What does the science say: H1N1

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Introduction

It seemed like a good idea to do a quick entry addressing the H1N1 "swine flu" strain as well as the vaccine for it. A friend of mine suggested adding it to my previous entry on vaccines, but I thought I'd do a separate one instead so people's eyes don't glaze over from an already over-long article.

I have no intention of promoting the quack H1N1 claims that are floating around the Internet, so I won't be linking to them. What you will find here is the official information that is available about the disease and the vaccine. As usual, if you are convinced that the government is lying to us about the flu, then you may as well stop reading now, as I am really just summarizing CDC and FDA data.

As always, I welcome comments on my blog (http://whatdoesthesciencesay.wordpress.com) or to my email address (josh at 40two org). If anything in here seems factually inaccurate to you, please let me know, but cite your sources. I'm truly not interested in what "Mr. Fit" or any number of random Internet flu scare sites have to say unless they have any genuine science to back them up.

Summary

The "pandemic" H1N1 (aka "swine flu") is a very serious strain of flu. It is separate from the standard seasonal flu and to be protected for both you have to vaccinate from both. The actual effects are similar to the normal flu, which kills about 36000 people a year. The expected combined deaths of seasonal flu (3 strains) and H1N1 is about 65000 deaths. The H1N1 vaccine has been shown to be as safe and effective as the normal seasonal vaccine that people take yearly.

Disclaimer

I am not a doctor. None of my words should be construed at medical advice. If you still have questions about H1N1, speak with your own doctor. You may safely ignore any statements that appear to be opinion from me or not directly supported by any research or authority I cite.

The H1N1 virus

So what is H1N1 any way?

There actually is already a different version of H1N1 that circulates as part of the seasonal flus.
From the CDC's Q&A about H1N1 (http://www.cdc.gov/h1n1flu/qa.htm):

> This virus was originally referred to as "swine flu" because laboratory testing showed that many of the genes in this new virus were very similar to influenza viruses that normally occur in pigs (swine) in North America. But further study has shown that this new virus is very different from what normally circulates in North American pigs. It has two genes from flu viruses that normally circulate in pigs in Europe and Asia and bird (avian) genes and human genes. Scientists call this a "quadruple reassortant" virus.

Symptoms:

> The symptoms of 2009 H1N1 flu virus in people include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may have vomiting and diarrhea. People may be infected with the flu, including 2009 H1N1 and have respiratory symptoms without a fever. Severe illnesses and deaths have occurred as a result of illness associated with this virus.

Severity, risk, infection rates:

In seasonal flu, certain people are at “high risk” of serious complications. This includes people 65 years and older, children younger than five years old, pregnant women, and people of any age with certain chronic medical conditions. About 70 percent of people who have been hospitalized with this 2009 H1N1 virus have had one or more medical conditions previously recognized as placing people at “high risk” of serious seasonal flu-related complications. This includes pregnancy, diabetes, heart disease, asthma and kidney disease.

With seasonal flu, we know that seasons vary in terms of timing, duration and severity. Seasonal influenza can cause mild to severe illness, and at times can lead to death. Each year, in the United States, on average 36,000 people die from flu-related complications and more than 200,000 people are hospitalized from flu-related causes. Of those hospitalized, 20,000 are children younger than 5 years old. Over 90% of deaths and about 60 percent of hospitalization occur in people older than 65.

Is anybody really dying from H1N1?

http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm
Sadly, yes.

As of October 17th (so a month before this writing), the CDC estimates that there have been 2500 to 6100 deaths. 63,000 to 153,000 people have been hospitalized. And the season is really just getting started.

