USER GUIDE: Report of Adverse Events Following Immunization

This guide is intended to be used when completing the Report of Adverse Events Following Immunization (AEFI) for submission to provincial and territorial authorities. Its purpose is to provide assistance on how to accurately complete the form. It is not intended to guide treatment. Treatment of all AEFIs should proceed, as appropriate, prior to completing the AEFI form. Following the immediate care of the vaccine recipient, the AEFI form can be completed with all available information.

Please print all written responses clearly.

What is an Adverse Event Following Immunization (AEFI)?

An AEFI is any untoward medical occurrence in a vaccinee which follows immunization and which does not necessarily have a causal relationship with the administration of the vaccine (based on International Conference on Harmonisation (ICH) Topic E6 definition). The adverse event may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease.

Should all AEFIs be reported?

No. During their development, vaccines undergo rigorous testing for safety and efficacy. During these "pre-licensure trials" efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common adverse events such as inflammation at the injection site or mild fever is well known. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions, but there is no need to report such expected events unless they are more severe or more frequent than expected.

What type of AEFI should be reported?

AEFIs should be reported when the event:

Has a temporal association with a vaccine

Has no other clear cause at the time of reporting: A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).

Of particular interest are those AEFIs which meet one or more of the following criteria:

Are of serious nature: A serious adverse event is one that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.

Require urgent medical attention.

Are unusual or unexpected: An event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency. For additional information regarding unusual or unexpected events, please refer to the Canadian Immunization Guide which can be accessed on-line at http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php.

*****If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported.**

Adverse Events Following Immunization Form
Vs.
Canada Vigilance Adverse Reaction Reporting Form

When an adverse event follows the administration of an active immunizing agent (e.g., vaccine) that is administered simultaneously with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin skin test), complete the AEFI Report form. Provide the name of the active immunizing agent, in addition to the passive immunizing agent and/or diagnostic agent, in Section 3c. This information will subsequently be forwarded to the appropriate agencies. Alternatively, if **no** active immunizing agent (vaccine) has been administered, **do not** complete and submit AEFI Report form. Instead, please complete of the Canada Vigilance Reporting Form for reporting an adverse drug reaction to Health Canada (please also forward a copy to the Regional Immunization Coordinator).

To whom do I submit my completed AEFI Form?

Your completed AEFI form should be forwarded to your Nurse Manager or Nurse in Charge, as per your local reporting procedure. This person will be responsible for forwarding the form on to the Regional Immunization Coordinator.

Where and when can copies of the AEFI report form be obtained?

The new form will be introduced early in 2012 throughout the Saskatchewan FNIH region. The form itself, along with the user guide and appendices, will be available in the Saskatchewan Immunization Manual (SIM 2011). Hard copies will also be available through your Nurse Managers and the Regional Immunization Coordinator.

Guidelines on how to complete the AEFI Form:

On the top right hand corner: Indicate whether the AEFI report being submitted is an "Initial" or a "Follow up" report. For all "Follow up" reports, provide the "Unique episode number" and/or "Region #" of the initial report.

Section 1: Client Identification

This section is intended to capture client information for use by regional and/or provincial health officials. This information is kept confidential and should **not** be forwarded to PHAC.

Provide the client's first and last name, health number, Treaty number, 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 (any or all of the following may apply: residential, cellular or business) where the client can be reached.

Date of Birth: Please indicate the client's date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (e.g. month and/or year).
Sex: Please indicate the client's gender (e.g., male or female). If the gender is unknown or ambiguous, please choose "other".
Age at time of immunization: Please indicate the client's age at the time of immunization. Use days for infant's aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. Fractions should be used as appropriate (e.g., 6 weeks should be captured as 1.5 months; 15 months should be captured as 1.25 years). If the client's exact age is unknown, please estimate client's age.
Information Source: If the source of the information for the AEFI report is someone other than the client (a parent, or another care provider) please provide their name and relation to the client. Please also provide source's contact information (including their full mailing address and phone number(s) where they can be reached) **only** if it is different from the client's.

