Update: January 28, 2010

All vaccines authorized for use in Canada have been carefully tested for safety. The H1N1 flu vaccine had been authorized for use based on preliminary clinical trial data, and continues to be monitored and tested as it is administered across the country.

The Public Health Agency of Canada (PHAC) and Health Canada, with the collaboration of provinces and territories, the Canadian Paediatric Society and a network of researchers are actively monitoring adverse events following immunization to the H1N1 flu vaccine in Canada. This is a key component of the Government of Canada approach to ensuring vaccine safety that is used to produce regular reports on the safety of the H1N1 vaccine.

PHAC is using the existing system - the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). CAEFISS is supported by healthcare professionals who report adverse events to their provincial/territorial public health offices, which then share the information with PHAC.

This existing system is supported by additional projects to provide more detailed data, specifically related to the H1N1 flu vaccine. These include:

- The Immunization Monitoring Program-Active (IMPACT). IMPACT is made up of a network of paediatric teaching hospitals that report on serious adverse events following immunization in children. At each participating site, nurse monitors look for adverse events and report on any which follow immunization.

- A Severe Outcomes Surveillance (SOS) Network mirrors the IMPACT network and monitors adult hospitalizations. This system can also be adapted to monitor for additional symptoms, diseases or disorders if necessary. This project is being funded by the PHAC/CIHR Influenza Research Network (PCIRN).

- Additional PCIRN projects are monitoring vaccine safety in various groups and settings, including children, Aboriginals, people living with HIV, healthcare workers and people with egg allergies.

The existing surveillance system and these additional projects will help PHAC monitor adverse events following immunization (AEFI), detect any possible signals of concern and determine which, if any, are possibly linked to vaccine.

There are internationally accepted definitions for post marketing surveillance of adverse events following medications or vaccines:

**An adverse event following immunization (AEFI)** is any unwanted medical reaction following immunization. The majority of adverse events are not serious and include soreness, swelling or redness at the injection site, fever, rash, headache or muscle aches and pains.

**A serious adverse event following immunization** is any adverse event that is life-threatening.
or results in death, requires hospitalization, prolongs an existing hospitalization or results in residual disability.

Serious adverse events following immunization are rare. In any immunization campaign, from regular childhood vaccines to seasonal flu shots, the reported rate of serious adverse events is on average about 1 case for every 100,000 doses distributed.

The 1 in 100,000 rate is based on tens of millions of vaccine doses distributed over several years. This rate is based on the administration of several different types of vaccines, some of which have higher or lower rates of adverse events. Rates can also vary by age. For more information, visit our vaccine safety and surveillance Frequently Asked Questions.

Regular reporting from these sources provides an early warning system that can help PHAC officials identify whether there is any need for further investigation to ensure vaccine safety.

This report contains data on the total aggregate numbers of adverse events reported to PHAC by provinces and territories and other sources. It provides a breakdown on the number of reported serious adverse events as well as selected serious adverse events of special importance, such as anaphylaxis (a severe allergic reaction) and the overall rate of adverse event reporting per 100,000 doses of vaccine distributed in Canada.

Reporting an adverse event does not mean that the vaccine was the cause. Careful investigation is needed to determine whether an event is directly linked to the vaccine or not. The number of adverse events and serious adverse events reported in the weekly snapshot are subject to further investigation and may change over time. The risk of the flu far outweighs the risk of vaccination.

### Weekly Snapshot

As of January 16, 2010, 25.143 million doses of three types of vaccine had been distributed across Canada:

- Arepanrix (adjuvanted H1N1 flu vaccine from GlaxoSmithKline)
- Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (without adjuvant from GlaxoSmithKline)
- Panvax (unadjuvanted H1N1 flu vaccine from CSL Australia)

Since the start of the H1N1 flu vaccine campaign through January 16, a total of 5,944 adverse events have been reported to PHAC by provincial and territorial immunization programs, of which 230 met one or more of the criteria to be considered serious. There were 126 cases of anaphylaxis included among the serious adverse events.

The reporting rate of adverse events per 100,000 doses distributed is 23.6. The reporting rate of serious adverse events is 0.91 per 100,000 doses distributed. To date, the overall frequency of anaphylaxis following H1N1 immunization is 0.50 per 100,000 doses distributed, which does not exceed the normal range observed after receiving any vaccine.

