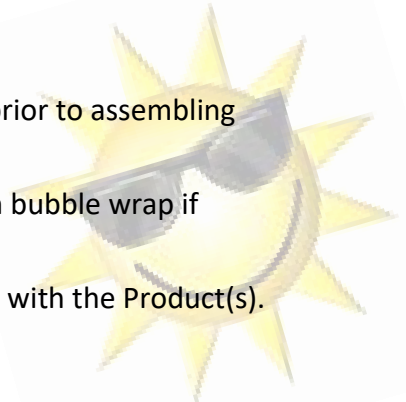
Packing Diagram for Vaccine Shipment – 16 Quart Cooler (Winter – Nov 15 to April 1)



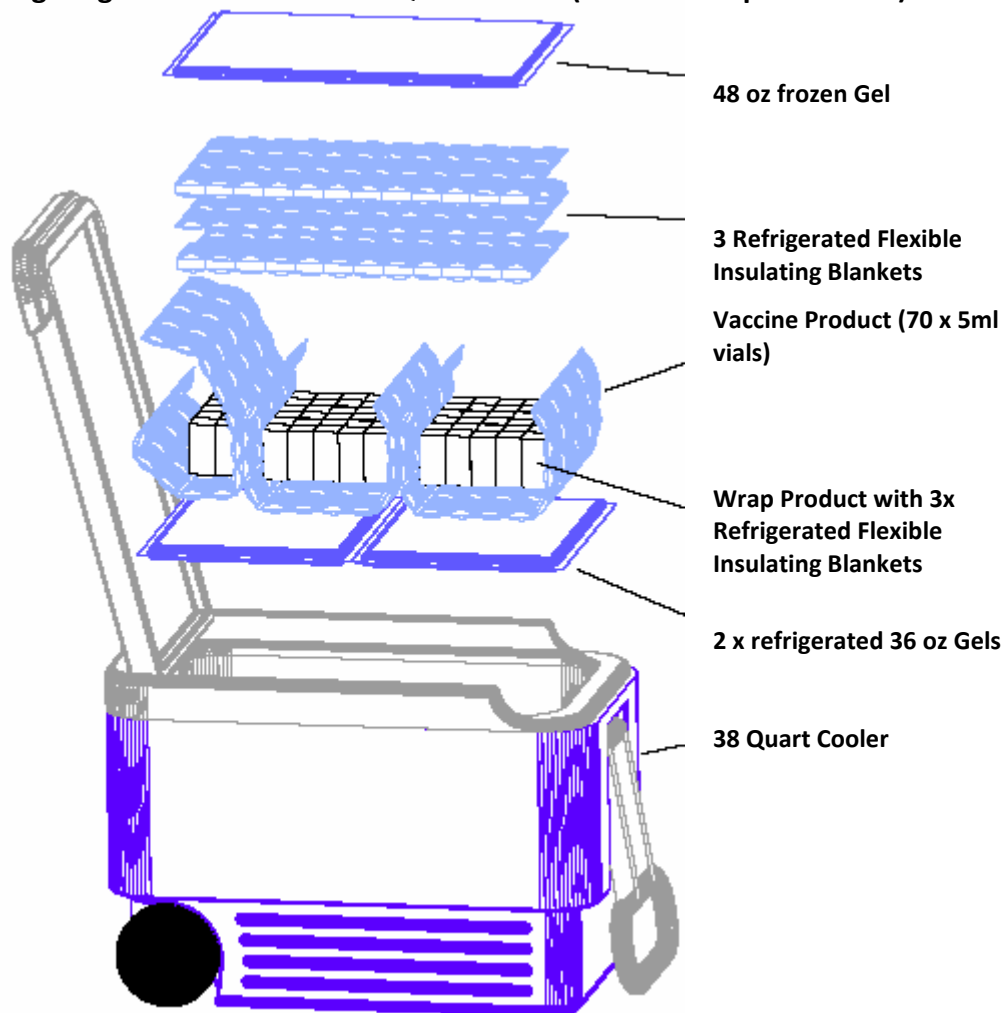
Vaccine Cooler Packing for School-Based & Community Mass Immunization Clinics

38 Quart Igloo Vaccine Cooler (Summer Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated **temperature monitoring device(s)** inside the carton with the Product(s).
4. Obtain one 38 quart vaccine cooler.
5. Spread two 36 oz refrigerated gel on the bottom of the container.
6. Wrap product carton with three refrigerated flexible insulating blankets.
7. Fan fold three layers of refrigerated flexible insulating blankets on top of the product carton.
8. Place one 48 oz frozen Gel on top.



Packing Diagram for Vaccine – 38 Quart Cooler (Summer – Apr 2-Nov 14)

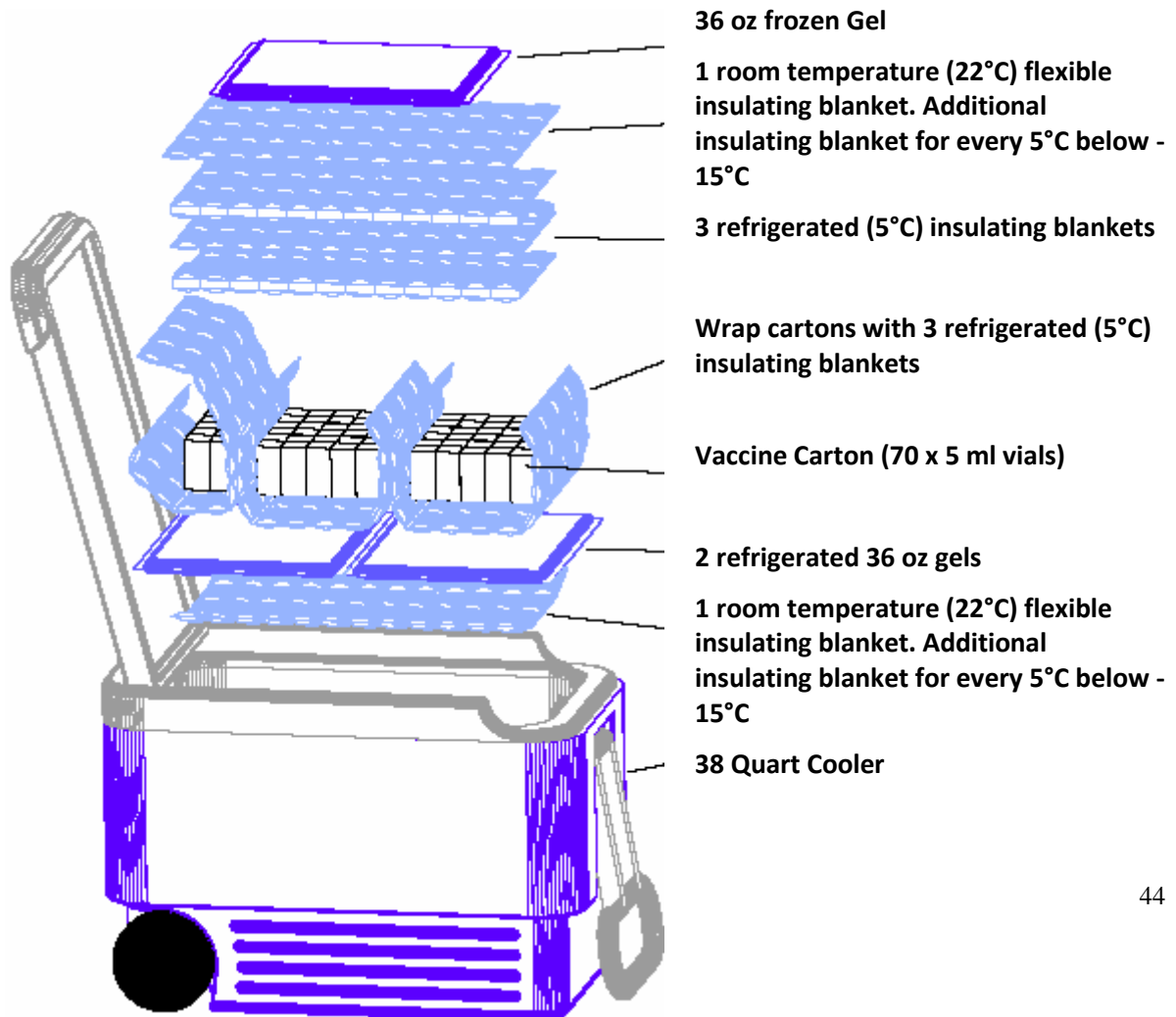


Vaccine Cooler Packing for School-Based & Community Mass Immunization Clinics

38 Quart Igloo Vaccine Cooler (Winter Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated **temperature monitoring device(s)** inside the carton with the Product(s).
4. Obtain one 38 quart vaccine cooler.
5. Spread one room temperature (22°C) flexible insulating blanket on bottom of container. Add one additional blanket for every 5°C below -15°C.
6. Place two 36 oz refrigerated (5°C) gel on top of the flexible insulating blanket.
7. Wrap product carton with three refrigerated (5°C) flexible insulating blankets.
8. Fan fold three layers of refrigerated (5°C) blankets on top of the product carton.
9. Spread one room temperature (22°C) flexible insulating blanket on bottom of container. Add additional layer for every 5°C below -15°C.
10. Place one 36 oz frozen Gel on top.

Packing Diagram for Vaccine Shipment – 38 Quart Cooler (Winter – Nov 15 to April 1)



Remember:

- Let ice pack sweat 5–10 minutes before loading vaccine.
- Put insulating material between ice packs and vaccine.
- Pack vaccines with a temperature monitoring device, placed in the centre of the vaccine package.
- Transport immediately. Due to temperature changes in vehicles, never transport vaccine in the trunk or leave in a parked car for extended periods of time.
- Do NOT use Styrofoam coolers because the temperature does not remain constant.

Emergency Procedures for Vaccine Storage and Handling

Emergency procedures should address the protection and/or retrieval of vaccines at both the depot and the provider level.

When there is reasonable cause to believe that there is the potential for a weather event, disruption of power, etc., where vaccine is stored, emergency procedures should be implemented in ADVANCE OF THE EVENT.

All providers should ensure the following:

- identification of an alternative storage facility, with backup power, where vaccine can be stored and monitored for the duration of the event
- the availability of staff to pack and move vaccine
- the use of the appropriate packing containers and cold packs
- the transport of the vaccine to the alternative storage facility

Emergency Procedures

- List emergency phone numbers, companies, and points of contact for
 - power company
 - refrigeration company
 - temperature alarm monitoring company
 - backup storage facility
 - manufacturers:
 - Merck
 - Novartis
 - Grifols
 - Pfizer
 - GSK
 - Sanofi

- Establish working agreements with hospitals, long-term care facilities, or other facilities to serve as emergency vaccine storage facilities, and communicate these agreements with both parties.
- Entering vaccine storage facilities: Describe how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and locations of:
 - doors
 - flashlights
 - spare batteries
 - light switches
 - keys
 - locks
 - alarms
 - packing/insulating materials
- Identify who to call for the following assistance:
 - equipment problems
 - packing containers
 - back up transportation
 - security
- Pack and transport all vaccines or, if that is not possible, determine the types and amounts to save e.g., save only the most expensive vaccines to minimize dollar loss or save some portion of all vaccines to ensure a short-term supply.
- Follow vaccine packing procedure for transport to backup storage facilities.
 - Have vaccine packing instructions readily available for staff unfamiliar with packing procedures.
 - Open refrigerated units only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to alternative storage sites.
 - Use properly insulated containers.
 - Use a properly placed temperature-monitoring device in each container.
 - Record vaccine type(s), quantity, date, time, and originating facility on the container.
- Move the vaccine to the backup storage according to prearranged plans:
 - how to load transportation vehicle
 - routes to take (alternative routes if necessary)
 - time en route
- Ensure that vaccine containers are stored properly in the emergency backup facility

Emergency Event Recovery Plan

PHS office: _____ Date _____

Person completing form: _____

This plan offers guidance for developing a vaccine emergency event recovery plan. Included are steps to follow when your refrigerator fails. Fill in the contact information for the emergency service providers identified on this form.

In advance of an event, all providers should

- identify an alternative storage facility with backup power where the vaccine can be properly stored and monitored for the interim
- ensure the availability of staff to pack and move the vaccine
- maintain the appropriate packing/insulating materials
- ensure a means of transportation for the vaccine to the alternative storage facility
- train staff and post information about these emergency procedures

Note: Whenever possible, suspend immunization activities BEFORE the onset of the emergency event to allow sufficient time for packing and transporting of vaccines.

- **Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or it is after hours.**

These instructions should include the building security and after-hours access procedure and location of the following:

- doors
- flashlights
- spare batteries
- light switches
- keys
- locks
- alarms
- packing materials

Emergency Procedures

A. Emergency phone numbers, companies, and points of contact

- List the designated person(s) responsible for
- monitoring the operation of the vaccine storage equipment and systems daily
- tracking inclement weather conditions
- assuring the appropriate handling of the vaccine during the emergency event.

Name of employee	Title of employee	Work phone	Home phone

- Determine if your refrigerator is having a mechanical failure or if the building has lost electrical power. Check with the building maintenance to ensure that the generator is operational and has been activated.

Building maintenance	Point of contact	Work phone	Emergency phone

- Contact the designated company responsible for restoring power to the location in the event of a power failure.

Power company	Point of contact	Work phone	Emergency phone

- Contact the designated company responsible for repair where the compressor or the refrigeration equipment has been destroyed or you need emergency maintenance.

Repair company	Point of contact	Telephone number

- If a time frame for the restoration cannot be determined, implement the following procedures for transferring the vaccines to an alternative storage facility with backup power.

B. List emergency phone numbers and points of contact for location with a backup generator

- This may be the local hospital, LTCF, etc. Make arrangements with the site to store your vaccine there when weather predictions call for inclement weather or when your vaccine storage equipment cannot be fixed or the power cannot be restored within 6 hours. Before moving your vaccine, call the location to ensure that their backup generator is working.

Alternative facility	Point of contact	Work phone	Emergency phone

C. Describe how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and the locations of the following

Item	Location(s)
Doors	
Flashlights	
Spare batteries	
Light switches	
Keys	
Locks	
Alarms	
Packing/insulating materials	

- D. Conduct an inventory before you move the vaccine.**
- E. Package the vaccine as per packing instructions.**
- F. Move vaccine to backup storage according to prearranged plans.**

THINGS TO DO NOW BEFORE IT IS TOO LATE

- Complete this plan and update as staff changes occur. It will only take a few minutes and may save you hours of work later, not to mention provincial dollars.
- Fill the empty space in your refrigerator with jugs/bottles of water and line the bottom of your freezer with ice packs. In the event that your refrigerator/freezer is out of order, this practice will help maintain the temperature for a longer period of time.
- Post your recovery plan on or near the vaccine storage equipment. Ensure that all staff (both current and new) read the plan and understand it as part of their orientation.

Vaccine storage units must be selected carefully and used properly. Any refrigerator or freezer used for vaccine must

- be able to maintain the required vaccine storage temperatures through all seasons
- be large enough to hold the year's highest monthly inventory, including influenza vaccine
- have a calibrated thermometer or data logger inside each storage compartment
- be dedicated to the storage of vaccine only
- be placed in a secure location away from unauthorized and public access

Technical Features

There are many different types of refrigerator and freezers available. Knowing the functions and components of the refrigerators will help in understanding why certain types of refrigerators and freezers are recommended for vaccine storage. The technical features of refrigerators that can affect the safe storage of vaccines are outlined below.

Temperature regulation

The compressor functions to cool the inside of the refrigerator. The compressor is controlled by either a thermostat or a digital controller, depending on the type of fridge. When the temperature exceeds the set temperature of the thermostat, the compressor turns on and operates to cool the fridge. The point at which the compressor turns on depends on the design of the thermostat and fridge. Therefore, a thermostat that has a large differential between its switch points will cause, in turn, long compressor on and off periods. This may produce large temperature fluctuations that are undesirable for the storage of vaccines.

Defrost mechanism

The cooling area in the refrigerator is called the evaporator. It consists of cooling coils usually located behind the surface of the wall at the back of the refrigerator or

in the exposed area at the back of the refrigerator. Heat from the warm air inside the fridge transfers to the refrigerant in the coils. As warm air passes over the evaporator, water vapour in the air condenses and freezes on the evaporator. During the process of cooling the refrigerator, an icy buildup is created on the evaporator. The ice that forms may reduce the cooling capacity and efficiency of the system. Therefore, refrigerators for vaccine storage must have a defrost cycle that allows the ice to melt off the evaporator. Ideally, the temperature remains at the set point during the defrost cycle.

Spatial temperature differential

Spatial temperature differentials are the differences in temperatures within the fridge. Vaccine storage requires a uniform temperature distribution to prevent placement of vaccines outside the recommended temperature ranges.

Effects of changes in ambient temperature

Ambient temperature is the temperature of the environment where the fridge is kept. The aim is to have a refrigerator that can maintain a stable temperature within, even when the surrounding temperatures change.

Temperature recovery

Temperature recovery is the ability of the refrigerator to return to its set temperature after being exposed to elevated temperatures.

Purpose-Built Refrigerators

A purpose-built vaccine refrigerator is the standard for storing large inventories of vaccines for several reasons. The advantages of a purpose-built refrigerator, in terms of the technical features, are outlined below.

Temperature regulation

The temperature regulation mechanism in a purpose-built vaccine refrigerator has a very tight temperature tolerance and a quick reaction time to temperatures outside of the set range. A temperature probe for the temperature control is usually located in the path of the return airflow, thereby measuring the temperature of the warmest air in the refrigerator.

Defrost mechanism

Purpose-built vaccine refrigerators have a mechanism to defrost ice from the evaporator without raising the temperature in the unit. There is a small heating element wrapped around the evaporator coils that has the capacity to melt the frost off the evaporator frequently. This feature prevents the lengthy period of time needed for defrosting in other refrigerator designs. This method of regular defrosting also prevents fluctuations of temperatures within the unit.

Spatial temperature differential

The spatial temperatures are tightly controlled in purpose-built vaccine refrigerators. There is constant fan forced air circulation within the refrigerated compartments. Generally, the temperature does not vary within the storage area from the set point.

Effects of changes in ambient temperature

The forced air circulation helps to keep internal temperatures within a range even when the ambient temperature changes.

Temperature recovery

The temperature is digitally managed in purpose built refrigerators. Any deviation in temperatures from the pre-set one is sensed very rapidly.

Domestic Refrigerators

A domestic combination refrigerator and freezer unit is acceptable, but requires significant modifications to store vaccine. The refrigerator and freezer compartments must have separate external doors, and the unit must meet the criteria set out in this manual. There are two types of domestic refrigerators: domestic frost-free and manual and cyclic defrost.

Domestic frost-free refrigerators

Domestic frost-free refrigerators refer to the freezer compartment where food is supposed to stay relatively frost-free. The evaporator is located in the freezer. The evaporator defrosts automatically with a heater that dissipates the defrost water. When the compressor is on, a fan blows the cool air through vents to the freezer and then to the refrigerator. Thus, the air being circulated to the refrigerator may be below 0°C. The cool air may damage vaccines if they are placed near the vents. Depending on the refrigerator model, some frost-free refrigerators may provide more uniform temperatures than manual and cyclic defrost models and may be more suitable for vaccine storage.

Manual and cyclic defrost refrigerators

Manual and cyclic defrost refrigerators refer to the refrigerator. The evaporator in the refrigerator automatically defrosts, whereas the freezer needs to be manually defrosted. The evaporator is most commonly found as an exposed vertical plate at the back of the refrigerator. Manual and cyclic defrost refrigerators have not been recommended for vaccine storage because of the significant temperature variations and the risk of vaccines freezing. Generally, while the compressor is running, the area near the evaporator can be very cold, whereas other areas are much warmer.

Bar Fridge Units

Any style of small single-door fridge is unpredictable in terms of maintaining temperatures and should NOT be used. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccine. Even when the freezer temperature is not adjusted, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines. Temperatures vary inside the compartment. The temperature-control sensor reacts to the temperature of the evaporator rather than to that of the air in the compartment, resulting in varying temperatures in the refrigerator as the ambient temperature changes.

Backup

No piece of equipment is infallible. At some point equipment failure will happen as a result of a power outage, breakdown, or normal wear and tear. Vaccine security requires that these failures be anticipated and that backup equipment and backup plans be available. Regular maintenance of all equipment is recommended to maintain optimal functioning.

The Cold Chain Break

The stability of various immunizing agents can vary considerably. For example, some can tolerate long periods of exposure to heat without exhibiting a serious lack of activity. But for others, exposure to a higher temperature translates into degradation in their activity, and each exposure produces a cumulative effect. Most immunizing agents are unstable when exposed to freezing.

When immunizing agents are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Immunizing agents affected by a break in the cold chain must be placed in cold quarantine, that is, packaged separately, identified with a sticker reading "DO NOT USE," and stored in a refrigerator at between 2°C and 8°C separately from immunizing agents in current use, until the public health staff decides whether or not they can be used. A decision on whether to destroy a product will be made by local public health on the basis of several considerations.

If you become aware of inappropriate vaccine storage conditions, the following steps should be taken immediately.

Cold Chain Incident Reporting Process

1. Providers should notify the local PH office of the cold chain break.
2. Local PH will advise the provider reporting the cold chain incident that:
 - Vaccines must be bagged, dated and labeled 'Do not use: Quarantined'
 - Vaccines are to be kept refrigerated between 2 to 8 °C until it is determined which vaccines can or cannot be used.
3. PH will complete cold chain investigation as per guidelines established by the provincial Biodepot.

