ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Quick Reference

- 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: AEFI form should not be filled out and submitted if an incorrect immunization has been given
- Expected side effects from immunizations 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 all reactions that may occur post-immunization
- There must be no co-existing condition that could explain the reaction that occurs
- Remind individual or parent 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 immunizations should know the difference between minor, moderate, and major reactions following vaccination

Publicly funded vaccines (ex. Influenza)

- AEFI form is sent to local Public Health Office

Out-of-pocket/ Non-publicly funded vaccination *(*ex. Pharmacist prescribed Twinrix)

- AEFI form sent to health care professional that prescribed the vaccine, patient's primary physician, and Health Canada
- Prescriber/primary physician 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
- This AEFI does NOT go to public health

Note: There is no central documentation, therefore it is important that the patient understand they are responsible for future vaccine safety.

The AEFI report has 12 sections that must be completed as appropriate, before the report is forwarded.

Tips for filling out the AEFI:

For more in-depth information, please see the user guide for reporting adverse events available at Government of Canada website.

Section 1: Unique Episode Numbers can be found at the SIM website. This number should only be filled out by those persons who are authorized to assign numbers at provincial health authorities. If you are not authorized to fill out this number, please leave it blank.

Section 2: IMPACT LIN (local inventory number) is a code assigned by nurses at IMPACT centers. Please leave the section blank if you are not an IMPACT hospital/centre.

Section 3: **Patient Identifier**

Patient Identification Information: Provide the patient's first and last name, health number (if applicable), address of usual residence including postal code (with the understanding that this address might be in a different province/territory than where the vaccine(s) was administered or where the AEFI is being reported) and a telephone number (either residential or 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

- Use only accepted biological product abbreviations assigned by PHAC in Appendix 11.5;
- Indicate if any vaccines were given, even if out of country;
- Family physicians/nurse practitioners may be consulted to complete client's medical history;
- Specify if a female client was pregnant at time of immunization; and
- Dose number in series and dosage/unit must be recorded.
- Provide province/ territory where immunization was received, and date and time of administration.
- If complete information is unknown, provide as much detail as possible.

When completing section 4C, provide all information as outlined below:

Immunizing agent(s): Please record the proper name or accepted abbreviation as outlined in Appendix II for all immunizing agent(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 in Appendix II.
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) or indicate if known. For the Influenza vaccine, unless a patient receives two doses in one season, the "dose #" should be recorded as one.

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
Intramuscular: IM
Subcutaneous: SC
Intranasal: IN
Oral: PO
Other: please specify (no abbreviations)
Site: Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:
Left arm: LA
Right arm: RA
Arm: Arm
Left leg: LL
Right leg: RL
Leg: Leg
Left gluteal: LG
Right gluteal: RG
Gluteal: Glut
Mouth: Mo
Nose: Nose
Multiple sites: MS

Section 5: Immunization Errors For example, inappropriate vaccine for specific age group (in SK, some vaccines may have off-label uses) or vaccine given by the inappropriate route, or dose

Section 6: Previous AEFI If the answer is "yes", the patient had previously experienced an AEFI following a previous dose of one or more of the immunizing agent(s) listed in section 4C, 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.

- Please check unknown if the answer is unknown. This may apply to parents and caregivers of adopted children.

Section 7: Impact of AEFI, Outcome, and 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 is not yet recovered, provide all available details in section 10 and provide updates as they become available. 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 symptom or sign. Inter vals 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 res olution 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
- Please see user guide for reporting adverse events for event definitions

Section 10: Supplementary Information

- Concise, detailed charting required, indicating section numbers, investigations and/or treatments.
- Should be used 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

Section 12: Follow up information for a Subsequent Dose of Same Vaccine(s) This section is not routine ly used in SK as of this date.

Resources:

Public Health Agency of Canada (2012) Canadian Immunization Guide (Evergreen Ed.)

Saskatchewan Immunization Manual (January 2017) Chapter 11: Adverse Events Following Immunization