

## Two Types of People Who Should Never Get the Flu Shot

Analysis by Dr. Joseph Mercola



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#### STORY AT-A-GLANCE

- > Secondary infections such as pneumonia and other respiratory diseases, as well as sepsis, are included in "influenza death" statistics, and account for a majority of deaths attributed to influenza every year
- > U.S. Centers for Disease Control and Prevention data have repeatedly demonstrated that the flu vaccine does not work for seniors. The 2018/2019 flu vaccines against influenza A and B viruses had an adjusted effectiveness rating of just 12% for those over age 65
- > Studies have also demonstrated that influenza vaccination has little or no impact on mortality among the elderly
- > The flu vaccine is routinely recommended for all pregnant women during any trimester, yet some scientific evidence suggests it could place their pregnancy at risk. Research funded by the CDC found an association between flu vaccination during pregnancy and an eightfold risk of miscarriage
- > Injury following influenza vaccination is now the most compensated claim in the federal Vaccine Injury Compensation Program (VICP). Between January 1, 2006, and December 31, 2019, a total of 5,407 injury claims for flu vaccine were filed

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Flu season is creeping up on us again and there are widespread calls to get your annual flu shot, despite the fact that, year after year, this strategy turns out to have an abysmal rate of effectiveness across the board. One group that consistently turns out to draw the short end of the stick when it comes to influenza vaccine failures is the elderly. U.S. Centers for Disease Control and Prevention (CDC) data have repeatedly demonstrated that the flu vaccine does not work for seniors.

Pregnant women are another group that should carefully evaluate the risks and failures of influenza vaccine. The CDC recommends routine flu shots for women during any trimester in every pregnancy, but some scientific evidence suggests it could place their pregnancies at risk.

I've written many articles questioning the scientific basis for routine influenza vaccination in general. Here, my focus is the elderly and pregnant women, as there is scientific evidence detailing risks of flu vaccination for both groups.

First, though, I want to remind you of a little-known fact about influenza mortality estimates: Secondary infections such as pneumonia and other respiratory diseases, as well as sepsis,<sup>1</sup> are included in "flu death" statistics, and account for a majority of deaths attributed to influenza every year.

# **Beware of Sepsis**

As discussed in a Health magazine article<sup>2</sup> published in 2018, the symptoms of sepsis can actually mimic influenza symptoms — with disastrous results. In this particular case, a strep infection progressed to sepsis, which presented as influenza and, unfortunately, led to the amputation of the woman's arms and legs. She says:<sup>3</sup>

"... if you have a fever that doesn't go away or your body temperature is abnormally low, you have signs of any type of infection (whether it's a cold or a UTI) that's not getting better, you feel confused, or are in a lot of pain, go to your doctor and ask about sepsis."

To learn more about sepsis and its treatment, see "Recognizing the Signs and Symptoms of Sepsis." It's worth finding out about a relatively new sepsis treatment using intravenous vitamin C, hydrocortisone and thiamine, discussed in these articles.

The treatment has been shown to be extremely effective — far more so than conventional treatments — but many hospitals have yet to make it routinely available, which means it can be difficult to convince them to use it. It's worth a try, though.

### Why Is the Flu Vaccine so Ineffective?

It's important to remember that the influenza vaccine contains only three or four type A or B vaccine strain influenza viruses, of which there are hundreds. So, even if those vaccine strain viruses are a perfect match for influenza viruses that are circulating in a given flu season, the vaccine does not prevent the majority of other respiratory infections that make people sick and often mistake for influenza unless lab testing is done.<sup>4</sup>

Twice a year, the World Health Organization issues recommendations on the composition of the upcoming season's flu vaccines. For the 2019/2020 season, trivalent vaccines distributed in the U.S. will contain: 5,6,7

- A/Brisbane/02/2018 (H1N1)pdm09-like virus
- A/Kansas/14/2017 (H3N2)-like virus
- B/Colorado/06/2017-like (Victoria lineage) virus

