1.0 **PURPOSE:**

1.1 To reduce morbidity and mortality caused by Influenza and Pneumococcal Infection by offering immunization to all residents who meet the criteria established by the National Advisory Committee on Immunization (NACI) and Manitoba Health Seniors and Active Living (MHSAL).

2.0 **DEFINITIONS:**

2.1 Adverse Event Following Immunization (AEFI): any untoward medical occurrence in an individual following immunization which does not necessarily have a causal relationship with the administration of the Vaccine. The adverse event may be any unfavorable and/or unintended sign, abnormal laboratory finding, symptom or disease.

2.2 Anaphylaxis: an often severe and sometimes fatal systemic reaction in a susceptible individual following administration of drugs (e.g. Vaccines, toxoids, immunoglobulins, antitoxins, diagnostic solutions, antibiotics); pollen; food; or other allergic extract or after stinging by venomous insects.

2.3 Cold Chain: refers to all equipment and procedures used to ensure that Vaccines are protected from inappropriate temperatures and light, from the time of transport from the manufacturer to the time of administration.
2.4 **Fluzone® High-Dose**: A high dose influenza vaccine approved by MHSAL for residents of LTC who are 65 years of age and older. This vaccine contains four times the amount of influenza virus antigen per strain (60ug vs. 15ug) compared to the standard inactivated influenza vaccine. Fluzone® High-Dose is a trivalent inactivated vaccine (TIV) and protects against three (2A + 1B) of the influenza strains predicted to be circulating in North America during the influenza season. Given the burden of Influenza A(H3N2) disease and evidence of better efficacy in this age group, it is expected that high dose TIV will provide superior protection compared with the standard dose influenza vaccine.

2.5 **Immunization Provider**: Registered nurse (RN), physician, licensed practical nurse (LPN), registered psychiatric nurse (RPN), pharmacist, or student (RN, LPN, RPN, pharmacy, or medical) under direction of a clinical instructor or physician.

2.6 **Influenza (Influenza-like illness (ILI))**: is characterized as acute onset of respiratory illness with fever and cough and with one or more of the following:
- Sore throat
- Arthralgia (joint pain)
- Myalgia (muscular pain)
- Prostration (extreme exhaustion) that could be due to Influenza virus
In children < 5 years of age, gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea) may be present. In individuals < 5 years or ≥ 65 years old, fever may not be prominent. *Note: Illness associated with novel Influenza viruses may present with other symptoms.*

2.7 **Informed Consent**: A process involving dialogue, understanding and trust between the patient/Resident/client or Substitute Decision-Maker and the responsible party or authorized designate. Informed Consent requires:
- a) The patient/Resident/client or Substitute Decision-Maker to have decision-making capacity;
- b) Requires disclosure of the Information;
- c) Must be specific to the act performed; and
- d) Requires the consent to be given freely and voluntarily, without undue promise of favorable outcome, threat of penalty for non-compliance, or overt or covert coercion.

2.8 **Invasive Pneumococcal Disease (IPD)**: a serious and sometimes fatal bacterial infection of the blood (bacteremia) and or brain (meningitis) caused by the pneumococcal bacteria *Streptococcus pneumoniae.*
2.9 **Pneumococcal Infection:** caused by bacteria that can spread easily from one person to another. The bacteria normally live in fluids in the nose, mouth and throat and many people carry them without getting sick; however some people can develop severe disease. There are more than 90 different types of pneumococcal bacteria that can lead to infections of the ears, sinuses, lungs (pneumonia), blood (bacteremia) and covering of the brain (meningitis). Pneumococcal Infections may occur following a viral infection like **Influenza**.

2.10 **Pneumococcal Conjugate Vaccine (Pneu-P-13):** an inactivated (killed bacteria) Vaccine that provides protection against most of the serious infections caused by 13 types of pneumococcal bacteria in children under 2 years of age, and adults who are solid organ transplant or hematopoietic stem cell transplant (HSCT) recipients and/or have human immunodeficiency virus (HIV).

2.11 **Pneumococcal Polysaccharide Vaccine (Pneu-P-23):** an inactivated (killed bacteria) Vaccine that provides protection against most of the serious infections caused by 23 types of pneumococcal bacteria in people over the age of 2 who are risk for pneumococcal disease.

2.12 **Quadrivalent Inactivated Influenza Vaccine (QIV):** an injectable suspension of four different strains (or types of) inactivated Influenza virus designed to establish immunity when the body responds to the immunization by creating antibodies.

