

H1N1 Vaccine – Weighing The Risks

by Katia Bailetti ND

As of November 1st, all provinces and territories in Canada began their vaccination program against pandemic H1N1 influenza.¹ Across the nation, the numbers of new hospitalizations, ICU admissions and deaths reported the week of October 18-24th, 2009 were approximately three times higher than the previous week. Canada has officially entered the second wave of the H1N1 pandemic.

Making an informed decision about the H1N1 pandemic vaccine is very challenging at this time as relevant information is being updated daily and some information is not yet available. Below you will find a summary of the information that is currently available about serious H1N1 infections and vaccine complications.

Disclaimer

This is by no means a comprehensive representation of the information that every person will need in order to make their H1N1 vaccination decision and it is not meant as a substitute for information and advice provided by your primary health care provider. Dr. Bailetti assumes no responsibility from any effects associated with making decisions about vaccinations and the opinions included do not represent the opinions of anyone other than the author at the time of writing. Any decision regarding your health should be made in consultation with your health care provider. All efforts were made to ensure the accuracy of information as of the date of writing.

What is the risk of a serious H1N1 infection?

- The overall risk of a serious H1N1 infection is estimated to be small² and the risk appears similar to that associated with the seasonal influenza virus.^{3,4} The majority of people infected with H1N1 experience mild symptoms and recover rapidly without the need for hospitalization or medical care.⁵
- Below are some H1N1-related statistics that provide a perspective on the incidence rate and severity in Canada:
 - As of Sept 26th, 1,479 people have been hospitalized with H1N1 in Canada and 20% of cases were admitted to an intensive care unit.⁶ The estimated number of people who die from H1N1 if they catch H1N1 (in the U.S.) is 0.05%.⁷
 - As of November 5th, 2009, 115 people have died due to H1N1 in Canada.⁸ In comparison, the number of deaths due to influenza viruses reported by Statistics Canada in 2003 was 218⁹, in 2004 was 296¹⁰ and in 2005 was 678¹¹. These numbers are quite a bit lower than the number of deaths due to influenza reported per year by the Public Health Agency of Canada, (2,000-8,000 deaths).¹² The discrepancy between the annual deaths reported by Statistics Canada and the Public Health Agency of Canada may be due to the inclusion of influenza-like illness (not strictly the laboratory confirmed influenza cases).
 - As of November 1st, 2009, there have been over 5,000 H1N1 deaths¹³ worldwide reported to the World Health Organization (3,205 deaths reported to the WHO as of September 6th 2009).¹⁴
- There is a higher risk of a serious infection in the following groups:
 - People with an underlying medical conditions have 5 times greater risk than those without.¹⁵ An underlying medical condition was present in 79% of the people who died from H1N1.¹⁶
 - Pregnant women have 4-5 times greater risk. The risk appears to be related to the stage of pregnancy. Over two thirds of hospitalized cases occur in the third trimester.¹⁷
 - As of October 24th, 2009, 4 deaths due to H1N1 have been reported in children under 16 years of age.¹⁸ Children less than 2 years of age have the highest rate of hospitalization, Intensive Care Unit admission, and ventilation rates of all age groups.¹⁹ 472 pediatric hospitalizations have been reported since the beginning of the pandemic and 89.8% of these hospitalizations were due to Pandemic (H1N1) 2009.²⁰ In the first wave, 54.4% of reported H1N1 influenza cases (not deaths) in Canada occurred in people under 20 years of age. The highest hospitalization rates were seen in children under 15 years (10.4 cases per 100,000).²¹ By comparison, in 2004 there were 3 deaths due to influenza in children 14 years and younger²² (2 were less than 12 months and 1 was between 1 and 4 years) and 1 death

- in a child aged between 1 and 4 years in 2005.²³ and 6 deaths in 2003 (3 between 1 and 4, 1 between 5 and 9 and 2 between 10 and 14).²⁴
 - Adults over 45 years of age and over have the highest mortality rate²⁵ (0.33 per 100,000)²⁶
 - People living in remote areas, particularly First Nations, Inuit and Metis populations, have also experienced higher rates of hospitalization and severe outcomes (Intensive Care Unit admission and death).²⁷
 - For a summary of the characteristics of hospitalized cases, ICU admissions and deaths as of October 24th 2009, visit this website: http://www.phac-aspc.gc.ca/fluwatch/09-10/w42_09/index-eng.php#1
- Preliminary research shows that those with previous seasonal flu shot are at increased risk of infection with H1N1.²⁸

What risks are associated with the H1N1 vaccine?