Quadrivalent vaccines will contain the three above, plus B/Phuket/3073/2013-like (Yamagata lineage) virus. The selected strains for this year are anticipated to improve coverage. In Australia, where the flu season got an early start in the Southern Hemisphere, health officials told people to get vaccinated because it could be an unusually severe season.<sup>8</sup> The predominant influenza viruses circulating in Australia this year have been H3N2 influenza A virus followed by influenza B virus.<sup>9</sup>

In the U.S., health officials have said that the selection of influenza viruses for inclusion in the vaccine this year occurred later than usual. There are reports that flu vaccine production and shipments have been delayed and there will a shorter window of opportunity to get vaccinated.<sup>10</sup>

A study<sup>11</sup> published in 2018 sheds some much-needed light on unvaccinated individuals at risk for influenza and how as many as half of unvaccinated people infected with influenza do not know they have it. Researchers found that "approximately 1 in 5 unvaccinated children and 1 in 10 unvaccinated adults were estimated to be infected by seasonal influenza annually, with rates of symptomatic influenza roughly half of these estimates."

# Flu Vaccine Effectiveness Has Always Been Low

Historically, regardless of how well-matched the vaccine is to circulating strains, your chances of getting influenza after vaccination are still greater than 50/50 in any given year. According to CDC data updated September 10, 2019, 12 the 2018/2019 flu vaccine (all vaccine types) against influenza A or B viruses had an adjusted effectiveness rating of:

29% for all ages	49% for children aged 6 months through 8 years
6% for children ages 9 through 17	25% for adults between the ages of 18 and 49
12% for those over 50	12% for those over 65

Ironically, despite offering no protection for more than two-thirds of the population, health officials in February touted higher numbers, calling them a great success, as the numbers they had at that time outperformed the 2017/2018 vaccine. Obviously, as the Southern Hemisphere's season wore on, the numbers wore down, and they're just as abysmal, if not more so, than other years.<sup>13</sup>

The 2017/2018 seasonal influenza vaccine's adjusted overall effectiveness for the U.S. was just 36% against influenza A and influenza B virus infection.<sup>14,15</sup> To put this into context, gargling with tea has been shown to lower your relative risk of the flu by 30%.<sup>16</sup>

Between 2005 and 2015, the flu vaccine's adjusted overall effectiveness was less than 50% more than half the time — with a low of only 10% in the 2004/2005 season. 17,18

#### Vaccinated Individuals Pose a Hidden Threat to Public Health

It's also important to realize that you can get vaccinated, show few or no symptoms of infection, and still shed and transmit influenza to other people. 19,20 This scientific fact flies in the face of statements claiming that vaccination is a "social responsibility" that "protects others around you, including family, friends, co-workers and neighbors." 21

In reality, after vaccination, you may actually become a contagious silent carrier of disease. A person with influenza who fully expresses symptoms of fever, body aches, cough and other signs of respiratory illness would likely stay at home. However, a vaccinated individual, who is silently contagious, would go to work and into stores and other public places and be unaware they are spreading infection.

This is an especially important fact for vaccinated health care workers, who move freely among patients in hospitals and other medical facilities because everyone assumes vaccinated medical personnel are "immune" to influenza if they get a flu shot every year.

A study<sup>22</sup> published in the journal PNAS January 18, 2018, showed that people who receive the seasonal flu shot and then contract influenza excrete infectious influenza viruses through their breath.

What's more, those vaccinated two seasons in a row have a greater viral load of shedding influenza A viruses. According to the authors, "We observed 6.3 times more aerosol shedding among cases with vaccination in the current and previous season compared with having no vaccination in those two seasons."

They also note that other studies suggest annual flu vaccination leads to reduced protection against influenza, which means each vaccination is likely to make you progressively more prone to getting sick.

