COVID-19 Vaccine

Active Surveillance and Reporting of Adverse Events Following Immunization (AEFI)

Revised: July 15, 2021

This policy is evergreen and will be updated as new information becomes available.

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I. Introduction

The monitoring of adverse events following immunization (AEFI) involving vaccines and biologicals administered in Alberta is an important evaluation component of the provincial immunization program. AEFI reporting and monitoring is also a key contributor to public confidence in vaccine programs; is critical to vaccine safety surveillance; is used to confirm results of pre-licensure clinical trials; and provides a process to identify previously unknown concerns for each product.

Alberta has a robust passive AEFI surveillance system. In the context of COVID-19 vaccine introduction, as these are new vaccines based on new technology, it is essential to establish an active surveillance system to supplement the routine passive reporting system. Active surveillance will ensure information on AEFIs are collected rapidly and safety signals are detected and responded to early. It also enables enhanced monitoring of pre-specified adverse events of special interest (AESIs) for COVID-19 vaccines in the context of overall AEFI surveillance.

This document has been developed specifically for COVID-19 vaccine AEFI active surveillance. Active AEFI surveillance for COVID-19 vaccine in Alberta involves a collaboration between Alberta Health, Alberta Health Services Provincial AEFI Team, and the Canadian National Vaccine Safety Network (CANVAS).

For AEFI reporting guidance in Alberta see Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers.

II. Legislative Authority

The AEFI Policy for Alberta Immunization Providers is provided under the authority of the Public Health Act (Act) and Part 2 of the *Immunization Regulation* which outlines the requirements for the reporting of adverse events following immunization.

III. Reporting to Alberta Health Services (AHS)

When to report to Alberta Health Services

Health practitioners are to report an adverse event following immunization to AHS within 3 days of determining or being informed that a patient has experienced an adverse event following immunization unless it has already been reported.

What to report to Alberta Health Services

Any "adverse event following immunization" defined as an unfavourable health occurrence experienced by a patient that:

a) follows immunization,
b) cannot be attributed to a pre-existing condition, and
c) meets one or more of the following criteria, as determined by a health practitioner:
    i. the health occurrence is life threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;
    ii. the health occurrence is unusual or unexpected, including, without limitation, an occurrence that
        A. has not previously been identified, or
        B. has previously been identified but is being reported at increased frequency;
    iii. the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.

If unsure or if there are questions contact AHS.

Data elements

The following data elements must be reported in respect of the adverse event following immunization:

a) patient first name and last name;
b) patient personal health number or unique lifetime identifier;
c) patient date of birth;
d) patient sex at birth;
e) description of the adverse event, including, without limitation, any applicable symptom or diagnosis listed in the *Immunization Regulation* Schedule as reported by the patient or observed or diagnosed by the health practitioner, as the case may be, and the onset and duration of the adverse event;
f) vaccine code of the vaccine used in the immunization preceding the adverse event following immunization, if available;
g) lot number of the vaccine used in the immunization preceding the adverse event following immunization, if available;
h) manufacturer of the vaccine used in the immunization preceding the adverse event following immunization, if available;
i) date of the immunization preceding the adverse event following immunization;
j) delivery management site code for the immunization preceding the adverse event following immunization, if available;
k) first name, last name and telephone number of the person reporting.

How to report an adverse event following immunization

The health practitioner shall ensure that the adverse event following immunization is reported to the AHS Provincial AEFI Reporting Line at 1-855-444-2324 (1-855-444-CDCI) or online see Alberta Health Services information on how to report an adverse event following immunization for information.

IV. AEFI versus AESI (Adverse Events of Special Interest)

AEFI

Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Ref: https://www.who.int/vaccine_safety/committee/Module_AESI.pdf?ua=1

AESI in the context of COVID-19

A pre-identified and predefined event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies. The AESI descriptions and definitions provided in this document are for passive reporting. This list of AESIs will also be assessed through CANVAS or special studies and the timeframe for monitoring may be longer.

Note: These Adverse Events of Special Interest are in addition to the current reportable AEFIs summarized in section VI and detailed in Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers.

The AESIs defined for COVID-19 vaccines are described in Section V.

