

Immunization against communicable diseases has been, and continues to be, one of the most important public health programs available. Although many diseases have now been curtailed or eradicated by immunization programs in this country, children and adults require immunization for continued protection.

The Immunization Manual (IM) provides policy for the provision of immunization services. More specifically, the IM will:

1. Provide general and specific policy and procedure information on the Department of Health & Community Services' immunization programs
2. Facilitate consistency in the application of the principles of the Department's mandate for immunization
3. Provide for the uniform adoption of modifications and additions to the contents of the previous manual
4. Assist in the orientation of new staff

The Immunization Manual was first compiled and released in 1988 for the use of the public health nurses (may include community health nurses) in the province, as well as for other health professionals involved in immunizing both children and adults. Since 1988, there have been several major revisions of the document.

The authority for the Newfoundland and Labrador Immunization program comes from the Communicable Diseases Act, 1998, with the Department of Health and Community Services, providing budgetary resources for the publicly funded programs. The programs are then implemented in the four (4) Regional Health Authorities under the authority of the Chief Medical Officer of Health (CMOH).

Although general principles of immunization and some standard procedures apply in all health regions, there are cases where regional policies govern the fulfillment of the general public health mandate of immunization. Provision has been made for the inclusion of such policies within the body of the manual. Sections are numbered in such a way as to allow for future revisions and regional policies to be inserted in the appropriate sections of the manual.

Historically, public health nurses have delivered the immunization program in this province, resulting in a high rate of immunization for the population. The continued success of the Department of Health & Community Services' immunization program depends upon the work of public health nurses. It is a challenge for these health professionals in the field to remain current on immunization issues, new products, changes in practice, and consumer concerns. The editor of this edition of the manual once again gratefully acknowledges the significant contribution made by the communicable disease nurses and public health nurses to the ongoing revision of this manual and to the success of the provincial immunization programs.

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1.0 Immunization Practice

Public health nurses have a major role in the delivery of immunization programs in this province. In some areas immunization are also delivered by registered nurses, licensed practical nurses, nurse practitioners and family physicians. Regional Health Authorities are expected to provide immunization programs according to the provincial immunization schedule and immunizations as identified for special populations and high risk groups

A record of immunization is requested whenever a child registers for childcare or school. It is also a requirement for most applicants to post-secondary training or university. In the event of an outbreak of a vaccine preventable disease, children or adults who have not been adequately immunized may be excluded from attendance for the duration of the outbreak.

Immunization prevents more deaths than any other public health intervention and is the most cost effective means of protecting the public's health. Immunization coverage rates in the province have been high compared to other provinces and territories. Annual surveillance of coverage rates provides an indicator of success for the immunization program.

Immunization schedules in Newfoundland and Labrador (NL) are in keeping with the recommended schedules as published in *The Canadian Immunization Guide (CIG)* located at <http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>

The scope of the Immunization Manual includes both **passive** and **active** immunization as well as testing procedures that use biological products (i.e. the Tuberculin Skin Test).

Passive immunization involves the injection of preformed immune complexes, or antibodies, which will protect an individual for a limited time, usually for one to three months. There is no long lasting protection afforded by passive immunization.

Active immunization refers to any procedure that stimulates an immune response in a person. Once the procedure has been completed (as in a single dose immunization or a primary series) a person's immune system should mount a defence whenever challenged by infection. Boosting with additional doses of vaccine may be necessary to maintain satisfactory levels of immunity.

There are two types of active immunization products: **live** (attenuated) and **inactivated** (killed) vaccine.

Live vaccines (Measles Mumps and Rubella, Varicella, Rotavirus) contain very small amounts of disease causing organisms (usually viruses) that have been substantially weakened, or attenuated. The organisms are thus strong enough to provoke an immune response, but too weak to cause disease.

Inactivated vaccines contain organisms that have been inactivated by heat or chemicals. The products may contain parts of cells, such as tetanus and diphtheria toxoids, which are made up of specific antigen complexes or acellular vaccine such as pertussis vaccine.

Immunization and testing products are biological products and must be handled with extreme care, in order to ensure that they retain optimum potency. The products must be stored and transported under controlled temperatures, as specified by the manufacturer. Section 7; Management of Biological Products of this manual covers this topic.

The Regional Health Authorities are required to:

- Provide vaccine to persons who are eligible according to the provincial policy and schedule.
- Eligibility for school based programs, such as HPV and Meningococcal vaccines, ends once the person has left the school system. There are specific cases where a person, due to an identified risk factor, may be eligible; this is outlined in Section 5, Immunization Programs for High-Risk Groups.
- Facilitate immunization program delivery by trained health care providers, who follow prescribed standards of practice.
- Maintain an adequate supply of vaccines for the region.
- Ensure proper storage, handling and use of vaccines within the region by all those using publicly funded vaccine.
- Assess vaccination coverage rates for the eligible population to identify gaps and plan for changes needed so that at least 95% of children are protected from vaccine-preventable diseases at the earliest age.
- Provide a record of immunization to the client (this is a legislated requirement).
- Enter immunization data into the Client Referral Management System (CRMS).
- Maintain a record of immunization, with minimum data standards.
 - Name of product using vaccine abbreviation (See **Appendix A**)
 - Date given
 - Dose
 - Site and Route
 - Lot #
 - Provider name and title
 - Adverse events, if they have occurred
- Submit coverage rates to the provincial office on an annual basis for the following (See **Appendix B**)
 - Age two years
 - School entry
 - Grade 4 (Men-C-ACYW-135)
 - Grade 6 (HPV and HB)
 - Grade 9 (Tdap)
 - Influenza
 - Other catch-up programs as necessary
- Report adverse events following immunization.
- Be prepared to provide mass immunization in the event of a vaccine-preventable disease.

1.1 Immunization Authority Policy

Authority for the Immunization Program comes from the Department of Health and Community Services and respective provincial legislation. Immunizations are delivered throughout the province in accordance with policies within the Newfoundland and Labrador Immunization Manual. This policy outlines the authority by which health professionals undertake immunization and the conditions under which immunization activities are to take place.

