Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg — Caring for Health / À l'écoute de notre santé	**TITLE** ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)	
WRHA IMMUNIZATION PROGRAM CLINICAL PRACTICE GUIDELINE	**Approved by:** Population and Public Health	**Pages:** *1 of 5*
	Approval Date: November 9, 2022 Updated	**Supersedes (if applicable)** **Target Review Date:** *November 2027*

1.0 PURPOSE

1.1 To monitor vaccine safety and report adverse events following immunization.

1.2 To contribute to maintaining the safety of vaccines.

2.0 DEFINITIONS

2.1 Adverse events following immunization (AEFI): An AEFI is any untoward medical occurrence in a vaccinee that follows immunization and that does not necessarily have a causal relationship with the administration of the vaccine (based on International Conference on Harmonisation (ICH) Topic E6 definition). The adverse event may be any unfavorable and/or unintended sign, abnormal laboratory findings, symptom or disease.[1]

2.2 Serious adverse event following immunization (Serious AEFI): is one that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.[1]

2.3 Substitute decision maker: a designated person able to make a legal decision on behalf of an individual who is not capable to make a decision for him/herself. This may include: a parent or guardian, a decision maker for a person living with a disability under the Vulnerable Person Act, a public trustee.[2]

2.4 Immunization Provider: A health care professional who is registered or licensed to provide health care under an Act of the Legislature and who is authorized under that Act to administer vaccines [3] Eg. registered nurse (R.N.), physician, licensed practical nurse (L.P.N.) registered psychiatric nurse (R.P.N.), pharmacists, health care provider students under the supervision of a clinical instructor or physician.

2.5 Individual: Patients, residents, clients, tenants or staff (including volunteers)

3.0 SCOPE & GOAL

3.1 All individuals immunized shall be advised of possible side effects of vaccines as part of the informed consent process.

3.2 All individuals immunized shall be advised to contact the immunization provider, as soon as possible, if they have an adverse event following an immunization.

---

[1] Manitoba Health, User Guide: Report of Adverse Events Following Immunization (AEFI)

[2] Manitoba Health, Communicable Disease Control, Immunization Manual Protocol, Informed Consent Protocol

[3] Manitoba Health, Communicable Disease Control, Immunization Manual Protocol, Informed Consent Protocol

3.3 According to Manitoba legislation, C.C.S.M. c. P210 The Public Health Act (in effect since April 1, 2009), Division 4 # 59 states there is a duty to report adverse events following immunization." Within seven days after becoming aware of a reportable event, a health professional must report it in accordance with the regulations."

3.4 The immunization provider shall obtain relevant information about the adverse event.

3.5 Immunization providers are responsible to report all vaccine adverse events as defined on the Adverse Events Following Immunization Report form. The prescribed form will be used. See resources for the form and user guide.
https://www.gov.mb.ca/health/publichealth/cdc/docs/mhsu_2334.pdf

http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_manual.pdf

3.6 The immunization recipient or substitute decision maker will be advised of recommendations for future immunization.

4.0 PROCEDURE

4.1 Health care providers should report all clinically significant events that:
• 1. Is temporally **associated with a vaccine AND**
• 2. Has **no other clear cause at the time of reporting,**
regardless if they believe the event was caused by the vaccine or not. 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.

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).

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

a. Is of a serious nature
b. Requires urgent medical attention
c. Is an unusual or unexpected event

4.2 If the adverse event does not meet the criteria according to the AEFI Report form (e.g. is an expected common adverse event such as inflammation at the injection site or mild fever), the information should be documented in the client health record. An AEFI Report is not necessary.

4.3 Any health care provider can report an adverse event by completing the AEFI Report with as much information as possible.
Refer to Appendix A* – *Flow Chart for AEFI Reporting

For the Population and Public Health Program:

4.3.1 If an immediate AEFI is experienced at a WRHA Clinic Setting and is severe enough that the client is transported to the hospital;

4.3.1.1 The immunization provider will contact the Communicable Disease Coordinator as soon as possible by phone. The name of the hospital receiving the client will be documented on the AEFI form.

4.3.1.2 The AEFI Report form should be completed with as much information as is available at the time of the report. The consent form should be attached to the AEFI report and faxed to the WRHA Communicable Disease Unit within 24 hours.

4.3.1.3 The Communicable Disease Coordinator or the assigned nurse will complete any further AEFI follow-up required. The receiving hospital should be contacted to determine the diagnosis, outcome, and planned follow-up from the ER visit.

4.3.2 Other serious AEFIs should be reported as soon as possible, within 24 hours. "Serious AEFI" should be written on the top of the AEFI form.

4.3.3 Other non-serious AEFI should be reported within 7 days of notification.

4.3.4 Documentation of AEFI and interventions are also to be documented in the Immunization notes section of the client record in PHIMS.

For all other WRHA programs/sites:

4.3.4 Serious AEFIs should be reported as soon as possible, within 24 hours. "Serious AEFI" should be written on the top of the AEFI form.

4.3.5 Other non-serious AEFI should be reported within 7 days of notification

4.4 Place a copy of the AEFI Report on the individual's health record.

4.5 The AEFI Report form must be forwarded to:

Communicable Disease Coordinator
Adverse Events Following Immunization,
2nd Floor, 490 Hargrave Street, Winnipeg MB, R3A 0X7
Fax 204-940-2690

4.6 The AEFI Report is reviewed by the Communicable Disease Coordinator in consultation with the Regional Medical Officer of Health (MOH). Recommendations are provided for further immunizations.

4.7 The Communicable Disease Unit will forward the AEFI Report form which includes the MOH recommendations to the health care provider that reported the adverse event.

4.7.1 For Public Health: The Public Health Nurse will verbally communicate the recommendations for further immunizations to the individual or the parent/ substitute decision maker.

4.7.2 The PHN will request the name and address of the individual's primary care provider if one is available and forward the contact information to CDC Coordinator and WRHA Centralized Admin. WRHA Centralized Admin will fax the AEFI report and recommendations to the identified health care provider. If the individual does not have a primary care provider and requests documentation of the event, discuss with the CD Coordinator.

4.8 The health care provider is responsible to advise the individual or substitute decision-maker of the recommendations regarding future immunizations and provide any further follow-up or investigations required.

4.9 All reports will be entered centrally into PHIMS and subsequently submitted to Manitoba Health. Manitoba Health submits electronic data to the Public Health Agency of Canada, Vaccine Safety Section. Reports are entered into the national CAEFI database and coded using standard international coding systems.

5.0 VALIDATION

5.1 Public Health Agency of Canada, Adverse Events Following Immunization
http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php

5.2 Manitoba Health, Communicable Disease Control, Adverse Events Following Immunization, User guide, November 2016
http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_manual.pdf

5.3 Reporting Form for Adverse Events Following Immunization (AEFI)
https://www.gov.mb.ca/health/publichealth/cdc/docs/mhsu_2334.pdf

5.4 Manitoba Public Health Act C.C.S.M. c. P210 The Public Health Act
http://web2.gov.mb.ca/laws/statutes/ccsm/p210e.php

6.0 RECOMMENDED READING

6.1 Canadian Immunization Guide, Evergreen version
http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

6.2 Public Health Agency of Canada, Adverse Events Following Immunization
http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php

6.3 Manitoba Public Health Act C.C.S.M. c. P210 The Public Health Act
http://web2.gov.mb.ca/laws/statutes/ccsm/p210e.php