

Pharmacovigilance and Vaccine Safety

Pharmacovigilance for vaccine safety is the detection, assessment, understanding and prevention of adverse events particularly long term and short term side effects of vaccination. Generally speaking, pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of vaccines with a view to:

- identifying new information about hazards associated with vaccines in general or a particular vaccine,
- preventing harm to vaccine recipients.

An adverse response to a vaccine is noxious and unintended. A serious Adverse Event Following Immunization (AEFI) is any untoward medical occurrence that at any dose

- is life-threatening,
- requires inpatient hospitalization or results in prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,
- is a congenital anomaly/birth defect, or
- is a medically important event or reaction

Under the Health Protection and Promotion Act a “reportable event” means,

- (a) persistent crying or screaming, anaphylaxis or anaphylactic shock occurring within forty-eight hours after the administration of an immunizing agent,
- (b) shock-like collapse, high fever or convulsions occurring within three days after the administration of an immunizing agent,
- (c) arthritis occurring within forty-two days after the administration of an immunizing agent,
- (d) generalized urticaria, residual seizure disorder, encephalopathy, encephalitis or any other significant occurrence occurring within fifteen days after the administration of an immunizing agent, or
- (e) death occurring at any time and following upon a symptom described in clause (a), (b), (c) or (d). (“événement à déclaration obligatoire”) R.S.O. 1990, c.H.7, s.38(1); 2007, c.10, Sched.F, s.11(1).

Physicians, nurses or pharmacists are required to report an AEFI to the local medical officer of health within seven days after recognizing the reportable event.

Surveillance

During the pandemic H1N1 (pH1N1) vaccine implementation phase, in addition to local reporting, AEFIs associated with the new vaccine will be monitored at the provincial and federal level.

At the provincial level, daily reports of adverse events will be done to observe for all AEFI as well as serious adverse events or expected events occurring at a higher level than would be expected.

Reports are then forwarded to the Public Health Agency of Canada (PHAC) electronically after personal identifying information has been removed. Serious AEFIs are posted on the Canadian Public Health Information system alert module by PHAC or Ontario to keep provinces and territories informed.

Because clinical trials with the new vaccine have involved several thousand patients at most, thus, less common adverse events are often unknown at the time the vaccine will administered. Even very severe AEFIs, such as Guillain Barré Syndrome are often undetected because study populations are small. Postmarketing pharmacovigilance will be important to identify any relationships between the vaccine and AEFIs.

Reporting methods

The pH1N1 vaccine is a new product with a novel formulation including a new adjuvant. Limited clinical trials for determining immunogenicity and safety are being done prior to the initiation of mass immunization campaigns. Therefore, it is essential that ongoing timely enhanced post marketing surveillance be conducted in order to support public health policy and decisions.

Please refer to the enhanced surveillance directive regarding reporting of AEFI with the new H1N1 vaccine in the iPHIS Weekly Notice 190, October 2, 2009 Volume, Issue 40.