POLICY

1. Health professionals will immunize eligible adults or children for whom valid consent has been received in accordance with this policy framework:
 - Patients and residents in Acute Care and Long Term Care will be immunized by Registered Nurses or Licensed Practical Nurses based on physician order.
 - In Community Health (including Personal Care Homes), Registered Nurses or Licensed Practical Nurses who are Regional Health Authority employees will immunize clients based on established professional scope of practice and as directed by NL Immunization Policy.
 - In Occupational Health settings a directive will be provided by the Occupational Health physician or a Regional Medical Officer of Health to Occupational Health staff or other health care providers to immunize employees including through Peer Immunization Programs.
 - Paramedics will be provided a directive from the Provincial Medical Director for Provincial Medical Oversight for the Paramedicine and Medical Transport Program to undertake Peer Immunization.
2. Clients are offered vaccines in clinical settings appropriate for immunization including:
 - Regional Health Authority sites
 - Schools
 - Alternate locations as designated by the Medical Officer of Health or Communicable Disease and Control (CDC) Department within each Regional Health Authority (RHA).
3. The Medical Officer of Health or CDC Department within each RHA must approve clinical settings used for immunization. Criteria for clinical settings for immunization include:
 - Sanitary surroundings,
 - Capacity for hand washing or hand sanitization,
 - Availability of an emergency response (anaphylaxis) kit.
 - Access to telephone service,
 - Availability of waiting area within line of sight of staff or volunteer observer,
 - Ability to maintain cold chain (dedicated refrigerator space or storage area for cooler),
 - Privacy considerations.

4. Adverse reactions such as localized swelling, redness, fever, rash or fainting exceeding the expected severity and more severe events like anaphylaxis or seizures must be reported by the immunizing Health Professional on an *Adverse Event Following*

Immunization (AEFI) report form as soon as possible after the episode. See Section 1.6 and Section 9, Appendices E and F.

http://www.health.gov.nl.ca/health/publichealth/cdc/im_appendix.pdf

Scope

All employees and agents of regional health authorities trained to deliver immunization in health services sites.

Purpose

To define the basic requirements for immunization programs and practice in Community Health, Acute Care, Long Term Care and Occupational Services across the province.

1.2 Vaccine Preventable Disease

The following table lists vaccine preventable diseases that are covered by routine immunization programs in Newfoundland and Labrador, as of September 1, 2015, see also the CIG.

Table 1.2-1: Routine Vaccine Preventable Disease Reference Chart

DISEASE	PROTECTIVE ACTION
<p>Diphtheria: Bacterial throat infection that can cause heart and liver failure. Droplet spread via coughs and sneezes. Highly contagious.</p>	<ul style="list-style-type: none"> • Primary immunization at 2,4,6 months with DTaP-IPV-Hib vaccine • Booster immunization at 18 months with DTaP-IPV-Hib vaccine • Booster immunization at 4-6 years with DTaP-IPV or Tdap-IPV vaccine • Booster immunization at 14-16 years with Tdap • Booster immunization for adult one dose of Tdap (10 years post-adolescent Tdap) • Booster immunization every ten years thereafter with Td • There is no minimal interval between Td and Tdap
<p>Haemophilis influenzae type b or Hib Disease: Bacterial infection that can lead to meningitis, epiglottitis and other invasive disease. Spread by contact with nasopharyngeal secretions.</p>	<ul style="list-style-type: none"> • Primary immunization at 2,4,6 months with DTaP-IPV-Hib vaccine • Booster immunization at 18 months with DTaP-IPV-Hib vaccine
<p>Hepatitis B Viral infection that can produce permanent liver damage and eventual liver cancer. Can be fatal. Spread by contact with infected blood and body fluids.</p>	<ul style="list-style-type: none"> • Immunization offered in grade six at 0 and 6 month intervals with Hepatitis B recombinant vaccine commencing in school year 2012. • Previous program was administered in Grade 4 from 1995 to 2010 as a three dose series.
<p>Measles Viral infection that can produce encephalitis and which is fatal in 1/3,000 cases. Spread by contact with nasopharyngeal secretions.</p>	<ul style="list-style-type: none"> • Immunization at 12 and 18 months with MMRV for those born January 1st 2013 and later. Combined with mumps, rubella and varicella as MMRV vaccine. • Individuals born prior to January 1st 2013 administer MMRV at 12 month and MMR at 18 month clinic visit.

<p>Pertussis Bacterial infection that can produce long-term respiratory disease. Severe disease can result in permanent brain damage and/or death. Highly contagious. Spread by contact with nasopharyngeal secretions.</p>	<ul style="list-style-type: none"> • Primary immunization at 2, 4, 6 months with DTaP-IPV-Hib vaccine. • Booster immunization at 18 months with DTaP-IPV-Hib vaccine. • Booster immunization at 4-6 years with DTaP-IPV or Tdap-IPV vaccine. • Booster at 14-16 years with Tdap. • Booster immunization for adult one dose of Tdap 10 year's post-adolescent dose. • Vaccination with Tdap between 27-32 weeks of every pregnancy
<p>Rubella Viral infection that produces mild disease. Teratogenic if contracted by mother during 1st trimester. Spread via contact with nasopharyngeal secretions and saliva.</p>	<ul style="list-style-type: none"> • Immunization at 12 and 18 months with MMRV. Combined with measles, mumps, and varicella as MMRV vaccine.
<p>Mumps: Viral infection that can lead to orchitis, deafness, and meningitis. Spread by contact with nasopharyngeal secretions and saliva.</p>	<ul style="list-style-type: none"> • Immunization at 12 and 18 months with MMRV for those born January 1st 2013 and later. Combined with measles, rubella and varicella as MMRV vaccine. • Individuals born prior to January 1st 2013 administer MMRV at 12 month and MMR at 18 month clinic visit.
<p>Polio: Viral infection that can affect CNS to produce partial or complete paralysis. Spread by direct contact with virus, usually by mouth.</p>	<ul style="list-style-type: none"> • Primary immunization at 2, 4, 6 months with DTaP-IPV-Hib vaccine. • Booster immunization at 18 months with DTaP-IPV-Hib vaccine. • Booster immunization at 4-6 years with DTaP-IPV or Tdap-IPV.
<p>Tetanus: Bacterial infection that affects the CNS, causing muscle tetany that can result in death. Contracted through contamination of skin breaks with soil, manure and dust containing the bacteria. Not contagious.</p>	<ul style="list-style-type: none"> • Primary immunization at 2, 4, 6 months with DTaP-IPV-Hib • Booster immunization at 18 months with DTaP-IPV-Hib vaccine. • Booster immunization at 4-6 years with DTaP-IPV or Tdap-IPV. • Booster immunization at 14-16 years with Tdap. • Booster immunization adult one dose of Tdap 10 year's post-adolescent dose. • Booster immunization every ten years thereafter with Td. • There is no minimal interval between Td and Tdap
<p>Meningococcal: Bacterial infection that causes inflammation of the meninges. Spread via contact with nasopharyngeal secretions and saliva.</p>	<ul style="list-style-type: none"> • Immunization at 12 months with one dose of Men-C-C. • Immunization Grade 4 students with Men-C-ACYW-135

