

I am concerned with the plethora of misinformation that seems to be circulating these days on influenza and the safety of flu shots. Even in a mild year, influenza is a major killer. However, millions of Americans get a flu shot, and as a result, thousands of lives are saved because of the availability of safe vaccines against seasonal flu.

This year, in addition to seasonal flu, we have a pandemic, i.e. a worldwide outbreak, with H1N1 flu, commonly known as “swine flu”. In a few short weeks last spring, we watched this virus travel from a few known cases in Mexico and southern United States, to infecting millions of people in over 200 countries.

H1N1 is different from seasonal (“regular”) flu since it is causing disease and death mostly in children, young adults, and especially pregnant women, whereas seasonal flu usually affects the elderly most severely.

Soon, an H1N1 vaccine will be coming to Maine. I, for one, will be getting a vaccine and hope others do too. The H1N1 vaccine is made the same way as the seasonal flu vaccine, and is expected to have the same excellent safety profile and track record.

The first few weeks the H1N1 vaccine will be focused on those at highest risk – pregnant women, children and youth, young adults with underlying conditions, caregivers of young infants, and health care workers. Eventually, there will be enough vaccine for everyone. Meanwhile, everyone, including senior citizens, can seek seasonal flu vaccine as it arrives in Maine as well.

And of course, we should all remain vigilant about washing our hands, covering our coughs and sneezes, and staying home when we’re sick. If we can also make sure we get our flu shots, Maine should have a relatively healthy winter. Get the facts at www.maine flu.gov or www.flu.gov.

I am concerned because I hear people say that the H1N1 (“swine flu”) vaccine is fast tracked, and because it is being monitored for safety, it must be riskier than other vaccines. This is not true.

First of all, vaccines against H1N1 are being produced the same way as seasonal flu vaccines are. There is a long and successful track record of safety and effectiveness of seasonal (“regular”) flu vaccines using these same technologies. Over the years millions of Americans have received seasonal flu shots, and millions of lives have been saved. Several hundred thousand Mainers receive flu shots every year, and the most common side effects reported are mild ones such as soreness, redness, or tenderness where the shot was given.

Second, the H1N1 vaccine is fully licensed by the U.S. Food and Drug Administration. The licensure standards used are the same as those used for seasonal flu vaccines every year.

The FDA and U.S. CDC will closely monitor the safety of H1N1 influenza vaccine, using the same systems they use for seasonal flu vaccine and all other vaccines licensed for use in the United States. These vaccine monitoring systems include the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) Project, and will be used to identify any clinically significant adverse events not identified in the clinical studies or in seasonal flu tracking to date.

This year we have two sets of flu seasons – seasonal and H1N1. We also have two sets of flu shots to protect us. I will be getting mine! Get the facts at www.maine flu.gov or www.flu.gov.

I am concerned because I hear people raise potential risks of the H1N1 (“swine flu”) vaccine, as if they are greater than the risks of the disease. What do we know about the risks of the H1N1 vaccine? We know it is being manufactured the same way as seasonal (“regular”) flu vaccine and has recently been licensed by the U.S. Food and Drug Administration.

Clinical studies, which are normally not done every year on seasonal flu vaccine, have been conducted on H1N1 vaccine in order to determine if one or two doses are needed and if there are any unexpected effects. So far, they have shown that people ages 10 - 65 need just one dose, and the vaccine is very effective at producing an immune response. These studies have also shown that the vaccine is very well tolerated, just as the seasonal flu vaccine is. Just as with seasonal flu vaccine, people who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

What do we know about the risks of the H1N1 influenza disease? We know this virus spread from a handful of detected cases in mid-April to over 200 countries in just a few weeks. This global spread is what makes H1N1 influenza a pandemic.

We also know thus far this pandemic is primarily a pediatric and young adult pandemic. The average age of identified cases, hospitalizations, and death are 12, 22, and 37 respectively. Pregnant women are especially vulnerable to severe effects, with one-third who are infected needing hospitalization, primarily for respiratory distress. By contrast, 90% of the deaths from seasonal influenza are among people 65 and older.

Like any medicine, no vaccine provides 100% protection, and influenza vaccines do not protect against other viruses that cause respiratory illness. Even after you are vaccinated, it is still important to wash your hands well and often, to cover your coughs and sneezes, and to stay home if you are sick. But, vaccines are an important tool, and I for one will be getting mine. Get the facts at www.maine flu.gov or www.flu.gov.

I am concerned because I have heard some people ask why we need the H1N1 vaccine if H1N1 disease (“swine flu”) is mild and most will experience mild symptoms and fully recover. Although the vast majority of people with novel H1N1 do have mild disease, young people and pregnant women are being disproportionately affected by this disease. Preliminary data show that one-third of pregnant women with H1N1 are ill enough with respiratory distress that they have to be hospitalized. The average age for hospitalization with H1N1 is 22, and the average age for death is 37. By contrast, 90% of deaths from seasonal (“regular”) flu are among those 65 and older.