2.13 **Substitute Decision Maker:** a third party identified to participate in decision-making on behalf of a patient/resident/client, who has been determined to lack Decision-Making Capacity, concerning a proposed Procedures(s), Treatment(s), or Investigation(s). The task of a Substitute Decision-Maker is to faithfully represent the known preferences or, if the preferences are not know, the best interests of the incapable patient/Resident/client. The following, in order of priority, may act as a Substitute Decision-Maker(s):

- Proxy named in a Health Care Directive;
- A committee of both property and personal care appointed by:
  a) The court under section 75(2) of The Mental Health Act (Manitoba);
  b) An order under section 61(1) of The Mental Health Act (Manitoba); or
  c) A Substitute Decision-Maker for Personal Care appointed under The Vulnerable Persons Living with a Mental Disability Act (Manitoba). A committee or a Substitute Decision-Maker for Personal Care may be an individual(s) or the Public Trustee.
- Family, friends, and other. This category does not have binding legal authority, the following principles may provide guidance. Within this
context, such a Substitute Decision-Maker must have the support of all interested and available parties. Such a person will usually, but not necessarily, be a close relative, who speaks for all. The listing contained in The Mental Health Act (Manitoba) is guidance and is as follows in order of preference:

a) The adult relatives being of whole blood is referred to relatives of the same description of the half-blood. The elder or eldest of two or more relatives described in any clause is preferred to the other of those relatives, regardless of gender:
   • Spouse or common-law partner;
   • Son or daughter;
   • Father or mother;
   • Brother or sister;
   • Grandfather or grandmother;
   • Grandson or granddaughter;
   • Uncle or aunt;
   • Nephew or niece

b) A supportive friend when family is unavailable or non-existent, or if the patient requested while competent.

c) On occasion, an existing power of attorney may be most appropriate to fulfill this role, since such an individual, although limited to property decision, has obviously been placed in a position of trust.

For the Responsible Party or Authorized Designate to feel confident in identifying a Substitute Decision-Maker from family, friends, and others it will be necessary, within reason, to:

a) Understand relationships, dynamics, hierarchy, and values;

b) Ascertain that there exists acceptance from involved family/friends in the designation of the Substitute Decision-Maker;

c) Clarify as necessary the role of the Substitute Decision-Maker for all interested parties.

If this is not possible, the Responsible Party or Authorized Designate shall act in the best interests of the patient/resident/client. The Responsible Party or Authorized Designate may refer to conflict resolution resources such as ethics services, medication with family/friends or referral to the Public Trustee or courts if apparent dissension among family/friends cannot be resolved.

2.14 **Vaccine**: a suspension of inactivated or live infectious agents, or part thereof, for the purpose of establishing immunity to the infectious agent.
3.0 OPERATIONAL GUIDELINE:

3.1 All Residents of a long-term facility are eligible to receive an annual Influenza immunization regardless of their age. Pneumococcal immunization is provided to all residents who meet the criteria as outlined in the Canadian Immunization Guide.

3.2 MHSAL establishes overall guidance and standards for immunization programs in Manitoba. Requirements for Immunization Providers, including consent and reporting adverse events, are addressed within Manitoba’s Public Health Act, Division 4 Immunization.

**Immunization Providers** shall be responsible for ensuring competency to provide immunizations as required by their professional licensing body. This includes:

- Knowledge of Vaccine preventable disease, benefits and risks of Vaccines, and recommended immunization schedules.
- Knowledge of target populations who are at risk for communicable diseases.

**Immunization Providers** are responsible to ensure they:

- Meet the requirements to provide immunization as required by the site/programs. Regional immunization competencies education is available at [http://www.wrha.mb.ca/education/clinical.php](http://www.wrha.mb.ca/education/clinical.php)
- Follow Routine Practices when administering immunizations.

3.3 Each resident shall be offered Influenza vaccination once the resident or their substitute decision maker has provided Informed Consent.

3.3.1 Consent for MHSAL recommended influenza vaccines must be obtained annually.

3.3.2 Consent for Pneu-P-23 and/or Pneu-P-13 must be obtained when the resident meets the criteria.

3.4 Storage of Vaccines must comply with MHSAL and Winnipeg Regional Health Authority storage and handling guidelines to maintain the Cold Chain available at [http://www.wrha.mb.ca/professionals/immunization/files/03_CPG_Storage.pdf](http://www.wrha.mb.ca/professionals/immunization/files/03_CPG_Storage.pdf).
3.5 In the event a resident has an anaphylactic reaction to the Influenza Vaccine the Immunization Provider shall follow the WRHA LTC Program Operational Directive Anaphylactic Shock - Management of Suspected Anaphylactic Shock in Residents.