<p>Pneumococcal: Bacterial infection causing otitis media, meningitis and pneumonia</p>	<ul style="list-style-type: none"> • Primary Immunization for children at 2, 4, and 12 months with Pneu C-13. • High risk children at 2, 4, 6, and 12 months. • Pneumo P-23 for those aged 65 years and older
<p>Varicella: Viral infection causing chicken pox</p>	<ul style="list-style-type: none"> • Immunization at 12 and 18 months with MMRV. Combined with measles, mumps and rubella as MMRV vaccine for individuals born January 1st 2013 and later. Individuals born prior to January 1st 2013 vaccine product and number of doses used are dependent on age and eligibility. • May be given at school entry as Var depending on child's immunization history and/or past history of disease.
<p>Human Papillomavirus (HPV): Viral infection that can cause cervical cancer</p>	<ul style="list-style-type: none"> • Immunization offered to Grade 6 students in a 2 dose schedule at 0 and 6 months with HPV vaccine.
<p>Rotavirus viral illness causing gastroenteritis</p>	<ul style="list-style-type: none"> • Initially started in September 2015, now offered to children at 2 and 4 months of age.

1.3 Consent for Immunization

Background

Immunization is an invasive procedure and therefore a valid consent must be obtained from either the person receiving the immunization, or the parent/legal guardian of a child who is to receive the immunization.

The procedure for obtaining consent varies, and it is impossible to provide a blanket statement that adequately explains immunization procedures in language that is appropriate to everyone. The nurse's assessment skills must be used in order to provide an explanation of all aspects of immunization. Some individuals will require only a brief explanation with the provision of pamphlets. Others will require more detailed verbal explanations, as written material may not be suitable.

Valid consent protects the nurse and the vaccinee, as it provides documentation to support the fact that the procedure was explained and appeared to have been understood.

A valid consent has the following characteristics:

- It is an informed consent; the person has been given an explanation (in appropriate language) of the purpose, risks, and side-effects of the procedure, and there has been an opportunity for the person to have any questions about the procedure answered.
- It is given voluntarily, and is genuine; given by an individual who demonstrates the capacity to understand the explanation and to distinguish between consent and refusal.
- The person signing for a child is a parent or legal guardian of that child, and is able to give an accurate health history for the child.
- The consent is signed and dated in ink; on a permanent record (a faxed copy is acceptable).
- The procedure is performed within a reasonable time after consent is given. The consent is valid for 12 months, with the exception of the primary series consent which is valid for 24 months. See section 1.4

Although this consent applies to all preparations that are given, it is still necessary to provide an explanation of the procedure at the time of each immunization. In this way the nurse ensures that the consent remains valid, and there is an opportunity for withdrawal of consent at any time. This allows for updating and exchange of information regarding illness or contraindications to further immunization.

There are special situations to consider when seeking consent, as listed below:

- **Foster Parents**

A foster parent is not a legal guardian. Consent for the immunization of an infant, child or teenager in foster care must be sought from the individual's legal guardian. It is preferred that consent be obtained by the social worker from the parent or other legal guardian. It is not the responsibility of the public health nurse to contact the parent/guardian. If the parent had signed consent or refusal a new consent should be obtained once the child is in foster care.

- **Parent Below the Age of Consent**

A parent under the age of sixteen years may sign for the immunization of his or her child. **A grandparent of the child, unless he or she is a legal guardian, cannot give consent.**

- **Teen Consent or Refusal of Immunization**

- Although it is preferable that consent or refusal be obtained from a parent, any teenager 16 years of age and older may sign consent or refusal for his or her own immunization, provided that the nurse feels that the teenager has the capacity to understand the risks and benefits of immunization, and the risks associated with acquiring disease.

- Where a teenager has the capacity but does not consent to immunization, regardless of his or her age, the public health nurse cannot administer immunization even if the parent consents. When a teenager under the age of 16 refuses immunization parents are advised.

- In a situation where a teenager 16 years of age or older consents to a vaccination but the parent does not, it is important that the public health nurse clearly document the information provided to the teenager and that some document be contained in the file recognizing the teenager's consent.

- The "emancipated minor rule " states that a child who has adopted a life style which indicates that he or she has assumed responsibility for own life (left home, married, entered work force) or in other ways has indicated that he/she has withdrawn from parental control and is making his/her own decisions can sign consent.

- Parental consent is not necessary if the child is considered a "mature minor" ; a child who has the capacity to understand the nature of the medical complaint or illness, treatment available, the foreseeable risks and benefits of the treatment, as well as the consequences of inaction

- **Ability of the Parent/Legal Guardian or Vaccinee to Write**

Inability to write does not indicate that the person lacks the capacity to provide consent. If a person is unable to write, an "X" mark, witnessed and dated by a third party, is used.