Keep Vaccine Safe

Ordering Vaccine

- Complete a refrigerator inventory once a month, prior to placing your order.
- Maintain no more than a one month supply of vaccine.
- Order vaccine for your patient population only.

Storing Vaccine

- Store all vaccine between 2°C and 8°C.
- Keep a digital high-low thermometer in refrigerator and record temperature twice daily.
- Contact your local Public Health office for advice when vaccine has been exposed to temperatures outside of 2°C and 8°C – i.e. power outage or refrigerator failure. Keep vaccine in a functioning refrigerator until you have made contact with Public Health.
- Develop a back-up plan for power outage/refrigerator failure.
- Protect refrigerator plug – secure it so it will not accidentally become unplugged.
- Do not store vaccine in the door of the refrigerator.
- Store full bottles of water on empty shelves and on the door of the refrigerator to maintain consistency in temperature.
- Do not use a “Bar” or half-size refrigerator.
- Use products with the earliest expiry dates first; place vaccine with the longest expiry dates behind those with the earliest expiry dates.
- Do not use your vaccine refrigerator for specimen storage and non-medical purposes such as staff lunches to limit opening your refrigerator door.
- Leave space between products in the refrigerator to allow air to circulate.



Handling Vaccine

- Never leave vaccine outside of the refrigerator.
- Remove vaccine from the refrigerator only for withdrawal of the required dose(s).
- Mark the date on all multi-dose vials of vaccine when first opened – use opened vials before opening a new multi-dose vial and use within the timeframe specified by the manufacturer.
- Refer to package insert to determine how long a multi-dose vial can be used after the first dose is withdrawn.

Transporting Vaccine

- Use insulated coolers with tight fitting lids and ice packs when transporting vaccine.
- Keep ice trays and ice packs in your freezer for use during transport of vaccine.
- Do not put vaccine directly on ice pack.
- Keep vaccine in original package.
- Wrap vaccine in bubble wrap.
- For long distance travel, wrap bubble-wrapped vaccine in newspaper for extra insulation and place a thermometer in the cooler.

Disposal of Vaccine

- Vaccine expires at the end of the month (i.e. June /12 means June 30, 2012).
- Return all expired/spoiled vaccine and unused vials to your local Public Health office.

Recording Vaccine

- Complete reciprocal notification form or EMR immunization report and submit to your local Public Health office monthly.
- Document in patient chart vaccine given, dose, site, route, date, Lot #, and person who administered the vaccine.

Public Health contact information:

South Shore Health
Bridgewater Tel: 543-0850

South West Health
Yarmouth Tel: 742-7141

Annapolis Valley Health
Wolfville Tel: 542-6310

Colchester East Hants Health
Authority
Truro Tel: 893-5820

Cumberland Health Authority
Amherst Tel: 667-3319

Pictou County Health Authority
New Glasgow Tel: 752-5151

Guysborough Antigonish Strait
Health Authority
Antigonish Tel: 867-4500 ext 4800

Cape Breton District Health
Authority
Sydney Tel: 563-2400

Capital Health
Dartmouth Tel: 481-5800



Public Health Services



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Background

Inventory management of biologicals is an integral part of any immunization program. There are many factors that necessitate appropriate biological inventory management. They include but are not limited to the following:

- Vaccines are Expensive
- Provide information used to assess immunization coverage rate for targeted individuals/groups
- Monitoring and management of the biological inventory budget

To support these statements, Nova Scotia implemented a Biological Inventory Management System (BIMS) in 2005.

BIMS is the materials management component of the larger SAP business application software system. It provides the ability to readily access information, at any given time, about the effective and efficient planning, ordering, distribution and utilization of all publicly funded vaccines, from manufacturer to service providers within the Nova Scotia health system. The features available include the ability to electronically manage the following:

- Receive Vaccines
- Transfer Vaccines
- Issue Vaccines
- Identify vaccine wastage within the PH system
- Return Vaccines (at District and Sub Office levels, but not Service Provider level)
- Create multiple reports
- Track Costs (DOH level)
- Obtain “real-time” information on the distribution of vaccines

The Provincial Biological Depot provides storage, inventory monitoring and distribution services in relation to the DHW’s provincial biological products including vaccines and immunoglobulin which are purchased by the DHW through supply contracts. The Provincial Biological Depot currently resides within the offices of Public Health Services (PHS), Capital District Health Authority (CDHA) and functions under a MOU between PHS, CDHA and the Department of Health and Wellness.

Introduction

This BIM Business Procedures document is to be used in conjunction with other supporting resources (e.g. BIMS User Manual and the NS Immunization Manual) to ensure consistent use of the application and to maintain accurate and complete entry of data. Quality data will help to ensure quality reporting from BIMS information.

General assumptions

- Entry into BIMS will be daily or as close to real time as possible.
- All biological products issued from the Provincial Biological Depot will be managed in BIMS including products in district sub-offices.
- BIMS users understand inventory, supply and distribution of vaccine used for the publicly funded immunization program in Nova Scotia.
- This document contains basic information regarding BIMS business procedures and will not answer all the questions that BIMS users may have.
- This is a 'living' document and will require regular updates (as required).
- Business procedure clarification will be done in consultation with representatives from the following:
 - Communicable Disease Prevention and Control Division
 - District PH Managers/Leads (who manage Immunization programs)
 - Biological Coordinators within local public health
 - Provincial Biodepot Immunization Coordinator
 - Provincial Biological Coordinator
- BIMS may not meet all the needs of the district or province for management of the biological inventory. Some products such as vaccines used in district travel clinics will still require management outside the electronic inventory system and will need to be maintained in the district.

Inventory Supply Management:

Forecasting

Order only the amount of vaccine you expect to use within the next month. When considering how much vaccine to order, consider the following:

- Past use of the product. This can be found in BIMS by running the MB 51 report for the previous 2-3 years using movement code 261-262. (Reminder: material numbers and package format changed in 2010- reports for dates earlier than 2010-2011 fiscal year will require the old material number)
- Demand based on the population being immunized for that month.e.g. numbers eligible for the school grade cohort
- Current inventory. Run a Z- batch report to identify the current inventory in stock. Place your order for the difference between the current stock and the forecasted demand and include replacement for vaccine that has or will expire that month.

Ordering

- Audit biological products inventory once monthly prior to ordering biological products from the main depot. Check for outdated products. Remove all expired biologicals and store in a clearly marked box/bag. Locally discard any opened, expired or wasted vaccine that is not eligible for return for credit. Enter in BIMS using the appropriate movement code.
- All biologicals for return to the Provincial Biodepot must be unopened and in the original packaging.
- Complete the Provincial Biologicals Depot Product Requisition form monthly and submit to the Provincial Biodepot, Public Health Services, and Capital Health via email: publichealthvaccineorders@cdha.nshealth.ca.
- A copy of the email is to be sent to the person who oversees the inventory in the district. Shipments will be coordinated with the Biological Coordinator at the Provincial Biodepot to ensure staff availability to receive the shipment at destination.
- Monthly orders should be submitted no later than the Friday of the week preceding the DHA delivery schedule. The delivery schedule is:
 - Week 1: Provincial Biodepot receives vaccine from the suppliers
 - Week 2: Wolfville, Bridgewater, Yarmouth
 - Week 3: Truro, Amherst, and New Glasgow
 - Week 4: Sydney and Antigonish.

Please note week 1 of the month is the first full calendar week of the month.

- In the event of a planned absence within the DHA, the DHA order may be submitted early but will be delivered in accordance with the schedule above. Deliveries outside this schedule will only be made in extenuating circumstances and will require a written explanation to the Provincial Biodepot.
- Upon receipt of the order the Biodepot will notify the district of the delivery date. Please allow 2-3 business days for processing and delivery.

Urgent orders:

- **During work hours:** Urgent vaccine/biological product requests during regular working hours please call (902) 481-5800 to speak to the Provincial Biodepot Immunization Coordinator or Provincial Biological Coordinator and email to publichealthvaccineorders@cdha.nshealth.ca.
- **After work hours:** For urgent after hour orders confirmed to be required before the next regular work day:
 - Call the MOH on-call at (902) 473-2222 to arrange for release of the vaccine or biological product.
 - The MOH on call will notify the CDC Nurse on call for CDHA at (902) 483-8238 to arrange for urgent delivery.
 - Ensure there is someone available to receive the after-hour delivery at the location receiving the product.

- Complete the Urgent Request for Vaccine/Immune Globulin form and fax to (902) 481-5923. Ensure the person who oversees the inventory in the district is aware of the request.
- Please note that release of any immune globulin from Public Health Services must be documented and stored in the PH office releasing the product. Please use the Immune Globulin Release Tracking Record to track the use of these products. This is done to provide the ability to identify any person receiving the product in the event of a recall or investigation related to the product.

Upon the release of any immune globulin, the following information must be collected and accessible within the local PH office dispensing the product:

- Type of immune globulin
- Lot number
- Patient's name
- DOB
- HCN
- Date
- Name of MOH authorizing the release of the product
- Name of Health Care provider the product is released to
- Signature of the person releasing the product

Receiving

On arrival of the vaccine, the Biological Coordinator or delegate will check to see if the temp tale has alarmed. If alarmed, quarantine the inventory and contact Provincial Biodepot Immunization Coordinator for further direction.

Count and verify the type and number of biological products sent. Accept in BIMS and reply via email to the Provincial Biological Coordinator at publichealthvaccineorders@cdha.nshealth.ca if there is any discrepancy.

Transferring

- **Between Provincial Bio depot and District Plants**
 - Movement from the Provincial Biodepot to the District Plant is documented under the section under "Receiving".
 - Movement from the District Plant to the Provincial Biodepot. (Return). Used to return biologicals to the provincial Biodepot for storage or re-distribution under cold chain. This does not include any expired or wasted vaccine. Notify the Provincial Biodepot of any products you are transferring back in advance.
 - The plant returning product to the Provincial Biodepot is required to transfer the product back in BIMS by using the 301 movement type code to plant V000 DO NOT use the movement code 919/920 for this type of transfer.
 - Returned product must be in the original packaging and have a packing slip enclosed with the following information: name of the plant sending the product, product name, lot number, expiry date and amount in doses being transferred.

- **District Plant to District Plant**
 - The plant transferring product to another district plant will perform the transfer in BIMS using the movement type 919 (and 920 to reverse it back if there is an error).
 - A temperature monitoring device should be used to monitor the temperature for this transfer of vaccine.
- **District Plant to District Sub-plant**
 - The plant transferring product to another district sub-plant will perform the transfer in BIMS using the movement type 919 (use 920 to reverse it back if there is an error). TempTale4 are to be used to monitor the temperature for this transfer of vaccine.

Issuing

Posting Date should reflect the actual date that goods were issued for all movement types. The date needs to be changed from the default date (today) to the date the movement occurred.

Service Provider - Recipient text field – enter name of the courier, clinic, or the person receiving the vaccine as you require for your particular district.

Issue of vaccine to a school clinic should be done on a daily basis in accordance with the scheduled immunization clinic. Entry into BIMS should be done when the amount of vaccine used is known at the end of the day.

Inventory Maintenance

- **Monthly Physical Count**- Physical Count should be done prior to placing your monthly order and adjustments made in BIMS if necessary.
- If there is a discrepancy in the physical count, investigate the discrepancy and if a reason is found, please record in BIMS under the appropriate movement type (i.e. wasted, issued out, etc.).
- Send a copy of the month end physical count sheet report once BIMS adjustments are made to publichealthvaccineorders@cdha.nshealth.ca by the last business day of the month. (ZBATCH)
- Expiry (Movement 917) - Expired vaccine is vaccine that is beyond the expiry date found on the vial. All expired vaccines within the Public Health Fridges should be removed from the inventory count at the time of the monthly physical count (or as needed) using the 917 movement type.
- Immunization providers such as physicians, pharmacists and nurses should be directed to return expired vaccine in unopened, original packaging to their local PH office. The expired vaccine from immunization providers outside PH does not have to be entered into BIMS.
- District PH offices should all return unopened, expired vaccine to the Provincial Biodepot from both PH and other immunization providers. The vaccine should not be expired more than one year based on the date on the vial. If expired more than 1 year, discard the vaccine using DHA processes. Maintenance of cold chain is not necessary for this vaccine.

- These products should be returned to the Provincial Biodepot in **April, September and December** at the same time as monthly vaccine deliveries are received. Ensure replacement vaccine is included for vaccines that will or have expired with the exception of the following:
 - Rabies Immune Globulin
 - Tetanus Immune Globulin
 - Diluent or open packages

Waste (Movement 911) - Vaccine in multi dose vials that is lost because it was open too long and vaccines that are not suitable for use due to cold chain breaks should be recorded as “waste” using the movement type 911 and Document Header Text as follows:

- CCPH (Cold Chain Public Health),
- OU (Open Unused i.e. Tubersol),
- D (Damaged)

The “recipient field ” will be used to record the final location managing the destruction of the vaccine/biological product e.g. District Biological Depot, Provincial Biological Depot or Manufacturer need to add cost centre and business area information.

Recall (913) – In the event of a vaccine recall you will be instructed to use this code. Otherwise this code would not be used for common transactions. Appendices are linked to fillable forms on the DHW website.

Appendix A Biological Product Requisition

Appendix B Urgent Request for Vaccine /Immune Globulin

Appendix C Immune Globulin Release Tracking Record

Appendix D Expired Biological Products for Return to Biodepot

Chapter 6: Immunization Techniques

Appropriate vaccine administration is critical to vaccine effectiveness. The recommended site, route, and dosage for each vaccine are based on clinical trials, practical experience, and theoretical considerations.

When they are manufactured, immunizing agents do not contain any contaminants and are therefore sterile. The strictest form of asepsis must be observed when preparing and administering vaccines:

- Wash your hands before handling the equipment used in vaccination.
- Use only sterilized equipment.

Gloves are not required for vaccination. The gloves should be worn only when the person administering the vaccine comes into contact with potentially biologically infectious fluids or has open lesions on their hands.

Choice of Needle Gauge, Length and Angle of Insertion

General Principles

- Only one vaccine is to be used in each syringe.
- The choice of needle length and injection site must be based on the person's age and weight, the amount to be administered, and muscle size.
- The needle gauge is selected based on the viscosity of the product to be administered.
- When administering a large volume of immunizing agent in a muscle, the size and circulatory condition of that muscle must be taken into account. When the reference points circumscribing the injection site are properly identified, there is no risk in administering the agent too deeply using a longer needle. If the needle strikes bone, simply withdraw it slightly and inject the agent into the muscle.
- Use nursing judgement to select the appropriate injection site and needle size. This nursing assessment is based upon the
 - client's age
 - volume of biological product to be administered
 - viscosity of the biological product
 - adequacy of muscle mass
 - recommended route of administration for the biological product
- After selecting the appropriate injection site, inspect the skin's surface over the site for bruises, scars, or inflammation. Palpate the site for masses,

edema, or tenderness. If any of these are found at the injection site, do not use the site, as there might be interference with absorption of the biological product.

Administration

General Principles

- An injection site is the area of a limb where a vaccination can be given. There are numerous injection sites in each limb, for example the middle anterior surface of the forearm, the middle third of the posterolateral surface of the arm, the upper third of the arm, the external anterolateral area of the thigh, and the vastuslateralis muscle.
- Immunizing agents must be given using the administration route indicated in the product monograph.
- Immunizing agents should not be injected where there is inflammation, itching, scars, nodules, sensitivity, induration, pain, or blood vessels.
- Whenever possible, avoid administering an immunizing agent in a limb that is likely to be affected by a lymphatic system problem, such as lymphedema or mastectomy with lymph node removal. However, if hepatitis B or rabies vaccines are indicated, even in the case of a bilateral mastectomy the agent should be administered in the deltoid muscle.
- Intradermal (ID) injections must be given properly in the dermis, since small quantities of the agent's antigen are used. If the agent is inadvertently administered subcutaneously, the result will be suboptimal immune response.
- A good intramuscular (IM) injection technique is important for the following reasons:
 - Injecting the agent into adipose tissue could adversely affect the immune response.
 - Vaccines containing adjuvants administered subcutaneously or intradermally can cause irritation, induration, a change in skin colouring, inflammation, or the formation of granuloma at the site.
- Hepatitis B and rabies vaccines must be injected into the deltoid muscle in persons 1 year of age or older. For children under 1 year of age, the vastus lateralis muscle is used to administer these vaccines. It has been shown that the immunogenicity of these vaccines is substantially lowered when they are administered into the gluteal muscle, as compared with the deltoid. This can be explained by the fact that the vaccine may have possibly been inadvertently administered into adipose tissue, instead of the muscle tissue. Any hepatitis B or rabies vaccines administered into the gluteal muscle should be considered not given and should be readministered in the deltoid muscle.
- If several injections are to be given at the same visit, consideration could be given to administering two injections at the same site. This means that 2 IM injections, or 1 IM and 1 SC injection, or 2 SC injections could be given at the same site (deltoid muscle or vastus

lateralis muscle). The distance between injections should be at least 2.5cm (1 inch) so that local reactions can be distinguished for each product administered and immune interference prevented.

Intradermal (ID) Injections

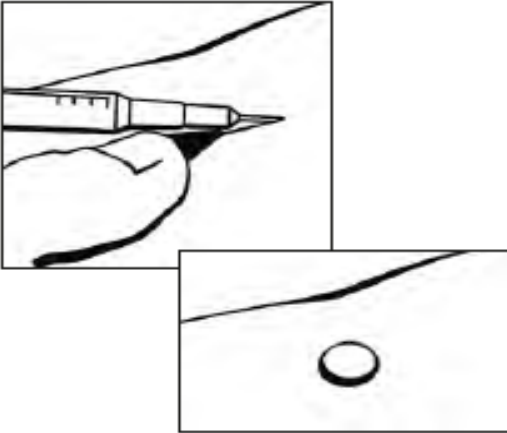
Definition

The introduction into the derma of a minimal amount (between 0.01 and 0.1 mL) of biological product; e.g. tuberculin skin test (TST) administration.

Site and needle size for ID injections

- Use a 1 mL TB syringe and 27-gauge needle of ½" length.
- The usual site for intradermal injections is the flexor surface of the forearm.
- Have client rest their arm on a firm surface, forearm turned up.
- Because of the decreased antigenic mass administered with ID injections, attention to technique is essential to ensure that the material is not injected subcutaneously.

Procedure	Important Points
<p>1. Select the injection site; palpate the area to ensure that the tissue is intact.</p> <p>When administering the TST, ask the user to extend their arm and press their elbow and forearm against the table.</p> <p>When administering rabies vaccine pre-exposure, ask the user to relax the limb.</p>	<p>Normal Site</p> <ul style="list-style-type: none"> • for the tuberculin skin test (TST, also known as PPD): middle anterior surface of forearm • for rabies vaccine used for pre-exposure: upper third of arm <p>This way, the injection site does not move and is easier to reach. Also, relaxing reduces distress for the user.</p> <p>In the case of a child, the provider holds the child's arm with the left hand so that the left hand is underneath the child's arm and the thumb and fingers surround the arm and stretch the skin.</p>
<p>2. Clean the site with an alcohol swab using a circular outward motion from the centre, describing a circle approximately 5 cm in diameter.</p>	<p>Allow the site to dry in order to prevent the user from feeling a burning sensation when the needle enters.</p>
<p>3. Hold the skin in the selected area between the thumb and index finger.</p>	

Procedure	Important points
<p>4. Introduce the needle, with the bevel facing upwards, maintaining an angle of 5° to 15° until the bevel disappears from sight.</p>	
<p>5. Release the skin.</p>	<p>This helps avoid splashes or leaks. When an ID injection is performed correctly, the plunger is difficult to push.</p> <p>Injecting the solution into the derma may cause a burning or stinging sensation. A pale-colored papule, similar to orange peel, will appear immediately after the agent is injected but will disappear spontaneously within a few minutes.</p> <p>If the papule does not appear immediately:</p> <ul style="list-style-type: none"> • For TST: repeat the injection on the other forearm. • For pre-exposure rabies vaccine: immediately stop the injection, correct the needle position and administer the remainder of the dose, but no more.
<p>6. Slowly inject the biological until it produces a papule.</p> 	<p>7. Wait several seconds after completing the injection before withdrawing the needle.</p> <p>Waiting allows the agent to diffuse.</p>
<p>8. Withdraw the needle and dab the injection site with a cotton swab or a compress; do not massage.</p>	
<p>9. Draw a circle around the injection site, preferably with a felt marker or pen, unless the injected product was a vaccine.</p>	<p>Tell the client not to scratch the site, but they may resume normal activities including showering and bathing. Do not cover the site with a bandage.</p>
<p>10. Dispose of soiled equipment in the container provided for that purpose.</p>	<p>Never replace the cover/cap on the needle.</p>

Subcutaneous (SC) Injections

Definition

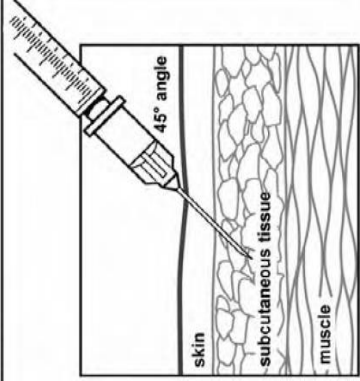
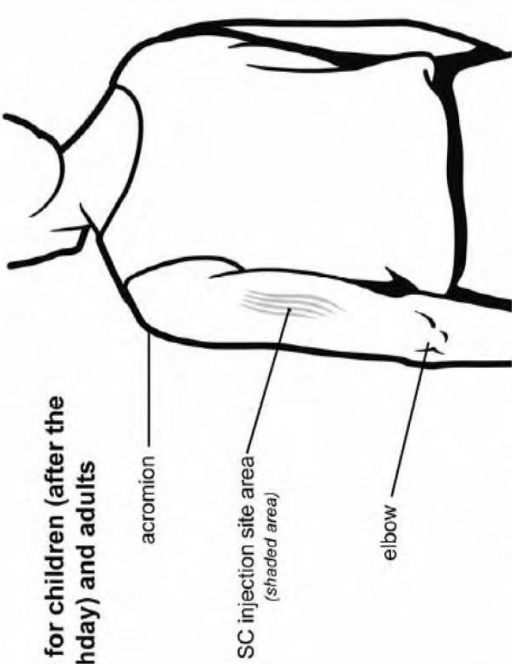
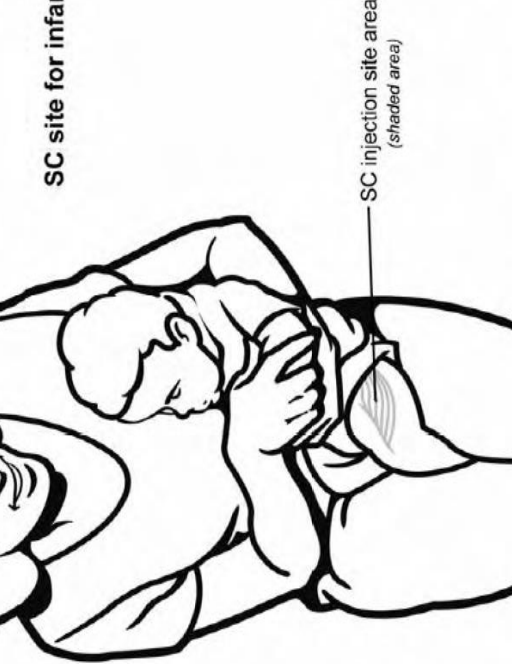
The introduction of an immunizing agent into the connective tissue layer beneath the skin.

