# ADVERSE EVENTS FOLLOWING IMMUNIZATION

An Adverse Event following Immunization (AEFI) is an event or reaction that occurs following immunization that may or may not be caused by the vaccine.

### **How do I report an AEFI to York Region?**

 Use the <u>Public Health Ontario AEFI reporting form</u> and fax the completed form to York Region Public Health at 905-898-5213, or call the Vaccine Information Line at 1-877-464-9675, ext. 73452.

## What kind of events should be reported?

You should report any adverse event which may be related to receipt of a vaccine as outlined on Public Health Ontario's <u>Factsheet on Adverse Event Following Immunization Reporting for Health Care Providers</u> and the <u>COVID-19 Vaccine Adverse Events of Special Interest (AESIs)</u>
<u>Document</u>. Of particular importance are events which require medical consultation or unusual/ unexpected events that do not have a clear alternative cause identified. In addition to the usual AEFIs that require reporting found in the above <u>Fact Sheet</u>, the following Adverse Events of Special Interest following COVID-19 vaccine should be reported if <u>definitions</u> are met:

Vaccine Associated	Myocarditio/Doriografitio	Acute Respiratory Distress		
Enhanced Disease	Myocarditis/Pericarditis	Syndrome		
Subacute Thyroiditis	Acute Kidney Injury	Acute Liver Injury		
Anosmia and/or Ageusia	Chilblain – Like Lesions	Single Organ Cutaneous Vasculitis		
Erythema Multiforme	Acute Pancreatitis	Rhabdomyolysis		
Acute Cardiovascular Injury	Multisystem Inflammatory Syndrome in Children and Adults	Coagulation Disorders (including thrombotic events)		
Thrombosis with Thrombocytopenia Syndrome (TTS) and Vaccine-Induced Immune Thrombotic				
Thrombocytopenia (VITT)				

 Additionally, please use the attached <u>AEFI reporting decision making tool</u> for quick reference on more common adverse events that should be reported.

#### **PUBLIC HEALTH**

## What should NOT be reported?

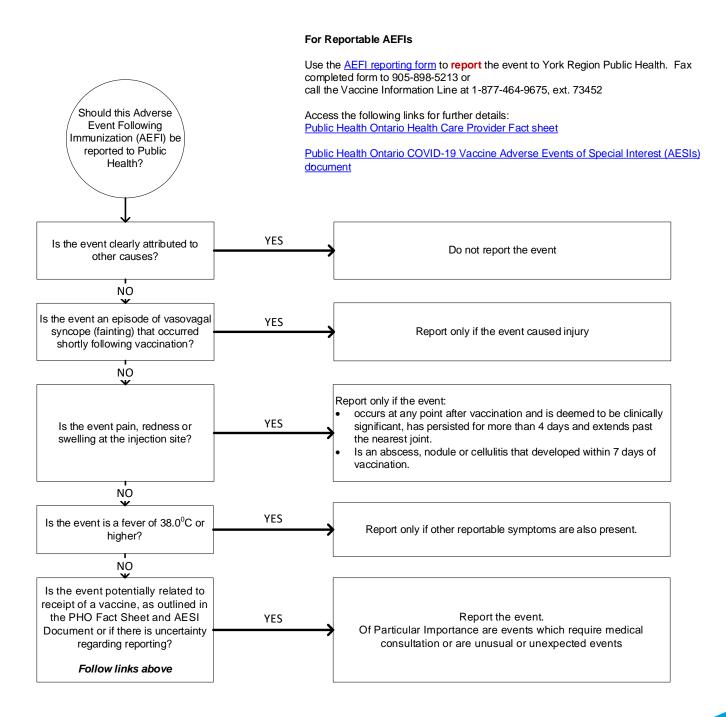
Some common or mild events following immunization do not need to be reported. These include:

- Events that are clearly attributed to other causes.
- Fever that is not accompanied by any other reportable symptoms.
- Injection site reactions lasting less than 4 days
- Vasovagal syncope (without injury)

## Who can I contact if I have questions or require additional information?

• If assistance in completing the form is required or for any questions regarding reporting criteria, please do not hesitate to contact the **Vaccine Information Line at 1-877-464-9675**, ext. **73452** and a Public Health Nurse will be happy to assist you.

# SHOULD YOU REPORT AN ADVERSE EVENT TO YORK REGION PUBLIC HEALTH?



#### **PUBLIC HEALTH**

Vaccine Information Line: 1-877-464-9675 ext. 73452 york.ca



# ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING

### FOR HEALTH CARE PROVIDERS IN ONTARIO

#### DO YOUR PART TO MONITOR ADVERSE EVENTS!



Advise patients to contact you or your team if they experience an adverse event after vaccination.