Refusal of Immunization

Any refusal of immunization must be documented in the appropriate space on the *Immunization and Health Record*, or other permanent record of immunization. A parent/legal guardian of a child may sign refusal, or in the special situation noted above, a teenager may sign refusal for him or her self.

Note: Regardless of who will be providing consent or refusal, it is essential that any adolescent who presents for immunization be provided with an explanation of the procedure.

Policy and Procedure for Obtaining Consent

Policy

Written consent or refusal must be obtained for all immunization and testing procedures.

Documentation is kept on the permanent immunization record at the discretion of the region.

Telephone consent can only be obtained at the discretion of the Regional Health Authority in extraordinary circumstances when it is not possible to obtain written consent.

Telephone consent for immunization must contain all the elements of a written consent.

Telephone consent must be witnessed by another employee of the Regional Health Authority.

When documenting telephone consent the consent form must be used. The witness must also sign the consent form.

The consent portion of the form must be affixed to the permanent record.

Procedure for consent given on site

- Provide the appropriate written material about the vaccine, risks and benefits. Allow time for the person to read the material, or explain the procedure to the person.
- Be prepared to answer questions and address concerns that the person may have regarding the product and procedure.
- Instruct the individual to sign and date the Immunization and Health Record or other form, as either consent or refusal. If the person is unable to write, then a mark is to be made, to be dated and witnessed by a third party.
- When using the Client Referral Management System (CRMS) see Appendix C, Section 9.

Procedure for consent sent home for completion

- Send the *Immunization Consent Form* (H-730-YY) to the parent or guardian, with additional information as required (some information on immunization is provided on the back of this form). The form must clearly identify the person to be immunized /tested.
- When the form is returned, detach the signed box, remove the backing tape, and affix in the appropriate or blank space on the Health Record. Do not obscure previous consents or refusals, if more space is required for consent a second card may be used numbered 2 of 2.
- Send another form and document this action on the Health Record if the form has not been completed (**either consent or refusal**) within a reasonable time period.
- Follow up with a telephone call to the home if second form is not returned and document this action on the Health Record. Stress to the parent that **either consent or refusal must be signed**.

- Document that you have been unable to obtain either consent or refusal if the above steps do not meet with success. No further action is necessary.

Procedure for obtaining telephone consent

- Consult with the program manager in the region to discuss the need for telephone consent.
- Secure a witness to obtain the consent with you.
- Contact the legal guardian of the client by telephone and ensure that the witness is able to hear the conversation and consent.
- Document “telephone consent obtained by PHN name from Legal guardian name and relationship to child” in the signature section of the consent form.
- Ensure that the signature of the witness is documented in the same section of the consent form.
- Detach the signed box of the consent form, remove the backing tape, and affix in the appropriate or blank space on the Health Record. Do not obscure previous consents or refusals, if more space is required for consent a second card may be used numbered 2 of 2.

1.4 Maintaining a Record of Immunization

Maintaining Records in District/Regional Offices

Once a child reaches school age, the record of immunization on the *Immunization and Health Record* is kept in either the individual clinic, or a general office file. At this time, the record is sorted into school files, (usually by grade and classroom) for each school. If facilities at school are suitable, i.e. a secure room with limited access, these current records can be kept at the school. If no suitable facilities exist, the records must be kept at the community health nursing office.

Once a child has left school, the record is usually transferred to a central filing system (as per regional policy), or at the regional community health nursing office, where it is filed by year of birth. Records are stored at district offices until one year after school leaving. Records are transferred to the provincial office, Public Health, Confederation Building (729-0724) from the region each year and then made available on a secure website to each of the regions. Older records have been processed as microfilm files, sorted alphabetically by year of birth.

When using the Client Referral Management System (CRMS), see **Appendix C**. Consent must be obtained from an individual before the release of the information.

Transferring Records - Within The Province (Also see section 1.4-4)

Within the province, the permanent record of immunization (*Immunization and Health Record*) is transferred from one district to another and from one region to another when a child moves.

If desired, a duplicate copy of this record may be kept at the region from which the client is moving, this should be labelled appropriately e.g. *Duplicate - original record sent to St. John's, Nov 12, 2011*. This permanent record is not to be released to an individual client, only to authorized personnel.

Any request for immunization records that comes from within the province from the individual or another health authority does not require consent. A consent from the individual whose record is being requested is required if a third party is making the request and is not a health authority.

The permanent record of immunization (*Immunization and Health Record*) **will not be transcribed to a new card**, except in the event of damage leading to illegibility. If transcription must occur the community health nurse in the district is responsible to ensure proper transcription, or she may appoint a designate under supervision. When using CRMS follow the guidelines developed for the system. To reduce duplicate records all immunization information should be entered into CRMS when a child transfers from one school to another.

Transferring Records - Outside The Province

If a person is transferring to a school outside of this province, a *copy* (written or clear photocopy) of the immunization record is to be given, as the permanent record does not leave the province. Any request for immunization records that comes from outside the province from the individual or a health authority does not require consent. A consent from the individual whose record is being requested is required if a third party (i.e. employer or school) is making the request and is not a health authority.

Copies of immunization records are frequently requested by individuals for various reasons. The information may be transferred (by the community health nurse or designate) to the *Immunization Record form* or a clear photocopy of the appropriate side of the Health Record may be used to provide this information. **NOTE: If photocopying the Health Record please ensure that the record has been screened for appropriate information only.**

Policy and Procedure for Documentation of Immunization

Policy

Written consent or refusal must be obtained for all immunization and testing procedures. The documentation is kept on the permanent immunization record. A duplicate copy of the record is only made in the event of damage leading to illegibility. The public health nurse is responsible for any transcriptions that are made. This includes a faxed copy of the consent or refusal.

CRMS Procedure

When entering electronic documentation please see **Appendix C**.

