COVID-19 VACCINE UPDATE #35 FROM HALTON REGION PUBLIC HEALTH

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TO: Halton Physicians, Nurse Practitioners, Emergency Departments, other Healthcare Providers

FROM: Dr. Joanna Oda, Associate Medical Officer of Health

DATE: May 4, 2021

RE: COVID-19 Vaccine Update 35: Important reminder about what constitutes an AEFI

QUICK FACTS

- Health care professions are mandated under the Health Protection and Promotion Act to report Adverse Events Following Immunization (AEFIs) to their local public health unit. Please do not ask patients to contact Public Health to report reactions or AEFIs.
- If patients experience a reportable AEFI, please complete the provincial form (pdf here) and fax to Halton Region Public Health at 905-465-3403 or email to AEFI@halton.ca. Use the most recent AEFI form (2021). See attached listing for which adverse events need to be reported.
- Not all immunization reactions need to be reported as Adverse Events Following Immunization (AEFI).

REPORTABLE ADVERSE EVENTS

- An AEFI is an unexpected health effect that happens after an individual receives a vaccine, which may or may not be caused by the vaccine.
- Health professionals should report adverse events when there is:
  - A temporal association with a vaccine
  - Urgent medical attention required or severe outcomes
  - Unusual or unexpected effects
- You **do not need to report the following:**
  - Expected side effects of vaccination
    - Fever or chills not accompanied by another reportable adverse event
    - Headache, muscle, joint pain or fatigue
    - Pain, redness or swelling at the injection site lasting less than four days
  - Vasovagal syncope (without injury)
  - Adverse events related to admininistration of passive immunizing agents (eg. Immune globulin), tuberculin skin tests or other drug products

REPORTING VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA (VITT)

- The AstraZeneca vaccine is associated with a very rare side effect known as Vaccine-Induced Thrombotic Thrombocytopenia (VITT).
- The Ontario Science Advisory Table has updated guidance for the diagnosis and treatment of VITT in both the inpatient and outpatient setting.
- Please report suspected or confirmed VITT, including thrombosis, using the provincial AEFI form.

ADDITIONAL RESOURCES

- Adverse Events of Special Interest (AESI) for COVID-19 Vaccines Surveillance, Public Health Ontario
- Adverse Event Following Immunization Reporting for Health Care Providers in Ontario, Public Health Ontario
- Provincial Case Definitions for Diseases of Public Health Significance (AEFIs), Ministry of Health

Please report all suspected/confirmed cases of Diseases of Public Health Significance to Public Health immediately by calling 311, 905-825-6000 or toll free at 1-866-442-5866.

PLEASE PROVIDE A COPY TO ALL PHYSICIANS IN YOUR OFFICE AND/OR POST IN EMERGENCY DEPARTMENTS AND PHYSICIAN LOUNGES. IF YOU HAVE ANY ISSUES WITH THIS ATTACHMENT, PLEASE EMAIL DOCTORS@HALTON.CA.

Public Health Ontario | Santé publique Ontario

ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING
FOR HEALTH CARE PROVIDERS IN ONTARIO

DO YOUR PART TO MONITOR ADVERSE EVENTS!

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

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

3 **Contact** your local public health unit 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 local public health unit. 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**

**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.*

For questions about AEFI reporting, contact your **local public health unit**.
PublicHealthOntario.ca/VaccineSafety

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