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Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI)

QUICK REFERENCE GUIDE

Adverse Events Following Immunization (AEFI)

- Report events which have a temporal association with a vaccine, and which cannot be clearly attributed to other causes.
- A causal relationship does not need to be proven and submitting a report does not imply causality.
- Of particular interest are those AEFIs which:
  - meet one or more of the seriousness criteria
  - are unexpected regardless of seriousness

Note: An AEFI form should not be filled out and submitted if an immunization error has occurred (unless an AEFI results from the immunization error).

Document the incident and follow-up plan in the case of immunization error (e.g., product expired, wrong vaccine given, incorrect route, inappropriate dose of vaccine given). Submit a report through the pharmacy's usual reporting process (e.g., CPhIR—Community Pharmacy Incident Reporting System) and communicate as appropriate with client or parent/caregiver and the primary care practitioner.

- Expected side effects from vaccines do not require reporting.
- Specific criteria must be met to define the events as true adverse events.
  - Healthcare professionals need to be familiar with the frequency and nature of reactions that may occur post-immunization.
- There must be no co-existing condition that could explain the reaction that occurs.
- Remind the patient or parent/caregiver to contact you as soon as possible if a serious reaction occurs, rather than waiting until the next visit.
- Mild fever and swelling are relatively common, predictable, and self-limiting.
- Pharmacists who are prescribing and administering vaccines should know the difference between minor, moderate, and major reactions following immunization.

Where to Submit AEFI Forms

Publicly funded vaccines (e.g., Influenza, COVID-19)

- **AEFI form** is sent to local **Public Health Office**.
  - Saskatchewan Public Health Offices **list of phone numbers**

Out-of-pocket/ non-publicly funded vaccines (e.g., Herpes zoster)

- Pharmacies are to submit AEFI reports related to non-publicly funded vaccines to **Health Canada** via the Canada Vigilance Program, to the prescriber (which may be a pharmacist), and to the primary care practitioner (if different from prescriber).
- The prescriber/primary care practitioner is to make a decision going forward (continuing the series, etc.).
- The pharmacist who filled out the AEFI is to communicate the decision to the patient and document on the patient's file.
- This AEFI does NOT go to Public Health.
- Options to report to the Canada Vigilance Program:
  - Use the **online reporting form**.
  - Download and fill out the **Side Effect reporting form** and fax to 1-866-678-6789.
    - If an **AEFI form** was already completed, it can be faxed to 1-866-678-6789 , no need to re-do it on the Canada Vigilance Forms listed above. The AEFI form asks for more vaccine-specific info than the Canada Vigilance reporting form. Note that the information in section 3 of the AEFI form is confidential and should not be included.
  - Phone 1-866-234-2345.
  - Hospitals that are already using sFTP (secure file transfer protocol) can report using this method.

Note: There is no central repository of AEFI documentation; therefore, it is important patients understand that they are responsible for informing future immunizers of past adverse reactions following immunizations.

Completing the Health Canada AEFI Form

The AEFI form has 12 sections that must be completed, as applicable, before submission.

Tips for filling out the AEFI form:

For more in-depth information, please see the Public Health Agency of Canada's **user guide for reporting adverse events.**

SECTION 1: Unique Episode Number and Region Number can be found in the **SIM, Chapter 11**. This should only be filled out by those authorized to assign numbers at provincial health authorities. Leave blank if you are not authorized to assign numbers.

SECTION 2: IMPACT LIN (local inventory number) is a code assigned by nurses at IMPACT sites. Leave the section blank if you are not an IMPACT site.

SECTION 3: Patient Identifier (This section is intended for use by regional and/or provincial health officials. Do not forward this section if submitting AEFI form to Canada Vigilance for non-publicly funded vaccines.)

PATIENT IDENTIFICATION INFORMATION: Provide the patient's first and last names, health services number (if applicable), address of usual residence including postal code (with the understanding that this address may be in a different province/territory than where the vaccine(s) was received or from where the AEFI is being reported), and a telephone number (either residential, business, or both), where the patient can be reached.

INFORMATION SOURCE: If the source of the information for the AEFI report is a parent or another care provider, provide their name, relation to the patient, and contact information (including their full mailing address and phone number where they can be reached), if it is different from the patient's. This is not the immunization provider.

SECTION 4: Information at Time of Immunization and AEFI Onset

- Use only accepted biological product abbreviations assigned by PHAC in **Annex 2**. A list of approved vaccines in Canada, including their abbreviations, can also be found **here**.
- Indicate where (geographically) the vaccine(s) were received, even if out of country (may be different from the patient's residence and/or from where the AEFI is being reported). Also include the date and time of administration.
- Family physicians/nurse practitioners may be consulted to complete the patient's medical history.
- Specify if the patient was pregnant or breastfeeding/chestfeeding at the time of immunization.
- If complete information is unknown, provide as much detail as possible.