Report adverse events to your local public health unit, using Public Health Ontario's Report of Adverse Event Following Immunization Reporting Form.



Contact your <u>local public</u>
<u>health unit</u> if you have any
questions about AEFI
reporting.

#### **QUESTIONS & ANSWERS**

#### What is an AEFI?

An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine.

#### Who should report an AEFI?

Health care providers (i.e. physicians, nurses and pharmacists) are required by law to report AEFIs. Reports should be made using the Ontario AEFI Reporting Form and sent to the local public health unit.

Vaccine recipients or their caregivers may also voluntarily report AEFIs to public health.

# Why is it important to report an AEFI?

When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information is also used to report on vaccine safety to Ontarians, which contributes to the success of immunization programs.

# What types of adverse events should be reported?

You should report any event which may be related to receipt of a vaccine, as outlined on the next page. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

# What does NOT need to be reported?

Some common or mild events do not need to be reported. These include:

- fever that is not accompanied by any other symptoms
- injection site reactions that last less than 4 days
- vasovagal syncope (without injury)
- events that are clearly attributed to other causes.

#### What do I need to know about reporting AEFIs for COVID-19 vaccine?

Similar to reports for other vaccines, reports of AEFIs for COVID-19 vaccine should be made using the Ontario AEFI Reporting Form and sent to your local public health unit. The AEFI reporting form has been updated to include adverse events of special interest for COVID-19 vaccine, in addition to the list of adverse events on the next page which apply to all vaccines.

IF YOU ARE UNSURE WHETHER TO REPORT AN AEFI, BE **PROACTIVE** AND **REPORT** THE **EVENT**.

#### TYPES OF ADVERSE EVENTS TO REPORT

The table below lists the types of adverse events that you should report to your <u>local public health unit</u>. For each event there are estimated timelines between vaccination and onset of symptoms (i.e., temporal criteria). Other events not listed below can also be reported if they are clinically significant. If you are unsure, be proactive and report.

Adverse event type	TEMPORAL CRITERIA for Non-live vaccines	TEMPORAL CRITERIA for Live vaccines
Injection site reactions	Non-live vaccines	Live vaccines
Pain or redness or swelling lasting 4 days or more OR extending beyond the nearest joint	0 to 2 days	0 to 7 days
Infected abscess	0 to 7 days	0 to 7 days
Sterile abscess	0 to 7 days	0 to 7 days
Nodule	0 to 7 days	0 to 7 days
Cellulitis	0 to 7 days	0 to 7 days
Systemic reactions	Non-live vaccines	Live vaccines
Rash	0 to 7 days	0 to 42 days
Adenopathy/lymphadenopathy	0 to 7 days	0 to 42 days
Severe vomiting/diarrhea	0 to 3 days	0 to 42 days
Parotitis	N/A	0 to 30 days
Hypotonic-hyporesponsive episode (HHE); under 2 years of age only	0 to 2 days	0 to 2 days
Persistent crying/screaming; under 2 years of age only	0 to 3 days	0 to 3 days
Allergic reactions	Non-live vaccines	Live vaccines
Event managed as anaphylaxis (i.e., epinephrine administered)	0 to 24 hours	0 to 24 hours
Oculorespiratory Syndrome (ORS)	0 to 24 hours	0 to 24 hours
Allergic skin reaction (e.g., hives)	0 to 2 days	0 to 2 days
Neurologic events	Non-live vaccines	Live vaccines
Convulsions/seizure	0 to 3 days	0 to 42 days
Encephalopathy/encephalitis	0 to 42 days	0 to 42 days
Meningitis	0 to 15 days	0 to 42 days
Anaesthesia/paraesthesia	0 to 42 days	0 to 42 days
Paralysis	0 to 42 days	0 to 42 days
Myelitis/transverse myelitis	0 to 42 days	0 to 42 days
Acute disseminated encephalomyelitis (ADEM)	0 to 42 days	0 to 42 days
Guillian Barré Syndrome (GBS)	1 to 8 weeks	1 to 8 weeks
Bell's palsy	0 to 3 months	0 to 3 months
Other events of interest*	Non-live vaccines	Live vaccines
Arthritis/arthralgia	0 to 30 days	0 to 42 days
Intussusception	N/A	0 to 42 days
Thrombocytopenia	0 to 42 days	0 to 42 days
Syncope (fainting) with injury	0 to 30 minutes	0 to 30 minutes
Kawasaki disease	0 to 42 days	0 to 42 days
Other severe/unusual events	Reportable regardless of timeline	Reportable regardless of timeline

<sup>\*</sup>Other adverse events of special interest for COVID-19 vaccine have been added to the Ontario AEFI Reporting Form, please refer to the form for a complete list of types of adverse events to report.

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