

Should i get the H1N1 Vaccine?



2 slides about making
decisions and 10 questions..

Dr. Mike Evans
Associate Professor, Family & Community
Medicine, University of Toronto,
Staff Physician, St. Michael's Hospital
Director, Health Design Lab
Director, Family Practice of the Future,
Scientist, Li Ka Shing Knowledge Institute

Getting the vaccine is a choice.

- This is a simple choice for some (either way) and a tough choice for many. There is no perfect answer as we do not have perfect data. I give my answer at the end, but feel free to disagree.
- It's hard to argue against vaccines at a population level (if we give it to everybody the clinics and E.R.'s will be much less busy, less missed work, less people getting sick or even dying) **but things get trickier at the individual level.**
- This presentation takes you through some of the issues so you can decide for yourself.

Values and Change

- When making a decision we usually combine the information with our values- which leads to different decisions with the same information.
- **Things will change.** We have lots of experience with vaccines but the H1N1 vaccine is new and so this is a story we will have to follow.
- We like to think of ourselves as rational, but “stories”, and the interactions of these stories with your social network, have considerable impact on our decisions.
- For example, a friend gets sick with H1N1 or has a side-effect to the shot, or an outbreak at your kids’ school or your work.

Question #1: How likely is it that I will get sick from H1N1 this year?

- Let's start with the usual rates of flu. Typically your chances are about 9-12%, or about 9-12 of 100 people. This attack rate can go up to 42% if you have young kids.
- H1N1 appears to have higher attack rates. Recent data from the US (they typically are a little ahead of us) show that they already at the highest flu rates in 5 years.¹
- So chances are still less than a coin toss that you'll get H1N1 influenza, but it is on the rise, especially if you have kids.

¹ <http://www.cdc.gov/h1n1flu/update.htm>

How likely is it that I will get sick of H1N1? (2)

- Canada monitors flu with “Fluwatch”. It takes 2 weeks to get all the test results. There has been a considerable increase in the influenza activity. Over 700 influenza outbreaks have been reported. This occurred in almost all provinces and territories.
- The Pandemic (H1N1) 2009 strain accounted for nearly 100% (99.8%) of the positive influenza A subtyped specimens.
- A total of 3,764 hospitalized cases including 606 cases admitted to ICU and 295 cases required ventilation as well as 135 deaths from H1N1 were reported to PHAC as of November 7, 2009.
- Another interesting indicator of flu activity is “google flu” which is a web based program that tells us how many people search for the symptoms of flu. When this was compared to the CDC it turns out it matched up very well with the more scientific process but gives us quicker answers (~2 weeks). Google flu shows a very steep incline in cases in the last month compared to the last 5 years (Likely part of this is H1N1 hysteria). This past week has dropped so hopefully this signals less illness (and likely “H1N1 media fatigue”).

Q2: How sick will I get?

Most of us get a cold seasonally. Definitely unpleasant but it is something we can cope with. Influenza can be mild but it can be much more severe as we can see from the chart below.

Symptoms	Cold	Influenza
Fever	Rare	Usual; high fever (102 °F/39 °C - 104 °F, 40 °C), sudden onset, lasts 3 to 4 days
Headache	Rare	Usual; can be severe
Muscle aches and pains	Sometimes, generally mild	Usual; often severe
Tiredness and weakness	Sometimes, generally mild	Usual; severe, may last up to 2 to 3 weeks
Extreme tiredness	Unusual	Usual; early onset, can be severe
Runny, stuffy nose	Common	Common
Sneezing	Common	Sometimes
Sore throat	Common	Common
Chest discomfort, cough	Sometimes, mild to moderate	Common; can be moderate to severe. Cough may last for weeks.
Complications	Can lead to sinus congestion or infection, and ear aches.	Can lead to pneumonia and respiratory failure, and become life-threatening. Can worsen a chronic condition.

Source: Ministry of Health and Long-Term Care http://www.health.gov.on.ca/english/public/program/pubhealth/flu/flu_06/flucomp/factsheets/difference.html

As Far as H1N1 is concerned it is really a version of influenza and here are the symptoms (at least in patients that have come to the hospital).