Procedure	Important Points
1. Select the injection site; palpate the area to ensure that the tissue is intact.	Customary sites for vaccination are the middle third of the posterolateral surface of the arm, the deltoid area and the external anterolateral area of the thigh.
2. Clean the site with an alcohol swab using a circular outward motion from the centre, describing a circle approximately 5 cm in diameter.	
3. Pinch the skin between the thumb and index fingers to raise the subcutaneous tissue.	
4. Release the skin.	
5. Inject the immunizing agent.	
6. Withdraw the needle and apply slight pressure to the injection site with a cotton swab or compress, but do not massage.	
7. Dispose of soiled equipment in the container provided for that purpose.	

How to Administer Subcutaneous (SC) Injections

Administer these vaccines via subcutaneous (SC) route: MMR, varicella, meningococcal polysaccharide (MPSV), and zoster (shingles). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPV) vaccines either SC or IM.

Patient age	Site	Needle size	Needle insertion
Birth to 12 mos.	Fatty tissue over the anterolateral thigh	5/8" needle, 23–25 gauge	<p>Pinch up on SC tissue to prevent injection into muscle.</p> <p>Insert needle at 45° angle to the skin.</p> <p>(Before administering an injection, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.*)</p> <p>Multiple injections given in the same extremity should be separated by a minimum of 1".</p> <p>*CDC. "ACIP General Recommendations on Immunization" at www.cdc.gov/nip/publications/ACIP-1st.htm.</p>
12 mos. and older	Fatty tissue over the triceps	5/8" needle, 23–25 gauge	

	 <p>SC site for children (after the 1st birthday) and adults</p>
 <p>SC site for infants</p>	<p>Insert needle at a 45° angle into fatty tissue over the triceps muscle. Make sure you pinch up on SC tissue to prevent injection into the muscle.</p>

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

Intramuscular (IM) Injections

Definition

Introduction of an immunizing agent into the muscle.

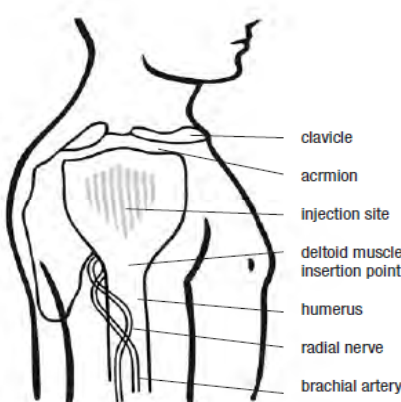
Sites, needle size, and positioning for IM injections

- The IM site of choice for infants less than 12 months of age is the vastus lateralis (anterolateral thigh). It should also be considered for older children with a small deltoid muscle mass. For children 12 months of age or over and for adults, the preferred site is the deltoid muscle. When the deltoid muscle is used for children 12 months of age or over, first assess the adequacy of the muscle mass.
- Use a needle length sufficient to reach the largest part of the muscle. This is to prevent the biological being deposited in subcutaneous tissue and to decrease or prevent abscess formation.
- For infants and toddlers, a 7/8"–1" needle is usually used, depending on the muscle size and the amount of subcutaneous tissue.
- For older children and adults, a 1"–1 1/2" needle is used.
- Use a 21 to 25 gauge needle, depending on the viscosity of the biological product.

Description of Intramuscular injection sites

Deltoid muscle

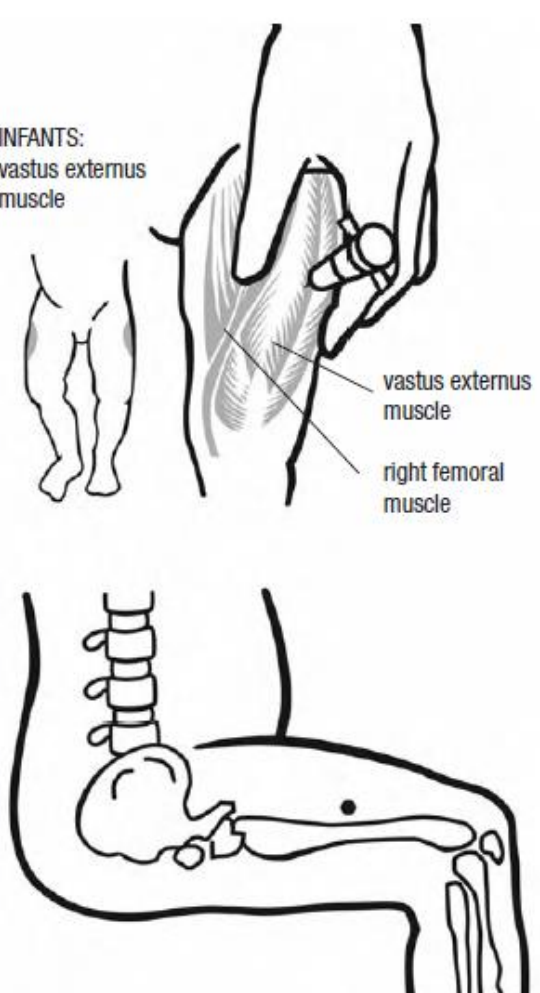
The deltoid muscle is the preferred injection site for adults and children 12 months of age or over; before the age of 12 months, this muscle is not sufficiently developed to be used. Preferably, the professional should not inject more than 2 ml of immunizing agent into the deltoid muscle.

Procedure	Important points
1. Ask the client to adopt the dorsal or lateral decubitus position or the sitting position.	
2. To make it easier for the deltoid to relax during the injection, have the client adopt either the supine position, with the arm stretched out along the body and the elbow slightly bent, or the sitting position, with the elbow bent and the forearm resting on the arm of a chair. Another option would be to have the client place one hand on the shoulder opposite to the arm chosen to receive the injection.	
3. Determine the injection site by drawing a triangle with the base at the lower edge of the acromion and the tip just above the deltoid muscle insertion point. This creates an area of approximately 5 cm ² (2 in x 2 in) located three finger widths below the acromion in the external portion of the arm.	

Vastus lateralis (externus) muscle

The vastus lateralis muscle is the preferred injection site for children under 1 year of age, because it is already well developed at birth and is far from any nerves or major blood vessels. This muscle can also be used for adults. In both children and adults, using this site can temporarily restrict movement of the leg.

The professional should never inject more than 5 mL of immunizing agent into the vastus lateralis muscle.

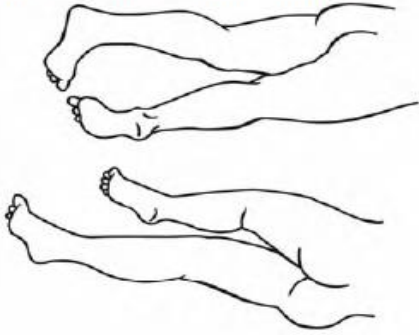
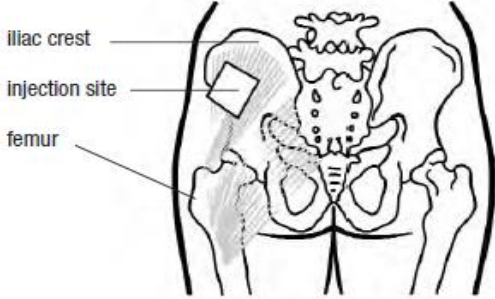
Procedure	Important points
<p>1. Ask the client to adopt either the dorsal or lateral decubitus position or the sitting position.</p> <p>A child should be seated on the parent's lap. Ask the parent to uncover the child's right or left leg, up as far as the top of the thigh.</p>	<p>Lying down assists in relaxing the muscle.</p>  <p>INFANTS: vastus externus muscle</p> <p>vastus externus muscle</p> <p>right femoral muscle</p>
<p>2. Determine the injection site by dividing the space between the greater trochanter of the femur and the top of the knee into thirds and drawing a horizontal line dividing the external portion of the thigh down the middle.</p> <p>The injection site is in the middle third, just above the horizontal line.</p>	

Dorsogluteal muscle

The dorsogluteal muscle should be used only for the administration of immunoglobulins. In adults, adolescents and children over 2 years of age, IM injections can be given in the superoexternal quadrant of the buttocks. However, before selecting this site, make sure that the child has been walking for at least 1 year, the time it takes for the gluteal muscle to be sufficiently developed. For children less than 2 years of age, use the vastus externus muscle.

This injection site is less immunogenic for several vaccines, primarily hepatitis B and rabies vaccines.

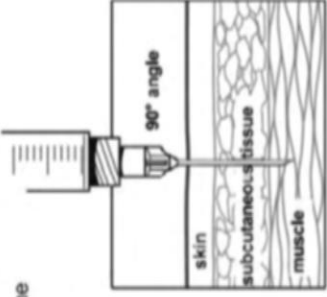

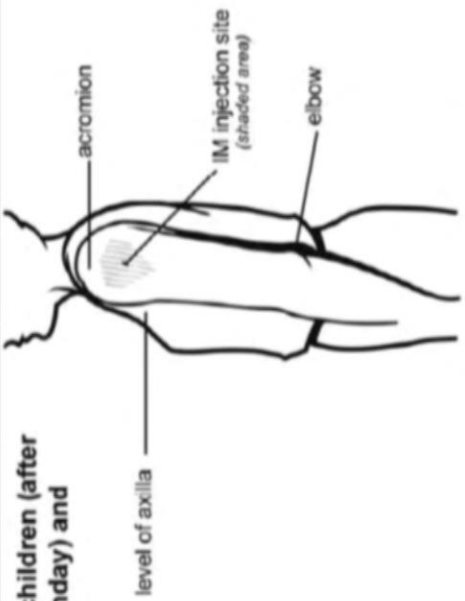
The amount of agent that a muscle can absorb varies: 5 mL is normally the maximum dose for a large muscle (such as the dorsogluteal). Babies, seniors and persons who are thin cannot tolerate more than 2 mL. When the amount to be administered is greater than the recommended volume, the dose must be divided into portions and injected into different muscles; the vastus externus muscle and the deltoid can be used in adults who require a large quantity of antirabies immune globulin.

Procedure	Important points
<p>1. Ask the client to adopt the ventral or lateral position.</p> <p>If the ventral position is chosen, ask the client to point their toes inward. For the lateral position, ask the user to flex their knee on the side where the injection is to be given.</p>	<p>These actions are designed to help the muscles relax and reduce distress.</p> 
<p>2. Determine the injection site by drawing a horizontal line from the top end of the gluteal cleft out toward the external surface of the buttocks and then a vertical line down through the centre of that line.</p> <p>The injection site will be in the upper median portion of the superoexternal quadrant.</p>	

Procedure	Important Notes
1. Clean site with an alcohol swab, using a circular outward motion from the centre, describing a circle approximately 5 cm in diameter.	Allow the site to dry in order to prevent the use from feeling a burning sensation when the needle enters.
2. Firmly stretch the skin between the thumb and index finger.	For persons of thin build and children, grip the muscle mass between the thumb and index finger before and hold during the injection.
3. Plunge the needle into the muscle at a 90° angle with a rapid, firm motion.	
4. Release the skin.	
5. Inject the immunizing agent.	It is not necessary to aspirate prior to administering the injection, since there have not been any problems reported in connection with the lack of aspiration.
6. Withdraw the needle and lightly press on the injection site with a cotton swab or compress.	
7. Dispose of soiled equipment in the container provided for that purpose.	

How to Administer Intramuscular (IM) Injections

Administer these vaccines via intramuscular (IM) route: Diphtheria-tetanus (DT, Td) with pertussis (DTaP, Tdap); Hib; hepatitis A; hepatitis B; human papillomavirus (HPV); inactivated influenza; meningococcal conjugate (MCV4); and pneumococcal conjugate (PCV). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPV) either IM or SC.

Patient age	Site	Needle size	Needle insertion
Birth to 12 mos.	Anterolateral thigh muscle	5/8" needle (newborns only), 1" (older infants), 22–25 gauge	 <p>Use a needle long enough to reach deep into the muscle.</p> <p>Insert needle at a 90° angle to the skin with a quick thrust.</p> <p>(Before administering an injection, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.¹⁾)</p> <p>Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.</p> <p>¹CDC. "ACIP General Recommendations on Immunization" at www.cdc.gov/nip/publications/acip-1st.htm.</p>
12 mos. to 10 yrs.	Thickest portion of deltoid muscle—above level of axilla and below acromion (if adequate muscle mass). The anterolateral thigh may also be used.	5/8" to 1" needle, 22–25 gauge	
Children and adults 11 yrs. and older	Thickest portion of deltoid muscle—above level of axilla and below acromion	1"–1½" needle, 22–25 gauge	
<p>*A 5/8" needle can be used if the skin is stretched tight and the subcutaneous tissue is not bunched. ¹A 5/8" needle may be used in the deltoid muscle in children ages 12 mos. or older and in adults weighing less than 130 lbs.</p>			
 <p>IM site for infants</p> <p>Insert needle at a 90° angle into the anterolateral thigh muscle.</p>		 <p>IM site for children (after the 1st birthday) and adults</p> <p>Insert needle at a 90° angle into thickest portion of deltoid muscle—above the level of the axilla and below the acromion.</p>	

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/cag/dj2002c.pdf • Item #P2020 (1/07)

Administration and Scheduling of Multiple Injections

- There are no contraindications to giving multiple injections at the same clinic visit. There is no increase in side effects, reduced vaccine effectiveness, or reduced parental compliance.
- When administering two biological products in the same limb, separate the two injections by a distance of at least 1–2" so that local reactions are unlikely to overlap.
- Give all vaccines a client is eligible for at every visit. This means fewer office visits and fewer periods of discomfort. It increases the probability that children will be fully immunized at the appropriate age.
- Do not administer rabies immune globulin in the deltoid; this site is for vaccine administration.

Measures to be Taken Prior to Immunization to Ease Distress or Pain

More and more, measures are being suggested in the literature for reducing the pain and distress associated with vaccination. [Reference guides](#) for parents on how to reduce pain during immunization can be found at Immunize Canada. Here are some of the suggestions:

Injection site

- Rub or stroke the skin near the injection site before and during the injection.
- Lightly tap the injection site to stimulate the nerve endings.
- Allow the injection site to dry after wiping with an alcohol swab.
- Insert the needle quickly and firmly into the injection site.
- Inject the vaccine quickly.
- Do not aspirate. Studies have shown that aspiration before an IM injection is more painful and takes longer. There are also no large blood vessels near immunization sites.
- During the injection, stabilize the syringe to prevent it from moving.
- Withdraw the needle quickly (IM injections) at the same angle as it was inserted.

Pharmaceutical techniques

- There is no evidence that administration of analgesics prior to the injection provides any relief from immunization pain.

- Local anesthetics (e.g. EMLA, Ametop, Maxilene) are currently available without a prescription in pharmacies and can be used to produce superficial anesthesia at the injection site. However, it should not be used if completing a TST.
- Immunization of an individual who has a topical anesthetic in place for pain relief may proceed as appropriate given that topical anesthetics appear to have no effect on the immunogenicity of any vaccine
- If the topical anesthetic has been placed incorrectly, immunization should be given in the appropriate place and not in the area of the anesthetic.
- It is recommended that parents/clients who use these products follow the manufacturer's instructions and check the contraindications, precautions, and possible side effects before using.
- These products need to be applied to the skin up to an hour before the injection.
- Public Health nurses will not apply the topical anesthetic to the arm.

Other techniques

- During the injection, an adult should take the baby into their arms; offering the breast, a pacifier, or a bottle, will make it easier to calm and reassure the baby.
- Caressing or rocking a child during an injection will reduce crying or pain.
- For older children and adults, distraction measures can be used such as: deep breathing or blowing hard, as if blowing out a candle or making soap bubbles; tell a story; play music; count numbers; talk about a favourite game or TV show, etc.

Positions

- Have the person adopt a comfortable position to allow the limb to relax.
- Having the child sit on the parent's lap in such a way that they do not move during the injection can make it less traumatizing for the child.
- Ask the parent to uncover the child's right or left leg up as far as the top of the thigh. The child should be seated on the parent's lap.
- Place one of the child's arms behind the parent, under the parent's arm. The child's other arm is controlled with the parent's arm and hand. In the case of children under 1 year of age, the parent can control both arms with one hand.
- The parent firmly holds the child's legs and feet between his or her thighs and controls them with the other hand.

Immunization Record

It is important to record the following information in the immunization record.

- If records are kept on paper, write legibly in ink. Erasures are not permitted; if a mistake is made, put a single stroke through the incorrect entry, write “error” above it and initial the change.
- If records are kept electronically, they are considered valid if the professional who performed the procedure is identified.
- The following items must be included:
 - ✓ the date the agent was administered
 - ✓ the time the agent was administered (optional)
 - ✓ the trade name of the agent
 - ✓ the lot number of the agent
 - ✓ the amount administered
 - ✓ the injection site
 - ✓ the administration route
 - ✓ the surname, first initial(s), and professional title of the person who administered the vaccine
 - ✓ any adverse event(s) that occurred following the vaccination; if there were adverse events, a reporting form must be completed
- The following information must be recorded in the user’s immunization record:
 - ✓ the date the agent was administered
 - ✓ the trade name of the agent
 - ✓ the amount administered
 - ✓ the administration route
 - ✓ the professional’s signature

Chapter 7: Vaccine Related Emergencies

Vasovagal Reactions

Vasovagal reaction or vasovagal syncope (faint) is an abnormal response of the autonomous nervous system to a significant emotional component, to a physical or psychological stress. It is a fairly common and mild reaction to immunization, particularly in adolescents and young adults. It is sometimes observed before immunization, but usually occurs a few seconds to a few minutes after an injection. Rapidity of onset is the key distinguishing element of this reaction. The principal symptoms are a fainting sensation, dizziness, hypotension, pallor, bradycardia (slow and weak, but regular pulse), clammy skin, diaphoresis, nausea, vomiting and loss of consciousness in some cases. With fainting, the subject changes from a normal to an unconscious state in seconds. Fainting is sometimes accompanied by brief tonic or clonic activity (jerky limb movements), but this generally requires no treatment or investigation.

The greatest risk for someone who faints is injury from a fall. According to U.S. passive surveillance data from 1990 to 1995, out of 697 reported cases of vasovagal syncope after immunization, 6 people experienced falls that resulted in injury, including cerebral contusion, skull fracture, and cerebral bleeding. Three of these patients required neurosurgery. These falls occurred 15 minutes or less after immunization.

It is possible to reduce the risk of fainting by taking measures to lessen stress in the vaccine recipient; for example, having them sit for the injection and providing a comfortable room temperature. Before the injection, clients should be asked if they have a tendency to faint; if so, they should be asked to lie down.

Patients who experience a fainting sensation should be asked to remain seated and place their head between their legs or lie on their back, legs elevated above the head. Place a damp, cold cloth on their face. At all times the client should be reassured.

Swelling and Urticarial rash at injection site

Swelling and urticarial rash (i.e., hives) at the injection site may occur following an immunization but are not always caused by an allergic reaction.

As per the [Canadian Immunization Guide](#), if there is swelling or hives at the injection site:

- observe the site for at least at least 30 minutes to ensure that the reaction remains localized.
- If there are no other symptoms, the hives or swelling disappear and there is no

evidence of further progression to other parts of the body during the observation period, further observation is not needed.

- **If any other symptoms develop, even if considered mild (e.g. sneezing, nasal congestion, tearing, coughing, facial flushing) or if there is evidence of any progression of the hives or swelling to other parts of the body during the observation period, implement the [anaphylaxis management protocol](#).**

Anaphylactic Reactions

Anaphylaxis is “a potentially life-threatening allergic reaction to foreign protein antigens such as food and bee stings. It is a rare complication of immunization but, even so, it should be anticipated in every vaccinee” (Canadian Immunization Guide, 2006).

Clients should be asked before immunization if they have ever had an anaphylactic reaction to any vaccine or any of the components of the vaccine. If so, the name of the product should be requested and a decision made accordingly.