Not currently reportable in Alberta:

- acute aseptic arthritis
- acute cardiovascular injury
- acute kidney injury
- acute respiratory distress syndrome
- acute liver injury
- anosmia/ageusia
- chilblain – like lesions
- coagulation disorder
- meningoencephalitis
- multisystem inflammatory syndrome in children
- single organ cutaneous vasculitis
- vaccine-associated enhanced disease

Currently reportable in Alberta:

- ADEM
- anaphylaxis
- convulsions
- erythema multiforme
- GBS
- thrombocytopenia

AESIs which are not currently reportable will be reported under the "AESI" category – include in comments the designated AESI.

Ref: https://www.who.int/vaccine_safety/committee/Module_AESI.pdf?ua=1

V. Adverse Events of Special Interest Following COVID-19 Immunization

The designated AESIs are:

AESI	Currently reportable in Alberta	Brighton Collaboration case definition link
"Acute aseptic arthritis"		10.1016/j.vaccine.2017.08.087
"Acute cardiovascular injury" (microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis)		Targeted for Nov 15, 2020
"ADEM" Acute disseminated encephalomyelitis	Yes	10.1016/j.vaccine.2007.04.060
"Acute kidney injury"		Targeted completion by Nov
"Acute liver injury"		Targeted completion by Nov
"ARDS" Acute respiratory distress syndrome		https://brightoncollaboration.us/bc-case-definition-acute-respiratory-distress-syndrome-ards/
"Anaphylaxis"	Yes	10.1016/j.vaccine.2007.02.064
"Anosmia", "ageusia"		Targeted completion by Nov
"Chilblain – like lesions"		Targeted completion by Apr 2021
"Coagulation disorder" (thromboembolism, haemorrhage)		Targeted for Nov 15, 2020
"Convulsion"	Yes	10.1016/j.vaccine.2003.09.008
"Erythema multiforme"	Yes	
"GBS" Guillain Barré Syndrome	Yes	10.1016/j.vaccine.2010.06.003
"Meningoencephalitis"		10.1016/j.vaccine.2007.04.060
"MISC" Multisystem inflammatory syndrome in children		https://brightoncollaboration.us/multisystem-inflammatory-syndrome-in-children-and-adults-mis-c-a-case-definition/
"Single organ cutaneous vasculitis"		10.1016/j.vaccine.2016.09.032
"Thrombocytopenia"	Yes	10.1016/j.vaccine.2007.02.067
"VAED" Vaccine-associated enhanced disease		https://brightoncollaboration.us/vaed/

https://www.who.int/vaccine_safety/committee/Module_AESI.pdf?ua=1

AESI Reporting Criteria

These criteria are under development and will be updated as new information becomes available

Acute aseptic arthritis

Definition: Acute aseptic arthritis is a clinical syndrome characterized by acute onset of signs and symptoms of joint inflammation, increased white blood count (WBC) in synovial fluid and the absence of an identifiable causative organism

Reportable if: Onset within 7 days of COVID immunization:

1. Physician or health care provider assessed septic arthritis

   AND

2. Without history of recent trauma

   AND

3. Develops one of the following
   - Joint or surrounding tissue swelling
     OR
   - Joint effusion
     OR
   - Joint and/or surrounding tissues erythema
     OR
   - Increased warmth palpable over the joint
     OR
   - Restricted range of movements in a joint

   AND

4. The above findings are present for less than 6 weeks.

Notes:

- Analysis of synovial fluid may or may not be performed
- One or more joints may be involved

See: Acute aseptic arthritis: Case definition & guidelines for *data collection*, analysis, and presentation of immunisation safety data. 2019, January 7. 10.1016/j.vaccine.2017.08.087

Acute cardiovascular injury

Definition: Acute cardiovascular injury (ACI) is an acute disorder which may manifest clinically either as microangiopathy, heart ischemia, myocarditis, pericarditis, cardiomyopathy, arrhythmia, heart failure, cardiogenic shock, stroke and/or thromboembolic events usually associated with abnormalities on ECG, echocardiography or cardia MRI and elevated biochemical markers.

Reportable if: Onset within 7 days of immunization:

1. Physician-diagnosed Acute cardiovascular injury

AND

2. Vaccine recipient develops a new-onset clinical symptom(s) compatible with acute cardiovascular illness/event (e.g., shortness of breath, chest pain, tachycardia, hypotension, headache, visual disturbances, motor/sensory/balance abnormalities)

OR

3. Has newly detected abnormalities on ECG (e.g., ST elevation, arrhythmia) or echocardiography or cardia MRI

OR

4. Has at least one cardiac troponin (cTn) or creatinine kinase-MB concentration that is above the 99th percentile upper reference limit regardless of symptoms

AND

5. No alternative cause for diagnosis was identified

NEW Myocarditis

Definition: Myocarditis is a disorder characterized by inflammation of the heart muscle and can affect heart's electrical system, leading to irregular heart rhythm or compromised cardiac function. Pericarditis is an inflammation of the outer lining of the heart. Myocarditis/pericarditis can be caused by infections, drugs, systemic illnesses, and sometimes the exact cause cannot be identified.