If you're curious about why it's an "estimate", it mainly has to due with the fact that states don't have to report all flu-related deaths, or the person might day later from complications. Specifically:

- First, states are not required to report individual seasonal flu cases or deaths of people older than 18 years of age to CDC.
- Second, seasonal influenza is infrequently listed on death certificates of people who die from flu-related complications.
- Third, many seasonal flu-related deaths occur one or two weeks after a person’s initial infection, either because the person may develop a secondary bacterial co-infection (such as a staph infection) or because seasonal influenza can aggravate an existing chronic illness (such as congestive heart failure or chronic obstructive pulmonary disease).
- Also, most people who die from seasonal flu-related complications are not tested for flu, or they seek medical care later in their illness when seasonal influenza can no longer be detected from respiratory samples. Influenza tests are most likely to detect influenza if performed soon after onset of illness.

- For these reasons, many flu-related deaths may not be recorded on death certificates.

The Vaccine

Was the vaccine rushed?

The key thing to know is that from a vaccine point of view, this is just another (better targeted) strain.

"The flu" vaccine changes every year because of the evolution and recombination of the strains. Or from the CDC's "key facts" about the seasonal flu[1]:

> The viruses in the vaccine change each year based on international surveillance and scientists' estimations about which types and strains of viruses will circulate in a given year. About 2 weeks after vaccination, antibodies that provide protection against influenza virus infection develop in the body.

My readers will probably agree that we don't hear yearly conspiracy theories about the "rush" to create the current year flu vaccine. Or maybe they do and, rightfully, ignore them.

The ones that circulate seasonally are:

- H3N2
- seasonal A (H1N1)
- seasonal B

"pandemic" H1N1 is the new version.

Additionally, the FDA has a Q&A about the 2009 H1N1 which addresses this concern[2].

> Vaccines used in the United States must be licensed by FDA. FDA approved these vaccines as a strain change to each manufacturer's FDA-approved seasonal influenza vaccine. Each of the manufacturers will make the Influenza A (H1N1) 2009 Monovalent vaccines using its well-established, licensed egg-based manufacturing process that is used for seasonal influenza vaccine.
>
> There is considerable experience with seasonal influenza vaccine development and

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1. "CDC: Seasonal Influenza Key Facts". http://www.cdc.gov/flu/protect/keyfacts.htm Visited 11/26/2009
2. US Food and Drug Administration. "Influenza A (H1N1) 2009 Monovalent Vaccines Questions and Answers." http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm182335.htm. Published September 15, 2009. Visited 11/28/2009

> production and influenza vaccines produced by this technology have a long and successful track record of safety and effectiveness in the United States. The safety and effectiveness demonstrated for seasonal influenza vaccine also support the licensure of the Influenza A (H1N1) 2009 Monovalent vaccines produced using the same process as for seasonal vaccine.
>
> The Influenza A (H1N1) 2009 Monovalent vaccines will undergo the same rigorous testing and lot release procedures that are in place for seasonal influenza vaccines.

Summary

Every year, it takes approximately 6 months to make the current season's batch of flu vaccine. The pandemic H1N1 strain (an earlier version of which circulated in 1976) vaccine is being produced using the same process as the seasonal flu. To call it rushed is to also claim that every year the seasonal flu vaccine is "rushed". I see no evidence of truth in that claim.

But I heard that I might get Guillain-Barré?

What is Guillain-Barré?

From the CDC's "Fact Sheet" on Guillain-Barré[3]:

> Guillain-Barré syndrome (GBS) is a rare disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis. GBS can cause symptoms that last for as little as a few weeks, or go on for several months. Most people recover fully from GBS, but some people have nerve damage that does not go away. In rare cases, people have died of GBS, usually from not being able to breathe due to weakness of their breathing muscles.

A key item in there is the fact that "most people recover fully".

And the risk from the swine flu vaccine?

Continuing in the same Fact Sheet:

> In very rare cases, someone may develop GBS in the days or weeks after getting a vaccination. In 1976, there was a small increased chance of GBS after getting a flu (swine flu) vaccination. This means about 1 more case per 100,000 people who got the swine flu vaccine
> ...
> Since 1976, many studies have been done to see if other flu vaccines may cause GBS. In most studies no link was found between the flu vaccine and GBS. However, two studies did

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3. http://www.cdc.gov/h1n1flu/vaccination/factsheet_gbs.htm CDC. "Fact Sheet: Guillain-Barré Syndrome". Published 11/2/2009. Visited 11/27/2009.