The signs and symptoms of anaphylaxis usually begin within 30 minutes after an injection. However, the most severe reactions occur when symptoms develop in the first 15 minutes. The clinical signs often involve multiple body systems (skin, respiration, circulation). The symptoms of anaphylaxis are varied and may progress to shock and cardiovascular collapse characterized by, among other things, a delayed loss of consciousness. It is important to recognize the first signs and symptoms of anaphylaxis quickly so that treatment can be administered without delay.

Signs and Symptoms of Anaphylaxis According to Clinical Progression and Severity of Attack

Clinical Progression	Signs and Symptoms	Severity of Attack
Mild, early warning signs	Itching of the skin, rash and swelling around injection site; dizziness, general feeling of warmth	Mild
	Painless swelling in parts of the body (e.g. face or mouth), flushing, itching, nasal congestion, sneezing, tears.	Mild to moderate
	Hoarseness, feeling sick, vomiting, swelling in the throat, difficulty breathing, abdominal pain	Moderate to severe
Life-threatening symptoms	Wheezing; noisy, difficult breathing; circulatory collapse, low blood pressure; irregular, weak pulse	Severe

Adapted from World Health Organization, Department of Vaccines and Biologicals, *Supplementary Information of Vaccine Safety: Part 1, Field Issues* (Geneva: World Health Organization, 2001)

The following table compares the signs and symptoms of a vasovagal reaction and anaphylaxis.

Signs and Symptoms	Vasovagal Reaction	Anaphylaxis
Interval (after injection)	Sometimes before, usually a few seconds to a few minutes after the injection	Within 30 minutes after injection; the most severe reactions will begin within the first 15 minutes
Consciousness	Fainting sensation, dizziness, loss of consciousness in many cases	Anxiety, which may progress to unconsciousness in severe cases
Breathing	Slow, within a few seconds to apnea in some cases	Respiratory difficulties; coughing, sneezing, dyspnea, wheezing, stridor
Pulse	Slow and weak, but regular	Rapid, weak and irregular
Skin	Diaphoresis, clammy skin, pallor	<ul style="list-style-type: none"> • Warm skin, progressing to clammy skin and pallor • Pruritis and urticaria (hives) (>90% of cases) • Swelling of face and tongue
Blood pressure	Hypotension	Hypotension (systolic pressure <90 mm Hg), which may progress to cardiovascular collapse
Gastrointestinal system	Nausea, vomiting	Nausea, vomiting, abdominal pain, diarrhea
Treatment	<ul style="list-style-type: none"> • Place client in recumbent position and elevate legs above head or have client sit with head between their knees. • Ventilate the room well. • Place cold, damp cloth on face • Give reassurance 	See Anaphylaxis Management Protocol (next page)
Prevention	Do not vaccinate a standing person. Before vaccinating, ask if the person tends to faint; if so, ask the person to lie down.	Before vaccinating, ask if the person has ever had an anaphylactic reaction to any product; if so, ask for the name of the product and decide accordingly.

Anaphylaxis Management Protocol

Prerequisite

All vaccine providers should know how to perform cardiopulmonary resuscitation and keep their skills up to date. Cardiopulmonary resuscitation is not covered in this manual.

Anaphylaxis Kit – Minimum Supply:

- 4x 1-cc syringes and 4 needles (25-G 1" and 1 ½" needles)
- 2 vials of epinephrine 1:1000
- 1 vial of injectable diphenhydramine hydrochloride or oral diphenhydramine hydrochloride
- Alcohol swabs
- Scissors
- Copy of the anaphylaxis procedures and doses recommended for epinephrine and diphenhydramine for weight and age

Note: The vaccine provider should check the contents of the emergency kit regularly (before each immunization session), particularly the number of epinephrine, diphenhydramine hydrochloride and the expiration dates.

Intervention

Steps 1 -4 should be done promptly and simultaneously

1. **Assess** circulation, airway, breathing, mental status, skin and body weight.
2. **Direct someone to Call** 9-1-1. Do not leave the patient alone under any circumstances. Speedy intervention is of paramount importance. Failure to use epinephrine promptly is more dangerous than using it improperly.
3. **Position** the client on their back or in a position of comfort if there is respiratory distress; elevate lower extremities. Place the client on their side if vomiting or unconscious. Clients who are pregnant should be placed semi-recumbent on their left side with their legs elevated.
4. **Administer epinephrine** intramuscularly (IM) in the mid-anterolateral aspect of the thigh. Administer 0.01mg/kg body weight of 1:1000 (1mg/ml) solution by weight (if possible) or by age (Table 1). Repeat every 5-15 minutes as needed, for a maximum of three doses.
5. If indicated, **as an adjunct to epinephrine**, administer one dose of diphenhydramine hydrochloride (Benadryl®) to relieve itching, flushing, urticarial, nasal and eye symptoms. Generally, the IM route is used although oral tablets or liquid elixir may also be used. See table 2 for dosing guidelines. **Note:** Diphenhydramine is generally not recommended for infants under 12 months of age and should be used with caution between 12-23 months because it may cause drowsiness or paradoxical excitement.

Diphenhydramine can be given at any time interval after the initial or repeated doses of epinephrine based on the client's status. **Never given diphenhydramine alone or before epinephrine.**

6. **Monitor** respiratory effort, pulse and level of consciousness.
7. **Transfer** the client to hospital for observation.
8. Document as per NSHA documentation guidelines and Management of Anaphylaxis Form.
9. Complete the Adverse Event Following Immunization form and forward to local Public Health.

Table 1: Dosing guidelines for epinephrine by age and weight (Canadian Immunization Guide, 2013)

Age	Weight ¹	Dose by injection
0 – 6 months	Up to 9 kg (20 pounds)	0.01 mg/kg body weight
7 - 36 months	9 - 14.5 kg (20-32 lb)	0.1 - 0.2 mg
37 - 59 months	15 - 17.5 kg (33-39 lb)	0.15 - 0.3 mg ²
5 - 7 years	18 - 25.5 kg (40-56 lb)	0.2 - 0.3 mg ²
8 - 12 years	26 - 45 kg (57-99 lb)	0.3 mg ²
13 years and older	46 + kg (100 lb or more)	0.5 mg ³

¹ Rounded weight at the 50th percentile for each age range

² Maximum dose for children 12 years of age and younger

³ Maximum dose for adolescents

Table 2: Dosing guidelines for diphenhydramine hydrochloride by age (Canadian Immunization Guide, 2013)

Age	Weight	Dose of diphenhydramine hydrochloride
12-23 months ¹	7-12 kg (15-25 lbs)	6.25 - 12.5 mg
2 to 4 years	12-25 kg (25-55 lbs)	12.5 - 25 mg
5 to 11 years	25-45 kg (55-99 lbs)	25 - 50 mg
12 years and older	45 kg + (99 lbs or more)	50 mg

¹ Use with caution in children 12-23 months due to risk of sedation or paradoxical excitement.

Aqueous Epinephrine (Adrenalin) 1:1000

The following information pertains to the administration of epinephrine in case of anaphylaxis.

Composition

Each 1 ml dose of aqueous epinephrine 1:1000 contains 1 mg of epinephrine hydrochloride dissolved in an isotonic sodium chloride solution.

Supply

1 ml ampoule of clear liquid

Storage

- Keep in the manufacturer's box at room temperature of 15–30°C.
- Avoid exposure to light.

Do not refrigerate.

- Do not freeze.
- Do not administer this product if it has a pinkish or darker than slightly yellow colour or contains any precipitate.
- Do not use after expiration date.

Indications

Severe immediate hypersensitivity reaction to immunizing products.

Contraindications

There is no contraindication in the event of anaphylaxis.

For information on precautions, warnings and potential adverse effects following epinephrine administration please refer to the product monograph.

The fillable [Management of Anaphylaxis Form](#) is available on the [DHW](#) website.

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Acknowledgements

The material contained in this NS Adverse Events Following Immunization Reporting Guidelines is adapted from the British Columbia Center for Disease Control (BCCDC) AEFI guidelines (2012) and is used with permission of BCCDC⁵⁷

Introduction

With the implementation of immunization programs and the decline in incidence of vaccine-preventable infections, the attention of the public and media has now shifted to vaccine safety. Vaccines are usually administered to those who are healthy, particularly children, and tolerance is low for the occurrence of adverse events following immunization.

During their development, vaccines undergo rigorous testing for safety and efficacy. During these “pre-licensure trials” efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common adverse events such as inflammation at the injection site or mild fever is well known. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions, but there is no need to report such expected events unless they are more severe or more frequent than expected.

One important way to ensure vaccine safety involves the close monitoring and timely assessment of suspected adverse events following immunization. Under the Nova Scotia Health Protection Act and the Regulations under the Act 2005, an Adverse Event Following Immunization (AEFI) is notifiable and must be reported to the Medical Officer of Health through local Public Health in the Nova Scotia Health Authority (NSHA).

This document has been developed to provide public health practitioners in Nova Scotia with a procedure for the reporting of Adverse Events Following Immunization (AEFI) using the Public Health Agency of Canada [AEFI Report Form](#).

Guidelines for the assessment of suspected adverse events can be found in the [Canadian Immunization Guide](#).

NOTE: When an adverse event follows the administration of a **passive** immunizing agent (e.g. immune globulin) and/or diagnostic agent (e.g. tuberculin skin test), an AEFI form should not be completed. Instead, the event should be reported to Health Canada on [Canada Vigilance Adverse Reaction Reporting Form](#).

General Overview

The purpose of this document is to provide criteria for the reporting of adverse events following immunizations, and to assist public health practitioners with the interpretation of adverse events following immunization and their implications for subsequent immunization.

What is AEFI surveillance?

AEFI surveillance (also known as vaccine safety surveillance) is a system designed to collect adverse events temporally associated with receipt of vaccines. This type of surveillance typically relies on health professionals associating an adverse event in an individual as a possible consequence of vaccination and reporting it to the appropriate authority.

Why do AEFI need to be reported?

The objectives of surveillance of AEFI are to:

- ensure that the vaccines used in Canada are safe,
- identify risk factors for AEFIs,
- identify problems requiring quick epidemiologic investigation,
- carry out lot-by-lot monitoring of unusually high rates of AEFI,
- maintain public confidence in Canada's immunization programs,
- meet the legislative requirement for mandatory reporting of AEFI by health care providers.

What is done with AEFI reports at the NSHA and DHW?

AEFI reports are received at the local Public Health Offices from multiple sources including physicians, nurses, pharmacists, public health, IMPACT, and the public. Investigation and documentation is completed by the local Public Health offices. Recommendations for future immunizations are made by the Medical Officers of Health. Data is entered into the Provincial electronic system Application for Notifiable Disease Surveillance (ANDS/ANDI). AEFI reports are reviewed, classified and analyzed by the MOH. AEFIs determined to be reportable to PHAC are then shared with the Department of Health and Wellness (DHW). DHW then sends the reports to the Public Health Agency of Canada (PHAC) by secure email transfer once identifying information has been removed to protect the privacy of health information.

What is done with AEFI reports at the national level?

Personnel at the Vaccine Safety Section of PHAC screen all submitted reports, ensure they are entered into the Canadian Adverse Event Following Immunization (CAEFI) database and coded using standard international coding systems. Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Canadian data are periodically forwarded to the World Health Organization (WHO) International Drug Monitoring Program in Uppsala, Sweden, where global data are analyzed for any evidence of safety concerns.

Reporting Requirements

Who should report AEFI?

Under the Nova Scotia Health Protection Act and the Regulations under the Act, an **Adverse Event Following Immunization** is notifiable and must be reported to the Medical Officer of Health, through the local Public Health Services office in accordance with the details outlined on the poster titled [“It's the Law: Reporting Adverse Events Following Immunization”](#).

For interjurisdictional notification, the DHW will be responsible to ensure the appropriate Province /Territory (P/T) is notified.

What type of AEFI should be reported?

An Adverse Event Following Immunization should be reported when the event:

- **Has a temporal association with a vaccine:** Please refer to the [Summary of Reporting Criteria](#). Temporal association alone (i.e. onset of an event following receipt of vaccine) is not proof of causation.
- **Has no other clear cause at the time of reporting:** A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s)
- **Is serious in nature:** A serious adverse event is one that is life threatening or results in death, requires hospitalization (≥ 24 hours) or prolongation of an existing hospitalization, results in residual disability or associated with a congenital malformation.
- **Is unusual or unexpected: An event that has either** not been identified previously or one that has been identified previously but is being reported at an increased frequency. For additional information regarding unusual or unexpected events, please refer to the [Canadian Immunization Guide](#).
- **Clusters of events:** known or new events that occur in a geographic or temporal cluster (e.g. 6 in a week, or 6 in a zone) that require further assessment, even if the total number of AEFIs may not be higher than expected.

Most reactions to vaccines are mild and self-limited. These can be local (e.g. tenderness or redness at injection site) or systemic (e.g. fever, joint or muscle pain) but are minor in severity. ***Minor expected reactions as outlined in the vaccine product monograph do not need to be reported.***

If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported.

Recommendations following an adverse event

Public Health in the NSHA may determine a process for assessment and decision-making regarding reported adverse events, and what events assessed by a health care provider will require reviewing by the Medical Officer of Health. The zone may have additional reports that are required to be completed following a suspected AEFI e.g. incident report forms or medication error reports etc.

The following are recommended criteria for events to be reviewed by the Medical Officer of Health:

- events which the client's health care provider considers may confer precautions, contraindications or a reason to postpone a future immunization

- all events managed as anaphylaxis
- all neurological events including febrile and afebrile convulsions
- allergic events
- all events where medical attention is required, and
- all events that are serious (resulting in hospitalization \geq 24hours, residual disability, death, or congenital malformation.)

Recommendations following adverse event review should be discussed with the client and provided to the client’s health care provider.

Timelines for AEFI Report Submission

Any adverse event that follows administration of an **active** immunizing agent (vaccine) should be reported in accordance with the timelines outlined below. Each Zone is responsible for ensuring that a process is in place to notify both the individual who reported the AEFI, and the primary care provider of the MOH recommendations for immunization.

To facilitate reporting and identification of signals or trends related to AEFI, it is imperative for DHW to receive the AEFI reports in a timely manner. Please follow the timelines below when investigating any AEFI following the administration of an active agent.

Serious Adverse Events:

On receipt of a **serious** AEFI (one that is life threatening or results in death, requires hospitalization (\geq 24 hours) or prolongation of an existing hospitalization, results in residual disability or congenital malformation), in accordance with the “It’s the Law: Reporting AEFI” poster:

- Enter the AEFI into the Application for Notifiable Disease Surveillance (ANDS)/ANDI **immediately**.
- Send a copy of the initial AEFI report to DHW **and** to the zone MOH for review **immediately**.
- MOH to review, classify, provide comments and recommendations, and return the report to the Public Health Nurse (PHN) managing the case within **one week**. PHN will send a copy of the report to DHW at that time.
- Send a copy of the final AEFI report, including all supporting documents such as ER reports, EHS reports etc., to DHW within **one month**. **Keep the original report for NSHA records.**

Other Adverse Events:

On receipt of **other** adverse events as listed on the “It’s the Law: Reporting AEFI” poster:

- Enter the AEFI into ANDS/ANDI
- Send a copy of the AEFI report to the zone MOH for review within **two weeks**.

- MOH to review, classify and signoff within **two weeks** of receiving the report and return the report to the PHN managing the case.
- Send a copy of the final AEFI report if determined to be reportable to DHW within **one month** of receipt of the AEFI. **Keep the original report for NSHA records.**

How to Report

Obtain the AEFI form and the User Guide from the Public Health Agency of Canada website at the following location: <http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php>. Report AEFI in accordance with the reporting timelines listed in the section [Timelines for AEFI Report Submission](#).

Reports to DHW;

- Should be faxed to the confidential fax at (902) 424- 0550 or
- Mailed: Attention Administrative Assistant, Office of the Chief Medical Officer of Health, NS Department of Health and Wellness, 1894 Barrington St, Barrington Tower, PO Box 488, Halifax NS, B3J 2R8.
- For urgent serious AEFI, DHW may be contacted by phone at 902-424-8160

8 Summary of Reporting Criteria

For events with reporting criteria for a physician diagnosis, where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner.

8.1 Local Reaction

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ①	
		Inactivated Vaccines	Live Attenuated Vaccines
LOCAL REACTION AT INJECTION SITE			
Abscess, Infected	<ul style="list-style-type: none"> • Material from abscess known to be purulent (positive gram stain or culture) OR • There are one or more signs of localized inflammation (erythema, pain to light touch, warmth) AND • Evidence of improvement on antimicrobial therapy OR • Physician-diagnosed 	0 – 7 days	0 – 7 days

Abscess, sterile	<ul style="list-style-type: none"> • Physician diagnosed AND any of the following: • Material from mass is known to be non-purulent • Absence of localized inflammation • Failure to improve on antimicrobial therapy 	0 – 7 days	0 – 7 days
Cellulitis	<ul style="list-style-type: none"> • Physician-diagnosed AND • Characterized by at least 3 of the following: pain or tenderness to touch, erythema, induration or swelling, warmth 	0 – 7 days	0 – 7 days
Nodule	<ul style="list-style-type: none"> • Is more than 2.5 cm. in diameter AND • Persists for more than 1 month 	0 – 7 days	0 – 7 days
Pain or Redness or Swelling	<ul style="list-style-type: none"> • Pain or redness or swelling extends past the nearest joint AND/OR • Pain or redness or swelling that persists for 10 days or more 	0 – 48 hours	0 – 48 hours

① The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

8.1.1 Abscesses at Injection Site

Definitions²:

Infected abscess: a confirmed localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues.

The abscess may be confirmed by spontaneous or surgical drainage of material from the mass, imaging technique (e.g., ultrasound, CT or MRI)

Sterile abscess: an abscess whose contents are not caused by pyogenic bacteria.

Reporting criteria:

a) Infected abscess

- Material from the abscess is known to be purulent (positive gram stain or culture)
- OR**
- There are one or more signs of localized inflammation (erythema, pain to light touch, warmth)
- AND**
- Evidence of improvement related to antimicrobial therapy **OR**
 - Physician-diagnosed

b) Sterile Abscess

- Physician diagnosed

AND any of the following:

- Material from the mass is known to be non-purulent
- Absence of signs of localized inflammation (erythema, pain to light touch, warmth)
- Failure to improve on antimicrobial therapy

Discussion:

An abscess is a fluctuant (i.e., there is a wave-like motion on palpitation due to liquid content) or draining fluid - filled lesion at the injection site, with or without fever, and generally seen within 7 days of vaccine receipt. An abscess at the injection site is a rare local reaction. Contamination of multidose vials (re-entering vial with a used needle, improper cleaning or improper storage) can result in infection and abscess formation. Sterile abscesses are typically not accompanied by fever. Sterile abscesses are primarily associated with aluminium-absorbed vaccines and may occur when these vaccines are injected into subcutaneous tissue instead of muscle. They are believed to be the result of irritation from components of the vaccine, especially the adjuvant.

Manage abscesses with analgesics (e.g., acetaminophen, and ice to injection site). Incision and drainage of infected abscess and antimicrobials may be required.

Recommendations:

Abscesses are not a contraindication to further doses of vaccine. Use an alternate site for the next dose. Ensure aseptic technique is used, and the correct needle length is used for an intramuscular injection.

8.1.2 Cellulitis

Definition:

Cellulitis³: an acute, infectious, expanding inflammatory condition of the skin, located in subcutaneous tissue, fat, fascia or muscle at the vaccine injection site.

Reporting Criteria:

- Physician diagnosed

AND

- Characterized by at least 3 of the following local signs or symptoms:
 - i) Pain or tenderness to touch
 - ii) Erythema
 - iii) Induration or swelling
 - iv) Warmth

Laboratory culture results would confirm the diagnosis, but such results are seldom available.

Discussion:

Cellulitis is a rare adverse event following immunization. It is distinguished from the expected local reactions by its intense erythema, tenderness to light touch, presence of induration, and substantial local warmth. Cellulitis is usually caused by infection with streptococci, staphylococci, or similar organisms. It can result from bacterial contamination of the vaccine during the manufacturing process, contamination of a vaccine vial or injection equipment, or can be due to introduction of surface bacteria into the deeper layers of the skin. Injection site cellulitis is generally seen within 7 days of vaccine receipt. Cellulitis is commonly treated with antimicrobials as it is generally a bacterial infection.

Recommendation: Cellulitis is not a contraindication to further doses of vaccine. Use an alternate site for the next injection. Ensure aseptic technique is used.

8.1.3 Nodule**Definition:**

Nodule⁴: a firm, small mass of tissue at the injection site with discrete or well demarcated borders in the absence of abscess formation, erythema and warmth.

Reporting Criteria:

- Nodule is more than 2.5 cm in diameter

AND

- Nodule persists for more than 1 month

Discussion:

Nodules are mainly associated with aluminium-adsorbed vaccines, particularly if the dose is deposited subcutaneously rather than intramuscularly. Sterile nodules can take up to 1 year or more to resolve, but most commonly resolve within 2 to 3 months.

Recommendation:

Nodules are not a contraindication to further doses of vaccine. Use an alternate site for the next dose. Use the correct length of needle for intramuscular injections.

8.1.4 Pain, Redness and Swelling**Definitions**^{4, 5, 6}

Swelling: a visible enlargement of a limb at the site of the injection(s).

Reporting Criteria:

One or both of the following:

- Pain or redness, or swelling extends past the nearest joint
- Pain or redness, or swelling persists for 10 days or more

Discussion:

Pain, redness and swelling at the injection site are common reactions to vaccine. These reactions tend to occur within 48 hours of vaccination. The injection of foreign material into the tissues and irritation of the tissues by the process of injection can produce an inflammatory response. These local reactions are well-reported in clinical trials.