Reportable if: Onset within 42 days of immunization:

1. Physician-diagnosed myocarditis

OR

2. Histopathological evidence of myocardial inflammation

OR

3. A new-onset of clinical symptom(s) compatible with myocarditis or pericarditis (e.g., one or combinations of dyspnea, chest pain, palpitations, syncope, edema, diaphoresis, fatigue/lethargy, nausea/vomiting or irritability and poor feeding in small children)

AND

Develops one or more of the following

- Elevated myocardial biomarker(s) (troponin I or troponin T or CK-MB)
- Non-specific ECG abnormalities (e.g., premature atrial or ventricular beats) and elevated inflammatory markers (e.g., ESR or CRP or D-dimer)
- ECG abnormalities (ST-segment or T-wave abnormalities, paroxysmal or sustained atrial or ventricular arrhythmias or conduction abnormalities)
- Abnormalities on echocardiography (e.g., abnormalities of ventricular function, segmental wall motion abnormalities, ventricular dilatation, intracavitary thrombi)
- Abnormalities on cardiac MRI

OR

4. No symptoms outlined above, but elevated myocardial biomarkers (troponin I or troponin T) **AND** at least one of the following
   - Abnormalities on cardiac MRI
   - Abnormalities on echocardiography (e.g., abnormalities of ventricular function, segmental wall motion abnormalities, ventricular dilatation, intracavitary thrombi)

WITH or WITHOUT

5. Associated pericarditis

AND

6. No alternative cause for diagnosis was identified

Acute kidney injury

Definition: Acute kidney injury (AKI) is a sudden episode of kidney failure or kidney damage which causes a build-up of waste products in the blood and may lead to alterations in fluid, electrolyte, acid-base and hormonal regulation.

Reportable if: Onset within 7 days of COVID immunization:

1. Physician diagnosed acute kidney injury;

AND

2. Has developed elevated serum creatinine and/or reduced urinary output

AND

3. There is no pre-existing condition or concurrent administration of medications which may explain this presentation

Acute liver injury

Definition: Acute liver injury is an illness of variable severity that occurs in persons who develops clinical symptoms of hepatotoxicity and/or laboratory evidence of elevated liver enzymes and/or altered liver function

Reportable if: Onset within 7 days of COVID immunization:

1. Physician diagnosed acute liver injury;

AND

2. Vaccine recipient develops a new-onset clinical symptom(s) of hepatotoxicity

AND/OR

3. Has developed elevated liver enzymes

AND

4. There is no pre-existing condition or concurrent administration of other medications which may explain this presentation

Acute respiratory distress syndrome

Definition: Acute respiratory distress syndrome **(**ARDS) is defined as an acute disorder which is characterized by bilateral lung infiltrates and severe progressive hypoxemia not fully explained by cardiogenic pulmonary edema.

Reportable if: Onset within 7 days of immunization:

1. Physician-diagnosed ARDS

AND

2. Vaccine recipient develops dyspnea, hypoxemia and/or altered mental status, which progressively worsens within hours to days

AND

3. Characterized by bilateral lung infiltrates on chest radiography or CT of a non-cardiac origin, and a PaO_2/FiO_2 ratio of less than 300 mmHg with a minimum of 5 cm H_2O PEEP (or CPAP)

AND

4. There is no pre-existing or known acute medical condition which may explain this presentation

Anosmia, Ageusia

Definition: Anosmia/ageusia is a condition characterized by subjective loss or alteration of sense of smell or taste.

Reportable if: Onset within 7 days of COVID immunization:

1. Vaccine recipient develops a subjective loss or alteration of sense of smell or taste

AND

2. It persists for at least 24 hours

AND

3. It is not associated with trauma, respiratory infections such as influenza or previously diagnosed medical condition manifesting as anosmia or ageusia

Note: Reporting does not require confirmation by physician

Chilblain – like lesions

Definition: Chilblains are the inflammation of small blood vessels in the skin that occur in response to repeated exposure to cold temperatures. Lesions resembling chilblain may be seen on toes, fingers, feet, or hands.