Additionally, if we don’t try to stop this pandemic through vaccination, we risk this virus continuing to circulate without much to slow it down, and risk it evolving to a more serious infection. We have already witnessed this virus spread from a few detected cases in late April to over 200 countries only a few weeks later. This global spread is what makes it a pandemic. As it continues to circulate, we risk more genetic changes, which could result in it evolving to even a more lethal form.

The answer to slowing the H1N1 pandemic and to minimizing its impact on our young people and pregnant women is for us to get vaccinated. Get the facts at www.maine flu.gov or www.flu.gov.

I am concerned because I have heard some people say that we should be against the H1N1 vaccine because we should not trust the pharmaceutical industry. First of all, we “trust” the

pharmaceutical industry every time we take medicine to reduce a fever or antibiotics to treat an infection.

Second of all, there are a number of checks and balances in the system, including FDA (Food and Drug Administration) oversight as well as the involvement of the CDC (Centers for Disease Control and Prevention), NIH (National Institutes of Health) and other agencies. The H1N1 (“swine flu”) vaccine has been manufactured the same way as seasonal (“regular”) flu vaccine. It has gone through the full FDA licensure, using the same licensure standards as seasonal flu vaccine.

While we all may not be fans of the pharmaceutical industry, we have the assurances of many checks and balances and the safety track record of the seasonal flu vaccine. Further information on H1N1 vaccine safety can be found at: www.flu.gov and www.maine flu.gov.

I am concerned because I hear the H1N1 vaccine may contain an adjuvant. This is not true. First, adjuvants are substances sometimes added to vaccine to boost the immune response.

The H1N1 (“swine flu”) vaccine licensed by U.S FDA does not have an adjuvant. According to current federal plans, only unadjuvanted vaccines will be used in the United States during the 2009 flu season. This includes all of the 2009 H1N1 and seasonal (“regular”) influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines will contain adjuvants.

Further information on H1N1 vaccine safety can be found at: www.maine flu.gov and www.flu.gov.

I am concerned because some pregnant women I know are saying they are worried about getting the H1N1 vaccine. All influenza infections can be dangerous to pregnant women and their babies. Pregnant women who are otherwise healthy have been severely impacted by the H1N1 flu virus (“swine flu”). Studies show that one-third of pregnant women with the H1N1 infection become ill enough that need to be hospitalized. Most of this illness is severe respiratory distress. Deaths due to H1N1 influenza infection have also occurred in pregnant women in the United States as well as here in New England. About one in 15 of all deaths in the United States due to H1N1 influenza are among pregnant women.

Influenza vaccines have not been shown to cause harm to a pregnant woman or her baby. The H1N1 influenza vaccine is licensed by the U.S. FDA using the same standards as is used for seasonal (“regular”) flu vaccine. Clinical studies show it is very well tolerated, similar to the seasonal flu vaccine.

Because pregnant women are also at higher risk for complications from seasonal flu, they should receive two influenza vaccines this fall –one against seasonal flu and one against H1N1 flu. Both should be with the injectable vaccine, and there are thimerosal-free formulations available for both vaccines for pregnant women.

The good news is that women can receive flu vaccines at any stage of pregnancy. Because infants under 6 months are too young to get flu vaccines, anyone who lives with or cares for young babies should also get both the seasonal and H1N1 vaccines.

While hand washing, staying away from ill people, and other steps can help to protect pregnant women and their babies from influenza, vaccination is the single best way to protect against the flu and its complications. Get the facts at www.maine flu.gov or www.flu.gov.

I am concerned because I hear a lot of people confused between the seasonal flu shot and the H1N1 flu shot. There are essentially two flu seasons this year – one with the pandemic strain of H1N1 (also known as “swine” flu), and one with more normal seasonal (“regular”) flu viruses. Therefore, there are two vaccines – one for H1N1 and one for seasonal flu.

The seasonal flu vaccine is not expected to protect against the new H1N1 influenza virus. If you normally get a seasonal flu shot, then you should get one. It is also now recommended for all children ages 6 months through 18 years of age.

On the other hand, the H1N1 influenza virus is a new and very different flu virus. Although influenza is unpredictable, scientists believe that the new H1N1 influenza virus will cause more illness, hospital stays and deaths in the United States over the coming months. So far, H1N1 flu has caused more illness in people younger than 25 years of age than older people. Medical conditions such as pregnancy, diabetes, heart disease, asthma and kidney disease have put people at high risk of serious complications from H1N1.

The H1N1 vaccine is expected to arrive shortly in Maine. When it first arrives, it will be focused on pregnant women, children and young adults, adults up to age 65 with underlying conditions, caregivers of young infants, and health care workers. Eventually, there is expected to be sufficient supplies for everyone.

Both the seasonal and H1N1 vaccines are licensed using the same standards by the U.S. Food and Drug Administration (FDA). And, the H1N1 vaccine has even gone through the extra step of clinical studies to confirm the doses and safety profile.

Find out if you are recommended to receive the H1N1 flu vaccine when it becomes available. Talk to your health care provider or visit www.maine flu.gov or www.flu.gov.

