March 1, 2011

To: All Healthcare Professionals

Subject: Reporting of Adverse Events Following Immunization in New Brunswick

Under the Public Health Act (Charter P-22.4) and New Brunswick Regulation (2009-136) all Healthcare Professionals have a duty to report to the regional Medical Officer of Health (MOH) if a person has or may have a reportable event. An Adverse Event Following Immunization (AEFI) became a reportable event under 2009 Public Health Act.

An AEFI is any unwanted medical event that follows immunization. Any adverse symptom or sign of disease following immunization can be classified as an AEFI.

After the vaccine is administered, the healthcare worker who administers it should observe the client for about 15 minutes afterward. If there is any reaction, he or she should document and report it. If a client experiences an adverse event after they left, they should be advised to call their healthcare provider to discuss it. In the unlikely event they need to seek an urgent medical care, the healthcare provider should ask about recent medical history, including the immunization history. The service provider should also advise the client/patient of the risk/benefit of future immunization.

The service provider upon becoming aware of a potential AEFI, should gather all necessary information in order to assess whether the case meets the definition of an AEFI. This may require consultation with an MOH or designate at the local Public Health Office (PHO). The event then should be documented by the service provider on the NB AEFI report form (if possible) and forwarded to the local PHO within 1 week of AEFI identification. The AEFI data can also be telephoned in, faxed, or sent electronically to the local PHO.

All serious adverse events should be reported. All events that require an urgent medical attention should be reported. Unusual or unexpected adverse events should also be reported, even if they are not serious.
Reporting these events is very important since there could be an early signal of a vaccine safety problem. The fact that an adverse event occurs following the vaccine does not necessarily mean that the vaccine was responsible for the event. It may have happened anyway, or it could have been caused by other factors/events than the vaccine. A prompt and thorough investigation should be carried out for all serious adverse events to look for possible causes of the event.

It is also important to remember that **timeliness** of AEFI reporting is very important as it facilitates effective risk management and allows addressing any safety concerns quickly and efficiently. In the event of a matter that requires immediate attention (e.g. anaphylaxis reaction to a vaccine), the regional MOH should be informed as soon as possible by telephone after the client had received an appropriate treatment.

The NB AEFI report form and its user guide can be obtained from either [http://www.gnb.ca/0051/pub/index-e.asp](http://www.gnb.ca/0051/pub/index-e.asp) website or the local PHO.

Yours sincerely,

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