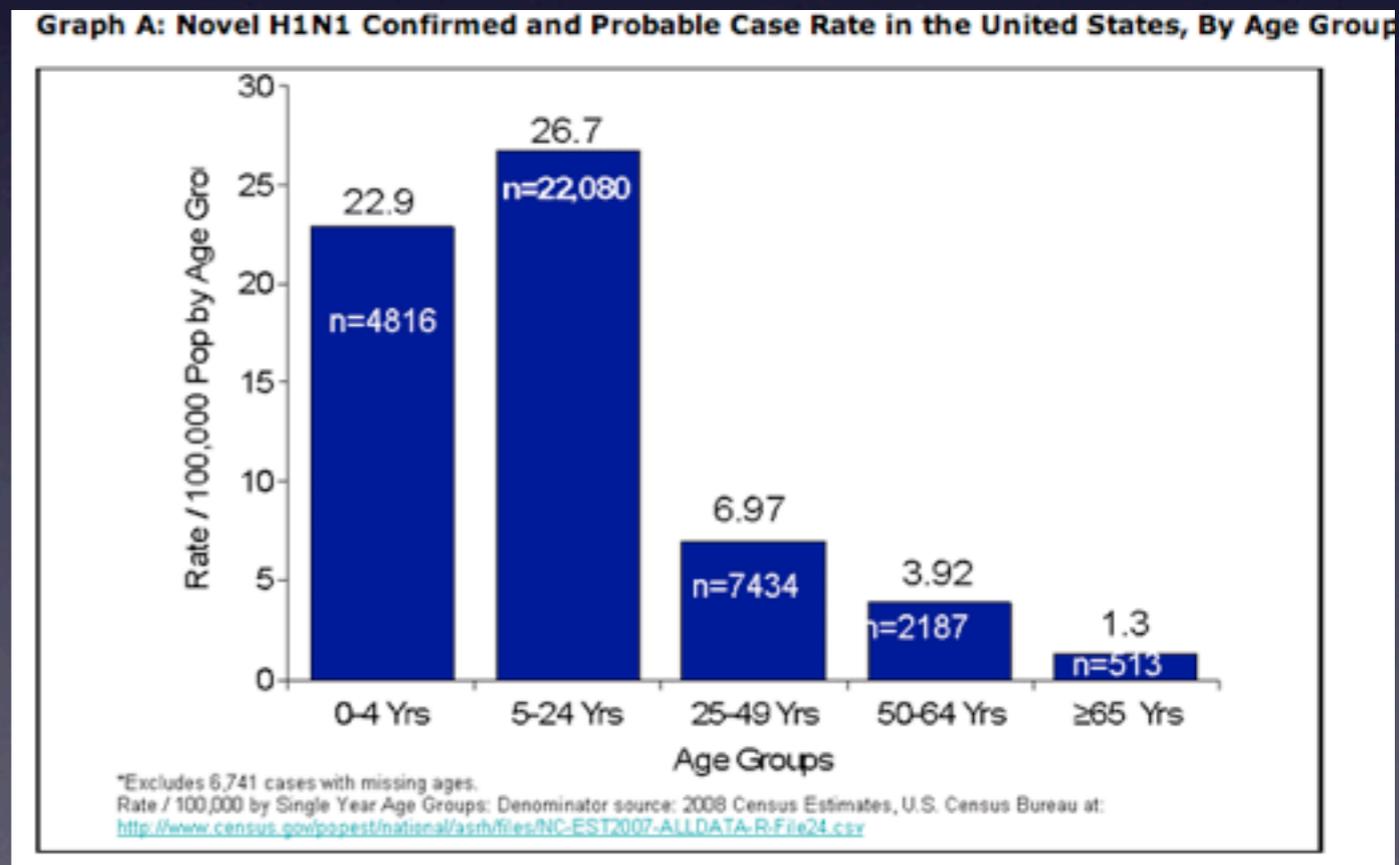


Table: Symptoms of hospitalized novel H1N1 patients

Symptom	Number (%)
Fever*	249 (93%)
Cough	223 (83%)
Shortness of breath	145 (54%)
Fatigue/Weakness	108 (40%)
Chills	99 (37%)
Myalgias	96 (36%)
Rhinorrhea	96 (36%)
Sore Throat	84 (31%)
Headache	83 (31%)
Vomiting	78 (29%)
Wheezing	64 (24%)
Diarrhea	64 (24%)

Q2: How sick will I get (2)?