Reportable if: Onset within 7 days of COVID immunization:

1. Vaccine recipient develops lesions resembling chilblain (usually on toes and fingers)

AND

2. One or more of the following symptoms/signs
   - Discoloration
   - Blisters
   - Swelling
   - Pain
   - Pruritis

AND

3. Lesions persist for at least 24 hours

AND

4. The appearance of lesions is not precipitated by exposure to cold

Note: Reporting does not require confirmation by physician

Coagulation disorder

Definition: Coagulation disorder is an abnormality of hemostasis cascade leading to either excessive bleeding or the increased risk of thrombosis.

Reportable if: Onset within 28 days of COVID immunization:

1. Physician diagnosed coagulation disorder

AND

2. Vaccine recipient develops a new-onset clinical symptom(s) compatible with thrombotic event or bleeding (e.g., organ bleeding, stroke, deep vein thrombosis, pulmonary embolism)

OR

3. Has newly detected elevations in fibrinogen and D-dimer levels and/or prolongation of PT/aPTT regardless of platelet count

AND/OR

4. Evidence of thrombotic event or bleeding detected ultrasonography or other imaging modality

AND

5. No alternative cause for diagnosis was identified

NEW Thrombosis with Thrombocytopenia Syndrome (TTS)

Interim Draft Case Definition – for investigation and reporting purposes.

Reportable if: Onset within 42 days of COVID immunization

1. Physician diagnosed Thrombosis with Thrombocytopenia Syndrome

AND

2. Patient presents with symptoms suggestive of acute venous or arterial thrombosis including one of the following specific clinical syndromes:
    - Cerebral venous sinus thrombosis / other Cerebral venous thrombosis (new onset of unexplained headache, often severe; focal cerebral dysfunction; encephalopathy; seizure)
    - Limb ischemia due to arterial thrombosis (new onset of a cold, painful, discoloured limb, reduced sensation, paralysis)
    - Deep vein thrombosis (new onset swelling usually but not always in lower extremities; localized swelling accompanied by pain [may be crampy in nature] and tenderness; reddened/discoloured/warm skin; pitting edema)
    - Pulmonary thromboembolism (sudden onset: shortness of breath[at rest or on exertion], pleuritic chest pain[sudden, intense, sharp, stabbing or burning in nature, made worse by breathing/coughing/sneezing/laughing], cough +/- hemoptysis), tachypnea, tachycardia, arrhythmia, cyanosis, hypotension)
    - Intra-abdominal thrombosis (abdominal pain [may be out of proportion to physical exam findings], bloating, nausea, vomiting, diarrhea, bloody stools, ascites, hepatomegaly if hepatic vein location)
    - Ischemic Stroke (sudden onset of focal neurologic deficits such as difficulty with speech [dysphasia or dysarthria], hemiparesis, ataxic gait abnormal eye movements, facial paresis)
    - Myocardial infarction (chest pain [often crushing in nature], shortness of breath, arrhythmias including asystole, cyanosis)

AND

3. Thrombocytopenia (defined as platelets count <150x109/L)

WITH or WITHOUT

4. Imaging studies supportive of diagnosis of thrombosis/thromboembolism

AND/OR

5. Lab findings supportive of diagnosis of thrombosis/thromboembolism

    e.g. D-dimer elevated above the upper limit of normal for age OR shortened PT, PTT – below the lower limit of normal for age

NOTE: Cases reported under TTS will be investigated and reviewed to determine if the criteria for Vaccine Induced Thrombotic Immune Thrombocytopenia (VITT) have been met.

Interim case definition developed by PHAC and based on draft Brighton Collaboration case definition and Case Finding Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)

For additional information: see Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following AstraZeneca COVID-19 Vaccination: Interim Guidance for Healthcare Professionals in Emergency Department and Inpatient Settings

Meningoencephalitis

Definition: Meningitis is an infection or inflammation of the membranes covering the brain and spinal cord. Encephalitis is central nervous system inflammation presenting with depressed or altered consciousness and signs of focal or multifocal central nervous system abnormality. Evidence of both conditions are required to diagnose meningoencephalitis.

