BC Centre for Disease Control
Provincial Health Services Authority

Data Elements Collected for Adverse Events Following Immunization

Objectives for Reporting

The objectives of reporting a new Adverse Event Following Immunization (AEFI) are:

1. Support signal detection and trigger investigation at the regional, provincial, and if required, national level.
2. Identify uncommon, rare, and serious or unusual adverse events for review including previously unrecognized events.
3. Review event and provide recommendations to recipients of vaccine(s) who have experienced AEFIs about further investigation, if appropriate, and for future vaccination.
4. Ensure that observed AEFIs in BC are in keeping with the expected profile based on clinical trial data and post-marketing use in other jurisdictions and be able to inform vaccine recipients about observed vaccine safety with products in use in BC.
5. Participate in national and international vaccine safety monitoring to inform safety of vaccines marketed in Canada.
6. Maintain public confidence in the safety of vaccines.

Data Elements to Report (i.e. Minimum Data Set)

The data elements to report (i.e. minimum data set) for AEFI include the following:

- Reporting Health Authority and Date of Report
- Patient Name, Date of Birth, Gender, and Health Card Number
- City, Postal Code, Province/Territory, and Country of Residence (if not Canada) at the time of the AEFI
- Pediatric Surveillance Reference Number
- System ID (e.g., Adverse event ID, Paris ID)
- Vaccine Administration Date, Immunizing Agent/Trade Name, and Lot Number.
- Onset of first sign/symptom, duration of resolution of all signs/symptoms, adverse event case diagnosis, signs and symptoms, and additional details.
- Highest impact of AEFI, outcome of event at time of report, and highest level of care obtained.
- If admitted to hospital, admission and discharge date as well as the number of days admitted.
- If prolonged existing hospitalization, the number of days.
- Treatment and recommendation(s).
- Review date, reviewer comments, and additional notes or comments.

Timelines for Reporting

The benchmarks for reporting delays (i.e. days between receipt of the report by the health authority and entry into the provincial system) are:

- 5 business days for the initial case report (in electronic public health system).
- 60 calendar days for remaining items of the minimum dataset (those requiring interview/follow up).

Additional criteria recommended for immediate provincial reporting to the Medical Lead - Immunization Programs and Vaccine Preventable Diseases Service (IPVPDS) at BCCDC:

- MHO opinion of a cluster of unusual or severe events.
- Death purported to be associated with vaccine.

Form for Reporting

To report a new AEFI, please see the AEFI Report Form (short and long versions) online in the *Adverse Event Following Immunization* tab in the Surveillance Forms page of the BCCDC website.

Approved

September 4, 2018, affirmed December 2, 2024.