WHEN COMPLETING SECTION 4C, PROVIDE ALL INFORMATION AS OUTLINED BELOW:

- **Immunizing agent(s) and diluent** (when applicable): Record the proper name or accepted abbreviation as outlined above for all vaccine(s).
- **Trade name:** Indicate the trade name of all vaccine(s) received.
- **Manufacturer:** Specify the name of the manufacturer as indicated on the product label and as referenced by PHAC in **Annex 2** (market authorization holder).
- **Lot number:** Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.
- **Dose number:** Provide the number in series (1, 2, 3, 4, or 5). For the influenza vaccine, unless a patient receives two doses in one season, the "dose #" should be recorded as 1.
- **Dosage/unit:** Indicate the dose (e.g., 0.5) and unit (e.g., mL) for each vaccine.
- **Route:** Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable:

Intradermal: ID	**Intranasal:** IN
Intramuscular: IM	**Oral:** PO
Subcutaneous: SC	**Other:** please specify (no abbreviations)

- **Site:** Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:

Left arm: LA	**Left leg:** LL	**Left gluteal:** LG	**Mouth:** Mo	**Other:** please specify (no abbreviations)
Right arm: RA	**Right leg:** RL	**Right gluteal:** RG	**Nose:** Nose	
Arm: Arm	**Leg:** Leg	**Gluteal:** Glut	**Multiple sites:** MS	

SECTION 5: Immunization Errors

Select the box next to the situation that most closely reflects the error. Examples include: inappropriate vaccine for specific age group (in SK, some vaccines may have off-label uses), vaccine given by inappropriate route, or inappropriate dose given.

SECTION 6: Previous AEFI refers to AEFIs previously experienced to the vaccine(s) listed in section 4c. Choose among four answers: No, Yes, Unknown, Not Applicable. If the patient had previously experienced an AEFI following a previous dose of one or more of the vaccines listed in section 4c, select "Yes" and provide all details of the previous AEFI in section 10, including the corresponding time to onset and duration, when known. Also, when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.

- Select "Unknown" if the answer is unknown, which may apply to parents and caregivers of adopted children.

SECTION 7: Impact of AEFI, Outcome, Level of Care Obtained, and Treatment Received

- Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 7a based on the patient's assessment of the impact on their daily activities.
- Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in section 7b. If the patient has not yet recovered, provide all available details in section 10, and provide updates as they become available (by filling out a new form indicating follow-up in the top right-hand corner and providing the initial unique episode # in section 1a). Similarly, should the event result in permanent disability and/or incapacity or death, provide all available details in section 10.

SECTION 8: Reporter Information

SECTION 9: AEFI Details

- Interval is the time passed from time of immunization until onset of first sign or symptom. Intervals may vary for different signs and symptoms.
- Duration is the time passed from the onset of a specific sign or symptom (see above) to the resolution of that specific sign or symptom.
- Always specify the site of a specific sign or symptom as appropriate.
- An asterisk (*) indicates that a specific event must be diagnosed by a physician.
- Fevers are only required to be reported if they are in conjunction with another reportable event.
- See **user guide for reporting adverse events** for event definitions.

SECTION 10: Supplementary Information

- Provide concise, detailed charting, indicating section numbers, investigations and/or treatments.
- Use this section to capture information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation.
- Document all known details of any investigations or treatments for the recorded AEFI and indicate the section of the AEFI report that the information applies to, if applicable.

SECTION 11: Recommendations for Future Immunizations

In Saskatchewan, this section is only to be completed by a Medical Health Officer (MHO), physician, or nurse practitioner.

SECTION 12: Follow-up Information for a Subsequent Dose of Same Vaccine(s)
Complete section 12 when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine (vaccines given in series).

Adverse Events of Special Interest (AESI)

- The Public Health Agency of Canada requires reporting of specific Adverse Events of Special Interest (AESI) following immunization with any COVID-19 vaccine.
- The national AEFI form includes a section on COVID-19 AESIs (9e), which lists several reactions. However, the list of reactions designated as AESIs is evolving and users of the form are directed to **Brighton Collaboration** for the most current list of COVID-19 AESIs.
- Complete the national **AEFI form**; indicate the AESI in Section 9e and provide details in Section 10.
- Submit immediately to local **Public Health Office.**

RESOURCES:

Saskatchewan Immunization Manual Chapter 11: Adverse Events Following Immunization

Saskatchewan User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports [Dec 2021]

Public Health Agency of Canada. Report of adverse events following immunization (AEFI)

Public Health Agency of Canada. User Guide to Completion and Submission of the AEFI Reports

Brighton Collaboration. COVID-19

NAPRA Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals. Published July 2021.

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