Reportable if: Onset within 15 days of COVID immunization:

1. Physician diagnosed Meningoencephalitis

AND

2. Vaccine recipient develops clinical symptoms of meningitis AND/OR encephalitis

AND

3. No etiological agent/cause for diagnosis was identified

AND

4. CSF evaluation and/or neuroimaging are usually performed and are supportive of the diagnosis.

See: Encephalitis, myelitis, and acute disseminated encephalomyelitis (ADEM): Case definitions and guidelines for collection, analysis, and presentation of immunization safety data. 2007, August 1. 10.1016/j.vaccine.2007.04.060

MIS-C - Multisystem inflammatory syndrome in children

Definition: Multisystem inflammatory syndrome in children (MIS-C) is a condition where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs

Reportable if: Onset within 42 days of COVID-19 immunization:

1. Physician-diagnosed MIS-C

AND

2. Vaccine recipients (typically aged 0-19 years old) develops fever lasting 3 days or longer

AND

3. Other signs/symptoms or abnormal test results involving at least two of the following
- Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs
- Hypotension or shock
- Features of myocardial dysfunction, or pericarditis, or valvulitis, or coronary abnormalities
- Evidence of coagulopathy (abnormal PT, PTT, elevated d-Dimers)
- Acute gastrointestinal problems (diarrhea, vomiting or abdominal pain)

see Public health disease management guidelines : Multisystem Inflammatory Syndrome in Children (MIS-C)

AND

4. Elevated inflammatory markers (e.g., ESR, CRP, procalcitonin)

AND

No etiological or infectious cause identified to explain this presentation

Single organ cutaneous vasculitis

Definition: Single organ cutaneous vasculitis (SOCV) is a syndrome characterized by clinical and histological features of small vessel vasculitis of the skin without involvement of other organ systems.

Reportable if: Onset within 7 days of COVID immunization:

1. Physician diagnosed single organ cutaneous vasculitis

   AND

2. Vaccine recipient has developed a new-onset cutaneous lesions including
   - Hemorrhagic papules
     OR
   - Urticaria-like lesions (hives)
     OR
   - Purpuric rash involving face or extremities AND edema AND low-grade fever

   OR

3. Confirmed by histology.

   AND

4. Exclusion of other organ or systemic involvement

See: Single organ cutaneous vasculitis: Case definition & guidelines for data collection, analysis, and presentation of immunization safety data. 2016 December 12. 10.1016/j.vaccine.2016.09.032

Vaccine-associated enhanced disease

Definition: Vaccine-associated enhanced disease (VAED) is an illness that occurs in persons who receive a vaccine and who are subsequently infected with the pathogen that the vaccine is meant to protect against.

Reportable if: Onset within 42 days of COVID immunization:

1. Physician-diagnosed VAED

   AND

2. Vaccine recipient develops laboratory confirmed (by RT-PCR performed by APL) COVID-19 infection after receiving a COVID-19 vaccine dose

   AND

3. Has severe and/or modified/unusual clinical symptoms compatible with COVID-19 infection as determined by the attending physician

   AND/OR

4. Hospitalized

   AND/OR

5. Has evidence of immunopathology in target organs as determined by the histopathologist

Note:

- Regardless of results of validated serological test for COVID-19 prior to receiving vaccine

See: Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data. 2020, October 19. https://brightoncollaboration.us/vaed/

VI. Reportable Adverse Events Following Immunization

Summary of AEFI Reporting Criteria

See the Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers for complete descriptions.

AEFI	Reporting Criteria	Vaccines (temporal criteria**)	
		Inactivated	Live
ADEM (acute disseminated encephalomyelitis)	• Physician-diagnosed encephalomyelitis AND • One or more focal or multifocal findings referable to the central nervous system	0 – 42 days	MMR 5 – 30 days Varicella 5 – 42 days
Adenopathy	• Enlargement of one or more lymph nodes, > 1.5 cm in diameter AND/OR • Draining sinus over a lymph node.	0 – 7 days **mRNA COVID-19** 5 – 30 days	5 – 30 days
Allergic Reaction	• One or more of the following signs/symptoms: hives, itching, edema, stridor, wheezing	0 – 48 hours	0 – 48 hours
Anaesthesia/ Paraesthesia	• Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more	0 to 15 days	MMR: 0 – 30 days Varicella: 0 – 42 days
Anaphylaxis	• Sudden onset* AND rapid progression of signs and symptoms AND • Symptoms include one or more of the following: progressive painless swelling around face or mouth, new onset of wheezing, shortness of breath, and/or stridor, hypotension/collapse OR • Event managed as anaphylaxis at the time of occurrence	0 – 24 hours Typically, within seconds to minutes, usually within 1 hour.	0 – 24 hours
Arthralgia/Arthritis	• Arthralgia or arthritis lasting ≥ 24 hours	n/a	5 – 30 days
Bell's Palsy	• Physician-diagnosed Bell's palsy	0 – 3 months	0 – 3 months
Cellulitis	• Physician-diagnosed cellulitis AND • Characterized by at least three of the following local signs or symptoms: pain or tenderness to touch, erythema, induration or swelling, warm to touch AND • Reaction is at the injection site	0 - 7 days	0 - 7 days