> suggest that about 1 more person out of 1 million people vaccinated with seasonal flu vaccine may develop GBS. This continues to be studied. For the most part, the chance of getting very ill from flu is far higher than the chance of getting GBS after getting the flu vaccine.

This 1976 increase is the part that scares people. In fact, as soon as the increase was noticed, they stopped doing mass vaccinations that year as a precaution (yes, despite what people would like to claim, the CDC is very concerned about the safety of vaccines and takes seriously any indication they they haphazardly vaccinate).

Despite a continued lack of real risk in subsequent flu vaccination programs, the CDC definitely monitors for any illness following vaccination [from Fact Sheet above]:

> During the 2009-2010 flu season, CDC and FDA will be closely looking at reports of serious problems, including GBS, which may be linked to the use of the 2009 H1N1 flu vaccine and to the seasonal flu vaccine. These systems already include some vaccination safety systems, such as the Vaccine Adverse Event Reporting System (VAERS), and new systems, such as the CDC Emerging Infections Program and a partnership with the American Academy of Neurology, which includes doctors who are most likely to see people with GBS. None of these systems existed in 1976.

If you'd like to take a look at some of the actual studies, the ones I found were:
One study found the risk after swine flu vaccine in 1976 to be approximately 11.7/1M (or 1.7/100K)[4]. Another found 13.3/1M (or 1.3/100K) using a different methodology[5].

Researches continued to look at the risk from the seasonal flu vaccine. I believe these are relevant because the process of creating the vaccine for seasonal and "pandemic" flu is the exact same. Nobody is quite sure what happened in 1976, but it has not been repeated and could have been a random blip.

A study in Great Britain found no real evidence of increased risk from 1990-2005 following seasonal flu vaccine, but "greatly increased" risk following flu-like illnesses[6].

There was a slight increase in the 1993-1994 season above the 1992-1993 which elicited a study that found: "There was no increase in the risk of vaccine-associated Guillain–Barré

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4. Breman, Joel G. "GUILLAIN-BARRÉ SYNDROME AND ITS RELATIONSHIP TO SWINE INFLUENZA VACCINATION IN MICHIGAN, 1976–1977". American Journal of Epidemiology Vol. 119, No. 6: 880-889 http://aje.oxfordjournals.org/cgi/content/abstract/119/6/880
5. Marks, James S. "Guillain-Barré Syndrome in Recipients of A/New Jersey Influenza Vaccine". JAMA. 1980;243(24):2490-2494.http://jama.ama-assn.org/cgi/content/abstract/243/24/2490
6. Stowe, Julia et a. "Investigation of the Temporal Association of Guillain-Barré Syndrome With Influenza Vaccine and Influenzalike Illness Using the United Kingdom General Practice Research Database". American Journal of Epidemiology 2009 169(3):382-388; doi:10.1093/aje/kwn310 http://aje.oxfordjournals.org/cgi/content/abstract/169/3/382

syndrome from 1992–1993 to 1993–1994. For the two seasons combined, the adjusted relative risk of 1.7 suggests slightly more than one additional case of Guillain–Barré syndrome per million persons vaccinated against influenza."[7]

Other insights

In what I saw as a great example of a person really looking at the science and weighing the risks, *even after recovering from Guillain-Barré*, Laura Claire Price submitted an editorial (not a clinical study) published in the September 2009 British Medical Journal. After summarizing much of the findings (some I have quoted above), she closes[8]:

> In view of the potential risks of and likely exposure to flu infection as a health care professional, the lack of relapse of the syndrome in a sizable number of people who have had the flu vaccine, and the lack of a persistent causal association, my current view is to consider "having the jab" when it becomes available.