I am concerned because I’ve heard parents say they don’t want their children vaccinated against the flu. All flu can be serious for kids, especially for younger children and children of any age who have one or more chronic medical conditions. CDC recommends seasonal and H1N1 flu (“swine flu”) vaccines for all children ages 6 months to 18 years of age.

Because the H1N1 influenza is a new virus that is disproportionately affecting youth, all people ages 6 months to 25 years of age are recommended to get the H1N1 influenza vaccine. The good news is that children 10 and older will only need one dose of the vaccine, though those younger than 10 will need one dose a month apart.

There are essentially two flu seasons this year – one with seasonal (“regular”) flu and one with the pandemic strain of H1N1 (also known as “swine” flu). Therefore, there are two vaccines – one for H1N1 and one for seasonal flu. Both vaccines are licensed using the same standards by the U.S. Food and Drug Administration (FDA). And, the H1N1 vaccine has even gone through the extra step of clinical studies to confirm the doses and safety profile.

Just as millions of children get seasonal flu shots every year that effectively protect them against seasonal flu, so this year they should also get the H1N1 flu vaccine, especially since there are no signs

of immunity in children against the H1N1 vaccine and children are disproportionately being affected by it. Get the facts at www.maineflu.gov or www.flu.gov.

I am concerned because I have heard some senior citizens say they are upset at not being able to get a H1N1 vaccine very soon. People age 65 and over are at increased risk for complications from seasonal influenza (“regular flu”), and are recommended for annual flu vaccines. This year is no exception.

However, current studies indicate the risk for H1N1 (“swine flu”) infection among people aged 65 years and over is less than the risk for persons in younger age groups. Scientists believe that most people age 65 and over have immunity against this virus because of exposure to similar flu viruses years ago.

Some people are very likely to get infected with the H1N1flu virus and are also at high risk to become very ill from the virus. These people are recommended to receive the first available doses of H1N1 vaccine. They include children, pregnant women, younger adults with medical conditions that put them at high risk, caregivers of young infants, and health care workers.

While people 65 and older are generally not included in these high risk groups, they can get the H1N1 influenza vaccine as soon as the high risk groups have had the opportunity to be vaccinated. Meanwhile, we are fortunate that seasonal flu vaccine is currently available or soon will be in many places in Maine. Seniors should check their local newspaper, health care provider, or 211 to find a flu shot near them.

Whether you’re vaccinated or not, don’t forget to cover coughs and sneezes, wash your hands, and stay home if you’re sick. And, get the facts at www.maineflu.gov or www.flu.gov.

I am concerned because of continued misinformation on thimerosal and the H1N1 vaccine. Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may otherwise contaminate them.

The H1N1 influenza (“swine flu”) vaccines that FDA is licensing will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal (“regular”) influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some 2009 H1N1 and some seasonal influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated versions of the vaccines, which are administered intranasally (through the nose), are produced in single-units and will not contain thimerosal. These thimerosal-free formulations are primarily being made available to pregnant women and young children.

We are aware that the presence of thimerosal in vaccines and suggestions of a relationship to autism have raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism.

Additionally, since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age

have been thimerosal-free, or contain only trace amounts. The exception is for some formulations of influenza vaccine.

Getting thimerosal out of the vaccine supply for young children was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems

Unfortunately, we have not seen reductions in the numbers of children identified with autism, indicating that the cause of autism is not related to a single toxin such as thimerosal.

The good news is that for those with ongoing concerns, there are some thimerosal-free H1N1 and seasonal flu vaccines for pregnant women and young children.

Get the facts at www.maine flu.gov or www.flu.gov.

Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine? GBS is a very rare disease occurring mainly in older adults. It is most commonly precipitated by an infection. As the person is recuperating from the infection, the body's immune system that was fighting that infection starts attacking a part of the peripheral nervous system. People with GBS experience temporary weakness and sometimes paralysis.

Although most commonly associated with infections causing diarrhea, sometimes GBS can occur after having the flu. On very rare occasions, GBS can occur after receiving a vaccine such as a flu vaccine.

In 1976, the year that 40 million doses of a swine flu vaccine were administered, the number of GBS cases was slightly higher than what is normally seen in the population - a 1 in 100,000 increase over the expected 1 in 100,000 incidence. Since then, numerous studies have been done to evaluate if other flu vaccines may be associated with GBS. No association has been found, though GBS was found possibly associated with flu vaccine for a couple of years in the early 1990s with a slight increase rate of approximately 1 additional person out of 1 million vaccinated people. No increase in GBS associated with flu vaccine has been found since then. FDA and CDC continue to closely monitor all vaccines for safety issues, including GBS, and will also be monitoring the H1N1 influenza vaccine.

It is important to note that the current H1N1 ("swine flu") is much different from the "swine flu" of 1976. The current H1N1 is actually not a swine flu but rather a combination of genetic materials from swine, avian, and human influenza viruses.

The current H1N1 virus is marching so quickly around the globe and causing so much illness and death, especially among young people, the strong evidence is that the risks of not being vaccinated are much higher than that of being vaccinated.

Get the facts at www.maine flu.gov or www.flu.gov.