- Most people H1N1 flu is very unpleasant but they cope. Some people do get sick enough to be hospitalized.
- Reviewing US H1N1 data¹ about 11/1000 got sick enough from H1N1 to be hospitalized and 7/10,000 died from H1N1.
- About 70% of people who have been hospitalized with H1N1 flu have had one or more medical conditions that placed them in the “high risk” category for serious seasonal flu-related complications. These include pregnancy, diabetes, heart disease, and kidney disease. This is likely especially true for asthma
- The graph at the right shows that H1N1 affects younger people more often. Having said that, even though older people are less often afflicted, their rates of hospitalization are significant because they are more likely to be frail or have other diseases.



¹From April 15 to July 24, 2009, the Center for Disease Control in the U.S. captured data on H1N1. There were 43,771 confirmed and probable cases of infection. Of these cases reported, 5,011 people were hospitalized and 302 people died. <http://www.cdc.gov/h1n1flu/surveillanceqa.htm>

Q4: How do vaccines work?

- Your body's immune system is very smart. When you get exposed to a virus your immune system makes a "photocopy" of the virus and sends it around to your "border patrol". When you bump into the virus again, your body neutralizes it and you don't get sick.
- Vaccines just give you a piece of dead virus (sometimes live- but the H1N1 vaccine in Canada is dead virus) so that the "photocopy machine" can go into action and your immune system is prepared to fight off the real virus.
- I often get asked whether it is better to get immunity "naturally". The answer is yes and no. If you get it "naturally" then you are immune, but the problem is that you also get sick!
- So, for example, if you have had documented H1N1 then you don't need the vaccine (if H1N1 was suspected but not tested for -which is common- it is still best to get the shot).

Q4 (2): How does an adjuvant work and do I need to worry about it?

- The H1N1 vaccine is like a normal flu shot with something called an adjuvant added in.
- An adjuvant “primes” the pump in your immune system. It means less vaccine will go farther and you only need to come for one shot instead of two.
- It has been used with >40,000 people in Europe, but the downside is that, for ethical reasons, there is limited data on very young children and pregnant moms.
- Hence, vaccine with adjuvant is not recommended for kids <6 months and pregnant moms less the 20 weeks pregnant.

Q3: Will the H1N1 vaccine actually protect me?

- The effectiveness depends on how well the vaccine matches with the virus that is circulating in the community. It also depends on your own immune system; eg., older people tend to have less of a response. Usually the effectiveness rates for seasonal flu vaccines is 70-90%.
- This years H1N1 vaccine has thus far been to shown match very well with what is in the community and is at the upper end of effectiveness.
- Typically we say that it takes 14 days for the flu vaccine to be effective. With H1N1 it looks like it works in about 10 days.

Pregnant Moms

- This is a tricky one. Pregnant moms are very focused on trying to keep a healthy lifestyle and protecting their baby and introducing a vaccine seems counterintuitive. Also, as you can imagine, pregnant moms are ethically very difficult to study.
- Having said that, a well done trial done last year showed that influenza vaccine was very protective for pregnant moms **and** their babies. It reduced proven influenza illness by 63% in infants up to 6 months of age and averted approximately a third of all respiratory illnesses with fever in mothers and young infants¹. **Sort of a two for one deal.**
- There has been limited experience with adjuvant + vaccine in pregnant moms. Monitoring systems so far have not signaled a problem. The trial mentioned above did not use an adjuvant.
- Pregnant moms seem to be at more risk for H1N1 and are more likely to be hospitalized.
- So.... balancing risks and benefits, the recommendation is that if you are <20 weeks pregnant to wait for the H1N1 vaccine **without** adjuvant. If you are over 20 weeks pregnant (most fetal development has happened by this time) the advice is to go ahead and get the vaccine **with** adjuvant.

¹Oct. 9, 2008, New Eng J of Med

Older People

- Many older people (>60) are asking whether they should get the swine flu shot as they seem to be more “resistant”. The theory is that pre-1957 there was more swine flu around and so people who were alive then have more resistance.
- The reason why the H1N1 vaccine is recommended, even though the infection rate is lower, is that the consequences are higher, because seniors tend to have other diseases going on or more frailty. They also are more likely to be in contact with someone with a weak immune system.
- You can get the flu shot at the same time. Pincushion!