A 2014 paper<sup>23</sup> also reveals how priming your immune system with influenza vaccine can make you more susceptible to infection from other viral and bacterial pathogens. This phenomenon is an effect inherent in what's known as "heterologous immunity."

#### **Year After Year, Flu Vaccine Proves Useless for Seniors**

As mentioned, the 2018/2019 flu vaccine had an adjusted effectiveness rating of just 12% for those ages 65 and above,<sup>24</sup> but the full range was between a negative 12% to a positive 31% for ages 50 to 64 and a negative 29 to 41 in those over age 65. That means that for some people, vaccination actually made them more susceptible to infection. Unfortunately, the 9- to 17-year-old group also had a negative confidence interval.

For infections caused by the A(H3N12) virus, the statistics were even more worrisome, with a mere overall adjusted effectiveness of 9% for all ages. For A(H1N1) the numbers were better at 44% — but it's worth noting that the CDC chose to lump all ages together in that report, rather than breaking them down by age (something they had done earlier in the year, and which they had done for all past years). For example:

- In 2017/2018,<sup>25,26</sup> the adjusted influenza vaccine effectiveness for all vaccine types against influenza A viruses for people aged 50 through 64 was 20% (range: -5% to 39%); for those over the age of 65 it was 11% (range: -8% to 38%)
- In 2016/2017,<sup>27</sup> the adjusted effectiveness for all vaccine types against influenza A or B viruses for those aged 50 through 64 was 40% (range: 24% to 53%), and those over 65 was 20% (range: -11% to 43%). This despite the fact that the vaccine for the 2016/2017 season was well-matched to the viruses in circulation<sup>28</sup>

Studies<sup>29,30</sup> have also demonstrated that influenza vaccination has no impact on mortality among the elderly. As noted in one such study,<sup>31</sup> "Because fewer than 10% of all winter deaths were attributable to influenza in any season, we conclude that observational studies substantially overestimate vaccination benefit."

Research<sup>32</sup> published in 2006 analyzed influenza-related mortality among the elderly population over age 65 in Italy, where flu vaccination coverage between 1970 and 2001

had significantly increased. Here too, investigators found no corresponding decline in deaths. According to the authors:

"These findings suggest that either the vaccine failed to protect the elderly against mortality (possibly due to immune senescence), and/or the vaccination efforts did not adequately target the frailest elderly. As in the U.S., our study challenges current strategies to best protect the elderly against mortality, warranting the need for better controlled trials with alternative vaccination strategies."

Another 2006 study,<sup>33</sup> which followed 72,527 seniors for eight years, showed that, even though seniors vaccinated against influenza had a 44% reduced risk of dying during flu season compared to unvaccinated seniors, those who were vaccinated were also 61% less like to die before the flu season ever started — a finding attributed to the "healthy user" effect.

According to the authors, "the magnitude of the bias demonstrated by the associations before the influenza season was sufficient to account entirely for the associations observed during influenza season." In other words, the vaccine played no role whatsoever in reducing the risk of death during flu season.

Research trying to ascertain whether flu vaccination has any impact on hospitalization rates among the elderly has found it difficult to draw any conclusions due to rampant bias. As noted in a 2019 study<sup>34</sup> in the journal Vaccine:

"... 22 studies were included in the systematic review. Overall, two studies (9%) were deemed at moderate risk of bias, thirteen (59%) at serious risk of bias and seven (32%) at critical risk of bias.

For outpatient visits, we found modest evidence of protection by the influenza vaccine. For all-cause hospitalization outcomes, we found a wide range of results, mostly deemed at serious risk of bias.

The included studies suggested that the vaccine may protect older adults against influenza hospitalizations and cardiovascular events. No article meeting our inclusion criteria explored the use of antibiotics and ILI hospitalizations. The high heterogeneity between studies hindered the aggregation of data into a meta-analysis."