Procedure

This procedure refers to the *Immunization and Health Record*. The record is to be completed and updated as follows, **Black Ball point ink is essential**:

- **Identification**
Name, date of birth, sex, parent/guardian, and MCP number.
- **School Information**
Year, school, grade, home room, address and telephone number (for contact with parent/guardian during school hours) are to be completed. This is updated each year as child moves grades.
- **Immunization Record**
All immunizations given are to be recorded in the following manner:
 - **Date** Record in numbers as Year/Month/Day YYYY/MM/DD
 - **Vaccine** Specify the preparation (not code) given: e.g. DTaP-IPV-Hib, Tdap, MMR, etc.
 - **Lot Number** Record full numbers as they appear on the vials or ampoules.
 - **Route** Record as: S.C. for subcutaneous and I.M. for intramuscular
Intranasal **or** NAS for intranasal
 - **Site** Record as: LA for left arm / RA for right arm
LT for left thigh / RT for right thigh
Nostril
 - **Dose** Record as: cc. or mL; when denoting less than a whole number please use 0.5 or 0.25, etc.
 - **Signature** Sign with full name, or first initial and last name and designation (i.e. RN). A sample of the suggested recording format is noted in Table 1.4-1 below:

Table 1.4-1: Sample of Immunization Recording Format

Date	Vaccine	Lot Number	Route	Site	Dose	Signature
20YY/09/09	MMR	09876567	SC	LA	0.5 mL	Ima Nurse RN
2008/02/09	MMR	09876098	SC	RA	0.5 mL	Ima Nurse RN

- **Allergies and/or Events**
Record any allergies or events to previous immunization in this space. If space is inadequate, the inside Notes portion of the card may be used to record details.

- **Immunizations Refused - Allergies – Events Boxes**

These three boxes are located at the top right hand corner of the Immunization and Health Record. These boxes should be checked in red ink if any immunizations are refused; if the child has any allergies; and/or if the child experienced an Adverse Event Following Immunization.

- **Consent or Refusal**

Separate signed and dated consents or refusals are required, as follows:

- **Primary**

This applies to the initial series given at 2, 4, 6, 12, and 18 months. This consent is valid for up to 24 months if schedule is delayed.

- **Kindergarten**

Consent or refusal is obtained and recorded on the *Immunization and Health Record* at a clinic visit or the *Immunization Consent Form* (H-730-YY) is sent to the parent/guardian for completion. When the form is returned, the consent or refusal is detached, the backing is peeled off, and the consent or refusal is placed directly over the space provided on the card.

- **Grade 4, 6, 9 and school based catch-up programs**

An *Immunization Consent Form* (H-730-YY) is sent to the parent/guardian for completion. When the form is returned, the consent or refusal is detached, the backing is peeled off, and the consent or refusal is placed directly over the space on the card. Do not obscure previous consents or refusals; if more space is required a second card may be used numbered 2 of 2.

- **Notes**

This section is reserved for the nurse's information only. Previous illness, such as chickenpox should be documented. If extensive or detailed charting is necessary, a client file is to be kept in the nurse's office.

- **Other Consents As Needed**

Do not obscure previous consents or refusals; if more space is required a second card may be used numbered 2 of 2.

Policy and Procedure for Obtaining a Record of Immunization

Policy

A signed release must be obtained from the person or parent/guardian before any request for a Record of Immunization is sent **to a third party** within the province or jurisdiction outside the province. If the immunization record is for someone living within the province, either in current files or on microfilm, no release is required to provide an individual with a copy of his/her own record.

Procedure for Requesting Records within the Province

- Obtain name (maiden name as well), date of birth, parents' names, and name/address of last high school attended.
- Using the date of birth, determine where the record is stored (BCG records are available for persons born after 1954).
 - If the person is of school age, the record will be found in school files or at the district office. If the person no longer attends school in the area, it may be in a central, regional file.
 - If the person is older than school age, but aged 20 or less, the record will be in either the district office or a central, regional file.
 - If the person is older than 20, the record will be available from the Regional Health Authorities
- Transfer the details of immunization to the appropriate spaces on the *Immunization Record* form or photocopy. The table **Immunization Schedules Previously in Use in Newfoundland** (Section 2.5) may be helpful in the interpretation of the older records.

Procedure for Requesting Records outside the Province

- Obtain name (maiden name as well), date of birth, parents' names, and name/address of last high school attended.
- Ensure that permission for release of the information has been obtained.
- The "Request for School Health (or Immunization) Record" form may be used for this purpose.
- Complete the request for information and forward to the jurisdiction (this information can be obtained from the client) where the record is held.

1.5 The Screening Process and Immunization

Background

Immunization can protect individuals from acquiring life threatening diseases. The products used are safe and present little risk to the person being immunized. However, some factors, such as pre-existing medical conditions, current illness, or allergies may influence the individual's response to immunization.

The public health nurse uses assessment and history taking skills to determine whether a person is to be immunized at a given time. There are four general categories to cover: previous immunization history, health history of the individual, current health status, and questions that are specific to the product being used.

- **Immunization History**
 - What immunizations has the person already received?
 - Has the person been adequately immunized?
 - Has the person ever had a reaction following a previous immunization?
- **Health History**
 - Does the person have a chronic illness, immunodeficiency, or recent history of treatment with either immunosuppressive drugs or immune globulin therapy (e.g., TIG)
 - Does the person have any allergies?
 - What are the allergy producing substances and the nature of the reaction(s)?
- **Current Health Status**
 - Is the person pregnant, or is there the possibility that she may be pregnant?
 - Is the person presently ill?
 - Does the person have a fever?
 - Is the person taking any medication, including using a topical medication?
- **Specific Product Precautions**
 - Information concerning specific precautions and contraindications may be found in the product monograph for each product and in the Canadian Immunization Guide. When the information may not be in agreement, the CIG is used.

The guidelines regarding precautions and contraindications that are provided in the Canadian Immunization Guide are based on the recommendations of the National Advisory Committee on Immunization, and are the guidelines used in this province.

If there is any question as to the interpretation of information on the product monograph, the MOH or designate should be consulted.

The following summarize action once the history and all information on the vaccine has been gathered:

- **Absolute Contraindication to Immunization**

In this case, the person has had an anaphylactic reaction to a previous dose, **or** to any constituent of a vaccine.