An Arthus reaction is a large, localized reaction characterized by pain, swelling, induration and edema. The reaction usually begins 2 to 12 hours following immunization and develops gradually over a period of hours. The reaction is due to circulating antigen-antibody complexes formed when there is a large amount of circulating antibody prior to injection of the antigen. This results in extensive swelling at the injection site which may involve the entire limb. Most arthus reactions resolve within one week.

An Arthus reaction in a young infant is probably due to high levels of maternal antibody in the child's blood. Arthus reactions may be seen with too frequent boosters of tetanus-containing vaccines, and have been observed following repeat doses of pneumococcal polysaccharide vaccine after short intervals. Manage pain and swelling with cold compresses at the injection site, and analgesics, if required. Avoid pressure on the injection site.

Recommendations:

Local reactions are not a contraindication to further doses of vaccine. If an Arthus reaction occurs with the initial dose in the primary infant series defer subsequent doses of the same vaccine for several months to await decline of maternally-acquired antibodies. If the child will be less than 6 months of age for the scheduled second dose, it should be deferred until 6 months of age and the third dose given 2 months later. Deferral is not necessary if the next dose of the vaccine is due when the child is ≥ 6 months of age because circulating maternal antibody will be greatly reduced.

If an Arthus reaction occurs with a tetanus-containing booster, future boosters can be spaced at longer intervals.

8.2 Systemic Reactions

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ❶	
		Inactivated Vaccines	Live Attenuated Vaccines
SYSTEMIC REACTIONS			
Adenopathy/ Lymphadenopathy	<ul style="list-style-type: none"> • Physician-diagnosed AND • Enlargement of one or more lymph nodes, ≥ 1.5 cm in diameter AND/OR • Draining sinus over a lymph node 	0 – 7 days	MMR: 5 – 30 days Varicella: 5 – 42 days
Fever	<ul style="list-style-type: none"> • Fever $\geq 38^{\circ}\text{C}$ that occurs in conjunction with another reportable adverse event 		
Hypotonic-Hyporesponsive Episode (HHE)	<ul style="list-style-type: none"> • Physician-diagnosed AND • Reduced muscle tone AND • Hyporesponsiveness or unresponsiveness AND • Pallor or cyanosis AND • Child less than 2 years of age 	0 – 48 hours	0 – 48 hours
Parotitis	<ul style="list-style-type: none"> • Physician-diagnosed parotitis following immunization with a mumps-containing vaccine 	N/A	MMR: 5-30 days
Orchitis	<ul style="list-style-type: none"> • Physician-diagnosed orchitis following immunization with a mumps-containing vaccine 	N/A	MMR: 5-30 days
Rash	<ul style="list-style-type: none"> • Inactivated vaccines: generalized rash for which medical attention is sought, when the rash is believed to be caused by the vaccine, and for which no alternative cause has been identified OR • Live vaccines: an expected rash following a live vaccine that requires hospitalization 	0 – 7 days	MMR: 0 – 30 days Varicella: 0 – 42 days
Screaming/ persistent crying	<ul style="list-style-type: none"> • Crying is continuous/ unaltered AND • Lasting for 3 or more hours 	0 – 72 hours	0 – 72 hours
Severe Vomiting/ Diarrhea	<ul style="list-style-type: none"> • 3 or more episodes of vomiting or diarrhea in a 24-hour period AND • Symptoms are severe, i.e., projectile vomiting or explosive, watery diarrhea 	0 – 72 hours	0 – 72 hours 0-7 days for Rotavirus

❶ The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

8.2.1 Adenopathy/Lymphadenopathy

Definitions:

Adenopathy or lymphadenopathy can include:

- Enlargement of one or more lymph nodes.
- Regional Adenopathy: abnormal enlargement of the lymph nodes closest to the injection site (e.g., inguinal adenopathy when associated with an IM injection in the thigh, axillary adenopathy associated with an IM injection in the deltoid).
- Draining sinus over a lymph node,
- Lymphadenitis: inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.
- Lymphangitic streaking: painful and inflamed red streaks below the skin's surface, following the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes.

Reporting Criteria:

- Physician-diagnosed **AND**
- Enlargement of one or more lymph nodes, ≥ 1.5 cm in diameter **AND/OR**
- Draining sinus over a lymph node

Discussion:

Live vaccines produce a low-grade infection which can include adenopathy. With any vaccine injection, if bacteria contaminate the injection site, adenitis may occur as part of the resulting infection. Adenitis in injection site-associated infections would usually occur first in the lymph nodes draining the injection site. The adjuvanted pH1N1 (2009) vaccine was known to be associated with axillary or supraclavicular lymph node tenderness.

Recommendation:

Adenopathy is not a contraindication to further doses of vaccine. Continue with further immunizations at a different injection site. Use aseptic technique.

8.2.2 Fever

Definition:

Fever⁷: elevation of temperature above the normal body temperature (37°C; 98.6°F).

Reporting Criteria:

- Fever $\geq 38^{\circ}\text{C}$ that occurs **in conjunction with** another reportable adverse event

Discussion:

Fever is a common expected systemic reaction that generally occurs within 72 hours of immunization with inactivated vaccines. Injected protein can affect the body's heat regulation. Fever following immunization with a live vaccine may occur at a later time (e.g., commonly 5-14

days after MMR or varicella vaccines). These delayed fevers result from a low grade non-transmissible infection produced by the live vaccine viruses.

A fever that occurs following immunization may not be due to the vaccine. Viral and bacterial illnesses are very common in children and can result in signs and symptoms similar to those which may occur following immunization. Evaluate fevers for other causes unrelated to immunization so treatment is not delayed for serious conditions. Consider intercurrent illness and other potential causes when interpreting an adverse events following immunization.

Recommendation:

Fevers are not a contraindication to further doses of vaccine. Please refer to the [Loving care documents](#) and the [HealthLink 811 Health File](#) for further detail related to fever management.

8.2.3 Hypotonic-Hyporesponsive Episode (HHE)

Definition⁸

HHE: the sudden onset, in a child under 2 years of age, of reduced muscle tone, **AND** either hyporesponsiveness or unresponsiveness, **AND** either pallor or cyanosis.

Reporting Criteria:

- Physician - diagnosed HHE in a child < 2 years of age

Discussion:

With a hypotonic-hyporesponsive episode, there is an acute decrease in sensory awareness or loss of consciousness, accompanied by pallor and muscle hypotonicity. Most reported episodes occur between 1 and 12 hours after immunization. Children are initially irritable and may be febrile. They then become pale, limp, and unresponsive or hyporesponsive. Respirations are shallow and cyanosis is frequently noted. As a result, parents may report that the child was not breathing. These episodes are usually transient (lasting a few minutes) and self-limiting.

HHE has been documented to occur after immunization with diphtheria, tetanus, *Haemophilus influenzae* type b, and hepatitis B vaccines. Most reported episodes have followed administration of pertussis-containing vaccines; there has been a decline in these reports with the use of acellular pertussis vaccines. HHE has been observed most frequently during the primary immunization series, mainly after the first dose. The cause of these episodes is unknown but they are most consistent with fainting spells. Some HH episodes may represent atonic seizures, consisting of sudden loss of postural tone and consciousness, perhaps triggered by fever. Other cases have been confused with anaphylaxis or hypoglycemia. Follow-up of children who have had hypotonic-hyporesponsive episodes has demonstrated complete recovery without persistent neurologic or developmental defects. No treatment is necessary. If the HH episode does not resolve spontaneously, other underlying problems should be sought and ruled out or treated.

Recommendation: HHE is not a contraindication to further doses of the same vaccine.

8.2.4 Parotitis

Definition:

Parotitis: inflammation of one or both parotid salivary glands with accompanying pain and tenderness.

Reporting criteria:

- Physician-diagnosed parotitis occurring 5-30 days following immunization with a mumps-containing vaccine.

Discussion:

Parotitis is a common manifestation of mumps infection. Since the mumps vaccine is a live virus vaccine, low-grade infection following immunization can occasionally produce the same manifestation. Vaccine-associated parotitis occurs most commonly 10 to 14 days after vaccination. It is transient and self-limiting, and can be managed with analgesics, as required and adequate fluid intake.

Recommendation:

Parotitis is not a contraindication to a future dose of a mumps-containing vaccine.

8.2.5 Orchitis

Definition ^{10, 11}:

Orchitis or inflammation of the testes may occur in pre-pubertal males. Primary orchitis is uncommon except with certain viral diseases, with mumps being the most common. Less frequently enterovirus or rarely adenoviruses, varicella-zoster virus, or West Nile virus is the causative agent. Orchitis can also be caused by bacterial infections.

When caused by mumps virus, orchitis usually occurs 4 to 8 days after parotitis but can develop up to 6 weeks later with or without parotitis. Viral orchitis can begin gradually but onset is usually abrupt when associated with mumps and preceded by fever, chills, nausea, and lower abdominal pain. The mumps virus can be detected in the semen for 14 days and mumps RNA can be detected for up to 40 days after wild type mumps infection. Identification of the virus following vaccine is less frequent. Laboratory testing can differentiate the wild type virus from the vaccine strain mumps virus. A recent publication of 3 cases following MMR receipt in Australia hypothesizes an immune mediated mechanism for mumps vaccine associated orchitis.

Reporting Criteria:

Physician diagnosed.

Discussion:

Mumps is a live attenuated virus vaccine; therefore, it is biologically plausible for orchitis to be associated with mumps vaccine. Case reports in the literature are rare. ^{12, 13 14} There are also rare reports of higher rates of orchitis following use of mumps vaccine attributable to a

mutated vaccine strain¹⁵ or inadequately attenuated vaccine¹⁶, in both instances in association with the Leningrad-Zagreb strain of the vaccine.

Recommendation:

A history of orchitis temporally associated with mumps vaccine is not a contraindication to further doses of the vaccine. Wild type mumps virus orchitis rarely causes infertility, even when bilateral, and infertility as a complication of mumps vaccination has not been described. Management of viral orchitis is supportive with symptomatic management of pain with analgesics and rest. Corticosteroid treatment is not recommended. Early treatment of mumps orchitis with interferon- α 2B in a single randomized trial suggested that it may lead to earlier symptom resolution and return to normal sperm count and motility.¹²

8.2.6 Rash

Definition¹⁷:

Rash: a temporary eruption of the skin

Reporting Criteria:

- Generalized rash, for which medical attention is sought, when the rash occurs within 7 days of immunization with an inactivated vaccine, is believed to be due to the vaccine, and for which no alternative cause has been identified **OR**
- An expected rash following MMR (up to 30 days) or varicella vaccine (up to 42 days) that requires hospitalization.

Note: A rash diagnosed as hives should be reported as an [allergic reaction](#).

Discussion:

MMR vaccine may produce a mild, non-transmissible measles-like illness which can be manifested by a generalized rash and fever. It occurs in 5-10% of persons following the first dose of MMR, usually 7 to 12 days (range 5-30 days) after vaccination. It is much less common following the second dose of MMR.

An erythematous, maculopapular, measles-like rash should be distinguished from a petechial rash. Petechiae are small, purplish, hemorrhagic spots on the skin that do not blanch with pressure. Petechial rashes should be referred for consultation to determine if further doses of the vaccine should be administered (see [8.5.4 Thrombocytopenia](#)).

A localized varicella-like rash occurs at the injection site in 3%-5% of individuals after a first dose of varicella vaccine, and in 1% of individuals after a second dose. A similar proportion of individuals will develop a small number of generalized varicella-like papules or vesicles. Lesions usually appear within 5 to 26 days of immunization. A varicella-like rash is rarely transmissible.

Most rashes occurring in children, even those temporally related to immunization, are caused by intercurrent viral illness.

A generalized rash is more likely to be vaccine-associated if it is accompanied by a local reaction at the injection site. The absence of a local reaction weakens the likelihood of a relationship between the reaction and the vaccine.

Recommendation:

Rashes other than petechial rashes are not a contraindication to further doses of a vaccine.

8.2.7 Screaming/Persistent crying

Definition¹⁸:

Crying of infants and children that is continuous and unaltered.

Reporting criteria:

- Screaming or persistent crying [continuous, unaltered (i.e., the quality of the crying does not change throughout the episode)] **AND**
- Onset within 72 hours of vaccine receipt and lasting for 3 or more hours

Discussion:

Crying in children is a common reaction to painful stimuli. Most often, the crying immediately following immunization is short-lived, has a familiar sound, and is viewed as normal by parents. However, parents are concerned when crying is prolonged, persistent, and high-pitched, and the infant is inconsolable. Use analgesics as prescribed to control pain. Products containing acetylsalicylic acid (ASA) should **not** be given to children because of their association with Reye syndrome.

Recommendation:

Persistent crying is not a contraindication to further doses of vaccine.

8.2.8 Severe Vomiting/Diarrhea

Definitions:

Vomiting: ejecting stomach contents through the mouth

Diarrhea¹⁹: abnormally frequent discharge of loose or watery fecal matter from the bowel

Reporting Criteria:

- 3 or more episodes of vomiting or diarrhea in a 24-hour period
- AND**
- Vomiting or diarrhea is severe, i.e. projectile vomiting or explosive, watery diarrhea.

Discussion:

Nausea and diarrhea have been particularly associated with oral typhoid vaccine, human diploid cell rabies vaccine (HDCV), and Japanese B encephalitis vaccine. In clinical trials, diarrhea was not more frequent in infants following receipt of rotavirus vaccines compared to placebo. Treat severe vomiting/diarrhea symptomatically to prevent dehydration and electrolyte imbalance.

Recommendation: Severe vomiting or diarrhea is not a contraindication to further doses of a vaccine.

8.3 Allergic Reactions

Adverse event Following Immunization	Reporting Criteria	Temporal Criteria ❶	
		Inactivated Vaccines	Live Attenuated Vaccines
ALLERGIC REACTIONS			
Anaphylaxis	<ul style="list-style-type: none">Any event managed as anaphylaxis following immunization	0 – 24 hours	0 – 24 hours
Oculo-respiratory syndrome (ORS)	<ul style="list-style-type: none">Bilateral red eyes ANDRespiratory symptomsFollowing influenza vaccine	0 – 24 hours	0 – 24 hours
Other Allergic reactions	<ul style="list-style-type: none">Skin ORRespiratory ORGastrointestinal manifestations	0 – 48 hours	0 – 48 hours

❶ The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

8.3.1 Anaphylaxis

Definition ²⁰:

Anaphylaxis: a rare but potentially life-threatening allergic reaction.

It is characterized by sudden onset, rapid progression of signs and symptoms and is set apart from simple allergic reactions by the simultaneous involvement of several organ systems.

Following appropriate clinical management of suspected anaphylaxis, complete the form titled "[Management of Anaphylaxis](#)" for the clinical record.

The [Brighton Collaboration](#) defines anaphylaxis according to diagnostic certainty, not clinical severity of the event. The highest level of diagnostic certainty, Brighton Level 1, is defined as

- ≥ 1 major dermatological

AND

- ≥ 1 major cardiovascular or ≥1 major respiratory criterion.

Brighton offers a tool to determine level of certainty for anaphylaxis, available at

<https://brightoncollaboration.org/public/resources/abc-tool/confirm-diagnosis.html>

This site requires registering with a user name and password.

A minority of cases reported as anaphylaxis will meet Level 1 degree of certainty. This may be because when suspected anaphylaxis is managed appropriately and promptly, escalation of symptoms and progression to a severe outcome is avoided.

Anaphylaxis must be distinguished from fainting (vasovagal syncope), breath-holding spells and anxiety, which are not reportable. Symptoms that are progressive or increasing in severity are more likely to represent anaphylaxis.

For management of anaphylaxis refer to the [NS Immunization Manual Chapter 10](#) – Vaccine-Related Emergencies. Provide a copy of the “[Management of Anaphylaxis](#)” form to the MOH with the AEFI report for review.

Reporting Criteria:

- Managed as anaphylaxis at the time of occurrence
- Occurs within 24 hours of immunization

Recommendation:

A true anaphylactic reaction to a vaccine is a **contraindication** to receipt of further doses of the same vaccine or to a component of a vaccine. Referral to the primary health care provider for consultation with an allergist may be sought to identify the component to which the client has hypersensitivity. It is important to avoid leaving clients inadequately immunized if they unnecessarily avoid vaccines to which they are not, in fact, hypersensitive. In addition, not knowing the particular component of a vaccine to which the client is allergic may pose a risk from future vaccines that contain the same component.

8.3.2 Oculo-respiratory Syndrome (ORS)

Definition:

ORS: the onset of bilateral red eyes and/or respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) with or without facial oedema, following influenza vaccine.

Reporting criteria:

- Bilateral red eyes **AND** respiratory symptoms **AND**
- Onset within 24 hours of influenza vaccine receipt.

Recommendation:

Most people who have had ORS after a previous dose of influenza vaccine do not experience it again. The event recurs in about 5 to 34% but it is usually milder. Most people who have experienced ORS can be safely revaccinated.

When an individual has had severe ORS symptoms such as wheeze, chest tightness/discomfort, difficulty breathing or severe throat constriction/difficulty swallowing following influenza vaccine and has not received influenza vaccine since, this is considered to be a precaution to future receipt of influenza vaccine. Such individuals who wish to receive influenza vaccine should consult with their primary health care provider and Medical Officer of Health for an expert review to distinguish between severe ORS and any anaphylaxis risk.

8.3.3 Other Allergic Reactions

Discussion:

Allergic reactions constitute a spectrum, the extreme end of which is anaphylaxis. Milder forms of allergic reactions may involve only dermatologic/mucosal, respiratory or gastrointestinal systems.

An allergic reaction is an acquired hypersensitivity to an antigen that does not normally produce such a reaction. Antigen-antibody complexes stimulate the release of chemicals, such as histamine, that produce overt signs and symptoms of hypersensitivity. An allergic reaction can occur in response to a component of a vaccine in a person previously sensitized (i.e. antibodies must be present from a previous exposure to the antigen.) When reported as an adverse event, enquire about a history of allergies and possible exposure to other allergens during the same time period. Refer to the [NS Immunization Manual Chapter 10](#) – Vaccine-Related Emergencies.

Allergic reactions may be limited to one system only and may include:

- i) Skin manifestations: urticaria (hives), erythema, pruritus, or prickle sensation, and localized or generalized edema (in the deeper layers of the skin, subcutaneous tissues or mucosa lining the throat, airways and gut.)
- ii) Respiratory manifestations: sneezing, wheezing, stridor, sensation of throat closure, sore throat, rhinorrhea, hoarse voice, dry cough, tachypnea, grunting, difficulty breathing, difficulty swallowing, indrawing/retractions, chest tightness or cyanosis.
- iii) Gastrointestinal symptoms: nausea, vomiting, or abdominal pain.

The vast majority of recognized 'other allergic reactions' following immunization are dermatological. Isolated gastrointestinal reactions are uncommon and / or difficult to differentiate from other causes such as gastroenteritis, and respiratory manifestations such as wheezing more commonly occur in those with a pre-existing diagnosis of asthma and are difficult to differentiate from an exacerbation of asthma. Therefore, the recommendations below are based on the temporal relationship between vaccination and the onset of dermatological manifestations. The presence of hives at the injection site is considered

important in the assessment of the likelihood that event was associated with the vaccine, as an IgE mediated reaction due to the deposition of the vaccine along the needle track indicates hypersensitivity to the product component(s).

Reporting criteria:

Allergic reactions occurring within 48 hours of immunization.

Note: If consultation on a rash is planned to be sought from a secondary provider who will be unable to assess the client in person it is recommended that photos be taken of the rash with client consent to further inform the consultation and recommendation.

Recommendation:

1. Generalized hives occurring from 0- 2 hours after immunization: (cause and effect likely):

Refer to primary health care provider with a recommendation for further assessment by an allergist prior to further doses of the same vaccine or its components.

2. Hives occurring from 2- 48 hours following immunization: (cause and effect less likely):

Consider providing next dose of the vaccine in a physician's office or an emergency setting and observe the patient for one to two hours following immunization. If there is no reaction following this dose, further immunization can be given in the routine setting. If a hive-like rash reappears with this dose, particularly a generalized rash appearing within 48 hours of vaccination dose, refer to primary care physician, with a recommendation for further assessment by an allergist prior to further doses of the same vaccine or its components.

3. Hives occurring \geq 48 hours after immunization: (cause and effect link unlikely):

Consider giving next vaccine dose under routine conditions. Consider other potential causes of the hives, particularly if there was no reaction at the injection site.