Section 2: Reporter Information

Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/setting/centre. Indicate the setting in which the reporter is located (e.g. public health clinic-please include clinic name, hospital or other). Sign and date the AEFI form in the space provided and specify your professional status (e.g. RN: Registered Nurse) or your affiliation (e.g., IMPACT) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.

Section 3: Information at Time of Immunization and AEFI Onset

Section 3a: At time of immunization

***Province/Territory of immunization*:** Please indicate the province or territory where the immunization was received. This may be different from the client's province or territory of residence and/or where the AEFI is being reported.
If the vaccine was administered outside of Canada, indicate the country in which the vaccine(s) was/were administered in the space to capture province/territory and also comment if it was received at a Canadian operated clinic in that country.
***Date and time vaccine administered*:** Indicate the date and time of vaccine administration remembering to specify if the vaccine was administrated in the "am" or "pm" by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g. month and/or year).

Section 3b: Medical history (up to the time of AEFI onset)

Please indicate the client's medical history prior to the time of AEFI onset by choosing all that apply from the list provided. Provide any additional details, when available, in Section 9.
***Concomitant medication(s)**:* Provide, in Section 9, the name of all current medications (e.g.: prescription, over the counter, herbal supplements, etc.) which the client had been taking up to the period immediately prior to the time of AEFI onset, including those taken only as needed.

When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.
***Known medical conditions**:* Please indicate all of the client's known medical conditions (underlying or acute) in Section 9. Please also indicate if an exacerbation of any of the known conditions were noted to occur following immunization, along with the corresponding date and time of the onset. If an exact date of onset is not known, please provide the greatest amount of detail that is available. Include any conditions for which the client is taking a concomitant medication, such as chronic conditions with intermittent symptoms (e.g.: migraine headaches). Also, specify in Section 9 if the subject was pregnant at the time of immunization.
***Acute illness/injury**:* Please indicate if the client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset in Section 9 if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset).
Known allergies: Please indicate all of the client's known allergies (diagnosed or suspected) in Section 9. Please indicate if an exacerbation of any of the known allergies was noted to occur immediately along with the corresponding date and time of the onset. If an exact date of onset is not known, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the client is taking a concomitant medication, such as chronic conditions with intermittent symptoms (e.g.: seasonal allergies).

Section 3c: Immunizing agent

Provide all information pertaining to the immunizing agent(s) administered just prior to the onset of the reported AEFI(s). There is space to record five (5) immunizing agents in this section; however, if more than five (5) were administered simultaneously, record the additional vaccines in Section 9. Please note that this form is indicated for use only with an adverse event following the administration of an active immunizing agent, or when an active immunizing agent is administered simultaneously with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent-for any other situation, please complete a Canada Vigilance Adverse Reaction Reporting Form.
When completing section 3c, provide all information as outlined below:
Immunizing agent(s): Please record the proper name or accepted abbreviation as outlined in Appendix 3 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 3.
Lot number: Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.
Dosage/unit: Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.
Expiry Date: Please provide an expiry date for the agent used, when this information is readily available.
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
Other: please specify (no abbreviations)

Section 4: Immunization Errors

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing "no", "unknown" or "yes". If "yes" is chosen, please indicate all that apply in Section 4 by checking the box next to the situation that most closely reflects the error and provide all known details in Section 9. Please note that this form should only be completed if there is an AEFI following an immunization, whether this immunization is given in error or not. For reporting of immunization errors alone, please complete the appropriate reporting forms and submit it as per your reporting policies.

Given outside the recommended age limits*:* The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

Product expired*:* The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days).

Wrong vaccine given*:* An unintended vaccine was administered.

Incorrect route: The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).

Dose exceeded that recommended for age*:* A larger dose of vaccine was administered than is recommended for the client's age group.