- **Immunization in a Controlled Setting**

Occasionally, a person will present with an allergic or medical condition such that there may be some added risk involved in immunizing this person. It is prudent to offer immunization to such an individual in a controlled setting, where emergency medical assistance is readily available, if needed.

- **Deferral of Immunization**

In the case where the person has a medical condition, current moderate to severe illness or immunization history that indicates the preparation cannot be given at this time. It is not a contraindication situation. Instead, immunization is to be deferred, or postponed, until such time that the condition resolves, stabilizes or is ruled out.

- **Straightforward Immunization**

Most individuals who present for immunization are generally well and considered to be fit for the procedure.

Tables 1.5-1, 1.5-2, and 1.5-3 on the following pages outline the general issues concerning screening. More specific information can be found in the procedures for administration of vaccines, in Section 3.0 and in Section 5.0 of the manual and the *Canadian Immunization Guide*.

Policy on the Screening Process in Immunization

Policy

Screening is a process undertaken as a part of every immunization. Each individual is to be assessed for factors that might result in contraindication or postponement (deferral) of the immunization. In the event of conflicting information regarding screening information on specific products, the guidelines that are provided in the *Canadian Immunization Guide* are to be used in this province. CIG: <http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>

Table 1.5-1: Screening Guidelines for All Vaccines

These guidelines must be considered at the outset of any immunization procedure and apply to all vaccines that are given. Persons who are to be immunized are questioned on all of these items.

All Vaccines

CONDITION	IMMUNIZATION ACTION
Anaphylactic reaction to a previous dose of vaccine, or known anaphylactic-type allergies to any component of vaccine, as listed in the product monograph	Do not immunize. These conditions are absolute contraindications
Moderate to severe illness, with or without a fever	Defer immunization until person has recovered.
Latex Allergy - some products or vial closures contain latex	Follow latex free guidelines in Appendix D.
Acute mild illness with or without a fever	Immunize
Recent <i>exposure</i> to infectious illness	Immunize
Recent antimicrobial therapy	Some types of live bacterial vaccines require deferral until 48 hrs after an antibiotic therapy has been completed, see product monograph.
Severe immunodeficiency	Defer immunization see CIG and consult with MOH
Coagulation disorders	Immunize. Modify the procedure by using a small diameter needle (25G) and by applying direct pressure over the site for a five minute period following injection. Do not massage the site.
Prematurity	Immunize as per recommended schedule
Pregnancy	See product monograph
Breastfeeding	Not a contraindication for inactivated vaccines. For live vaccines they may be contraindicated , the mom should consult with her family doctor during pregnancy and prior to the 2 month visit regarding the receipt of live vaccines.
Progressive, evolving or unstable neurological condition	Immunization should be rescheduled when the condition has been resolved or controlled

Table 1.5-2: Screening Guidelines for Inactivated Vaccines

CONDITION	IMMUNIZATION ACTION
Hypotonic or hyporesponsive episode within 48 hours after previous dose of a vaccine	Defer immunization and consult with MOH or designate
Fever $\geq 39.5^{\circ}\text{C}$ after previous dose of a vaccine.	Immunize
Febrile or afebrile convulsion within 48 hours of previous dose of a vaccine	Immunize. Febrile convulsions may be reduced with the administration of acetaminophen
Family history of convulsions or SIDS	Immunize
Pre-existing neurological condition	Immunize
Guillain - Barré syndrome (GBS) within 6 weeks after receiving an influenza or a tetanus containing vaccine	Withhold subsequent influenza or tetanus containing vaccines and consult MOH
Prior history of vaccine preventable disease	Immunize
Persistent inconsolable crying lasting >3hr within 48 hr after prior dose	Immunize
Previous immunization with OPV	Continue series with IPV as per schedule. These products are interchangeable

* **For complete information see product monograph and section specific to that vaccine.**

Table 1.5-3: Screening Guidelines for Live Vaccines

CONDITION	IMMUNIZATION ACTION
Active tuberculosis, positive PPD test or scheduled PPD testing	Immunize. If PPD testing is required, immunize on the day of reading, or defer PPD test until 4-6 weeks later, as live vaccine can suppress a positive PPD result
Administration of another live vaccine within 4 weeks or 28 days.	Do not immunize. Live vaccines can be given the same day at different anatomical site or with 4 weeks between vaccines. See CIG
Has the mom has been taking immunosuppressant medications during pregnancy and while breastfeeding?	For live vaccines they may be contraindicated, the mom should consult with her family doctor during pregnancy and prior to the 2 month visit regarding the receipt of live vaccines.

* **For complete information see product monograph and section specific to that vaccine**

Policy for Post-Immunization Waiting Period

Policy

The Department of Health & Community Services advises that all recipients of immunization remain in the clinic area for a minimum 15 minute post-immunization waiting period, so that any immediate immunization reaction can be assessed and attended to. When there is a specific concern about possible vaccine events 30 minutes is a safer interval for observation. There are some vaccines or instances where clients may be required to remain for a 30 minute observation post immunization (CIG).

1.6 Adverse Events Following Immunization - Management of Symptoms

Background

Some immunizations have mild to moderate effects associated with them, and individuals being immunized or their caregivers must be informed of these before the procedure is carried out. The “*After Immunization*” information sheets contain information on treatment for specific events following immunization and should be provided after each procedure. General information is provided in Table 1.6-1 below.

Table 1.6-1 Treatment for Minor Effects of Immunization

DESCRIPTION	TREATMENT
Fever	Use acetaminophen* as directed dress in light, loose clothing and give fluids
Swelling, edema or tenderness at injection site	Apply cool wet cloths to site, avoid tight clothing
Favouring of injected limb	Encourage movement, avoid tight clothing
Irritability and fussiness, difficulty settling	No specific treatment recommended

* Refer parents to product information for dosage and scheduling of acetaminophen

1.7 Adverse Events Following Immunization

Background

An adverse event following immunization, or AEFI, is an adverse reaction that can be linked in time to an immunization procedure. Specific criteria must be met to define the events as true adverse events, and there must be **no co-existing condition** that could explain the reaction that occurs. It is important to note that the occurrence of a reportable adverse event does not mean that further immunization with that product is contraindicated.