#### Cell-Based Flu Vaccine No Better Than Egg-Based

The "new and improved" flu shot, Flucelvax — a cell-based<sup>35</sup> rather than egg-based vaccine — introduced during the 2017-2018 flu season, has also demonstrated disappointing results. Research by the U.S. Food and Drug Administration found it protected just 26.5% of those over the age of 65.<sup>36</sup>

A study<sup>37</sup> published September 2019, "Comparison of Vaccine Effectiveness Against Influenza Hospitalization of Cell-Based and Egg-Based Influenza Vaccines, 2017-2018" also concluded that:

"For any influenza, the adjusted relative VE [vaccine effectiveness] of cell-based vaccine versus egg-based vaccines was 43% for patients ages < 65 years and 6% for patients ages  $\geq$  65 years.

For influenza A(H3N2), the adjusted relative VE was 61% for patients ages < 65 years and -4% for patients ages  $\geq$  65 years. Statistically significant protection against influenza hospitalization of cell-based vaccine compared to egg-based vaccines was not observed ..."

#### Is Flu Vaccine Safe for Pregnant Women?

Historically, pregnant women have been discouraged from taking drugs and vaccines because there's very little scientific data evaluating risks for the pregnant woman or the growing fetus. Including pregnant women in clinical trials has been considered unethical because there are unknown risks for both mother and child.

For better or worse, that is changing. In 2018, the FDA issued nonbinding recommendations<sup>38</sup> for industry detailing when and how pregnant women can be enrolled in clinical trials for drugs and therapies.

Coincidentally, the increased push for women to get flu shots during any trimester in every pregnancy seems to coincide with an amendment to the 1986 National Childhood Vaccine Injury Act that was included in the 21st Century Cures Act passed by Congress at the end of 2016.

The amendment gives a liability shield to drug companies producing CDC-recommended vaccines for pregnant women so they can't be sued if a pregnant woman or her child developing in the womb born alive suffers injury from maternal vaccinations.<sup>39</sup>

As noted by Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center in a public statement given at a hearing September 17, 2018:40

"This is a stunning expansion of vaccine product liability protection for the pharmaceutical industry in a 1986 tort reform Act that created a federal compensation program option for children injured by government recommended and mandated vaccines that was never intended to cover adults or be an exclusive remedy."

Despite the lack of safety data when it comes to maternal vaccination,<sup>41</sup> the CDC now urges all pregnant women to get vaccinated against the flu. In a 2018 article,<sup>42</sup> CNN quotes Dr. Laura E. Riley, professor and chair of the department of obstetrics and gynecology at Weill Cornell Medicine, saying "The flu vaccine is safe and effective for both pregnant women and their fetuses" and can be given during any trimester.

A definitive statement like that deserves strong supporting evidence, but not only is safety data for pregnant women sorely lacking, some of the data published in the medical literature suggests maternal vaccination may actually be deeply problematic.

# Flu Vaccination Linked to Eightfold Risk of Miscarriage

Importantly, research<sup>43,44</sup> funded by the CDC itself linked flu vaccination during early pregnancy to an eightfold risk of miscarriage. In all, 485 pregnant women aged 18 to 44 who had a miscarriage during the flu seasons of 2010/2011 and 2011/2012 were compared to 485 pregnant women who carried to term.

Women who had received an inactivated 2009 pandemic H1N1-containing flu shot the previous year were more likely to suffer miscarriage (spontaneous abortion) within 28 days of receiving another pH1N1-containing flu shot during pregnancy.

While most of the miscarriages occurred during the first trimester, several also took place in the second trimester. 45,46 The median fetal term at the time of miscarriage was seven weeks.

Of the 485 women who miscarried, 17 had been vaccinated twice in a row — once in the 28 days prior to miscarriage and once in the previous year. For comparison, of the 485 women who had normal pregnancies, only four had been vaccinated two years in a row. CDC adviser for vaccines Amanda Cohn told The Washington Post:<sup>47</sup>

"I think it's really important for women to understand that this is a possible link, and it is a possible link that needs to be studied and needs to be looked at over more [flu] seasons. We need to understand if it's the flu vaccine, or is this a group of women [who received flu vaccines] who were also more likely to have miscarriages."