Other: If an error has occurred that is not accurately reflected in the list of provided errors, please choose "other" and provide all details.

Section 5: Previous AEFI

Indicate whether the client has ever experienced an AEFI following a previous dose of any immunizing agents, including those listed in response to question 4c.
No: The client had previously received immunization and has not experienced a subsequent AEFI.
Yes: The client has previously received immunization and had subsequently experienced an AEFI. Provide all details of the previous AEFI in Section 9, 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.
Unknown: It is unknown if the client has previously received immunization **and/or**, if an AEFI followed.
Not applicable: The client has never previously received immunization with any immunizing agent.
If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the client's past AEFI experience can be captured in Section 5), please provide additional details in Section 9.

Section 6: Previous Reactions

Has there been a pre-existing history of a reaction following any immunization not reported in AEFI form? This would occur if a reaction had been within expected range, but still noted in the client's chart. If the answer is "yes" please provide details of previous reaction in Section 9.
Have any prior doses of the above immunizing agent(s) as listed in table 4c been received by the client? Please indicate if the client has received any prior doses of the above immunizing agents in the past. If the answer is "yes" please provide a copy of the client's immunization record along with the AEFI form.
Was there evidence of any anxieties or other factors which may have contributed to the post immunization event? Please provide details in Section 9.
Was there travel outside of Canada prior to/post immunization that may be related to the post immunization event? Please provide timeline for travel, if more than one area outside of Canada visited by the client. Please provide all available details in Section 9.

Section 7: Impact of AEFI, Outcome, and Level of Care Obtained

Section 7a: Highest impact of AEFI

Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 7a based on the client's assessment of the impact on their daily activities:
Did not interfere with daily activities*:* No change or only minimal change is reported by the client in relation to their daily activities (e.g., work, exercise, social commitments, etc.).

***Interfered with but did not prevent daily activities**:* Moderate change is reported by the client in relation to their daily activities (e.g., interfered with work, exercise and/or social commitments).
***Prevented daily activities**:* Significant change is reported by the client in relation to their daily activities (e.g., prevented work, exercise and/or social commitments).

For young children (e.g., infants and toddlers), indicate the highest perceived impact of the AEFI on their daily activities as assessed by the child's parent/caregiver according to the following:
***Did not interfere with daily activities**:* No change or only minimal change is observed in the child's daily patterns and/or habits (e.g., eating, sleeping, playing, etc.).
***Interfered with but did not prevent daily activities**:* Moderate change is observed in the child's daily patterns and/or habits (e.g., reduced appetite, disrupted sleep, disrupted play, etc.).
***Prevented daily activities**:* Significant change is observed in the child's daily patterns and/or habits (e.g., not eating, not sleeping, not playing, etc.).

Section 7b: Outcome at time of report

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 client is not yet recovered, provide all available details in Section 9 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 9.
When completing section 7b, provide the information as outlined below:
***Death**:* Client died (record the corresponding date of death in the space provided).
***Permanent disability/incapacity**:* An injury which impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.
***Not yet recovered**:* Residual signs and/or symptoms remain (at the time of the report).
***Fully recovered**:* All the reported signs and symptoms have resolved.
***Unknown**:* The outcome of the AEFI is unknown or unclear.

Section 7c: Highest level of care obtained

Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in section 7c, described in detail below.
Unknown: It is unknown if the client received care for the reported AEFI.
None: No care was received for the reported AEFI.
Telephone advice from a health professional: The client received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.
Non-urgent visit to a Health Care Professional: The client was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted in Section 9.
Emergency visit: The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all available details in Section 9.

Required hospitalization: The client was hospitalized for the assessment and/or treatment of the reported AEFI. Indicate the number of days the client was hospitalized, the date of admission and the date of discharge. Document all available details in Section 9.
Resulted in prolongation of existing hospitalization: If a client was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please check: "Resulted in prolongation of existing hospitalization" and indicate the number of additional days stayed in hospital as a result of the AEFI. Also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all available details in Section 9.