In terms of the relative risks themselves, two statisticians did an analysis of relative risk and whether it necessarily indicates an actual association. The analysis seems generic to me, but it was specifically in response to a civil case regarding Guillain-Barré and flu vaccine (in tort law, 2.0 relative risk is used). They concluded[9]:

> The scientific connection between a relative risk of 2.0 and specific causation is doubtful. Large relative risks argue for general causation, while small ones argue against. If the relative risk is near 2.0, problems of bias and confounding in the underlying epidemiologic studies may be serious, perhaps intractable. Problems created by individual differences may be equally difficult. Bias and confounding affect the estimation of relative risk from the underlying data. By contrast, individual di fferences affect the interpretation of relative risk:namely, the application to any specific individual.

In short, when the relative risk indicates an increased risk, but that relative risk is still low, then it is not necessarily indicative of an actual association.

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7. Lasky T, Terracciano GJ, Magder L, Koski CL, Ballesteros M, Nash D, Clark S, Haber P, Stolley PD, Schonberger LB, Chen RT. The Guillain-Barré syndrome and the 1992-1993 and 1993-1994 influenza vaccines. N Engl J Med. 1998 Dec 17;339(25):1797-802. PubMed PMID: 9854114. http://content.nejm.org/cgi/content/full/339/25/1797

8. Price, Laura C. "Should I have an an H1N1 flu vaccination after Guillain-Barré syndrome?". BMJ 2009;339:b3577. http://www.bmj.com/cgi/content/full/339/sep09_1/b3577. Visited 11/27/2009

9. Freedman, D. A., Stark, P. B. (1999). The Swine Flu Vaccine and Guillain-Barré Syndrome: A Case Study in Relative Risk and Specific Causation. *Eval Rev* 23: 619-647

Summary

Guillain-Barré Syndrome is rare to get and generally a person recovers fully. Guillain-Barré appears to be triggered from many illnesses (including the flu) as well as other factors that affect the immune and nervous system. In rare causes (1/1,000,000) the flu vaccine itself can be this cause (as obviously the intent of the vaccine is the trigger an immune reaction). During the 1976 swine flu vaccination program, there appeared to be a 1/100,000 extra cases for those who were vaccinated. The health risks (as well as the incidence) of H1N1 itself is much higher and easily outweighs the risk of Guillain-Barré.

But what about the crazy ingredients?

General Overview

Because people are unnecessarily scared, none of the US approved vaccines have adjuvants (basically they help to "annoy" the immune system into producing more antibodies) such as aluminum in them. But for some of the more "controversial" ingredients (for all US vaccines, not just flu), the FDA has produced a nice FAQ[10].

They specifically cover formaldehyde, preservatives, amino acids, sugars, etc.

I'll quote from a portion of the section on formaldehyde (emphasis mine):

> Although high concentrations of formaldehyde can damage DNA (the building block of genes) and cause cancerous changes in cells in the laboratory, formaldehyde is an essential component in human metabolism and is required for the synthesis of DNA and amino acids (the building blocks of protein). **Therefore, all humans have detectable quantities of natural formaldehyde in their circulation. In addition, quantities of formaldehyde at least 600-fold greater than that contained in vaccines have been found to be safe in animals**.

Additionally, some of the sugars, proteins and amino acids:

> These materials may be added as stabilizers. They help protect the vaccine from adverse conditions such as the freeze-drying process, for those vaccines that are freeze dried. Stabilizers added to vaccines include: sugars such as sucrose and lactose, amino acids such as glycine or the monosodium salt of glutamic acid and proteins such as human serum albumin or gelatin. Sugars, amino acids and proteins are not unique to vaccines and are encountered in everyday life in the diet and are components that are in the body naturally.

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10. "Common Ingredients in U.S. Licensed Vaccines". fda.gov. http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm187810.htm. Visited 11/27/2009

The approved H1N1 vaccines for usage in the United States

You can see this same list at the FDA's "2009 Monovalent Descriptions and Ingredients" site[11].