#### **Contradictory Findings Proclaimed 'Unequivocal' Evidence**

The same researchers have now completed a second study and, this time, they found no link between flu vaccination and miscarriage. A quote by Dr. Edward Belongia, head of the Center for Clinical Epidemiology and Population Health at Wisconsin's Marshfield Clinic, in STAT news reads:<sup>48</sup> "For women right now who are wondering if it's safe to get a vaccine in early pregnancy, we can say unequivocally, 'Yes, it is safe."

The data, presented at a February 2019 Advisory Committee on Immunization Practice meeting, has yet to be published so I cannot give any details on the findings as of yet. I'd

like to point out the obvious, though.

When the 2017 study came out, detractors were quick to point out that you can't draw conclusions based on a single study. Yet now, they're claiming to have "unequivocally" proven safety — based on a single study. In my view, the issue is still wide open for discussion and contemplation. Far more research needs to be done before a claim of safety can be made for women receiving influenza vaccine during pregnancy.

Categorical claims of safety cannot be made for vaccinating infants younger than 6 months against influenza, either.

The 2019 scientific review,<sup>49</sup> "Influenza Vaccination: Effectiveness, Indications, and Limits in the Pediatric Population," published in the journal Frontiers in Pediatrics, points out that "questions and limits about influenza vaccine in pediatric population remain open," and that "vaccine effectiveness in children is variable and suboptimal, with reported differences according to vaccine types, seasons, and child age." It also states that "there is no influenza vaccine that directly protects infants <6 months of age."

#### **Questions Abound About Vaccine Safety for Pregnant Women**

In the 2013 article, "Vaccination During Pregnancy: Is it Safe?"<sup>50</sup> Loe Fisher lists 10 vaccine facts pertaining to the lack of evidence of safety in pregnant women, including the following:

- 1. Drug companies did not test the safety and effectiveness of giving influenza vaccine to pregnant women before the vaccines were licensed in the U.S.<sup>51,52</sup>
- 2. Data on inflammatory and other biological responses to vaccination during pregnancy that could affect pregnancy and birth outcomes are still lacking.<sup>53</sup> For example, it's still unknown whether the influenza vaccine can cause fetal harm or affect your reproductive capacity,<sup>54</sup> which is why the vaccine manufacturer product inserts state that the influenza vaccine should be given to a pregnant woman only if it's "clearly needed."

- 3. The biological mechanisms of how maternal vaccination affects the immune and neurological systems of mother and child are not known. Loe Fisher points out, "There are no published biological mechanism studies that assess pre-vaccination health status and measure changes in brain and immune function and chromosomal integrity after vaccination of pregnant women or their babies developing in the womb."
- 4. There are very few studies comparing health outcomes between pregnant women and their children who receive the flu vaccine and those who do not.

### Flu Vaccine Has Thousands of Vaccine Injury Filings

Importantly, injury following influenza vaccination is the most compensated claim in the federal Vaccine Injury Compensation Program (VICP). Between January 1, 2006, and December 31, 2019, a total of 5,407 injury claims for flu vaccine were filed, 4,614 of which were compensated. Being one of the riskiest vaccines, based on VICP injury filings and awards, is it really wise to proclaim the flu vaccine is safe for all pregnant women at all times?

Influenza vaccine package inserts<sup>56,57,58</sup> will also inform you that flu vaccine safety and effectiveness have not been established in pregnant or breastfeeding women. This means there is a lack of scientific evidence demonstrating conclusively that pregnant women will benefit from flu vaccination or that getting vaccinated during pregnancy is, in fact, safe.