Section 7d: Treatment received

Indicate whether the client received any treatment, including self-treatment, for the reported AEFI by choosing yes, no or unknown. Provide details of all treatments received, following the onset of the AEFI in Section 9 when applicable.

Section 8: AEFI Details

Indicate the details of the AEFI being reported by checking all that apply. Please provide all pertinent details (e.g., results of medical investigations, laboratory test, treatment, etc.) that are on hand at the time of reporting in this section. For convenience and consistency, high level definitions have been provided in Appendix 1 for most of the events listed in Section 8. Please note: **If there is an asterisk (*) beside an AEFI term, this specific event should be diagnosed by a physician.** If there is no physician diagnosis, the reporter must provide sufficient information (in Section 9) to support the selection(s).

Interval: indicate the time period between the client having received the immunization to onset of the client's first symptom/sign.
Duration: indicate the time period between the onset of the first symptom/sign to the resolution of all of signs and symptoms. If the report is submitted prior to client's full resolution, please provide this information in Section 9. When possible, please provide follow-up with the client to ensure full resolution and communicate this information to the Medical Health Officer or delegate.
The interval and duration of the signs and symptoms of the specified AEFI should be documented according to the following guidelines for all AEFIs:

If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes.

If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours.

If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.

If there is a pruritic, maculopapular vesicular rash following a dose of MMRV or Varicella: Rationale

Varicella-like (vaccine) rash: A varicella-like rash in a recently vaccinated person that may be caused by either wild- or vaccine-type virus. Approximately 4% of children receiving varicella vaccine (compared with 2% of placebo recipients) develop a generalized rash with a median of

five lesions 5–26 days post vaccination, and 4% develop a localized rash with a median of two lesions 8–19 days post vaccination.[43] The rash may be atypical in appearance (maculopapular with no vesicles). Approximately 2% of children who received a placebo in the clinical trials also developed generalized rashes, some of which were varicella-like, indicating that not all rashes following vaccination are attributable to the vaccine.[43] Rash occurring within 2 weeks of or more than 42 days after vaccination are more likely to be wild-type virus, and rash occurring 15–42 days post vaccination are more likely to be vaccine-type virus.[44] Attribution of disease to vaccine strain VZV can only be confirmed by strain differential real-time PCR or by PCR combined with restriction fragment length polymorphism (RFLP) analysis.
Secondary transmission of vaccine virus: A varicella-like rash occurring 10–21 days after exposure to a person recently vaccinated. It is extremely rare. Since 1995, only eight secondary cases of transmission of vaccine virus from seven vaccinees have been documented with the varicella (Oka/Merck) vaccine, five of which occurred in e immunocompetent people. Most secondary transmissions occur from vaccine recipients who develop at least a limited rash illness. One case of secondary transmission was reported from a woman vaccinated post-partum who developed no vaccine rash to her infant. All laboratory-confirmed cases of Oka vaccine secondary transmission have resolved without complications. Transmission of vaccine strain VZV can only be confirmed by strain differential real-time PCR or by PCR combined with restriction fragment length polymorphism analysis. In addition to these episodes, there have been two reports of transmitted vaccine virus from herpes zoster that occurred 5 months after varicella vaccination.

(From the CDC website: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt17-varicella.html)

Vaccine providers are requested to report the following using the Canadian Adverse Event Following Immunization Surveillance System report form:
(a) any adverse events occurring within 6 weeks of vaccination, (b) vaccine-modified varicella that is moderate (50-500 vesicular lesions) or severe (with any one of the following: > 500 vesicular lesions, associated complications or admission to hospital) and (c) any persons who develop vaccine-strain varicella within 6 weeks of being in contact with a vaccinee. (CIG, 7th ed, p.337)

Section 9: Supplementary Information

Section 10 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. Indicate the section of the AEFI report that the information applies to, if applicable, when recording information in section 10.