Q5: What are the side-effects of the shot? or Didn't I get sick last time I got it...?

- The flu shot gets blamed for lots of sickness. But is that fair? Below are results of an interesting trial that gave 1/2 the participants the real flu vaccine, and half got fake, (or placebo) injection. So what happened?

Adverse Events of Flu Shot in Healthy Adults

Symptom	Placebo	Real Flu Vaccine
Fever	6.1%	6.2%
Tiredness	19.4%	18.9%
“Under the Weather”	17.5%	16%
Muscle Aches	5.7%	6.2%
Headaches	14.4%	10.8%
Arm Soreness	24%	63.8%

- Almost 20% of people got sick after the shot but it was equal whether you got the real vaccine or not. Put another way, if you look around you in the fall ~20% will feel under the weather in the next two weeks (plus it takes 14 days for the shot to work). If you just had a flu shot and you get sick you blame it. Arm pain was truly more common with real vaccine, and is likely at higher rate with H1N1 vaccine (>70%) as the adjuvant causes a bit more inflammation. I tell people to take a tylenol or acetaminophen before bed for the first night.

*Nichol KL, Lind A, Margolis KL, et al. “The effectiveness of vaccination against influenza in healthy, working adults”. NEJM. 1995; 333:889-93.

Q5: What are the side-effects of the shot?(2) or *What about these scary things I read on the internet about mercury and paralysis?*

- About 1 in a million will have a severe reaction (anaphylaxis or possibly Guillain-Barré Syndrome (GBS))¹:

- GBS is a disease where people have numbness, imbalance, loss of motor control, and some paralysis. There is a wide spectrum of effect but 85% get better at 6-12 months. GBS typically happens to about 1-2 in 100,000 people. We don't know why it happens but it often happens after surgery or a virus. Data is conflicting as to whether a causal relationship exists between modern influenza vaccines and GBS. If one exists, the risk is estimated to be very low (no more than 1 to 2 cases per million doses). Since the introduction of universal influenza immunization in Ontario, there has been no detectable increase in the number of new cases of GBS requiring hospitalization at the population level.²³ Just to be safe I would not give the vaccine to somebody where this condition was evolving or who had had a GBS reaction soon after vaccine in the past.

- Concerns about Thimerosal:

- Thimerosal is a preservative for vaccines that if we didn't have in there we would have other safety concerns. Most influenza vaccines available in Canada contain minute amounts of thimerosal. Thimerosal has some mercury in it so it is rational to be concerned. Because of this there has been large reviews of the safety of thimerosal. No studies have demonstrated an association between thimerosal-containing vaccines and adverse outcomes. H1N1 has an adjuvant which means we need about 1/10 of the usual amount of thimerosal. To keep things in perspective, there is less mercury in the shot than in a tuna sandwich.⁴⁵

¹Considering the Options - Getting the flu versus getting a vaccine or taking an antiviral PHAC,

²Juurlink DN, Stukel TA, Kwong J, et al. "Guillain-Barre Syndrome after influenza vaccination in adults: A population-based study". Arch Intern Med. 2006; 166:2217-21.

³Committee on Infectious Diseases. "Prevention of Influenza: Recommendations for Influenza Immunization of Children, 2007-2008". Pediatrics. 2008;121(4):1016-31.

⁴Andrews N, Miller E, Grant A, et al. "Thimerosal exposure in infants and developmental disorders: A retrospective cohort study in the United Kingdom does not support a causal association". Pediatrics. 2004; 114:584-91.

⁵Thompson WW, Price C, Goodson B, et al. "Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years." NEJM. 2007; 357(13):1281-92.

Q7: Does my decision affect others?

- We've talked about your chances of getting sick, but what we haven't talked about is the effect of your health on others.
- It's interesting, and I am biased because I see many older and/or sick people, but my main reason to get the flu shot is to protect these people.
- If you get the shot you reduce the risk for people in your life who may struggle with dealing with H1N1 swine flu (eg., people with other diseases).
- Conversely, if you get the kids the shot, your chances of getting sick go down quite a bit.

Q8 Can you summarize the Risks + Benefits?

See next page for simplified version

Time stamped:
Nov 19 2009. May
be out of date
soon...