If safety and effectiveness have not been scientifically established through methodologically sound and rigorously controlled, replicated studies, the issue is still open for debate, and that's certainly true when it comes to vaccinating pregnant women.

Sanofi Pasteur's patient information sheet<sup>59</sup> for Fluzone quadrivalent vaccine states that "Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes following vaccination with Fluzone Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive Fluzone

Quadrivalent during pregnancy in Sanofi Pasteur Inc.'s vaccination pregnancy registry by calling 1-800-822-2463."

The American College of Obstetricians and Gynecologists also tracks vaccine safety for pregnant women after the fact, while claiming it's perfectly safe to receive the flu vaccine during pregnancy.<sup>60</sup> The sad reality is that pregnant women who are given influenza vaccinations during any trimester during every pregnancy are basically participating in an uncontrolled experiment. They just don't know it.

### **Vaccinating During Pregnancy Is a Risky Proposition**

Aside from the 2017 study linking flu vaccination to miscarriage, research has shown that stimulating a woman's immune system — which is what vaccination does and must do to stimulate production of antibodies and artificial immunity — during midterm and later-term pregnancy significantly increases the risk that her baby will develop autism<sup>61</sup> during childhood, and/or schizophrenia during the teenage years or early adulthood.<sup>62</sup>

Strong inflammatory responses during pregnancy may also increase the risk of seizures in the baby, and later, as an adult.<sup>63</sup> In fact, a number of neurodevelopmental and behavioral problems can occur in babies born to women immunologically stimulated during pregnancy.<sup>64,65,66</sup>

Overall, given the uncertainty about how flu vaccination affects health in the short and long term, and the absolute unknowns about how it may affect the future health of the baby, it seems as reasonable to avoid vaccination during pregnancy as it is to avoid alcohol, smoking and exposure to other toxins.

As noted by Jeremy R. Hammond in his May 14, 2019, article, "The CDC's Criminal Recommendation for a Flu Shot During Pregnancy," the CDC relies on retrospective observational studies for its recommendation. The problem with that is that retrospective observational studies are designed to test a hypothesis. They're not designed to prove or disprove causation and, in fact, cannot do that.

So, a finding of "no association" in an observational study does not mean that a causal relationship is nonexistent. Observational studies also make it difficult for researchers to detect unexpected harms. If they're not specifically looking for an outcome, it likely will not show in the data.

It's a rather long and detailed article, but well worth reading. In it, Hammond points out the hypocrisy of relying on observational data for vaccine safety, saying:68

"[W]hen Aaron E. Carroll in the New York Times advocated the CDC's flu shot recommendations, he was telling pregnant women, too, to get vaccinated.

He was, in other words, parroting the CDC's implicit message that we can trust that observational studies are methodologically robust enough to rule out the possibility, with a high degree of confidence, that vaccination could cause harm to the expectant mother or her child.

Yet just a few months earlier, Carroll had reassured the public that observational studies finding a link between alcohol consumption and cancer aren't determinative and suggested that more randomized controlled trials are needed to establish what harms and benefits are associated with drinking!

As he advised Times readers in that case, 'Don't give too much weight to observational data' ... Why should we forego our skepticism when it comes to the lives and health of entire future generations of children? ...

Carroll's credulous acceptance of the observational studies that the CDC relies upon to support its claims is another good example of the kind of institutionalized cognitive dissonance that exists when it comes to the practice of vaccination. It has become a religion, and we are supposed to believe in the safety and effectiveness of vaccines as a matter of faith ...

When it comes to vaccines, we are not supposed to concern ourselves with the methodological weaknesses of the kinds of studies the CDC relies on to support its flu shot recommendation for pregnant women.

We are not supposed to notice that the CDC's statement that 'there's a lot of evidence' that it's safe to vaccinate pregnant women also implies that there's at least some evidence that it is not ...

[I]f pharmaceutical companies made the same claims that the CDC makes about the safety of vaccinating pregnant women, they could be sued for fraud."

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