4.0 PROCESS:

4.1 Determine which residents are eligible for immunization:

**Influenza Vaccine:**
- All residents of a long term care facility are eligible regardless of their age.
- Residents who are less than 65 years of age are eligible for QIV. Residents who are 65 years and older are eligible for Fluzone® High-Dose.

**Pneu-C-13 Vaccine:**
- **Routine infant immunization:** administer three doses of Pneu-C-13 Vaccine at minimum 8-week intervals beginning at 2 months of age, followed by a fourth dose at 12 to 15 months of age. For healthy infants, a three-dose schedule may be used, with doses at 2 months, 4 months, and 12 months of age.
- **12 to 23 months of age:** administer two doses of Pneu-C-13 Vaccine at least 8 weeks apart to children not previously vaccinated with a conjugate pneumococcal Vaccine or who received only 1 dose before 12 months of age.
- **24 to 35 months of age:** administer one dose of Pneu-C-13 vaccine to children with no or incomplete vaccination schedules with any conjugated pneumococcal vaccine.
- **36 to 59 months of age** - administer one dose of Pneu-C-13 vaccine to:
  - Healthy children who are of aboriginal origin or who attend group child care who have received age-appropriate pneumococcal conjugate vaccination but have not received Pneu-C-13 vaccine. Consider one dose of Pneu-C-13 vaccine for other healthy children.
  - Children at high risk of IPD who have received age-appropriate pneumococcal conjugate Vaccination but have not received Pneu-C-13 vaccine.
  - Children with no or incomplete vaccination schedules with any conjugate pneumococcal vaccine.
- **60 months to 17 years of age:** administer one dose of Pneu-C-13 Vaccine to children and adolescents at high risk of IPD who have not previously received Pneu-C-13 vaccine.
• **Adults with immunocompromising† conditions (except hematopoietic stem cell transplant [HSCT]):** administer one dose of Pneu-C-13 followed 8 weeks later by one dose of Pneu-P-23 (if not previously immunized with Pneu-P-23). The Pneu-C-13 dose should be administered at least one year after any previous dose of Pneu-P-23. A single re-immunization with Pneu-P-23 is recommended.

**NOTE:** Adults who are hematopoietic stem cell transplant (HSCT) recipients, living with human immunodeficiency virus (HIV) and/or solid organ transplant recipients are eligible for publicly funded Pneu-C-13 Vaccine. Adults not meeting these criteria are not eligible for coverage and would need to purchase the Vaccine.

• **Adults with HSCT:** administer three doses of Pneu-C-13 starting 3-9 months after transplant. These doses should be administered at least 4 weeks apart, followed by a dose of Pneu-P-23 12 to 18 months post-transplant (i.e. 6 to 12 months after the last dose of Pneu-C-13). A single re-immunization with Pneu-P-23 is recommended.

**Pneu-P-23 Vaccine**

• Administer one dose of Pneu-P-23 vaccine after Pneumococcal Conjugate Vaccine to children 24 months of age and older, adolescents, and adults who are at high risk of IPD.

• Administer one dose of Pneu-P-23 vaccine to all adults 65 years of age and older and to immunocompetent adults less than 65 years of age in long-term care facilities. Immunocompromised adults should be immunized with Pneu-C-13 and Pneu-P-23 as indicated in the preceding bullet.

• **One lifetime re-immunization with Pneu-P-23 vaccine is recommended for those at highest risk of IPD 5 years after the first dose.**
  - The following individuals are at highest risk for Invasive Pneumococcal Disease (IPD):
    - Asplenia (functional or anatomic)
    - Sickle cell disease
    - Hepatic cirrhosis
    - Chronic renal failure
    - Nephrotic syndrome
    - HIV infection
    - Immunosuppression related to disease or therapy †

† For a list of patients eligible under this category, see the Canadian Immunization Guide at: [www.phac-aspc.gc.ca/publicat/cig-gci/p03-07-eng.php](http://www.phac-aspc.gc.ca/publicat/cig-gci/p03-07-eng.php)
4.2 The **Immunization Provider** shall ensure the resident has no contraindications or precautions to receiving the specified **Vaccine**.

4.2.1 Pneumococcal Vaccines are contraindicated in persons with a history of **Anaphylaxis** after previous administration of the **Vaccine** and in persons with proven immediate or anaphylactic hypersensitivity to any component of the **Vaccine** or its container. For pneumococcal Vaccines, potential allergens include:
- Prevnar®13: diphtheria CRM197 carrier protein
- SYNFLORIX®: latex in plunger stopper of pre-filled syringe, diphtheria toxoid carrier protein, tetanus toxoid carrier protein, non-typeable Haemophilus influenzae protein D carrier protein.