- There is limited information available about adverse events associated with the H1N1 vaccine because the clinical trials are still in progress (as of October 21st 2009 only two small clinical trials in adults have been conducted).²⁹
- Once vaccination begins, the Public Health Agency of Canada has declared they will prepare a weekly report summarizing the adverse events reported in Canada on Fightflu.ca.³⁰
- GlaxoSmithKline is the manufacturer of the Arepanrix vaccine and they have identified the following reactions with their product:
 - **Very common** (may occur with more than 1 in 10 doses, are usually mild and only last one or two days):
 - Pain at the injection site
 - Headache
 - Fatigue
 - Redness or swelling at the injection site
 - Shivering
 - Sweating
 - Aching muscles, joint pain
 - **Common** (may occur with up to 1 in 10 doses):
 - Reactions at the injection site such as bruising, itching and warmth
 - Fever
 - Swollen lymph nodes
 - Feeling sick, diarrhea
 - **Uncommon** (may occur with up to 1 in 100 doses):
 - Dizziness
 - Generally feeling unwell
 - Unusual weakness
 - Vomiting, stomach pain, uncomfortable feeling in the stomach or belching after eating
 - Inability to sleep
 - Tingling or numbness of the hands or feet
 - Shortness of breath
 - Pain in the chest
 - Itching, rash
 - Pain in the back or neck, stiffness in the muscles, muscle spasms, pain in extremity such as leg or hand
 - **Rare** (may occur with up to 1 in 1000 doses):
 - Allergic reactions leading to a dangerous decrease of blood pressure, which, if untreated, may lead to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases
 - Fits
 - Severe stabbing or throbbing pain along one or more nerves
 - Low blood platelet count which can result in bleeding or bruising
 - **Very Rare** (may occur with up to 1 in 10,000 doses):
 - Vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems)