AEFI	Reporting Criteria	Vaccines (temporal criteria**)	
		Inactivated	Live
Convulsions (febrile and afebrile)	• Seizures (febrile or afebrile) with generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations, occurring within AND • History or report of loss of consciousness.	0 – 72 hours	5 – 14 days
Encephalitis	• Physician diagnosed encephalitis AND • At least one listed indicator of central nervous system inflammation AND • > 24 hours of 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	0 – 42 days	MMR 5 – 30 days Varicella 5 – 42 days
Erythema Multiforme	• Rash specific to Erythema Multiforme • Must be diagnosed by a physician.	5 days or more	5 days or more
GBS (Guillain-Barre syndrome)	• Physician-diagnosed GBS	0 to 6 weeks	0 to 6 weeks
HHE (hypotonic-hyporesponsive episode)	• Hypotonia (muscle limpness) AND • Either hyporesponsiveness or unresponsiveness AND • Either pallor or cyanosis	0 – 72 hours	0 – 72 hours
Infected Abscess	• Spontaneous or surgical drainage of purulent material from the mass OR • Demonstration of material by an imaging technique AND • Localized sign(s) of inflammation, which would include one of the following: erythema, pain to light touch, swelling, and warmth to touch AND • Evidence of resolution/improvement temporally related to antimicrobial therapy	0 - 7 days	0 - 7 days
Intussusception	• Physician-diagnosed intussusception following rotavirus vaccine receipt AND • Evidence of intestinal obstruction and/or invagination and/or vascular compromise	n/a	Rotavirus vaccine: 0 – 42 days
Meningitis	• Physician-diagnosed aseptic meningitis for which no other cause has been identified.	0 – 15 days	MMR: 5 – 30 days Varicella: 0 – 42 days
Myelitis	• Physician-diagnosed myelitis AND • Two or more indicators suggestive of spinal cord inflammation.	0 – 42 days	5 – 42 days

AEFI	Reporting Criteria	Vaccines (temporal criteria**)	
		Inactivated	Live
Narcolepsy	• Narcolepsy is characterized by excessive daytime sleepiness and episodes of muscle weakness brought on by emotions. See www.who.int/vaccine_safety/initiative/BC_Narcolepsy_case_definition.pdf (Reported under "Other Severe or Unusual Events)	0 – 4 weeks	0 – 4 weeks
Nodule	• Firm nodule is at the injection site AND • Persists for > 1 month	0 - 7 days	0 - 7 days
ORS	• Onset of bilateral red eyes AND • One or more of the following respiratory symptoms: Cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat WITH or WITHOUT facial edema.	Influenza: 0 – 24 hours	n/a
Orchitis	• Physician-diagnosed orchitis	n/a	Mumps: 5 – 30 days
Paralysis	• Physician-diagnosed paralysis with no other cause identified AND • Lasting more than 24 hours	0 - 15 days	MMR or OPV: 0 – 30 days Varicella: 0 – 42 days
Parotitis	• Physician-diagnosed parotitis	n/a	Mumps: 5 – 30 days
Rash	• Varicella-like rash with ≥ 50 lesions OR • Requiring hospitalization OR • Rashes or eruptions on the skin that are not expected, with an onset within 7 days of immunization and lasts ≥ 4 days AND either • Generalized rash: systemic eruption in two or more parts of the body OR • Localized at non-injection site; eruption localized at another part of the body, away from the injection site OR • Requires hospitalization.	0 – 7 days	Varicella: 0 – 42 days
Screaming Episode/Persistent Crying	• Presence of screaming or crying > 3 hours	0 – 72 hours	0 – 72 hours
Severe Diarrhea and/or Vomiting	• Three or more episodes of vomiting or diarrhea within a 24-hour period AND • Vomiting and/or diarrhea is severe	0 – 72 hours	0 – 72 hours