4.2.2 Influenza vaccines are contraindicated in persons who developed an anaphylactic reaction to a previous dose of Influenza vaccine or to any of the vaccine components (with the exception of egg), or developed Guillain-Barré Syndrome (GBS) within six weeks of Influenza vaccination should not receive a further dose.

4.2.2.1 Regarding egg-allergic individuals, after careful review, NACI has concluded that egg-allergic individuals may be vaccinated against **Influenza** using **QIV**, 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.

4.2.3 Administration of either Influenza or pneumococcal vaccine should usually be postponed in persons with serious acute illness until their symptoms have abated. Immunization should not be delayed because of minor acute illness, with or without fever. For pneumococcal vaccines, where hypersensitivity is suspected or allergy not associated with **Anaphylaxis** to vaccine components, investigation is indicated, which may involve immunization in a controlled setting. Consultation with an allergist is advised.
4.3 The **Immunization Provider** will obtain **Informed Consent** from the resident/Substitute Decision Maker prior to administering the pneumococcal vaccine. The discussion to enable **Informed Consent** should include the following:

- The risk of the disease in the absence of vaccination and with vaccination
- The benefits and risks of the **Vaccine**
- Route and schedule
- Common side effects and their management
- Contraindications

4.3.1 Document consent using the WRHA LTC Program Immunization Consent Form (Appendix A). Provide the resident and/or Substitute Decision Maker with the appropriate MHSAL Communicable Disease Control Fact Sheet:

- QIV  
- Fluzone® High Dose  
- Pneu-P-23  
- Pneu-P-13  

4.4 Administer the specific **Vaccine** the resident is eligible for as directed by the **Vaccine** product monograph.

4.5 Document each resident’s **Vaccine** administration information and follow up in the resident’s health record. Document the date the **Vaccine** was administered, manufacturer and lot number, vaccination site and route, and the name and title of the person administering the **Vaccine**. If **Vaccine** was not given, document the reason(s) for non-receipt of the **Vaccine** (e.g., medical contraindication, resident/Substitute Decision Maker refusal). Residents who refuse **Fluzone® High Dose** should be offered **QIV**.

4.6 Be prepared for management of a medical emergency related to the administration of **Vaccine**. Have a written emergency medical protocol available, as well as equipment and medications.
4.7 **Adverse Events Following Immunization** (AEFI) should be reported when the event:

- Has a temporal (time) association with the Vaccine. That is, it occurs in a short time frame (less than 48 hours) after immunization.
- 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 causality. Sometimes the medical history, recent disease, concurrent illness/conditions and/or concomitant medications(s) can explain the event.

Of particular interest are those serious AEFIs which meet the following criteria:

- One that is life threatening or results in death, requires hospitalization or a prolonged stay in an existing hospitalization, results in residual disability or causes congenital malformation.
- Requires urgent medical attention
- Is an unusual or unexpected event: 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.

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


4.8 The Immunization Submission tab contained in the seasonal influenza immunization and oseltamivir spreadsheet [http://www.wrha.mb.ca/extranet/ipc/files/manuals/ltc/seasonalspreadsheet2017.xlsx](http://www.wrha.mb.ca/extranet/ipc/files/manuals/ltc/seasonalspreadsheet2017.xlsx) may be used to record, print and send via certified courier to report the Pneumococcal Vaccine information to WRHA Population and Public Health for entry into the immunization database. See the [Influenza Management Resource Guide](http://www.wrha.mb.ca/extranet/ipc/files/manuals/ltc/seasonalspreadsheet2017.xlsx) for additional detail.
**Operational Directive Contact:**  WRHA LTC Manager of Infection Prevention and Control

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Updated August 22, 2017 with MHSAL recommendations for [Fluzone® High Dose](#).
5.0 REFERENCES:

5.1 Communicable Disease Control, Cold Chain Resources
http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html


Influenza and Pneumococcal Immunization Consent Form

I, ______________________________, voluntarily consent (or give consent on behalf of the patient/resident named) to receive the annual influenza vaccine and/or a pneumococcal vaccine if required as recommended and funded by Manitoba Health.

I have been informed of the purpose, anticipated benefits, contraindications, risks and possible side effects of immunization as well as the risks of not having the immunization. I am aware that the record of my immunization will be shared with Manitoba Health.*

☐ Written Consent

Signature of patient/resident or substitute decision maker

Witness to consent

Date

Date

☐ Verbal Consent

Consent provided by: _____________________

Witness to consent

Date

Date

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