Standard 3.8 - Reporting of Adverse Events Following Immunization in New Brunswick

Preamble:
The information herein is intended for use by all those who administer vaccine (publically funded or non-publically funded) and/or who care for clients who may have experienced an adverse event following immunization (AEFI). Outlined below are reporting requirements necessary in completing a report of an AEFI for submission to Regional Public Health, on behalf of the Regional Medical Officer of Health (RMOH), subsequently to Office of the Chief Medical Officer of Health (OCMOH) which forwards the report to Public Health Agency of Canada (PHAC).

Personnel at the PHAC screen all submitted reports, ensure they are entered into the Canadian Adverse Event Following Immunization (CAEFI) database and coded using standard international coding systems. Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Canadian data are periodically forwarded on to the World Health Organization (WHO) International Drug Monitoring Program in Uppsala, Sweden, where global data are analyzed for any evidence of safety concerns.

Triggers for reporting
AEFI should be reported when the event:

- Has a temporal association with a vaccine;
- Has no other 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;
- Is serious, urgent or unusual.

Of particular importance are those AEFIs which:

- Are life threatening; result in death or residual disability; require hospitalization or prolongation of an existing hospitalization; or cause congenital malformation; or
- Are unexpected regardless of seriousness (i.e. an event that has either not been identified previously or one that has been identified previously but reporting frequency seems to have increased).

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.

NOTE: 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), an AEFI Report Form **should** be completed.

However, when an adverse event follows the administration of a **passive** immunizing agent (e.g. immune globulin) and/or diagnostic agent (e.g. tuberculin skin test), an AEFI form **should not** be completed. Instead, the event should be reported to Health Canada on Canada Vigilance Adverse Reaction Reporting Form (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php).

Reporting Requirements

1. Report Criteria

AEFI report should contain:

1. Client – unique identifier, date of birth and gender;
2. Immunization event(s) – province where given, date, all vaccines given including name, manufacturer, lot number, administration site and route, as well as the number in series of vaccine doses if relevant;
3. Adverse event(s) – description, including time of first onset following immunization, duration, health care utilization, treatment and outcome;
4. Relevant medical and treatment history – underlying disease, known allergies, prior AEFI, concomitant medication;
5. Associated event(s) – acute illness, injury, exposure to environmental toxins; and
6. Reporter details.

In the event that the above information is unavailable at the time of the initial report **minimal criteria for AEFI reporting to the RMOH should contain:**

1. Client identification (ID) (name, date of birth and gender);
2. Vaccine(s) received (name, date of administration, route, dose);
3. Event description (onset, duration, symptoms, highest level of care); and
4. Reporter ID (name, contact information).

Lack of any of these four elements means that the report is incomplete.

- If the client has had more than one AEFI following the vaccination(s) administered at the same time, then all AEFI details can be reported on the same form.

More than one form can be completed for the same client under these circumstances:

- If the client has had more than one AEFI following vaccination(s) administered at different dates, then the separate AEFI details should be completed on separate forms.

2. Timing of reporting

All AEFIs should be reported as close to the event as possible. When providing immunization services, remind the individual or parent to contact you as soon as possible if a serious reaction occurs, rather than waiting until the next visit.

- HCPs should notify their regional PH office (RPHO) in writing within **one week** of AEFI identification/notification.
- Any AEFI that is life threatening or caused death should be verbally reported within one day to PH, followed by written notification within one week.

3. How to report:

For Public health Nurses

- Enter AEFI report in CSDS within one week of receiving report.

For other healthcare providers:

- fill in the NB AEFI form

  Both the form and user guide are available on the Government of New Brunswick (GNB) website or it can be obtained from your local PHO
- FAX or mail the form to your local PHO
- See appendix 4.8 *Data Dictionary for completing NB AEFI Reporting Form*

NOTE: the NB AEFI form supersedes that of the national AEFI form and user guide available on the PHAC website.