Over 100,000 pregnant women received the H1N1 vaccine. There were 26 reports of adverse events involving pregnant women. Twenty one of these were non-serious. There was one report of decreased fetal movements and four reports of fetal loss. There is no evidence to suggest that the vaccine led to the fetal losses. This number of fetal events is within the range of expected fetal loss among unvaccinated pregnant women.

### Analysis

Detailed review of the surveillance data to this point continues to support the safety of the vaccine. The overall reporting rate of adverse events is higher than for the seasonal influenza vaccine, while the reporting rate for serious adverse events is below the average reporting rate of about 1 case for every 100,000 doses distributed. Several factors contribute to reporting rates for the H1N1 influenza vaccines, including:

- Heightened awareness around the H1N1 flu vaccine means that frontline healthcare workers have increased their vigilance and are reporting more potential adverse events. Increased surveillance in hospitals has also generated more reports.
- The one clearly recognized serious adverse event risk for immunization is anaphylaxis, a severe allergic reaction that generally occurs within minutes of vaccination, while the vaccine recipient is at the vaccination clinic. Cases of anaphylaxis are the most consistently reported and most easily measured serious adverse event.
- Upon investigation, some adverse events turn out not to meet the criteria for being classified as serious, or, for example, do not turn out to be true anaphylaxis. As closer follow-up and analysis is done on cases initially reported as serious adverse events or anaphylaxis by the provinces and territories, the rates may change.

The average rate of serious adverse events, which is 1 per 100,000 doses distributed, has been calculated based on several years of data. It is also calculated on completed immunization campaigns, when we have total numbers of vaccine distributed and adverse events reported, and all investigations into serious adverse events have been completed. As H1N1 vaccine campaigns are completed and more analysis is conducted, a more meaningful number on the rate of serious adverse events will emerge.

In addition, the analysis has found that:

- The types and frequency of adverse events (both serious and non-serious) reported to date remain consistent with what was seen in clinical trials, and what has been seen in other countries where the adjuvanted vaccine is being used.
- The most frequently reported events were not serious and included injection site reactions, nausea, vomiting, dizziness, headache and fever.
- The 230 serious reported cases, other than anaphylaxis as described below, do not reveal any specific pattern of adverse event. Twelve deaths have been reported to date and are under investigation.

No safety concerns regarding H1N1 vaccines given to pregnant women have been identified to date in Canada or internationally. Most reported adverse events have been minor, and the reported events including fetal loss have been far less than would be expected to occur in this many pregnancies.

There have been 24 cases of Guillain-Barre Syndrome (GBS) reported to date (0.95 per million doses distributed) following vaccination. The cases reported following vaccination with the H1N1 vaccine are under investigation.

GBS is an acute illness characterized by sudden onset of weakness or paralysis (see Guillain-Barre Syndrome Frequently Asked Questions). There are about 600-700 new cases of GBS reported in Canada per year. Causes include foodborne bacteria, respiratory infections including influenza-like illness, and surgery. Since 1997, during 12 annual season influenza vaccine campaigns, a total of 79 cases of GBS have been reported following influenza vaccine. The risk of getting GBS after getting the flu shot is, at most, one extra case per 1 million doses administered. Canadians are at far greater risk of developing GBS after getting the flu than they are after getting a flu shot.
Based on surveillance in Canada and internationally of cases of GBS following vaccination, concerns about GBS have not emerged in connection with H1N1 vaccines.

More than half of the serious adverse events reported, 126, were anaphylaxis. For reporting purposes a standard case definition of anaphylaxis is used, as published by the Brighton Collaboration. The number of reports reflects cases that have been reviewed by federal and/or provincial and territorial public health authorities and that met a high level of diagnostic certainty.

The overall frequency of anaphylaxis following H1N1 immunization is 0.50 per 100,000 doses distributed, which does not exceed the normal range observed after receiving any vaccine.

One of the reported cases of anaphylaxis from earlier in the vaccination program was fatal and is being investigated. The others were treated and recovered.

There were more than 500 reports to PHAC of non-serious allergic reactions consisting of a variety of symptoms and signs. These have onset mostly within minutes of immunization and have been treated promptly by clinic staff.

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