It will protect me from getting sick vs. it will make me sick

- Your risk in general of getting pretty sick with normal influenza is about 9-12/100. This can go up to 42/100 if you have kids. This attack rate will likely be higher with H1N1.
- So far it looks like about 11/1000 with H1N1 get extremely sick and admitted to the hospital. You are more at risk if you have another condition like asthma.
- Having said that, most people feel unwell, often miss work, but cope fine.
- Having the vaccine will be very protective as there is a good match with circulating H1N1 thus far.

- At least 70% will have some arm pain. The pain doesn't limit activity and is gone typically in 2 days.
- The likelihood of a severe reaction or lasting consequence from the vaccine is 1-2 in a million.¹²³⁴⁵

Two other things to think about....

1. When you get the vaccine you protect those around you. Especially those at risk eg., Seniors, kids, people with underlying diseases, pregnant moms, etc..

2. In a perfect world we would have large trials over years to reassure you (and me) that the vaccine is perfectly safe. However, if we waited for this, millions of people would get very sick. The H1N1 vaccine is like a new version of the flu shot that we have lots of experience with and an excellent safety record. As well, there is now enhanced reporting systems in North America to gather this data and there have been no concerning signals. The adjuvant is new to this influenza shot and has been less tested on pregnant moms and children under 6 months so we are cautious with these two groups. Ultimately you and I have to make a decision without all the data we would like.

¹ Considering the Options - Getting the flu versus getting a vaccine or taking an antiviral, Public Health Agency of Canada, ² Juurlink DN, Stukel TA, Kwong J, et al. "Guillain-Barre Syndrome after influenza vaccination in adults: A population-based study". Arch Intern Med. 2006; 166:2217-21. ³ Committee on Infectious Diseases. "Prevention of Influenza: Recommendations for Influenza Immunization of Children, 2007-2008". Pediatrics. 2008;121(4):1016-31.

⁴ Andrews N, Miller E, Grant A, et al. "Thimerosal exposure in infants and developmental disorders: A retrospective cohort study in the United Kingdom does not support a causal association". Pediatrics. 2004; 114:584-91.
⁵ Thompson WW, Price C, Goodson B, et al. "Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years." NEJM. 2007; 357(13):1281-92.

H1N1 vaccine oversimplified

- My best guess looking at the data is that your chance of getting H1N1 flu and getting quite sick is likely about one in four. Higher if you have small kids.
- The chance of a negative lasting consequence from the vaccine is around 1-2 in a million. Your arm will likely be sore for 2 days.

Q9: What are the recommendations for the H1N1 vaccine?

Recommendations from the Public Health Agency of Canada (these have just changed -Nov 14, 2009)

- Kids 6 mos to 3 years old should receive two half-doses of adjuvanted H1N1 flu vaccine, administered at least 21 days apart. Guidance for children in this age group is unchanged.
- Children with chronic health conditions who are between 3 and 9 years of age should receive their first half-dose of the H1N1 flu vaccine as soon as possible. They should also receive a second half-dose of the H1N1 flu vaccine. The interval between the two half-doses should be a minimum of 21 days.
- Healthy children between 3 and 9 years of age should only receive a single half-dose of the H1N1 vaccine, and do not need to return for a second vaccine for now.
- Healthy people between the ages of 10 and 64 years should receive one dose of either the adjuvanted or unadjuvanted vaccine.
- Pregnant women should receive one dose of the unadjuvanted vaccine. In cases where the unadjuvanted vaccine is unavailable and H1N1 flu rates are high or increasing in the community, women more than 20 weeks pregnant and women less than 20 weeks pregnant with serious chronic diseases should be offered one dose of the adjuvanted vaccine.
- People over the age of 64 and people with weakened immune systems should receive one dose of the adjuvanted vaccine.
- **Who should not receive the vaccine?**
- The following groups of people should NOT receive the H1N1 flu vaccine
 - People who have had a previous anaphylactic (severe allergic reaction) to any element of the vaccine, OR
 - People with a hypersensitivity to eggs (e.g. hives, swelling of mouth and/or throat, breathing difficulty); OR
 - People experiencing a high fever, OR
 - People who have previously experienced Guillan-Barré Syndrome within 8 weeks of receiving a seasonal flu vaccine.
- The H1N1 flu vaccine is not approved for children under six months.

Q10: will you vaccinate your kids (and yourself)?

yes.

Thanks.
Hope Helpful.

Dr. Mike Evans