AEFI	Reporting Criteria	Vaccines (temporal criteria**)	
		Inactivated	Live
SIRVA	• Includes both pain and reduced range of motion AND these are limited to the shoulder in which the intramuscular vaccine was administered; and • No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; including no other condition or abnormality is present that would explain the patient's symptoms. • Lasting longer than 4 days (Reported under "Other Severe or Unusual Events"	0 – 7 days	0 – 7 days
Sterile Abscess	• Spontaneous or surgical drainage of non-purulent material from the mass OR • Demonstration of material by an imaging technique AND • Absence of localized signs of inflammation such as erythema, pain to light touch, and warm to touch at the injection site OR • Failure to resolve or improve on antimicrobial therapy	0 - 7 days	0 - 7 days
SSPE (subacute sclerosing panencephalitis)	• Physician-diagnosed SSPE	n/a	Measles: 0 – 10 years
Swelling and/or Pain	• Swelling extends past the nearest joint OR • Severe pain that interferes with the normal use of the limb lasts > 4 days OR • Reaction requires hospitalization	0 - 48 hours	0 - 48 hours
Thrombocytopenia	• Physician-diagnosed platelet count of less than 150 X 109/L	0 – 6 weeks	0 – 6 weeks
Other Severe or Unusual Events	• Not clearly covered by other reporting categories and fits description above or requires emergency room visit within 72 hours of immunization OR • Any death of a vaccine recipient temporally linked to immunization where no other clear cause of death can be established.	0 – 4 weeks	0 – 4 weeks

**Temporal criteria guidelines in this table are generally agreed upon approximate timelines. The timeframe between immunization and event onset is an important consideration in assessment of causality.

VII. Active AEFI Surveillance following COVID-19 Immunization

7.1 Population

The population that will be asked to enroll in the active AEFI surveillance program are those individuals eligible for receipt of the COVID-19 vaccine.

7.2 Active Surveillance Survey Timing

AHS Provincial AEFI Team	**CANVAS**
Two dose schedule • 8 days after dose 1 • 8 days after dose 2 • 6 month post-immunization One dose schedule • 8 days • 28 days • 6 months post-immunization	Two dose schedule • 8 days after dose 1 • 8 days after dose 2 • 6 month post-immunization One dose schedule • 8 days • 28 days 6 months post-immunization.

7.3 Participant recruitment and Consent

	AHS Provincial AEFI Team	**CANVAS**
Phase 0 (Early Phase 1)	N/A	**HCWs** • Recruitment to be done at time of immunization • Planning to have ability to recruit online when immunization appointment is made (end of January 2021). • Every vaccine recipient eligible to take part of active surveillance. • Require consent of the vaccine recipient to send information • Participants will be provided a brief description of what to expect on follow-up. **See CANVAS protocol.**
Phase 1	Congregate Care/Supportive Living Residents	
Phase 2	N/A	CANVAS is the lead on active surveillance
Phase 3	N/A	

PHAC/CANVAS goal – 50,000 individuals per province per vaccine

7.4 Participant follow-up

At follow-up, a standard AEFI questionnaire (see below 4.6), developed by PHAC and the Vaccine Vigilance Working Group (VVWG), will be used by all jurisdictions to ensure standard common data elements are collected.

CANVAS - See CANVAS documents and study protocol. https://canvas-covid.ca/

Reportable AEFIs and AESIs must also be reported using the current reporting process outlined above (Section III - Reporting to Alberta Health Services (AHS) and in the AEFI Policy for Alberta Immunization Providers.)

7.5 Data Elements

The **follow-up questionnaire** for self-reporting by participants will include the following data elements:

- Unique identifier
- Demographics (age, sex, occupation, race/ethnicity)
- Health Card number
- Adverse events experienced including time to onset and duration of event
- Level of care obtained
- Absenteeism from work/school or prevented daily activities
- Treatment received
- Outcome of events

7.6 Standard Questionnaire for Active Surveillance

1. Data elements are listed above. Below are individual questions to collect the data.

2. If female and 15-49 years old.
   a. Are you currently pregnant?
      - If Yes what trimester are you in?
        - 1st (0-14 weeks)
        - 2nd (15-28 weeks)
        - 3rd (29-42 weeks)

   b. Have you experienced a birth, stillbirth, or miscarriage in the last 7 days?
      - If Yes, what trimester were you in?
        - 1st (0-14 weeks)
        - 2nd (15-28 weeks)
        - 3rd (29-42 weeks)