8.4 Neurological Events

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ❶	
		Inactivated Vaccines	Live Attenuated Vaccines
NEUROLOGICAL EVENTS			
Anaesthesia/ paresthesia	<ul style="list-style-type: none"> Physician diagnosed anaesthesia or paresthesia lasting 24 hours or more 	0 – 15 days	MMR: 0 – 30 days Varicella: 0 – 42 days
Bell's Palsy	<ul style="list-style-type: none"> Physician diagnosed Bell's Palsy 	0 – 3 months	
Convulsion/ seizure	<ul style="list-style-type: none"> Seizures (febrile or afebrile) Include temperature if febrile seizure reported 	0 – 72hours	MMR: 5 – 30 days Varicella: 5 – 42 days
Encephalopathy / Encephalitis	<ul style="list-style-type: none"> Physician diagnosed encephalopathy or encephalitis 	0 – 42 days	MMR: 5 – 30 days Varicella: 5 – 42 days
Acute Disseminated Encephalomyelitis (ADEM)	<ul style="list-style-type: none"> Physician diagnosed monophasic ADEM with no other cause identified 	0 – 42 days	MMR: 5 – 30 days Varicella: 5 – 42 days
Myelitis/Transverse Myelitis	<ul style="list-style-type: none"> Physician diagnosed transverse myelitis 	0-6 weeks	
Subacute sclerosing panencephalitis (SSPE)	<ul style="list-style-type: none"> Physician diagnosed SSPE 	NA	Up to 10 years following immunization with a measles-containing vaccine
Guillain-Barré syndrome (GBS)	<ul style="list-style-type: none"> Physician diagnosed GBS 	0 – 56 days	
Meningitis	<ul style="list-style-type: none"> Physician diagnosed meningitis for which no other cause has been identified 	N/A	MMR: 5 – 30 days Varicella: 5 – 42 days
Vaccine Associated Paralytic Poliomyelitis	<ul style="list-style-type: none"> Physician diagnosed paralytic poliomyelitis 	N/A	OPV: 5 to 30 days

❶ The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

8.4.1 Anaesthesia/Paraesthesia

Definitions:

Anaesthesia: the loss of normal feeling or sensation; numbness

Paraesthesia: abnormal physical sensation such as tingling, burning or prickling.

Reporting Criteria:

- Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more
- Beginning up to 15 days following administration of inactivated vaccines, up to 30 days following MMR, or up to 42 days following varicella vaccine.

Supporting documentation of the diagnosis should be included with the adverse event report.

Discussion:

The cause of anaesthesia or paraesthesia following vaccination is often not determined. It may be related to deposition of the vaccine close to a nerve, with subsequent pressure causing symptoms. There is no specific treatment. Investigation by a neurologist should be done to rule out permanent nerve damage.

Recommendation:

If the cause is related to injection technique, avoid the site for future injections. In most cases, immunizations can continue. Proper landmarking of the injection site is important.

8.4.2 Bell's Palsy

Definition:

Bell's palsy: a unilateral paralysis or weakness of facial muscles.

Reporting criteria:

- Physician-diagnosed Bell's palsy occurring within 3 months of immunization.

Discussion:

The cause of Bell's palsy is not clear. There is a consideration that a viral infection such as viral meningitis or the herpes virus may be linked to Bell's palsy, since these infections can cause inflammation that can damage the nerve that controls muscles on one side of the face.

Although some variation in the prevalence of Bell's palsy has been reported, it does not appear to occur in a seasonal pattern. Influenza infection does not appear to be a precipitating event for Bell's palsy.

In only a single instance was Bell's palsy known to be causally related to vaccine. An intranasal inactivated influenza vaccine used only in Switzerland was removed from the market after an increase in cases of Bell's palsy was noted ²¹.

Recommendation: A temporal association between vaccine receipt and Bell's palsy onset is expected to be coincidental. Bell's palsy would not be a contraindication to further doses of vaccine

8.4.3 Convulsion/seizures

Definition²²:

Seizure(s): Episode(s) of hyperactivity in the brain resulting in sudden, involuntary muscle contractions and abnormal behaviour, loss or impairment of consciousness.

Reporting Criteria:

- Seizures (febrile or afebrile) that occur within 72 hours of inactivated vaccines, 5-30 days after MMR, or 5-42 days following varicella vaccine.

Specify in the reporting whether the seizure was afebrile or febrile; if febrile, include the temperature.

Discussion:

Seizures include paroxysms of generalized tonic skeletal muscle contractions and generalized clonic jerking, usually associated with decreased level of consciousness. Seizures may last for several minutes or more.

An abrupt rise in temperature is a risk factor for febrile seizures in susceptible children. Febrile seizures are the most common seizure disorder of childhood, and are age-dependant. They are rare prior to 6 months of age and after 5 years of age, with peak onset at 14-18 months of age. Incidence in this age group approaches 2-5%, with greater risk in those with a family history. While simple febrile seizures are disturbing for the child and parents, they have a uniformly excellent prognosis without residual sequelae and remit on their own as the child ages. There are no long-term sequelae, such as permanent brain damage, associated with simple febrile seizures. Remind parents that children susceptible to febrile seizures may have a recurrence following immunization or following other events, such as viral infections. Pre-emptive treatment with antipyretics such as acetaminophen has not been shown to prevent febrile seizures in such children.

Recommendations:

Uncomplicated febrile seizures are not a contraindication to further doses of a vaccine. Refer to the primary care physician, with a recommendation for a consultation with a neurologist when the febrile seizures are multiple or prolonged (complex seizures) (status epilepticus), or when the seizures are afebrile, to rule out an underlying disorder

8.4.4 Encephalopathy/Encephalitis,

Definitions¹⁵:

Encephalopathy: a term used to describe a constellation of signs and symptoms reflecting a generalized disturbance in brain function.

Encephalitis: inflammation of the brain.

Reporting Criteria:

- Encephalopathy or encephalitis diagnosed by a physician.
- Include appropriate medical documentation, physicians' assessments and test results, with the adverse event report.

Discussion:

Acute **encephalopathy** is the sudden onset of major neurological illness temporally linked with immunization and characterized by two of the following:

1. Severe alteration in level of consciousness or unresponsiveness, with or without generalized or focal convulsions. The symptoms must persist for more than a few hours, with failure to recover completely within 24 hours.
2. Increased intracranial pressure (as measured and diagnosed by a physician). A bulging fontanel as described by a parent to a nurse rather than observed by a physician is **not** sufficient to diagnose increased intracranial pressure. Intense crying can cause a bulging, pulsating fontanel.
3. Distinct change in behaviour or intellectual functions lasting one day or more and felt by a physician to indicate an alteration in neurological function.

Encephalitis includes central nervous system inflammation **AND** either >24 hours depressed or altered consciousness with one or more signs of reduced responsiveness **OR** one or more signs of focal or multi-focal central nervous system abnormality.

Immunizations may very rarely lead to acute encephalitis, particularly in the setting of live-attenuated viral vaccines. The risk of encephalitic complications from viral infections (1/1000 cases of measles; 1/6000 cases of rubella) is greater than the risk following vaccination (1/1,000,000 following MMR). Encephalitis has occurred rarely following Yellow Fever immunization in young infants and thus this vaccine is not recommended for infants less than 9 months of age.

Recommendation:

Encephalitis/Encephalopathy are not contraindications to further vaccination. Deferral of immunization may be considered until the neurologic condition has been diagnosed or is stable. If no other cause is found and the encephalopathy is temporally related to a combination vaccine, refer to a paediatric neurologist to determine which components of the vaccine may be continued.

8.4.5 Acute Disseminated Encephalomyelitis (ADEM)

Definition:

A uniphasic syndrome of brain inflammation and demyelination, occurring in temporal association with an antecedent immunologic challenge, which may rarely include immunization.

ADEM is distinguished from acute encephalitis by (a) a predominance of demyelinating, rather than cytotoxic injury and (b) a temporal association with a specific inciting immunogenic challenge²⁶.

Reporting Criteria:

Physician-diagnosed monophasic ADEM with no other cause identified. Monophasic nature of ADEM must be assessed after monitoring for 3 months from clinical nadir.

Discussion:

Clinically, ADEM may be difficult to distinguish from acute encephalitis in the early phase of the disease, presenting with global cerebral dysfunction, multifocal neurologic findings, and meningismus. The key distinguishing feature between these two conditions is the presence of acute demyelination, confirmed on MRI or by histopathology.

Various immunizations have been temporally associated with ADEM, including Japanese encephalitis, yellow fever, measles, influenza, smallpox, anthrax and others. However, the only epidemiologically and pathologically proven association of an antecedent event is with antirabies vaccination using the Semple rabies vaccine (a vaccine derived from sheep/ mouse brains (not used in NS). There has been no observed association with modern rabies vaccines. For most vaccines incidence rates are low (0.1-0.2 per 100,000 doses administered) compared to the reported 1 in 1000 incidence of post-infectious ADEM following infection with the measles virus.

Recommendation:

The decision to continue immunization must be made on a case-by-case basis. All cases should be evaluated by a neurologist.

8.4.6 Myelitis/Transverse Myelitis

Myelitis

Definition:

Myelitis is defined as inflammation of the parenchyma of the spinal cord.

Definition:

Transverse myelitis (TM) is an abrupt onset inflammatory demyelinating condition of the spinal cord that affects almost the entire thickness of the cord but spans only one or a few vertebral segments

Both of these conditions have multiple underlying causes similar to those associated with encephalitis/ ADEM, and include infectious, toxic, neoplastic, autoimmune, and metabolic etiologies but the most common are viral and post-viral, as well as multiple sclerosis or other autoimmune disease. Myelitis may occur in conjunction with encephalitis and transverse myelitis in conjunction with ADEM.

Reporting Criteria:

- Physician-diagnosed transverse myelitis with no other cause identified AND
- Occurring within 6 weeks of vaccine receipt.

Supporting documentation of the diagnosis should accompany the report.

Discussion:

In a 2009 systematic review of the relationship between transverse myelitis (TM) and vaccination, 43 cases of post-vaccination TM were identified in the literature between 1970 and 2009.^{24, 25} In 73% of cases, onset was within the first month post-vaccination and the age of patients ranged from several months to 50 years. Thirteen cases followed hepatitis B vaccination, 6 MMR, 4 DTP, 4 rabies, 3 OPV, 2 influenza, 1 typhoid vaccine, 1 pertussis, 1 Japanese B encephalitis and 2 in recipients of multiple vaccines.

In its recently published safety review of a number of vaccines, the Institute of Medicine (IOM) concluded that there is evidence of TM association to several of the diseases, with rare occurrences following wild type mumps, reactivated varicella zoster, and influenza; as well, measles and rubella can cause myelitis. However, the small number of case reports of TM associated with the vaccines reviewed by the Institute of Medicine (IOM) did not contain sufficient evidence of mechanisms such as autoantibodies, T cells, or molecular mimicry at play in such cases. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between MMR, varicella, influenza, hepatitis A and B, HPV, DPT and meningococcal vaccines and transverse myelitis.⁵²

Recommendation:

The decision to continue immunization must be made on a case-by-case basis. All cases should be evaluated by a neurologist.⁴⁵

8.4.7 Subacute Sclerosing Panencephalitis (SSPE)**Definition:**

SSPE^{27, 28}: a rare, degenerative central nervous system disease occurring as a late complication of measles infection (up to 10 years later).

Reporting criteria:

- Physician-diagnosed SSPE

Discussion:

SSPE is caused by persistence of defective measles virus in the central nervous system through means that are as yet unknown²⁹. It is characterized by behavioural and intellectual deterioration and convulsions due to inflammation of brain tissue. Seizures, blindness and dementia can occur. Remission occurs in only 4% of cases; it is otherwise fatal, and only supportive treatment exists. For vaccine-associated cases there is no temporal criterion for

reporting; as with cases following infection, the occurrence would be years following immunization.

The association between natural measles infection and SSPE has led to concern that live attenuated measles vaccine virus could also cause a persistent infection of the central nervous system. Genetic sequencing of viruses from the brains of patients with SSPE including those without a history of measles disease has only identified wild type measles virus.

Some reported cases of SSPE had history of measles vaccination and lacked a history of natural measles infection. If the vaccine indeed is associated rarely with SSPE, the risk following vaccination, if it exists, is estimated to be approximately one tenth or less of that noted after natural infection (less than 1/1,000,000 persons vaccinated versus 1/100,000 cases of measles). The results of a retrospective case control study by the Centres for Disease Control and Prevention suggest that the overall effect of measles vaccination has been to protect against SSPE by preventing measles disease. There has been a dramatic decline in the incidence of SSPE since the introduction of widespread measles immunization.

Recommendation:

A diagnosis of SSPE is a contraindication to receipt of a measles-containing vaccine.

8.4.8 Guillain-Barré syndrome (GBS)

Definition³⁰:

Guillain-Barré syndrome: an illness that includes acute onset of bilateral flaccid weakness/paralysis of the limbs with decreased or absent deep tendon reflexes. CSF test results, if available, must either be normal, or have <50 WBC/mm.

Reporting criteria:

- Physician-diagnosed GBS **AND**
- Occurring within 8 weeks after immunization

Provide documentation confirming the diagnosis.

Discussion:

Guillain-Barré syndrome is also called acute afebrile polyneuritis or acute idiopathic polyneuritis. It is a subacute, usually symmetrical ascending paralysis, with associated sensory disturbances. It can appear as a sequelae to a variety of infections after an interval of 1 to 8 weeks; approximately two-thirds of patients with GBS report an antecedent infectious illness, most commonly a diarrhoeal or respiratory illness, prior to the onset of neurologic signs; *Campylobacter jejuni* is the most commonly reported pathogen in adults. A maximum degree of weakness is reached from 12 hours to 28 days after onset, followed by a clinical plateau and then either improvement or death. Overall, approximately 5 – 15 % of patients die, and continued disability after 1 year has been estimated to be seen among 20% of patients. Studies in developed countries have suggested an incidence of 1-2 per 100,000 population per year.

There is limited evidence of an association between tetanus toxoid and GBS, and oral polio vaccine and GBS, in addition to a swine influenza vaccine (1976) that is no longer in use. While cases of GBS have been reported temporally associated with other vaccines (e.g., Menactra®), there is no evidence of a causal relationship.

Recommendation:

If GBS occurs in temporal relationship to a vaccine, subsequent doses of the same vaccine should only be given if the benefits of vaccination outweigh the risk of GBS recurrence if vaccine is given. There are no contraindications to immunization in persons with a previous history of GBS unrelated to vaccination.

8.4.9 Meningitis

Definition:

Meningitis: an infection or inflammation of the membranes covering the brain and spinal cord. It is characterized by sudden onset of fever, intense headache, nausea and vomiting, and pain and stiffness in the neck.

Aseptic meningitis³¹: a syndrome characterized by acute onset of signs and symptoms of meningeal inflammation, cerebrospinal fluid pleocytosis and the absence of microorganisms on Gram stain and/or on routine culture.

Reporting Criteria:

- Physician-diagnosed meningitis for which no other cause has been identified **AND**
- Occurring within 15 days of inactivated vaccines, 5-30 days following MMR, or 0-42 days following varicella vaccine.

Include medical documentation.

Discussion:

Measles and mumps viruses were important causative agents of aseptic meningitis before introduction of measles and mumps vaccines. Cases of aseptic meningitis have been reported after immunization with several live attenuated vaccines, including oral polio, MMR vaccine, varicella, yellow fever and smallpox. The postulated mechanism for aseptic meningitis following attenuated live virus vaccines is infection of the meninges with the vaccine virus. Such a causal relationship was established with the Urabe strain of mumps virus³² (1 case reported per 62,000 vaccinations), which is no longer used in vaccines in Canada. There is no evidence of a causal association with the Jeryl-Lynn strain of mumps used in MMR, or with any of the other routinely used live virus vaccines. Aseptic meningitis following immunization typically resolves without sequelae.

Recommendation:

Defer further vaccines until a determination is made as to the cause of the meningitis.

8.4.10 Vaccine Associated Paralytic Poliomyelitis

Definition:

Paralysis: loss of muscle tone and function with or without loss of sensation.

Reporting Criteria:

- Physician-diagnosed paralysis with no other cause identified **AND**
- Occurring within 5 -30 days following OPV, and lasting more than 24 hours.

Supporting documentation of the diagnosis should accompany the report.

Discussion:

Cases of paralytic poliomyelitis have been associated with oral polio vaccine (OPV). NS has used inactivated polio vaccine (IPV) exclusively since the mid-90s, and OPV has not been used since that time. In Canada from 1965 through 1992, vaccine-associated paralysis occurred in recipients of OPV at a rate of 1 case per 11.7 million doses of OPV distributed, and in contacts of vaccinees at a rate of 1 case per 3.1 million doses distributed.

Recommendation:

The decision to continue immunization must be made on a case-by-case basis. All cases should be evaluated by a neurologist.

8.5 Other events of interest

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ❶	
		Inactivated Vaccines	Live Attenuated Vaccines
OTHER EVENTS OF INTEREST			
Arthritis	<ul style="list-style-type: none"> • Physician-diagnosed • Lasting 24 hours or more 		MMR:5-30 days Varicella 0-42 days
Intussusception or hematochezia	<ul style="list-style-type: none"> • Physician-diagnosed intussusception or hematochezia 		Rotavirus vaccine: 0-42 days
Syncope with injury	<ul style="list-style-type: none"> • Syncope with injury following immunization 	0 – 30 minutes	0 – 30 minutes
Thrombocytopenia	<ul style="list-style-type: none"> • Physician-diagnosed thrombocytopenia 	0- 30 days	0 – 30 days
Other severe or unusual events❷	Refer to section 8.5.5	0 – 1 month	0 – 1 month

❶ The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

❷ Other serious or unusual events may include those events which:

- are life threatening or result in death; require hospitalization
- result in a residual disability; are associated with a congenital malformation
- require urgent medical attention
- have
 - not been identified previously (e.g., Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season), or

- been identified before but is occurring with greater frequency in the population (e.g. extensive local reaction) are clusters of events: known or new events that occur in a geographic or temporal cluster (e.g., 6 in a week, or 6 in a DHA.) that require further assessment, even if the total number of AEFIs may not be higher than expected.

8.5.1 Arthritis

Definitions:

Arthritis: joint inflammation, with swelling, redness and/or warmth

Arthralgia: joint pain.

Reporting criteria:

- Physician-diagnosed arthritis following receipt of a rubella-containing vaccine **AND**
- Lasting 24 hours or longer and associated with limitation of regular activities.

Discussion:

Arthritis is usually associated with arthralgia, but arthralgia may occur without obvious arthritis. Rubella vaccine-associated arthralgia involves, in order of decreasing frequency, the joints of the fingers, knees, wrists, elbows, ankles, hips and toes. Arthritis and arthralgia can be manifestations of natural rubella infection in adults.

Arthritis and arthralgia are recognized complications of rubella immunization. Reporting transient arthralgia is not necessary.

Transient acute arthritis or arthralgia has been shown to occur 7-21 days post immunization in susceptible adolescent and adult women immunized with the RA 27/3 strain of rubella (the strain in use in the measles-, mumps-, rubella-containing vaccine currently available in Canada). 25% of post-pubertal females develop arthralgia, while 10% develop arthritis-like signs and symptoms. Arthritis/arthralgia can also occur in children and adolescent and adult men, but at much lower rates. Persistence or recurrence of these symptoms is rare³³.

Analgesics or anti-inflammatory medications may be used to reduce inflammation, swelling and joint pain. Products containing acetylsalicylic acid (ASA) should **not** be given to children because of their association with Reye syndrome.

Recommendation:

Transient arthritis or arthralgia is not a contraindication to a further dose of MMR vaccine. Since the joint symptoms are likely related to seroconversion, the risk following a second MMR dose is lower than that following the first dose. It is important to offer rubella vaccine to seronegative women of childbearing age to reduce the risk of Congenital Rubella Syndrome.

8.5.2 Intussusception/Hematochezia

Definition:

Intussusception³⁴: the telescoping of one segment of the intestine with a neighbouring segment, most often the ileum into the colon, causing partial or complete intestinal obstruction. The walls of the two sections of intestine press on each other, causing irritation, swelling and eventually decreased blood flow.

Hematochezia: red blood in the stool, (described as “red currant jelly” material) which may be associated with intussusception.

Reporting criteria:

- Intussusception or hematochezia occurring within 42 days following rotavirus vaccine receipt.

Discussion:

Intussusception is an uncommon event. If left untreated, intussusception can cause internal bleeding, severe abdominal infection, and death of intestinal tissue. Intussusception is the most common cause of acute intestinal obstruction in infants and young children.

A rotavirus vaccine used in the United States was withdrawn from the market in 1999 because of the reported temporal association between the development of intussusception and receipt of the vaccine. New rotavirus vaccines have been licensed after undergoing large clinical trials to assess safety with regard to intussusception. Recent large-scale post-licensure trials in Mexico and Brazil found an association between rotavirus vaccine and intussusception with an excess of 1 case observed among 51,000 to 68,000 vaccinated infants.³⁵ A study from Australia found no overall increased risk of intussusception but did find some evidence of an elevated risk following the first dose of both rotavirus vaccines within the 1 to 7 and 1 to 21-day windows.³⁶

Recommendation:

Reports of intussusception following vaccination are not expected to exceed the number of cases that would be seen by chance alone. Intussusception following rotavirus vaccine is a contraindication for further doses of rotavirus vaccine. Hematochezia is not considered a contraindication to further doses of rotavirus vaccine

8.5.3 Syncope with Injury

Definition:

Syncope (vasovagal reaction) or fainting: a temporary unconsciousness caused by diminished blood supply to the brain.

Reporting criteria:

- Syncope **with injury** following immunization

Discussion^{37, 38:}

Syncope can be triggered by various stimuli, and is observed to occur following immunization, perhaps triggered by pain or emotional reaction to the immunization process itself. It happens suddenly, before, during, or after immunization. Recovery occurs within 1 – 2 minutes. Refer to the NS [Immunization Manual Chapter 10 – Vaccine-Related Emergencies](#) for signs, symptoms and management of syncope. The risk of fainting is the more common reason to keep vaccines under observation for 15 minutes post-immunization.

Syncope with injury has been reported following HPV vaccine and H1N1 vaccine receipt. These reports include head injuries after syncope-related falls, and motor-vehicle incidents where the individual lost consciousness while driving. Immunizers should be aware of presyncopal manifestations and take appropriate measures to prevent injuries if weakness, dizziness or loss of consciousness occurs. These events are potentially serious and may result in hospitalization, residual disability or death. They are related to the process of immunization, rather than to a specific vaccine.

Recommendation:

Syncope is not a contraindication to further immunizations.