CSL Limited

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182401.pdf
A single 0.5 mL dose of Influenza A (H1N1) 2009 Monovalent Vaccine contains:

- sodium chloride (4.1 mg)
- monobasic sodium phosphate (80 mcg)
- dibasic sodium phosphate (300 mcg)
- monobasic potassium phosphate (20 mcg)
- potassium chloride (20 mcg)
- calcium chloride (1.5 mcg)

From the manufacturing process, each 0.5 mL dose may also contain residual amounts of:

- sodium taurodeoxycholate (≤ 10 ppm),
- ovalbumin (≤ 1 mcg),
- neomycin sulfate (≤ 0.2 picograms [pg]),
- polymyxin B (≤ 0.03 pg),
- beta-propiolactone (< 25 nanograms)

ID Biomedical Corporation of Quebec

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf

Influenza A (H1N1) 2009 Monovalent Vaccine, for intramuscular injection, is a homogenized, sterile, colorless to slightly opalescent suspension in a phosphate-buffered saline solution formulated to contain:

- 15 mcg hemagglutinin per 0.5-mL dose of the influenza A/California/7/2009 (H1N1)v-like virus.
- Thimerosal, a mercury derivative, is added as a preservative. Each dose contains 25 mcg mercury.

Each dose may also contain residual amounts of:

- egg proteins (≤1 mcg ovalbumin)
- formaldehyde (≤25 mcg)
- sodium deoxycholate (≤50 mcg)

No doubt the first thing you will notice is the use of Thimerosal, which has absolutely not been found to be linked to Autism. However, this vaccine is still only used for adults over 18 years of age. I repeat, children do not receive this vaccine.

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11. US Food and Drug Administration. "Influenza A (H1N1) 2009 Monovalent Vaccines Descriptions and Ingredients". FDA.gov. http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm186102.htm Visited 11/27/2009

MedImmune LLC

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf

Each 0.2 mL dose contains 106.5-7.5 FFU of the live attenuated influenza virus reassortant of the pandemic (H1N1) 2009 virus: A/California/7/2009 (H1N1)v.

Each 0.2 mL dose also contains:

- 0.188 mg/dose monosodium glutamate
- 2.00 mg/dose hydrolyzed porcine gelatin
- 2.42 mg/dose arginine
- 13.68 mg/dose sucrose
- 2.26 mg/dose dibasic potassium phosphate
- 0.96 mg/dose monobasic potassium phosphate
- <0.015 mcg/mL gentamicin sulfate.

Novartis Vaccines and Diagnostics Limited

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182242.pdf

Influenza A (H1N1) 2009 Monovalent Vaccine is a homogenized, sterile, slightly opalescent suspension in a phosphate buffered saline. Influenza A (H1N1) 2009 Monovalent Vaccine is formulated to contain:

- 15 mcg hemagglutinin (HA) per 0.5-mL dose of the following virus strain: A/California/7/2009 (H1N1)v-like virus.

The 5-mL multidose vial formulation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5-mL dose from the multidose vial contains 25 mcg mercury.
Each dose from the multidose vial or from the prefilled syringe may also contain residual amounts of:

- egg proteins (≤ 1 mcg ovalbumin)
- polymyxin (≤ 3.75 mcg)
- neomycin (≤ 2.5 mcg)
- betapropiolactone (not more than 0.5 mcg)
- nonylphenol ethoxylate (not more than 0.015% w/v)

The multidose vial stopper and the syringe stopper/plunger do not contain latex.

Again, notice the Thimerosal in the multidose version. This vaccine is itself only for children over 4 years of age. Also I suspect that due to the unnecessary fears, the single dose version is what is given to those under 18.

Sanofi Pasteur, Inc.

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf

Influenza A (H1N1) 2009 Monovalent Vaccine is formulated to contain:
15 mcg hemagglutinin (HA) of influenza A/California/07/2009 (H1N1) v-like virus per 0.5 mL dose.
Gelatin 0.05% is added as a stabilizer.