Public Health Agency of Canada maintains a surveillance system to monitor adverse events that occur, administered through the Adverse Event Following Immunization Section of the Division of Immunization, Centre for Infectious Diseases Prevention and Control. This national databank (established in 1987) includes epidemiologic and medical information on all reported adverse events. Data are analysed by event, demographic characteristics, product used, lot number, manufacturer, and number in series.

Adverse events following immunization should be reported as close to the event as possible, but this does not always happen. With infant immunizations, a reaction may not be reported until it is time to receive another immunization, two to six months later. **When providing immunization, remind the individual or parent to contact you as soon as possible if a serious reaction occurs, rather than waiting until the next visit.**

Immunization involves the injection of biologically derived foreign substances into the body, and it is reasonable to expect the body to react. The reaction of a competent immune system to such a foreign substance is the basis of the immune response, as antibodies are formed that will protect the individual against future infection or disease.

Some of the products used in immunization are not completely purified. Trace amounts of proteins, cell products or preservatives can act on the body to produce side effects or vaccine associated adverse events and may preclude further immunization with that product. Such events range from **mild to moderate to severe**.

Mild to moderate events include:

- Transient fever
- Irritability
- Rash
- Swelling and pain at the site of injection
- Aches and pains
- Headache

Adverse events vary according to the vaccine being used, but in general, a mild to moderate event will last for less than 48 hours, and can be relieved with symptomatic treatment. This is alarming for parents and distressing for the child, but it does not mean that the child has had a true adverse event.

Severe events, both local and systemic include:

- Extremely high fever
- Severe pain and local swelling beyond the adjacent joint of the muscle used for administration of vaccine
- Neurological events
- Other severe or unusual events.

Severe events are reportable and must be documented and recorded on an Adverse Events

Following Immunization (AEFI) form.

Please see Section 1.7 for more information on recognizing and reporting adverse events

If an adverse event is reported, a face to face or telephone interview must be carried out to obtain an accurate and complete history of the event. The *Report of an Adverse Event Following Immunization* form is a useful tool for conducting the interview (refer to the information in this section titled **Guidelines for Completion of the AEFI Form**).

Policy and Procedure for Reporting an Adverse Event Following Immunization

Policy

Any individual who presents for immunization is to be questioned regarding any previous reaction to immunizations. If a reported reaction meets the criteria for an adverse event following immunization, then it is to be reported as per the procedure below. In special cases a specific detailed AEFI form may also be requested in addition, as was used with the Occulatory/Respiratory Syndrome.

The appropriate sections of CRMS are completed as well as the AEFI form.

Procedure

- Complete the form *Report of an Adverse Event Following Immunization*, using the guidelines provided in this manual and the *Canadian Immunization Guide*. The forms are available from the Communicable Disease Nurse in each region and on the PHAC website. <http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>
- Complete appropriate sections of the NL registry Client Referral Management System (CRMS).
- Forward the completed form to the Medical Officer of Health (or designate) for comments and signature.
- The name and personal information is removed prior to forwarding to Public Health Agency of Canada.
- Note that copies are then distributed as follows:

Communicable Disease Control Division, Department of Health and Community Services: for forwarding to PHAC

Regional copy: Communicable Disease Control Nurse or Supervisor of Public Health Nursing.

Public Health Nurse: for the health record.

Communicable Disease Nurse/Public Health Nurse: for forwarding to the individual's family physician. This is necessary only if there is a change in future immunization protocol due to AEFI or the family physician made the initial AEFI report.

The Adverse Event Following Immunization Form should be filed according to Regional Health Authority guidelines. The Immunization Reaction box on the top right hand corner of the Immunization and Health Record should be checked in red ink once an Adverse Event Following Immunization has been reported.

Guidelines for Completion of the AEFI Report

The AEFI report has twelve sections that must be completed before the report is forwarded to the Department of Health and Community Services Public Health Division.

Report events which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which meet one or more of the following criteria:

- Is of a serious nature
- Requires urgent medical attention
- Is an unusual or unexpected event

Mild to moderate expected side effects of a particular vaccine, as referenced in this document as well as the vaccine product monograph, do not need to be reported nor require an AEFI submission.

For more information on completing an AEFI, visit <https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html>

To access the AEFI reporting form, visit:

<https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/ae-fi-form-july23-2020-eng.pdf>

Note:

- **The numbers below correspond to the numbered sections of the AEFI form.**
- **All dates should be captured in the following format: Year/Month/Day.**
- **When reporting an AEFI, check one of the boxes on the top right hand corner of the first page of the AEFI form to indicate whether it is an INITIAL or FOLLOW UP report. For all follow up reports, please specify the Unique Episode number.**

- 1a. The “Unique episode number” is assigned by the Province/Territory. Leave it blank unless authorized to assign it.
- 1b. The “Region number” is a number that corresponds to a given health unit. Leave it blank if it doesn’t apply to your locale.
2. The “IMPACT LIN” is assigned by Impact nurse monitors (LIN: Local Inventory Number).
3. The information captured in this section is confidential and is intended for use only by the regional and/or provincial/territorial health officials.
- 4a. Indicate the Province/Territory where the vaccine was administered, abbreviations may be used.
- 4c. Provide all information as requested in the table. For the “Dose #”, provide the number in series (1, 2, 3, 4, 5 or booster) if known. For the Influenza vaccine, unless a patient receives two doses in one season, the “Dose #” should be recorded as “1”.
- 7a. Indicate the highest impact of the AEFI on the patient’s daily activities as assessed by the patient or the parent/caregiver.
- 7c. Provide details of any investigations or treatments in section 10. If the patient was already in hospital when immunized and the immunization resulted in a longer hospital stay, indicate “Resulted in prolongation of existing hospitalization” and provide the number of days by which the patient’s hospital stay was prolonged. For all hospitalizations, indicate the date

of admission and discharge.