8.5.4 Thrombocytopenia

Definition^{39, 40, 41}

Thrombocytopenia: an abnormal haematological condition in which the number of platelets is reduced to less than $150 \times 10^9/L$, accompanied by clinical signs and/or symptoms of spontaneous bleeding.

Petechiae: small, purplish, hemorrhagic spots on the skin that do not blanch with pressure.

Reporting criteria:

- Physician-diagnosed thrombocytopenia occurring within 30 days following vaccination.

Laboratory results should accompany the report.

Discussion:

Normal platelet counts are 150-450,000/mm. Thrombocytopenia can occur in persons of all ages. Approximately 70% of cases occur following viral illnesses, often in children. It can also occur as a complication of a variety of medications. Many cases are idiopathic. Most cases in children are mild and transient, although haemorrhagic complications can occur.

The incidence rate of thrombocytopenia is estimated to be between one in 25,000 to one in 40,000 doses of MMR. Most cases occur following vaccination with the first dose of measles-containing vaccine; the risk of recurrence is not known but is thought to be low.

Thrombocytopenia has also been reported following other vaccines such as diphtheria, pertussis and tetanus vaccine, and varicella.

Corticosteroids and gamma globulin may be used to treat idiopathic thrombocytopenia. Precautions should be taken, particularly for young children, to avoid the risk and complications of bleeding (e.g. precautions to avoid serious head injuries). Control of bleeding may be necessary, and transfusion of platelets may be required.

Recommendations:

Children with a history of thrombocytopenia may be at increased risk for developing thrombocytopenia after MMR vaccination. Such children should generally still be immunized because the benefits of immunization outweigh the risks. The risk of thrombocytopenia following natural measles or rubella infection is greater than the risk following immunization.

Children who develop thrombocytopenia temporally related to their first dose of MMR should be assessed for immunity to measles; if the child is susceptible, discuss the benefits/risks of revaccination with the parent. If proceeding with vaccination, ensure that the parent is aware of the potential risk of recurrence, watches the child closely for development of petechiae in the 2- 3 weeks post-vaccination, and is aware of the need for injury prevention.

8.5.5 Other Severe or Unusual Events

Criteria for Reporting:

Report other severe and unusual events with a temporal association to immunization, and for which there is no other known cause, and which are not covered under the categories previously described. These must be clinically intriguing or epidemiologically interesting events and they usually require medical intervention to meet the criteria for reporting. Provide all details of the event and include all necessary documentation with the report.

Report any death⁴² of a vaccine recipient temporally linked (within one month) to immunization, where no other clear cause of death can be established. Report fetal deaths that occur following immunization of the pregnant woman and deaths in infants diagnosed as Sudden Infant Death Syndrome when the investigation has concluded. Provide autopsy report when available.

Reporting of severe or unusual events is important not only to identify a possible causal relationship with vaccination, but also to rule out the vaccine as the cause. The severity of the adverse event and the plausibility of a causal association with vaccination will determine whether further doses of the implicated vaccine will be continued.

“Other severe or unusual” events may include those events which are:

Severe:

- are life threatening or result in death
- require hospitalization or result in a prolongation of a hospitalization
- result in a residual disability
- are associated with a congenital malformation

- require urgent medical attention

Unusual:

- have not been identified previously (for example, Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season)
- have been identified previously but are happening with greater frequency in the population
- are clusters of events: known or new events that occur in a geographic or temporal cluster (e.g., 6 in a week, or 6 in a DHA.) that require further assessment, even if the total number of AEFIs may not be higher than expected.

Frequently Used Acronyms

- AEFI- Adverse Event Following Immunization
- BGTD - Biologic and Genetic Therapies Directorate
- CAEFISS - Canadian Adverse Effects Following Immunization Surveillance System
- CIC - Canadian Immunization Committee
- CIRID- Centre for Immunization and Respiratory Infectious Disease
- GBS – Guillain-Barré syndrome
- HCP - Healthcare professional
- MOH - Medical Officer of Health
- PHAC - Public Health Agency of Canada

General References

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Appendix A: Instructions for NS [AEFI Reporting Form](#) Completion

AEFI form	AEFI form data fields	Definition
	Initial report	
	Follow up report	
1a	Unique episode #	The DHA to enter the ANDS Provincial Case Number preceded by NS prior to submission: e.g. NS-2012-05-0000
1b	Region #	Should be left blank.
2	IMPACT LIN	Do not complete this unless reporting on behalf of IMPACT.
3	Patient information	Provide the patient's first and last name, health number (if applicable), address of usual residence including postal code (with the understanding that this address might be in a different province/territory than where the vaccine(s) was administered or where the AEFI is being reported) and a telephone number (either residential or business or both), where the patient can be reached.
	First Name	
	Last Name	
	Health number	
	Address of usual residence	
	Province /Territory	
	Postal code	
	Phone:	
	Extension	
	Information source	
	First Name	
	Last Name	
	Relation to patient	
	Contact info, if different:	
4	Information at time of immunization and AEFI onset	
4a	At time of immunization:	Provide all information, as described below, in the space provided on the form:
	Province/Territory	Indicate the province or territory where the immunization was received.

AEFI form	AEFI form data fields	Definition
	Date of vaccine administration	Indicate the date and time of vaccine administration remembering to specify if the vaccine was administered in the “am” or “pm” by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g. month and/or year).
	Time	
	AM_PM	
	Date of birth (DOB)	Indicate the patient’s date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (e.g. month and/or year).
	Age	Indicate the patient’s age at the time of immunization. Use days for infant’s aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. Fractions should be used as appropriate (e.g., 6 weeks should be captured as 1.5 months; 15 months should be captured as 1.25 years). If the patient’s exact age is unknown, please estimate patient’s age.
	Sex:	Indicate the patient’s gender (e.g., male or female). If the gender is unknown or ambiguous, please choose “other”.
	Male	
	Female	
	Other	
4b	Medical history (up to the time of AEFI onset)	Indicate the patient’s medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details, when available, in section 10.
	Concomitant medication(s)	Provide the name of all medications, including prescription, over the counter and herbal supplements, which the patient had been taking immediately prior to the time of AEFI onset, including those taken only as needed in section 10. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.
	Known medical conditions/allergies	Indicate all known medical conditions and/or allergies that the patient experienced prior to the time of immunization with a corresponding date of onset in section 10. If an exact date of onset is unknown, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the patient is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.

AEFI form	AEFI form data fields	Definition
	Acute illness/injury	Indicate if the patient had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset in section 10 if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset).
4c	Immunizing agent	Please record the proper name or accepted abbreviation as outlined in Appendix II for all immunizing agent(s).
	Trade Name	Indicate the trade name of all vaccine(s) received.
	Manufacturer	Specify the name of the manufacturer as indicated on the product label.
	Lot number	Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.
	Dose #	Provide the number in series (1, 2, 3, 4, or 5) or indicate if known. For the Influenza vaccine, unless a patient receives two doses in one season, the “dose #” should be recorded as one.
	Dosage/unit	Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.
	Route	<p>Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable:</p> <ul style="list-style-type: none"> • Intradermal: ID • Intramuscular: IM • Subcutaneous: SC • Intranasal: IN • Oral: PO • Other: please specify (no abbreviations)
	Site	<p>Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:</p> <ul style="list-style-type: none"> • Left arm: LA • Right arm: RA • Arm: Arm • Left leg: LL • Right leg: RL • Leg: Leg

AEFI form	AEFI form data fields	Definition
		<ul style="list-style-type: none"> • Left gluteal: LG • Right gluteal: RG • Gluteal: Glut • Mouth: Mo • Nose: Nose • Multiple sites: MS • Other: please specify (no abbreviations)
5	Immunization errors	<p>Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing “no”, “unknown” or “yes”. If “yes”, please indicate all that apply in section 5 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in section 10.</p>
	Did this AEFI follow an incorrect immunization?	
	No	
	Unknown	
	Yes	
	Given outside the recommended age limits	The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.
	Product expired	The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days).
	Incorrect route	The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).
	Wrong vaccine given	An unintended vaccine was administered.
	Dose exceeded that recommended for age	A larger dose of vaccine was administered than is recommended for the patient’s age group.
	Other, specify	If an error has occurred that is not accurately reflected in the list of provided errors, please choose “other” and provide all details.
6	Previous AEFI	<p>Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents as listed in response to question 4c. Choose only one of the answers provided in section 6, as described below:</p>
	Did this AEFI follow a previous dose of any	

AEFI form	AEFI form data fields	Definition
	of the immunizing agents (Table 4c)?	
	No	The patient had previously received immunization with one or more of the immunizing agents listed in section 4c and had not experienced a subsequent AEFI.
	Yes (<i>provide details in section 10</i>)	The patient had previously received immunization with at least one of the immunizing agents listed in section 4c and had subsequently experienced an AEFI.
	Unknown	It is unknown if the patient had previously received immunization with any of the immunizing agents listed in section 4c and/or, if an AEFI followed.
	Not applicable	The patient had never previously received immunization with any of the immunizing agents listed in section 4c.
7	Impact of AEFI, Outcome, and Level of Care Obtained	Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 7a based on the patient's assessment of the impact on their daily activities:
7a	Highest impact: (<i>Choose one of the following</i>)	
	Did not interfere with daily activities	
	Interfered with but did not prevent daily activities	Moderate change is reported by the patient in relation to their daily activities (e.g., interfered with work, exercise and/or social commitments).
	Prevented daily activities	Significant change is reported by the patient in relation to their daily activities (e.g., prevented work, exercise and/or social commitments).
7b	Outcome at time of report	Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in section 7b. If the patient is not yet recovered, provide all available details in section 10 and provide updates as they become available. Similarly, should the event result in permanent disability and/or incapacity or death, provide all available details in section 10.
	Death	Patient died (record the corresponding date of death in the space provided)
	Date	

AEFI form	AEFI form data fields	Definition
	Permanent disability/incapacity	An injury which impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.
	Not yet recovered	Residual signs and/or symptoms remain (at the time of the report).
	Fully recovered	All signs and symptoms have resolved.
	Unknown	The outcome of the AEFI is unknown or unclear.
7c	Highest level of care obtained: <i>(choose one of the following)</i>	Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in section 7c.
	Unknown	It is unknown if the patient received care for the reported AEFI.
	None	No care was received for the reported AEFI.
	Telephone advice from a health professional	The patient received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI
	Non-urgent visit	The patient was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted in section 10.
	Emergency visit	The patient was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted in section 10.
	Required hospitalization: (days)	The patient was hospitalized for the assessment and/or treatment of the reported AEFI. Indicate the number of days the patient was hospitalized, the date of admission and the date of discharge. Document all investigations conducted in section 10.
	Resulted in prolongation of existing hospitalization by: (days)	If a patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please check: "Resulted in prolongation of existing hospitalization" and indicate the number of additional days stayed in hospital as a result of the AEFI. Also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all investigations conducted in section 10.
7d	Treatment received:	Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing yes, no or unknown.

AEFI form	AEFI form data fields	Definition
		Provide details of all treatments received, following the onset of the AEFI in section 10 when applicable.
	No	Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing yes, no or unknown. Provide details of all treatments received, following the onset of the AEFI in section 10 when applicable.
	Unknown	
	Yes (<i>provide details of all treatments including self-treatment, in section 10</i>)	
8	Reporter information:	Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/ setting/centre. Indicate the setting in which the reporter is located (e.g., physician office, public health clinic, hospital) or specify if other. Sign and date the AEFI form in the space provided and specify your professional status (e.g., MD: Medical Doctor; RN: Registered Nurse) or your affiliation (e.g., IMPACT) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.
	Setting:	
	Physician office	
	Public health	
	Hospital	
	Other, <i>specify</i>	
	Name	
	Phone, Extension	
	Fax	
	Address	
	City	
	Province/Territory	
	Postal code	
	Date reported	
	Signature:	
	MD	
	RN	
	IMPACT	
	Other, <i>specify</i>	
9	AEFI details	Indicate the details of the AEFI being reported by checking all that apply. All additional pertinent details (e.g., results of medical

AEFI form	AEFI form data fields	Definition
		<p>investigations, laboratory test, treatment, etc.) should be provided in section 10.</p> <p>For convenience and consistency, high level definitions have been provided for most events listed in section 9. However, if an asterisk (*) is present beside an AEFI term, this specific event should be diagnosed by a physician. If not, sufficient information should be provided (in section 10) to support the selection(s). For all AEFIs, indicate the time to onset or interval (time from immunization to onset of first symptom/sign), and the duration (time from onset of first symptom/sign to resolution of all of signs and symptoms). For each AEFI where a Brighton Collaboration Case Definition (BCCD) exists, the most current published version of the case definition has been cited.</p>
9a	Local reaction at or near vaccination site	Any description of morphological or physiological change at or near the vaccination site.
	Time interval - Mins	<p>Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes.</p> <ul style="list-style-type: none"> • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	Time interval - Hrs	
	Time interval - Days	
	Duration - Mins	
	Duration - Hrs	
	Duration - Days	
	Infected abscess	<p>A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues. (Note presence of any of the following by ticking the appropriate box on the form: erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details. If treated with antibiotics indicate if resolution/improvement was temporally related to treatment).</p>
	Sterile abscess	<p>An abscess whose contents are not caused by pyogenic bacteria. (Note presence of any of the following by ticking the appropriate box on the form: erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging</p>

AEFI form	AEFI form data fields	Definition
		technique, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details. If treated with antibiotics indicate if resolution/ improvement was temporally related to treatment).
	Cellulitis	A diffuse inflammatory process within solid tissues, characterized by edema, redness, pain, and interference with function, usually caused by infection with <i>streptococci</i> , <i>staphylococci</i> , or similar organisms. (Note presence of any of the following by ticking the appropriate box on the form: swelling, pain, tenderness, erythema, warmth, induration, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details).
	Nodule	Discrete, well demarcated soft tissue mass or lump at the vaccination site that has a firm texture and is not accompanied by erythema, warmth or abscess formation.
	Reaction crosses joint	Reaction extending past at least one joint adjacent to the site of vaccine administration.
	Lymphadenitis	Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.
	Other, specify	Specify all details of the vaccination site reaction in section 10 that are not already captured in section 9a above. Examples of “other” local reactions that may be reported here include necrosis, papule etc.
	<i>For any vaccination site reaction indicated above, check all that apply</i>	For all local reactions at or near the vaccination site, describe the signs and symptoms by checking all that apply from the list below. Provide any additional details in section 10:
	Swelling	Visible enlargement of the vaccinated limb that is assessed by any person, with or without objective measurement.
	Pain	An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony.
	Tenderness	Abnormal sensitivity to touch or release of pressure.
	Erythema	Abnormal redness of the skin.
	Warmth	A sensation/perception of an increase in temperature.
	Induration	Palpable thickening, firmness or hardening of soft tissue (subcutaneous tissue, fat, fascia or muscle) that is assessed by a health care provider.

AEFI form	AEFI form data fields	Definition
	Rash	A morphologically described change in the appearance of the skin or mucosa at or near vaccination site that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule), and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation).
	Largest diameter of vaccination site reaction (cm), Site(s) of reaction (e.g. LA, RA)	Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.
	Palpable fluctuance	Wavelike motion on palpation due to presence of liquid content.
	Fluid collection shown by imaging technique	An imaging device is used in the detection of fluid collection (e.g., ultrasound, Magnetic Resonance Imaging (MRI) and/or X-ray).
	Spontaneous/ surgical drainage	Draining of fluid from a site without intervention. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results or Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
	Microbial results	Tests that are carried out to identify organisms that can cause disease or infection.
	Lymphangitic streaking	Red streaks below the skin's surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes.
	Regional lymphadenopathy	Abnormal enlargement of the lymph nodes closest to the vaccination site (e.g., inguinal adenopathy when associated with an IM vaccination in the thigh, axillary adenopathy associated with an IM vaccination in the deltoid, etc.).
9b	Allergic and allergic-like events	Choose one of the following events below:
	Time interval - Mins	Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes.
	Time interval - Hrs	
	Time interval - Days	
	Duration - Mins	
	Duration - Hrs	

AEFI form	AEFI form data fields	Definition
	Duration - Days	<ul style="list-style-type: none"> • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	Anaphylaxis	An acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction. Check all applicable signs/symptoms referable to skin/mucosal, cardio-vascular, respiratory and/or gastrointestinal systems that were observed during the course of the event and use section 10 for additional details. Provide specific measurements, where available, for pulse, respiratory rate and blood pressure and indicate for each if before or after treatment with epinephrine if given.
	Oculo-Respiratory Syndrome (ORS)	The presence of “bilateral red eyes” plus ≥ 1 respiratory symptom (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hours of vaccination, with or without facial edema.
	Other allergic events	An event considered by reporter to be allergic in nature but not anaphylaxis, or ORS. Check all symptoms/signs in section 9b that were present and use section 10 for any additional details.
	<i>Skin/mucosal:</i>	Choose all that apply from the list provided below, and indicate the site of reaction:
	Urticaria	Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours). Specify site of reaction.
	Erythema	Abnormal redness of the skin without any raised skin lesions. Specify site of reaction.
	Pruritus	An unpleasant skin sensation that provokes a desire to rub and/or scratch to obtain relief. Specify site of reaction.
	Prickle sensation	Tingling or smarting (stinging) sensation. Specify site of reaction.
	Rash (For these events, specify site of reaction)	A morphologically described change in the appearance of the skin or mucosa that occurs in the context of and in conjunction with an emerging allergic event that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule) and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation). Specify site of reaction.
	<i>Angioedema:</i>	

AEFI form	AEFI form data fields	Definition
	Tongue	Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Reported symptoms of 'swelling of the lip' or 'swelling of the tongue or throat' should not be documented as angioedema unless there is visible skin or mucosal swelling. Check all of the locations where angioedema is seen on the AEFI report form and if "other" is checked, provide details.
	Throat	
	Uvula	
	Larynx	
	Lip	
	Eyelids	
	Face	
	Limbs	
	Other, <i>specify</i>	
	Eyes(s):	
	Red bilateral	Redness of the white(s) of the eye (s) (sclera).
	Red unilateral	
	Itchy	A sensation that provokes the desire to rub and/or scratch to obtain relief.
	Cardio-vascular	
	Measured hypotension	An abnormally low blood pressure and documented by appropriate measurement. Infants and children: age specific systolic BP of <3-5%percentile or greater than a 30% decrease from that person's baseline; Adults: systolic BP of <90mm Hg or greater than 30% decrease from that person's baseline.
	Decreased central pulse volume	Absent or decreased pulse in one of the following vessels: carotid, brachial or femoral arteries.
	Capillary refill time > 3sec	Capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is <3 seconds.
	Tachycardia	A heart rate that is abnormally high for age and circumstance (In beats per minute: <1year old: >160; 1 – 2 yrs: >150; 2-5 yrs: >140; 5-12 yrs: >120; >12 yrs: >100)

AEFI form	AEFI form data fields	Definition
	Decreased or loss of consciousness: <i>duration (sec)</i>	Reduced alertness or awareness of the outside world. Indicate duration of the event.
	<i>Respiratory</i>	
	Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
	Rhinorrhea	Discharge of thin nasal mucous
	Hoarse voice	An unnaturally harsh cry of infant or vocalization in a child or adult.
	Sensation of throat closure	Feeling or perception of throat closing with a sensation of difficulty breathing.
	Stridor	A harsh and continuous sound made on breathing in
	Dry cough	Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough).
	Tachypnea	Rapid breathing which is abnormally high for age and circumstance rapid breathing which is abnormally high for age and circumstance (<1yr: >60; 1-2 yrs: >40; 2-5 yrs: >35; 5-12 yrs: >30: >12 yrs: >16)
	Wheezing	A whistling, squeaking, musical or puffing sound made by breathing out.
	Indrawing/ retractions	Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing.
	Grunting	A sudden and short noise with each breath when breathing out.
	Cyanosis	A dark bluish or purplish discoloration of the skin and mucous membrane due to lack of oxygen in the blood.
	Sore throat	Discomfort or pain in the throat
	Difficulty swallowing	Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach.
	Difficulty breathing	Sensation of difficult/uncomfortable breathing or a feeling of not getting enough air
	Chest tightness	Inability or perception of not being able to move air in or out of the lungs.
	<i>Gastrointestinal</i>	

AEFI form	AEFI form data fields	Definition
	Diarrhea	Loose and/or watery stool which may occur more frequently than usual. Please provide details.
	Abdominal pain	Sensation of discomfort or pain in the abdominal region.
	Nausea	An unpleasant sensation vaguely referred to the upper abdominal region and the abdomen, with a tendency to vomit.
	Vomiting	The reflex act of ejecting the contents of the stomach through the mouth. Provide details.
9c	Neurologic events	
	Time interval - Mins	Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes.
	Time interval - Hrs	
	Time interval - Days	
	Duration - Mins	<ul style="list-style-type: none"> • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	Duration - Hrs	
	Duration - Days	
	Meningitis	Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results. (BCCD: Vaccine 25 (2007) 5793-5802)
	Encephalopathy/ Encephalitis	Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results. (BCCD: Vaccine 25(2007) 5771-5792)
	Guillain-Barre Syndrome (GBS)	Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results especially Electromyograph (EMG) and /or Lumbar Puncture (LP). (BCCD: Vaccine 29 (2011) 599-612)
	Bell's Palsy	Should be diagnosed by a physician. Provide any pertinent details.
	Seizure	Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations. (BCCD: Vaccine 22 (2004) 557-562)
	Other Paralysis, specify	Should be diagnosed by a physician. Provide all pertinent details.
	Other neurologic diagnosis, specify	Specify and provide all details.