Each 0.5 mL dose may contain residual amounts of:

- formaldehyde (not more than 100 mcg),
- polyethylene glycol p-isooctylphenyl ether (not more than 0.02%) [**Note: this is not anti-freeze, or even related to anti-freeze. Antifreeze is made from propylene glycol or ethylene glycol. It is non-toxic. It's also in laxatives!]**
- sucrose (not more than 2.0%)

There is no thimerosal used in the manufacturing process of the single-dose presentations of Influenza A (H1N1) 2009 Monovalent Vaccine.
The multi-dose presentation of Influenza A (H1N1) 2009 Monovalent Vaccine contains thimerosal, a mercury derivative, added as a preservative.
Each 0.5 mL dose of the multidose presentation contains 25 mcg mercury.

Anything crazy? Didn't think so.

For those wondering why no adjuvants are present, it's because they aren't. Again, from the FDA's Q&A about the swine flu vaccine:

> No, these vaccines are manufactured according to the same processes as the licensed (approved) seasonal influenza vaccines, which do not contain adjuvants.

Summary

Except for the formaldehyde, which the CDC addresses, and the Thimerosal (which no valid scientific study has demonstrated has any causal link to Autism), which is only in vaccines meant for people over 18 (and *possibly over 4 in one case*), there are no ingredients which seem to me even worth looking up. Some of the online scare sites will attempt to link polyethylene glycol with "anti-freeze", but this is a dishonest tactic.

One sad side effect of the scare tactics are that there is actually less vaccine available because adjuvants aren't being used (as they are in other countries). This means more attenuated virus and virus proteins must be used rather than a combination of proteins and adjuvants to stimulate the immune system. So less can be made and less live material is available for worldwide vaccines. Score one for pseudoscience.

Another personal comment is that are people genuinely more trustworthy of random "herbal cures" that they find on the internet (or even a health food store) that is unregulated and not demonstrated to have any natural effect, then regulated and **tested** vaccines? Seriously?

Is it safe for pregnant women?

The Recommendation

As usual, let's go straight to the CDC's statements about pregnant women and the flu vaccine[12]

Additionally, because the vaccine cannot be given to babies less than 6 months old, the antibodies will protect the baby after it is born until they can get themselves vaccinated.

> Yes. Besides protecting her from infection, the shot may also help protect her infant. Flu shots are only given to infants 6 months of age and older. Everyone who lives with or gives care to an infant less than 6 months of age should get both the seasonal flu and 2009 H1N1 vaccines. A woman can get either the shots or the nasal spray after she delivers.

It is true that the current swine flu vaccine has not been tested for pregnant women, as doing any clinical testing with pregnant women is not frequent.

They are actually doing some clinical trials currently to be sure, which you can look for at the US Government's clinicaltrials.gov. There is currently a study in Phase II being done specifically for pregnant women[13].

The studies

A 2009 study (a literature review I believe, I can only get to the abstract) continues to find no risk to pregnant women from flu vaccines[14]:

> No study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza vaccination. Moreover, no scientific evidence exists that thimerosal-containing vaccines are a cause of adverse events among children born to women who received influenza vaccine during pregnancy. In this article, we review the evidentiary basis for the recommendation of vaccination of all women who will be pregnant during the influenza season and safety data of influenza vaccination during pregnancy.

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12. Center for Disease Control. "2009 H1N1 Influenza Shots and Pregnant Women: Questions and Answers for Patients". http://www.cdc.gov/h1n1flu/vaccination/pregnant_qa.htm Updated November 2, 2009. Visited November 28, 2009.]:
13. ClinicalTrials.gov. "H1N1 Vaccine in Pregnant Women". http://www.clinicaltrials.gov/ct2/show/NCT00963430?term=NCT00963430&rank=1 Updated 11/25/2009. Visited 11/28/2009
14. Tamma PD, Ault KA, Del Rio C, Steinhoff MC, Halsey NA, Omer SB. Safety of influenza vaccination during pregnancy. Am J Obstet Gynecol. 2009 Oct 20. [Epub ahead of print] PubMed PMID: 19850275.