- Neurological disorders such as encephalomyelitis (inflammation of the central nervous system), neuritis (inflammation of nerves) and a type of paralysis known as Guillain-Barré Syndrome³¹
- CSL Biotherapeutics is the manufacturer of Panvax, which does not include an adjuvant but does include 50 µg of thimerosal. This vaccine is available for some pregnant women. Below is a summary of adverse event information that is currently by the Public Health Agency of Canada:
 - “No deaths, serious adverse events, or adverse events of special interest resulting from administration of Panvax® H1N1 were reported by Greenberg et al in their trial of 240 healthy adults.³ Further data collection related to unsolicited adverse events is ongoing.
 - Local adverse events were reported among 46.3% (95% CI, 40.1-52.6) of subjects (94.6% graded as mild), the most common of which were injection-site tenderness (36.7%); pain (21.7%); redness (9.2%); induration (8.8%); and ecchymosis (5.0%).
 - Systemic adverse events reported among 45.0% (95% CI, 38.8-51.3) of subjects with 30.4% considered related to H1N1 vaccine. Headache (31.3%) followed by malaise (17.5%); myalgia (17.1%); nausea (7.1%); chills (6.7%); fever (3.8%) and vomiting (0.8%) were the most frequently reported.
 - Two reported adverse events were graded as severe: one with vaccine-related myalgia, malaise, nausea resolving after 5 days; one with non-vaccine-related nausea from day 6-10. Three subjects had an influenza-like illness (ILI) following vaccination, one of whom tested positive for pH1N1 on day 8 post-vaccination.
 - There are currently no published post-marketing data available for Panvax H1N1 vaccine. It is anticipated that the adverse events after vaccination will be similar to those spontaneously reported during post-approval use of CSL’s seasonal influenza vaccine, Fluvax® / Afluria®. The seasonal vaccine is manufactured by CSL Biotherapies Inc. using the same process.
 - The following data reflect experience in children and adults with Fluvax®/Afluria®, vaccine. Adverse event frequencies are defined as follows: very common (≥ 1/10), common (≥ 1/100 and < 1/10), uncommon (≥ 1/1000 and < 1/100), rare (≥ 1/10 000 and < 1/1000) and very rare (< 1/10 000).). Most adverse events have been mild injection site or systemic reactions. Other reported adverse events include: transient thrombocytopenia (rare); allergic reactions including anaphylactic shock (rare); neuralgia, paraesthesia and convulsions (rare); encephalitis, neuritis or neuropathy and Guillain-Barré syndrome (very rare); vasculitis with transient renal involvement (very rare); and pruritus, urticaria and rash (uncommon).”³²
- According to the Public Health Agency of Canada, the average rate of adverse reaction of any vaccine is 1 in 100,000 vaccines distributed³³. The number of vaccines actually administered to Canadians is not currently tracked in Canada, therefore the average rate is likely more than 1 in 100,000 since some of the doses delivered to clinics and hospitals are not administered. For a more in depth discussion of vaccine risks, please refer to the the Risk of Vaccines section in *Childhood Vaccinations – Answers to Your Questions* by Katia Bailetti ND. This book is currently being revised. The new edition will be released soon. To place your order: http://www.doctormom.me/vaccine_resources.htm
- The systems in place to maximize vaccine safety include regulatory bodies, clinical trial requirements for licensing, postlicensing surveillance, and research. For more information, please review vaccine safety information from the Public Health Agency of Canada at www.phac-aspc.gc.ca/im/vs-sv/caefiss-eng.php. In spite of these checks and balances, a number of safety issues remain such as underreporting of serious vaccine complications, lack of long-term safety studies, few randomized placebo-controlled trials, conflicts of interest, little independent evaluation of vaccine safety and lack of safety guidelines for vaccine components. For a discussion of these safety issues, please refer to the Safety section in *Childhood Vaccinations – Answers to Your Questions* by Katia Bailetti ND. This book is currently being revised. The new edition will be released soon. To place your order: www.doctormom.me/vaccine_resources.htm

Decrease Your Risk of a Serious Infection – Dr. Bailetti’s Top 5 Recommendations:

1. **Keep your distance.**
 - When possible, keep your distance from people who are coughing or sneezing (2 meters). Sneezing, coughing and even breathing can propel small virus-containing droplets into the air. Giving them space will decrease the number of droplets that enter your nose and mouth.
 - Discourage visits to your home from people who are sick or who have a lot of contact with sick people. Ensure play dates are scheduled on days where everyone is healthy.

- If someone in your home is sick, keep them home, when possible. If your immune system is fighting off an infection, it will likely be more susceptible to other infections and to developing serious complications. Encourage friends, family and coworkers to stay home if they are sick.
- If you are coughing or sneezing, use a disposable tissue, throw it out and wash your hands.
- 2. **Avoid sharing** drinks, utensils, baby chew toys, wind instruments, toothbrushes or lipstick with others as all of these objects can transfer virus-containing saliva from one person to another.
- 3. **Keep it clean.**
 - Wash your hands thoroughly and often. Especially when entering your home, before eating, after riding public transit and using the washroom, after shaking hands, touching commonly used objects (public telephones, escalator hand rails) and after touching someone who is sick. Avoid touching your face unless your hands are clean. An easy way for infections to enter the body is through mucous membranes in your eye lids, nose and mouth.
 - Keep commonly used surfaces and items clean. The H1N1 Flu Virus can live outside the body on hard surfaces, such as stainless steel and plastic, for up to 48 hours and on soft surfaces, such as clothing, paper, and tissues for less than 8-12 hours; however, it can only infect a person for up to 2-8 hours after being deposited on hard surfaces, and for up to a few minutes after being deposited on soft surfaces. Even though your hands may be clean, clothes, toys and other objects you bring into your home may not be. Be aware of where purses, backpacks, jackets and toys have been (bathrooms, daycare, public transit, medical clinics), clean them when possible and avoid placing them on the dining room table or beds. Take your shoes off especially if you have little people crawling or sitting on the floors.
- 4. **Make conscious lifestyle choices.**
 - Minimize sugar intake. Sugar is an immune suppressant.
 - Enjoy the sunshine. Vitamin D could decrease your risk of getting sick.
 - Get good quality sleep. Sleep is essential for proper immune system function.
 - Manage your stress. Stress disrupts normal immune system function. Avoid unnecessary stress or manage it with relaxation techniques and empower your children to manage their stress too.
 - Avoid toxins. Toxins can interfere with immune function. Make conscious decisions to avoid toxins in your air, food and water.
 - Breast is best. Breastfeeding not only provides infants with immune boost, it decreases their risk of respiratory infections for years after.
- 5. **Be prepared.**
 - Visit your naturopathic doctor for information on how to optimize your immune function through using safe and natural remedies such as herbs, homeopathics, hydrotherapy, acupuncture and nutritional supplements.
 - Stay informed about local outbreaks and new vaccine safety information.
 - Update your family emergency plan to be prepared for a pandemic. For more information on emergency planning at home, visit Emergency Management Ontario <http://www.emergencymanagementontario.ca/english/prepare/emergency.html> and the Public Health Agency of Canada's *Your H1N1 Preparedness Guide*: www.phac-aspc.gc.ca/alert-alerte/h1n1/guide/pdf/h1n1_guide-eng.pdf