AEFI form	AEFI form data fields	Definition
	Depressed/altered level of consciousness	Impairment of the ability to maintain awareness of self and environment combined with markedly reduced responsiveness to environmental stimuli.
	Lethargy	A general state of sluggishness, listless, or uninterested, with being tired, and having difficulty concentrating and doing simple tasks.
	Personality change lasting for ≥ 24 hrs.	Change in personal behaviour-response patterns.
	Focal or multifocal neurological sign(s)	Neurological impairment which is caused by a lesion in one particular focus or many foci of the central nervous system.
	Fever $\geq 38.0^{\circ}$ C	Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions. (BCCD: Vaccine 22 (2004) 551-556)
	CSF (Cerebral Spinal Fluid) abnormality	Alteration in normal CSF visual appearance, measured hydrostatic pressure, chemistry (protein, sugar) and/or cellular content (white blood cells, red blood cells) as well as Gram stain/routine bacterial culture results or other tests for presence of microbes.
	EEG abnormality	Abnormal EEG as interpreted by a qualified health professional.
	EMG abnormality	Abnormal skeletal EMG as interpreted by a qualified health professional.
	Neuroimaging abnormality	Abnormal results of any test used to detect anomalies or trace pathways of nerve activity in the central nervous system; includes Computed Tomography (CT) scans, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scans.
	Brain/spinal cord histopathological abnormality	Microscopic changes of the diseased brain/spinal cord tissues. Abnormalities seen on routine and/or electron microscopy by qualified health professionals using appropriately prepared (e.g.: using special stains) tissue samples from brain and/or spinal cord.
	<i>Seizure details:</i>	Check all that apply and record additional details in section 10. Indicate if the event was witnessed by a health care professional by choosing yes or no/unknown.
	Witnessed by healthcare professional	
	Yes	
	No	
	Unknown	

AEFI form	AEFI form data fields	Definition
	Sudden loss of consciousness	Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). If Yes, indicate duration of the event.
	Yes	
	No	
	Unknown	
	Generalized (<i>Specify:</i>	Bilateral, with more than minimal muscle involvement.
	Tonic	Sustained increase in muscle contraction lasting a few seconds to minutes.
	Clonic	Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions/second.
	Tonic-clonic	A sequence consisting of a tonic followed by a clonic phase.
	Atonic	Sudden loss of tone in postural muscles often pre-ceded by, a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hypo-responsive Episode, syncope, or myoclonic jerks).
	Absence	The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.
	Myoclonic	Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.
	Partial	Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.
	<i>Previous history of seizures: specify</i>	Individuals who have had seizures at any time prior to this vaccination.
	Febrile	With fever of $\geq 38.0^{\circ}\text{C}$.
	Afebrile	Without fever.
	Unknown type	It is unknown if the seizure was febrile or afebrile. Provide all known details.
9d	Other Events	For a selected event, describe the signs and symptoms by checking all that apply. Provide all additional details in section 10.
	Time interval - Mins	Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the
	Time interval - Hrs	

AEFI form	AEFI form data fields	Definition
	Time interval - Days	specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. <ul style="list-style-type: none"> • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	Duration - Mins	
	Duration - Hrs	
	Duration - Days	
	Hypotonic-Hyporesponsive Episode (age < 2yrs)	Sudden onset, in a child aged less than two years, of two to three of: limpness, change in skin colour (pallor or cyanosis) and/or reduced responsiveness. Check each appropriate box in section 9d and use section 10 to indicate if muscle tone, responsiveness or skin colour is known to be normal. Do not use the HHE checkbox if the patient is two (2) years of age or older; instead please check “Other severe or unusual events not listed above” and describe the episode.
	Limpness	Lacking firmness and strength, no muscle tone.
	Pallor/cyanosis	Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).
	Decreased responsiveness	Change in usual responsiveness to sensory stimuli.
	Unresponsiveness	Lack of responsiveness to sensory stimuli.
	Persistent crying	Crying which is continuous unaltered and lasts for 3 or more hours.
	Intussusception	The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction, and should be diagnosed by a physician. Provide all pertinent details.
	Arthritis	Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided, and described, below:
	Joint redness	Redness of the skin at the joint(s).
	Joint warm to touch	Sensation of increase in temperature, above body temperature, at the joint(s) to touch.
	Joint swelling	An abnormal increase in the size of the joint(s).
	Inflammatory changes in synovial fluid	Laboratory synovial or joint fluid analysis indicative of inflammatory response.

AEFI form	AEFI form data fields	Definition
	Parotitis	Parotid gland(s) swelling with pain and/or tenderness.
	Rash (Non-allergic)	A skin or mucosal change (either new or an exacerbation of a previous condition) following immunization that consists of clearly identified primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). When possible provide a written description of the rash, using the terminology provided. (BCCD: Vaccine, 25 (2007) 5697-5706)
	Generalized	Systemic eruption in 2 or more parts of the body.
	Localized (<i>site</i>)	Eruption localized at another part of the body, away from the vaccination site.
	Thrombocytopenia	Should be diagnosed by a physician. Platelets count of less than 150 X 10 ⁹ /L; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding (epistaxis, hematoma, hematemesis, hematochezia, hematuria, hemoptysis, petechia, purpura, ecchymosis). Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details, including the clinical evidence for spontaneous bleeding.
	Platelet count < 150x10 ⁹ /L	
	Petechial rash	
	Other clinical evidence of bleeding	
	Anaesthesia	The loss of normal feeling or sensation.
	Paraesthesia	Abnormal physical sensation such as tingling, burning, prickling, formication, etc.
	Numbness	Loss of sensation often accompanies by tingling. Indicate site of reaction.
	Tingling	Sensation commonly described as 'pins and needles'. Indicate site of reaction.
	Burning	Sensation of stinging or heat not necessarily accompanied by redness, or physical signs of skin irritation. Indicate site of reaction.
	Formication	Sensation of insects crawling over or within the skin. Indicate site of reaction.
	Other, <i>specify</i>	Specify in section 10.
	Fever ≥ 38.0°C (Note: report ONLY if fever occurs in conjunction with a reportable event. For fever in a	Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions.

AEFI form	AEFI form data fields	Definition
	neurologic event, use section 9c)	
	Other serious event not listed in the form (Specify and provide details in section 10)	Is any untoward medical occurrence that at any dose that results in death, is life-threatening, requires inpatient hospitalization or results in prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is a medically important event or reaction.
	Unexpected event(s) not listed in the form(Specify and provide details in section 10)	Is an event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency.
10	Supplementary Information <i>(Please indicate the section number when providing details). Please provide details of any investigation or treatment for the recorded AEFI. If not, provide sufficient information to support the selected item(s)</i>	Section 10 should be used to capture information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation. Document all known details of any investigations or treatments for the recorded AEFI. Indicate the section of the AEFI report that the information applies to, if applicable, when recording information in section 10.
11	Recommendation for further immunization according to Federal/Provincial/Territorial best practices <i>(Provide comments, use section 10 if extra space needed)</i>	This section is to be completed by the health professional. In some P/T's, only the MOH or MD can provide recommendations for future immunizations. In others, RNs have been trained to provide the recommendations as well. Indicate, by choosing all that apply in section 11, your recommendations for the patient with regard to future vaccinations and specify additional information when requested. A comments section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in section 10. Complete the reporter information section in full providing your full name and professional status (MOH/MHO: Medical Officer of Health/Medical Health Officer; MD: Medical Doctor; RN: Registered Nurse).
	No change to immunization schedule	
	Expert referral, <i>specify</i>	

AEFI form	AEFI form data fields	Definition
	Determine protective antibody level	If your professional status is not listed, describe under other. In addition, indicate a phone number where you can be reached and sign and date the AEFI form in the space provided.
	Controlled setting for next immunization	
	No further immunizations with: <i>specify,</i>	
	Active follow-up for AEFI recurrence after next vaccine	
	Other, <i>specify</i>	
	Name:	
	Professional status	
	MOH/MHO	
	MD	
	RN	
	Other, <i>specify</i>	
	Comments	
	Phone: Ext	
	Date	
12	Follow up information for a subsequent dose of same vaccine(s) <i>(Provide details in section 10)</i>	Complete section 12 when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine. Choose one of the responses as described below to describe the outcome following the administration of the subsequent dose of vaccine and provide all pertinent details in section 10.
	Vaccine administered without AEFI	A subsequent dose of vaccine was administered without the occurrence of any AEFI.
	Vaccine administered with recurrence of AEFI	A subsequent dose of vaccine was administered and followed by the occurrence of the same adverse event that was previously experienced by the patient. Please fill out a new AEFI form for the subsequent AEFI.

AEFI form	AEFI form data fields	Definition
	Vaccine administered, other AEFI observed	A subsequent dose of vaccine was administered and followed by the occurrence of a different adverse event than was previously experienced by the patient. Please fill out a new AEFI form for the subsequent AEFI.
	Vaccine administered without information on AEFI	A subsequent dose of vaccine was administered and it is unknown if it was followed by the occurrence of any AEFI.
	Vaccine not administered	A subsequent dose of the vaccine was not administered.

Appendix B: ANDS Quick Reference: AEFI Entry

<i>ANDS Variable</i>	Definition and Use
<i>Case Status*</i>	<p>The classification of the case at time of entry according to the following:</p> <p>Confirmed – Do Not Use</p> <p>Confirmed – Laboratory confirmed – Do Not Use</p> <p>Confirmed – Epidemiologically linked – Do Not Use</p> <p>Probable – Do Not Use</p> <p>Possible – Enter all AEFI as Possible</p> <p>Note that an AEFI is never determined to be “confirmed”</p>
<i>Investigation Status*</i>	<p>Please enter status as indicated, noting the following:</p> <p>Open – pending further information – Use</p> <p>Close – completed – Changed at DHW after Provincial review</p>
<i>Investigation Closed Date</i>	The date the investigation was completed
<i>Date Reported*</i>	The earliest date that Public Health was notified of the case/condition
<i>DHA*</i>	The DHA responsible for AEFI management, that enters the case into ANDS
<i>Disease Name*</i>	Enter Adverse Event Following Immunization (AEFI).
<i>Types of Adverse Event</i>	Select the appropriate type or types from the selection box. Please refer to the comment section below for selection choice in bold.
<i>Related Immunizations</i>	Select the provincial immunization id of the related immunization(s) to ‘link’ to this AEFI case.
<i>Agent Sub/Serotype</i>	Free text field. Enter all lot numbers that apply.
<i>Other lab Info</i>	Do Not Use
<i>Episode Date*</i>	Enter the onset date of symptoms of AEFI (See ANDS Episode Date Hierarchy for data entry example)
<i>Episode Date Type*</i>	<p>The episode date type entered should follow the following hierarchy:</p> <ul style="list-style-type: none"> • Onset date of symptoms – Use as Episode Date • Clinical diagnosis date – Do Not Use for AEFI • Specimen collection date – Do Not Use for AEFI • Lab test result date – Do Not Use for AEFI
<i>Clinical Presentation</i>	Do Not Use
<i>Outcome</i>	The outcome of the case. Note that if “deceased” is selected, a date of death must be entered
<i>Risk Factors for STI’s Only</i>	Do Not Use
<i>Where case’s illness was most likely acquired?</i>	Do Not Use
<i>Associated with an outbreak?</i>	Do Not Use
<i>Outbreak Number</i>	Do Not Use
<i>Received Vaccine</i>	Enter Yes
<i>Vaccine Date 1 (& 2)</i>	Enter the date of vaccine administration
<i>Vaccine Name</i>	Select the vaccine name from the drop down list.
<i>Comments</i>	Enter the detailed sub-type of adverse event from the following (refer to case report form):

<p><i>(Note that the comments field is being used to capture details around the sub-type of AEFI as indicated on the AEFI report form)</i></p>	<p><u>Local Reaction</u></p> <ul style="list-style-type: none"> • Abscess at injection site • Cellulitis • Nodule • Pain/Redness/Swelling <p><u>Systemic</u></p> <ul style="list-style-type: none"> • Adenopathy/Lymphadenopathy • Fever • Hypotonic/hyporesponsive • Parotitis • Orchitis • Rash • Screaming/Persistent Crying • Severe vomiting/diarrhea 	<p><u>Neurologic</u></p> <ul style="list-style-type: none"> • Anaesthesia/Paraesthesia • Bell's palsy • Convulsions/Seizures • Encephalopathy/Encephalitis/ADEM • Guillain Barré • Meningitis • Subacute Sclerosing Panencephalitis (SSPE) • Other neurologic: Paralytic poliomyelitis/Transverse Myelitis <p><u>Allergic</u></p> <ul style="list-style-type: none"> • Anaphylaxis • ORS • Other Allergic 	<p><u>Serious</u></p> <ul style="list-style-type: none"> • Death • Congenital Malformation • Extension of hospitalization • Hospitalization • Residual Disability <p><u>Other Events of Interest</u></p> <ul style="list-style-type: none"> • Arthritis • Intussusception • Syncope with Injury • Thrombocytopenia • Other severe/unusual
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Chapter 9: Tuberculin Skin Test

Tuberculin Skin Test

This test is also known as the Mantoux test, PPD test, or tuberculin test. Other similar tests (Tine test, cuti-BCG) have been used in the past. The following protocol only pertains to TST.

Composition

One tuberculin purified protein derivative is distributed in Canada: Tubersol (Sanofi).

Each 0.1mL dose of the solution contains:

- the biological equivalent of five tuberculin units (TU) obtained from a human strain of *Mycobacterium tuberculosis* grown on a protein-free synthetic medium
- 0.0005% of Polysorbate 80
- 0.28% of phenol, as a preservative

Supplied

1 mL or 5mL vial. The product is a clear, colourless solution.

Storage

- Keep in the refrigerator between 2°C and 8°C for no more than 1 month from the date on which the first dose was withdrawn.
- Do not freeze.
- Avoid exposure to light, except when withdrawing a dose.
- Do not use after expiration date

Indications

- to detect prior or recent *Mycobacterium tuberculosis* infection (one-step testing):
 - people who have had recent close contact with a case of infectious tuberculosis
 - people with a high risk of infection, such as immigrants from areas that have high prevalence of tuberculosis
 - people with an immune deficiency putting them at high risk of developing tuberculosis disease if infected, for example, people with HIV infection, diabetes, renal failure or silicosis and people receiving corticosteroid or other immunosuppressive therapy
 - people who have had an abnormal chest X-ray consistent with active tuberculosis
- to obtain a baseline for people at risk of exposure to *Mycobacterium tuberculosis*, such as travellers, trainees, and health-care workers (two-step testing)

Contraindications

- anaphylactic allergy to any component of the product or to a previous dose of either the same product or another product with the same components

Factors that are not contraindications

- prior history of BCG vaccination
- pregnancy

- prior reaction to a Tine test or cuti-BCG, since interpretation of those tests was difficult to standardize

Precautions

- It is not appropriate to perform a TST on people with documentation of a significant response to testing, treated latent tuberculosis infection, or tuberculosis disease, since the TST does not provide any additional information and will provoke a severe local reaction.
- The tuberculin solution should not be injected into a cutaneous lesion.
- Factors that suppress cell-mediated immunity and may suppress the reaction to tuberculin should be taken into account when interpreting the TST results. These factors are very young age, advanced age, malnutrition, leukemia, lymphoma, sarcoidosis, tuberculosis, immunosuppressive therapy, and certain viral infections (especially HIV infection, varicella, measles, and influenza).

Interactions

The measles vaccine may temporarily depress the reaction to tuberculin. It is possible that other injectable live vaccines, such as the varicella and yellow fever vaccines, may similarly falsify TST results. If both an injectable live vaccine and a TST are indicated, testing should be done before, at the same time as, or at least 1 month (4 weeks) after the vaccination.

Adverse reactions to TST

- In rare cases, immediate erythematous or other reactions may occur at the injection site.
- In very rare cases, vesiculation, ulceration, or necrosis may appear at the test site in a highly sensitive person. Strongly positive reactions may result in scarring at the test site.
- Cases of acute allergic reaction (skin rash, hives, swelling or a feeling of constriction of the pharynx, puffiness of the lips, anaphylactic reaction) have been reported in less than 1 case per million of doses distributed in persons with no history of exposure to tuberculin.

Dosage and administration

Dosage ¹	Route of Administration	Site
0.1 mL	ID ²	Mid-anterior aspect of forearm

¹ The minimum age is 6 weeks, since reactivity to tuberculin does not develop before this age.

² Make sure that a wheal forms; if not the injection should be repeated in the other forearm.

There is no risk in repeating a negative TST.

One-step testing

When investigating contacts of a case of tuberculosis disease, a TST should be done as soon as a close contact is identified. If the response to the first TST is negative (less than 5 mm), it should be repeated 8 weeks after the last contact with the index case in order to check for recent infection. A hypersensitivity reaction to tuberculin may appear within 3 to 8 weeks of the initial infection. This procedure is not considered two-step testing.

Two step testing

In individuals sensitized to tuberculin, the reaction to tuberculin may gradually wane over a period of years. An initial TST, done several years after sensitization, may produce a weak reaction. When a second TST is done within less than 1 year, a more significant reaction may sometimes be observed, without indicating new contact with the tuberculin bacilli. In this case, the reaction should not be interpreted as a conversion reaction. It is, in fact, a booster phenomenon.

A two-step TST is indicated only if tuberculin testing is likely to be repeated subsequently. The purpose in this case is to establish a precise baseline for future comparison. This is why two-step testing is recommended for some groups who may be exposed to *Mycobacterium tuberculosis* (travellers, trainees, and health-care workers), when response to the first TST is less than 10mm. The second TST should be performed 1 to 4 weeks after the first. The final interpretation will be based on the second test. A test carried out less than a year before may be considered an initial TST if there is no history of exposure to *Mycobacterium tuberculosis* during that year.

A two-step TST needs to be performed ONCE only if properly performed and documented. It never needs to be repeated. Any subsequent TST can be one step, regardless of how long it has been since the last TST.

Reading a TST

Technique

The TST is read 48 to 72 hours after administration. The result should not be interpreted if the reading is not done within the required time. In case of delay, the TST should be repeated immediately.

Equipment

- a ball point pen and a ruler marked in millimetres

Steps

- Palpate the injection site.
- Using a medium ballpoint pen held at right angles to the skin, move towards the induration while pressing lightly on the skin. The pen will stop when it reaches the raised area, indicating the edge of the induration.
- Mark this point.
- Repeat from the opposite site of the reaction.

- Measure the transverse diameter of the induration, perpendicular to the direction of the injection, disregarding any redness. The distance between the two points indicates the diameter of the induration.
- Record the result in millimetres; if there is no induration; record the result as 0 mm.

Classification of TST results

Positive response

- $\geq 5\text{mm}$
 - person with HIV
 - close contact of a case of infectious tuberculosis
 - person with a history of untreated tuberculosis disease (inactive)
- $\geq 10\text{mm}$
 - any other person

Negative response

For each of the categories mentioned above, TST reactions below their respective levels of significance are considered non-significant.

Course of action

In the case of a significant response or one that is difficult to interpret, the person who underwent the TST should be referred to a physician for management.

Chapter 10: Policies, Protocols and Guidelines

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10.1 Publicly Funded Vaccine Eligibility/Immunoglobulin Eligibility Policy

For more information and to view this policy please visit the following link:

<https://novascotia.ca/DHW/CDPC/info-for-professionals.asp>

10.2 Publicly Funded Vaccine Eligibility for Individuals at High Risk of Acquiring Vaccine Preventable Diseases Policy

For more information and to view this policy please visit the following link:

<https://novascotia.ca/DHW/CDPC/info-for-professionals.asp>

10.3 Process for Immune Globulin Release and Documentation

There are various immune globulins (IG) available in Nova Scotia, including Rabies IG, Tetanus IG, held at Public Health and Varicella IG, Hepatitis B IG, and Standard IG, held at Canadian Blood Services.

The following outlines the process for the release of IG and documentation required.

Release of Immunoglobulin:

1. Within the NS Public Health system, the request for release/use of these products held at Public Health and Canadian Blood Services should be made to the Medical Officer of Health (MOH).

The zone MOH should be contacted during regular business hours. If after hours, please contact the MOH *on call* to obtain approval for use. This is done by contacting QE II located at 473-2222. Once approved by the MOH, the immune globulin can be released to the requesting provider following NSHA Public Health cold chain packing protocols:

- a) For Public Health cases *managed out of hospital* where the Medical Officer of Health has deemed it necessary, all immunoglobulines are released by Public Health.
- b) For Public Health cases *managed in the hospital* where the Medical Officer of Health has deemed it necessary, hospital staff will contact the blood bank to request immunoglobulin (HBIG, IG and VZIG). Public Health will released RIG, TIG for cases managed in hospital.

Documentaton:

1. The release of any immune globulin from Public Health must be documented.
2. The documentation must be stored in the PH office releasing the product. This is done to provide the ability to identify any person receiving the product in the event of a recall or investigation related to the product.
3. Upon the release of any immune globulin, the following information must be collected and accessible within the local PH office dispensing the product:
 - Type of immune globulin
 - Lot number
 - Patient's name
 - DOB
 - HCN
 - Date
 - Name of MOH authorizing the release of the product
 - Name of Health Care provider the product is released to
 - Signature of the person releasing the produc

Chapter 11: Immunization Program Related Forms

[General Immunization Consent Form](#)

[High Risk Special Release Vaccine Order Request](#)

[Immune Globulin Release Tracking Record](#)

[Management of Anaphylaxis Form](#)

[Reciprocal Notification Form](#)

[School Entry Immunization Record](#)

[Urgent Request for Vaccine or Immune Globulin Form](#)

To access additional immunization forms please go to:

<https://www.cdha.nshealth.ca/public-health/documents>

and

<http://www.cdha.nshealth.ca/immunization-forms>