8. MOH/MHO: Medical Officer of Health, MD: Medical Doctor, RN: Registered Nurse.
9. Choose, from section 9 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the time of onset and duration of signs/symptoms using the most appropriate time unit: Days, Hours or Minutes. Provide additional details of any investigation, therapy, and other information as appropriate in section 10.
11. This section is to be completed by the MOH/MHO, MD, RN or their designate who are assigned to provide public health recommendations according to the P/T best practices.
12. Information in this section is not collected by all P/Ts.

Management of anaphylaxis

Anaphylaxis is a medical emergency and rapid recognition and management can be life-saving. Every vaccine provider should be familiar with the signs and symptoms of anaphylaxis and be prepared to act quickly.

Protocols

Advance preparation for emergency management of anaphylaxis is essential. It is recommended that vaccine providers develop, post, and regularly rehearse a written anaphylaxis emergency management protocol. Protocols should specify the necessary emergency equipment, drugs and dosages, and medical personnel necessary to safely and effectively manage anaphylaxis. It is also recommended that the PH Nurse note the epinephrine dosage prior to immunizing such that it is readily available should anaphylaxis occur.

Steps for basic management of anaphylaxis in a non-hospital setting

1. **Assess** airway, breathing and circulation.
2. **Direct someone to call 911** (where available) or emergency medical services
3. **Position** the vaccinee on their back or in a position of comfort if there is respiratory distress; elevate the lower extremities. Place the vaccinee on their side if vomiting or unconscious. Pregnant anaphylactic vaccinees should be placed semi-recumbent on their left side with their legs elevated.
4. **Administer epinephrine intramuscularly in the mid-anterolateral aspect of the thigh:** Epinephrine should be administered by 0.01mg/kg body weight of 1:1000 (1mg/mL) solution. Repeat every 5 to 15 minutes as needed, for a maximum of **three doses**.

Rapid assessment and positioning

Rapid intervention is of paramount importance. Assess airway, breathing and circulation and initiate cardiopulmonary resuscitation (CPR) if necessary. When assessing the airway, look specifically at the lips, tongue and throat for signs of swelling. Position the person flat on the back, unless he/she is vomiting or unconscious (if this is the case place the person on their side) or in respiratory distress (may need to elevate head and chest for comfort). Legs should be elevated to help maintain blood pressure. Direct someone to call 911 or emergency medical services for transportation to hospital.

Epinephrine

Administration of epinephrine is the priority and should not be delayed. Epinephrine is the treatment of choice for management of anaphylaxis in community and health care settings as it prevents and relieves upper airway swelling, hypotension and shock. In addition, it causes increased heart rate, increased force of cardiac contractions, increased bronchodilation, and decreased release of histamine and other mediators of inflammation. Epinephrine reaches peak plasma and tissue concentrations rapidly. Failure to administer epinephrine promptly may result in greater risks to the anaphylactic vaccinee than using epinephrine improperly. If uncertain, err on the side of treatment; there are no contraindications to the use of epinephrine. If time is lost early in the treatment of an acute anaphylactic episode; subsequent management can become more difficult.

Epinephrine 0.01 mg/kg body weight of a 1:1000 (1 mg/mL) solution is used to treat anaphylaxis. Dosing is outlined in Table 1.8-2. Weight is the preferred basis for determining dosage of epinephrine but if unknown, age can be used as a guide. Epinephrine should be administered into the mid-anterolateral aspect of the thigh; the deltoid muscle of the arm is not as effective as the thigh in absorbing epinephrine. Scissors may be needed to cut clothing to establish access. If scissors are not available, epinephrine may be administered through clothing. Although there is a slight increased risk of infection, timely administration of epinephrine is the priority. The risk of infection can be addressed once the person has stabilized.

Table 1.8-2: Epinephrine Dosage Recommendations

1:1000, 1mg/mL solution		
Age	Weight	Dose by Injection
Birth to less than 5kg	Less than 5kg	0.1mL
Greater than 5kg but less than 2 years of age	5-10kg	0.1mL
2 to less than 4 years of age	11-15kg	0.15mL
4 to less than 7 years of age	16-20kg	0.2mL
	21-25kg	0.25mL
7 to less than 10 years of age	26-30kg	0.3mL
	31-35kg	0.35mL
10-12 years of age	36-40kg	0.4mL
	41-45kg	0.45mL
Older than 12 years of age	46kg and above	0.5mL

Mild and transient effects such as pallor, tremor, anxiety, palpitations, headache and dizziness occur within minutes after injection of a recommended dose of epinephrine. These effects confirm that a therapeutic dose has been given. Ensure the person lies down. Fatality can occur within seconds if the vaccinee stands or sits suddenly after epinephrine. People should remain in a recumbent position following receipt of an epinephrine injection and be monitored closely. People on beta-blockers may be more resistant to epinephrine.

Transfer to hospital or clinic

All vaccinees receiving emergency epinephrine must be transported to a hospital or clinic immediately for evaluation and observation. Since the symptoms of an anaphylactic reaction can reoccur after the initial reaction (biphasic anaphylaxis) in up to 23% of adults and up to 11% of children, hospitalization is recommended for monitoring. Generally, patients are hospitalized overnight or monitored for at least 12 hours. A biphasic course of anaphylaxis is more likely to occur if the administration of epinephrine is delayed.

Use of Antihistamines

Antihistamines do not have a role in preventing or treating respiratory or cardiovascular symptoms of anaphylaxis in a community setting. Swelling and urticarial rash at the injection site can occur and may be the first indication of an evolving anaphylaxis. In this type of scenario, the individual should be observed for 30 minutes post immunization administration to ensure that swelling or hives remain localized. Ice can be applied to the injection site as a comfort measure. If the swelling or hives disappear and there is no other evidence of any new or worsening symptoms, no further observation is necessary. **If other symptoms arise, even if considered mild (sneezing, nasal congestion, tearing, coughing, facial flushing), or there is evidence of progressive swelling and/or hives to other parts of the body during the 30-minute observation period, epinephrine should be given.**

Source PHAC :

<https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html#a18>