As the provincial COVID-19 vaccination program continues to expand, a centralized intake process for the follow-up of Adverse Events Following Immunization (AEFI) specific to COVID-19 immunizations has been established to streamline a provincial approach and ensure timely investigation.

Effective April 22, 2021 all COVID-19 vaccine related AEFI’s are to be reported by calling HealthLine 811. The new process for reporting AEFI’s was soft launched on April 13. HealthLine 811 has processes in place to centrally triage and refer all potential AEFIs to Public Health teams, who will follow up with patients in their local areas.

What you need to know:

- If you or someone in your care is experiencing an AEFI, you should report it by calling HealthLine 811
- When a patient, resident, healthcare worker or member of the public experiences an adverse event following immunization (AEFI), immunizing staff and physicians have a legal obligation as per The Public Health Act, 1984 to report the event to the medical health officer (MHO) within a certain time frame, depending on the severity of the event.
- AEFI’s are reported in order to:
  - continuously monitor the safety of marketed vaccines in Canada;
  - identify increases in the frequency or severity of previously identified vaccine-related reactions;
  - identify previously unknown AEFIs that could possibly be related to a vaccine (unexpected AEFI);
  - identify areas that require further investigation and/or research; and
  - provide timely information on AEFI reporting profiles for vaccines marketed in Canada that can help inform immunization-related decisions.

Questions and Answers:

What is an Adverse Event Following Immunization (AEFI)?

- According to the Saskatchewan Immunization Manual, Chapter 11, page 1, an AEFI is any untoward medical occurrence which follows immunization but which does not necessarily have a causal relationship with the administration of the vaccine.
- Specific criteria must be met to define the events as true adverse events, and there must be no coexisting condition that could explain the reaction that occurs.

What are potential reactions from the COVID-19 immunization?

- Symptoms are categorized as either local, systemic or other reactions.
- Local reactions are related to injection site pain, swelling, or redness whereas systemic reactions are usually non-specific and can include tiredness, headache, muscle pain, joint pain, chills or fever. Enlarged lymph nodes (swollen glands) that last for several days may also occur. Other reactions may include thrombosis or thrombocytopenia.
- If needed, pain or fever medication (such as acetaminophen or ibuprofen) may be taken following immunization to assist with local or systemic reactions.
- The severity of a local or systemic reaction can range from mild to moderate or major.
- Mild reactions can be “expected” and do not require reporting. Reactions that are moderate or major in severity must be reported to the MHO and an assessment and recommendation by the MHO must take place prior to providing further immunizations.
- Examples of moderate and major reactions include:
Provincial reporting process for COVID-19
Adverse Events Following Immunization

- Moderate: Extremely high fevers, severe local reactions
- Major: Anaphylaxis, neurological events, thrombolytic events

**If you or someone you are caring for thinks they may have had or are having a reaction to the COVID-19 immunization, even if it is mild, please call HealthLine 811 to have your symptoms triaged.**

**How do I report a COVID-19 AEFI?**
- All COVID-19 related AEFI’s should be reported by HCWs or the general public calling HealthLine 811
- Family physicians should continue to follow their local procedures. However, if you were referring patients to public health for reporting, please now ask them to call HealthLine811
- Pharmacists should continue to support their clients and complete the AEFI notification form for all reportable AEFIs. If a client, who received a COVID-19 vaccination from a pharmacist, calls HealthLine 811, HealthLine 811 will triage them appropriately and will complete a notification form for reportable AEFIs and will send the completed form to public health.
- A summary of the AEFI reporting criteria, the form and more information can be found at [https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-july23-2020-eng.pdf](https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-july23-2020-eng.pdf)

**What happens when an AEFI is reported?**
- Clients and health care workers who believe they are experiencing an AEFI should call in to HealthLine811.
- The HealthLine811 clinician will triage your symptoms and provide care advice. Referrals will be sent to local public health teams when a reportable AEFI is identified.
- Public Health will follow-up with client to collect more information and complete an AEFI report form, if appropriate, which will then be sent to the local medical health officer (MHO).
- The MHO reviews the report, provides a recommendation and the AEFI form is returned to the author of the form. The author will follow up with the client with any recommendations.
- Once reviewed, it will be documented and uploaded into Panorama and forwarded to the Ministry of Health
- The Ministry of Health will de-identify information and send it to the Public Health Agency of Canada (PHAC).
- On both a provincial and national level these reports are regularly reviewed to identify any unusual concerns.

**What should I do if a patient or resident in my care within our facility has what I feel might be an adverse event following a COVID-19 immunization?**
- Review [chapter 11 of the Saskatchewan Immunization Manual](https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-july23-2020-eng.pdf) to see if the event is reportable
- Inform the most responsible physician if needed
- The most responsible physician or you may then report to HealthLine811
- Each facility/home will need to develop a work standard on how you will report an AEFI to HealthLine811

**What should a HCW do if they experience what they feel is an adverse event following a COVID-19 Immunization?**
- Call 911 if there is a life threatening reaction
- If you are experiencing side-effects following your COVID-19 immunization, call HealthLine811 to report your adverse event and to receive care advice.