Decrease Your Risk of a Serious Vaccine Complication - Dr. Bailetti's Top 5

Recommendations:

1. **Ensure you are healthy** before getting vaccinated.
2. **Review the list of vaccine contraindications and cautions** with your health care provider prior to receiving the vaccine.
3. **Stay in your doctor's office** (or vaccination clinic) for at least 15 minutes after each injection. Although the risk is likely rare, in the event of an anaphylactic reaction, you want to be very close to life-saving medication.
4. **Avoid stressors.** Keep a close eye on family members after each injection and allow their body time to recover. Minimize their exposure to extreme temperature changes, large crowds, significant travel or other significant stressors for one week after the vaccine (or longer if they have a vaccine reaction).
5. **Consult your naturopathic doctor** about natural vaccine support pre and post vaccination. Be cautious about lowering mild fevers as they are useful for helping the body recover from infections. Seek medical help promptly if your child develops any symptoms that concern you.

Key Resources

- **Health Information Numbers across Canada.** You can call them if you need information on when to seek medical care and about health care facilities in your area:
 - Alberta 1-866-408-5465
 - British Columbia 8-1-1
 - Newfoundland and Labrador 1-888-709-2929
 - Manitoba (204) 788-8200
 - or toll-free at 1-888-315-9257
 - New Brunswick 1-800-580-0038
 - Northwest Territories 1-888-920-3026
 - Nova Scotia 8-1-1
 - Nunavut www.fluNU.ca*
 - Ontario 1-800-476-9708, TTY : 1-800-387-5559
 - Prince Edward Island 1-888-748-5454
 - Quebec 8-1-1
 - Saskatchewan 1-877-800-0002
 - Yukon 8-1-1
- **Influenza Self-Assessment Tool**
www.health.gov.on.ca/en/ccom/flu/h1n1/public/tools/assessment/default.aspx
- **Handwashing Technique**
www.health.gov.on.ca/en/ccom/flu/h1n1/public/docs/factsheets/handwash_tech.pdf
- **Ontario Vaccination Clinics** www.health.gov.on.ca/en/ccom/flu/h1n1/public/clinics.aspx
- **Weekly H1N1 Incidence Maps** by the The Public Health Agency of Canada: <http://dsol-smed.phac-aspc.gc.ca/dsol-smed/fluwatch/fluwatch.phtml?lang=e>
- **Ontario Influenza Bulletin**
www.health.gov.on.ca/english/providers/program/pubhealth/flu/flu_09/bulletins/flu_bul_01_20091030.pdf
- **Public Health Agency of Canada on Twitter:** http://twitter.com/PHAC_GC
- **Find a naturopathic doctor** www.cand.ca

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