A study done in 2004 comparing pregnant women getting vaccines with those who hadn't between 1998 and 2003 and found no important statistically significant difference between them [15]:

> Among 7183 eligible mother-infant pairs, only 252 pregnant women (3.5%) received the influenza vaccine. Women with medical insurance were more likely to be vaccinated, although the rates for women with chronic underlying conditions were similar to those of healthy women, regardless of insurance status. The mean gestational age at the time of influenza vaccination was 26.1 weeks (range, 14-39 weeks). No serious adverse events occurred within 42 days of vaccination, and there was no difference between the groups in the outcomes of pregnancy (including cesarean delivery and premature delivery) and infant medical conditions from birth to 6 months of age.

I dove into the study a bit and it should be noted that "abnormal glucose tolerance" test was just at the 95% CI p-value of .05, but there was no increased gestational diabetes. Additionally there was increased "transient hypertension", but no additional preclampsia (which is what would normally follow). There was non-statistically significant increase in acute respiratory illnesses in the *unvaccinated* women, especially during the peak of flu season. And at the p-value of .05 (1.8% of cases), the children of *unvaccinated* women had congenital anomalies reported. The point here is really that there is no meaningful difference, as both as statistically insignificant increases in one form or another. They authors note: "**Overall, a greater variety of pathologic conditions was observed in the group of infants of unvaccinated mothers throughout the first year of life.**"

Miscarriages

There is some unfortunate anecdotal stories of women who miscarry following flu vaccination. This is heartbreaking, but is a case of correlation without causation. There are thousands of spontaneous miscarriages a month (possibly daily), so it is not surprising that there will exist expectant mothers who will have happened to have gotten a vaccine recently (just as they might have had Burger King that morning, or gone to the gym, or been around a smoker, or any number of events that might correlate but are not the cause).

I had a section where I attempted to calculate how many miscarriages might be occurring per day to demonstrate how likely it is. I've deleted this section because a) my math is probably wrong b) no matter the number it is heartbreaking. Instead I will simply provide the numbers of how many live births there are and the miscarriage rates.

Every month there are approximately 320,000 successful live births (obviously depends on the year, this is from 2000)[16].
While about 10-15% of pregnancies after the first few months end in spontaneous miscarriage, the rate is about 3% once in the 3rd trimester (*unfortunately, I can't seem to*

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15. Flor M. Munoz, MD et al. "Safety of influenza vaccination during pregnancy". American Journal of Obstetrics and Gynecology (2005) 192, 1098–106. http://www.i-lumens.com/DOCUMENTS/VACCINATION%20ET%20GROSSESSE.pdf
16. CDC National Center for Health Statistics. "National Vital Statistics Reports. Births:Final data for 2000". Vol:50,Number 5. February 12, 2002. Visited 11/29/2009.

find a reliable source for this number, just various pregnancy sites mentioning it. The normal number is 10-15%, but that is across the entire pregnancy and not specifically for the 3rd trimester, which is what the anecdotal claims are about).

Summary

Pregnant women should really speak with their physician. The CDC's recommendation is for them to get vaccinated, due to the high risk of complications from the flu itself and as there is no indication that the vaccine would cause harm. There is anecdotal evidence, as there is for many things, of women who get a vaccination and then shortly afterwards miscarry. No study has been able to find this linkage.

Further Resources

The government's flu information center: http://flu.gov/
CDC's "key facts" about the flu vaccines: http://www.cdc.gov/flu/protect/keyfacts.htm
As usual, Brian Dunning of Skeptoid manages to make the same topic entertaining: http://skeptoid.com/episodes/4180
Additionally, the bloggers are Science-Based Medicine are in fact real doctors and genuinely know what they are talking about: http://www.sciencebasedmedicine.org/?p=2733