3. In the first week (7 days) after your COVID vaccine did you develop a new health problem or did an existing health problem get worse?
   - If Yes
     - Was this health problem severe enough to prevent/stop normal activities?
     - Was this health problem severe enough to miss work/school?
     - Did you see a health care provider for this health problem?
       i. If Yes, what type of medical visit did you have? (check all that apply)
          - Clinic/family physician (telephone or in-person)
          - Emergency room
          - Hospitalization
          - COVID-19 Testing
          - Other: _____ e.g. Physiotherapist, chiropractor

       ii. Did the health care provider give you a diagnosis?
       If Yes, specify the diagnosis: _____

4. [If Yes to 3.]: How long after the vaccine did your health problem start or your existing health problem get worse?
   - Within the first hour (60 minutes) after my COVID vaccine
   - Within the first day (2 to 24 hours) after my COVID vaccine
   - 2-3 days after my COVID vaccine
   - 4-5 days after my COVID vaccine
   - 6 -7 days after my COVID vaccine
   - 8 or more days after my COVID vaccine

5. [If Yes to 3.]: How long did your health problem last?
   - Lasted less than one hour (60 minutes)
   - Lasted 1 to 10 hours
   - Lasted one day (11-24 hours)
   - Lasted 2-3 days
   - Lasted 4-5 days
   - Lasted 6 or more days
   - It is still present: [If Yes], has your health problem improved, stayed the same, or worsened?

6. [If Yes to 3.]: Please check all the symptoms you experienced as part of your health problem. We are interested in the symptoms that started in the first week (7 days) after your COVID vaccine. This does not mean these are common symptoms of the COVID vaccine (check all that apply):
    - Any of the following: Feeling unwell, tiredness, weakness, muscle aches, fatigue, or chills.
    - Any of the following: Nausea, Vomiting, Diarrhea, or Stomach pain
    - Fever (temperature at least 38.0°C or higher)
    - Headache or migraine
    - Arthritis/joint pain/stiffness
    - Inability to walk
    - Loss of taste/smell
    - Loss of vision
    - Hoarseness (raspy or strained voice; "frog in throat")
    - Sore throat
    - Chest tightness/discomfort/pain/angina
    - Difficulty breathing/shortness of breath without throat/tongue swelling
    - Wheezing
    - Cough
    - Runny nose
    - Nasal congestion(stuffed nose)/sinus congestion
    - Swelling of the throat and/or tongue with difficulty breathing or swallowing
    - Swelling of a part of your face or lips (excluding eyelids)
    - Swelling of the eyelid(s)
    - Redness of both eyes
    - Painful eyes
    - Itchy eyes
    - Tearing or eye discharge
    - Earache/ear pain/ear symptoms/decreased hearing/hearing loss
    - Rash or hives
    - Bruising or pinpoint dark red rash (NOT at injection site)
    - Shingles
    - Rapid heart rate (pounding or racing heart; palpitations)
    - Symptoms of a blood clot or bleeding: swelling/pain in legs/blood clot/low platelets
    - Sudden weakness or paralysis on one side of the face
    - Numbness, tingling, pins and needles, decreased sensation or burning sensation anywhere in the body
    - Dizziness/vertigo/light-headedness
    - Fainting
    - Seizure or convulsion
    - Neurologic symptoms: weakness or paralysis of the arms or legs/confusion/change in personality/behavior or difficulty with urination or defecation
    - Difficulty or pain with urination (urinary tract infection symptoms)
    - Jaundice/yellowing of eyes
    - Anaphylaxis
    - Other (specify) _____

    [If Yes to 3.] and If pregnant:
    - Stillbirth or miscarriage
    - Preterm labour (regular contractions starting before 37 weeks gestation (>3 weeks before your due date))
    - Preterm birth (delivery of infant before 37 weeks gestation (>3 weeks before your due date))
    - High blood pressure
    - [if yes to above] eclampsia/preeclampsia
    - Vaginal spotting or vaginal bleeding
    - Abnormal fetal heart rate (heart rate that is too fast or too slow)
    - Other complication of pregnancy (specify: _____)

7. [If Yes to 3.]Did you experience any of the following:
    - Redness, pain or swelling at the injection site
    - Redness, pain or swelling above the shoulder or below the elbow in the immunized arm

8. [If Yes to 3.]: If you had more than one symptom that started in the first 7 days after your vaccine what was the most severe symptom?

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This is Exhibit "F" referred to in the Affidavit of:

David Thomas Dickson

Sworn before me this

18th day of October, 2021

Redacted

Commissioner for Oaths, Justice of the Peace,

or Notary Public in and for Alberta

A Commissioner for Oaths
for the Province of Alberta

Redacted

Print Name and Expiry Date

Alberta