Influenza Vaccines

The Other Side of the Story

by Judd Handler

After years of touting the benefits of influenza vaccines, mainstream medical journalism seems to be in the midst of a paradigm shift. It's only recently that articles with titles such as "Flu Vaccine Not as Effective as Thought"[1] have counterbalanced the strong recommendation—put forth by the most influential medical associations as well as the health arms of the U.S. government—that all persons six months of age or older should get the "flu shot" every year.

We are warned by vaccine proponents that nearly 50,000 Americans die from influenza each year and that the next pandemic is right around the corner. Although "flu season," we are commonly told, starts in October, pharmacies start advertising and administering influenza vaccines earlier every year, and are now doing so in the middle of summer.[2]

Consumers have the right to know whether or not the recommendations to get the influenza vaccine are backed by its efficacy. They also should have the right to know whether the injections (and nasal mist) are safe, and if ingredients in the vaccine have been studied extensively on both the molecular and epidemiological levels. In other words, people should be told whether any studies exist on how their cells will react weeks, months, years, and decades after being exposed to the influenza vaccine, rather than simply being informed of symptoms (or lack thereof) that may develop in the immediate days after getting the shot.

The decision of whether or not to vaccinate against influenza can be complicated, especially in the case of children six months to four years old, adults age 50 and over, women pregnant during flu season, and people who are immunocompromised—groups for whom the benefit-to-risk ratio may be less attractive. People need to give serious and careful thought to issues such as these in order to make an informed decision. They should also consider whether the vaccine will actually prevent severe illness or death from influenza—and whether or not contracting influenza is, in itself, likely to be fatal.

EFFICACY OF THE INFLUENZA VACCINE CONTESTED

Tom Jefferson, MD, is an epidemiologist with The Cochrane Collaboration, an international nonprofit research organization based in Rome that has extensively reviewed the medical research pertaining to the influenza vaccine. Jefferson, a preeminent authority on healthcare interventions, is lead author of a recent Cochrane Review analyzing the efficacy, effectiveness, and safety of giving influenza vaccines to healthy children. The reviewers appraised 75 studies involving more than 300,000 children and concluded that "inactivated [influenza] vaccines in children aged two years or younger are not significantly more efficacious than placebo."[3]

Although parents may be told by physicians that there is no risk, or only a minute one, of children developing adverse side effects from the influenza shot, the findings of Jefferson and his co-authors negate that viewpoint. They found that the data necessary to draw such a conclusion simply does not exist. Their report stated, "It was surprising to find only one [safety] study of inactivated vaccine in children under two years [of age], given current recommendations to vaccinate healthy children from six months of age in the USA, Canada, parts of Europe and Aus-

tralia."[3] (More on the safety of the influenza vaccine later.)

In a 2009 editorial published in the BMJ Group's *Clinical Evidence*, Jefferson observed that there are few randomized clinical trials (RCTs) that assess the effectiveness of inactivated vaccines in children and the elderly. (The Centers for Disease Control [CDC] states that 90 percent of seasonal flu-related deaths occur in people 65 and older.[4]) "Only five RCTs have been carried out in elderly people, of which only one was carried out in the past two decades using vaccines available today. Although the evidence is more robust in healthy adults, and partly supports the use of vaccines, this is the population who are universally considered to need them least," added Jefferson.[5]

Dan Harper, MD, a PPNF board member, also questions the figures put forth by vaccine makers. "The pharmaceutical industry skews the data to make it appear as if the influenza vaccine has a success rate of 60 percent," said Harper in an interview. He explained that, according to industry research, only 2.7 people out of 100 exposed to influenza will ordinarily contract it, and that figure drops to 1.5 out of 100 in vaccinated people. However, he added, that research included people in the generally healthy ages of 20 to 50. "What was skewed," Harper suggested, "is that the group they studied was the healthiest. They knew not to use the children or elderly for the study." Throw in the elderly and toddlers, and the efficacy would likely plummet, he concluded.[6]

Seniors (those 65 and older) are perhaps the group most frequently advised to receive a yearly anti-influenza shot (and for this group, a special high-dosage vaccine is formulated). But as for the efficacy of the vaccine in this group, the most comprehensive studies to date, according to the journal *Vaccine*, concluded that the mortality reduction was a maximum of only five percent.[7] And while some epidemiological studies claim the influenza vaccine can reduce hospitalization in the elderly by up to 50 percent, recent research caps the efficacy well south of 10 percent.[8]

A Cochrane Review examining the effects of influenza vaccines in healthy adults—the population in which inactivated vaccines work best—found only limited effectiveness. In this report, Jefferson and his colleagues found that in instances where there was a good match between the strains of flu targeted by the vaccine and the ones actually circulating among the population, four percent of unvaccinated adults developed influenza symptoms versus one percent of vaccinated ones. Looked at slightly differently, these vaccines "can reduce the risk of developing influenza systems by about four percent"—in a scenario where there is good vaccine matching. The researchers also found that influenza vaccines "had no effect on hospital admissions or complication rates."[8]

DISTINGUISHING BETWEEN INFLUENZA AND FLU-LIKE ILLNESSES

Let's examine the validity of the CDC estimate that at least several thousand Americans, and up to 49,000, die every year from influenza.[9] (This range replaces the CDC's longstanding previous estimate of 36,000 deaths per year.)

For one thing, the illnesses and deaths supposedly caused by influenza viruses may instead be largely due to other causes. In fact, the official annual respiratory viral surveillance data for the seasons 1976-1977 through 1998-1999 show that a mean of only 12 percent of "influenza specimens" actually tested positive for influenza virus.[5]

Jefferson observes that there's a "systematic failure to distinguish between influenza (a disease) and influenza-like illness (a syndrome, caused also in minor part by influenza viruses)." He adds, "The causal relationship between the two is scarcely investigated and is frequently overlooked, perhaps because of technical difficulties in quantifying the incidence of 'seasonal' influenza and its complications."[5]

Researchers stated in the *Journal of the American Medical Association (JAMA)* that when patients present typical syndromes of influenza-like illness (ILI) to a physician, these syndromes can be caused by various agents. Only a proportion of them, the researchers concluded, are caused by influenza A and B viruses, which are the two most common major influenza strains.[10] The nonprofit National Network for Immunization Information, known for their pro-vaccine stance, concurred, officially stating: "The respiratory illnesses caused by influenza viruses are clini-

cally difficult to distinguish from the illnesses caused by other respiratory infections."[11]

Other researchers are skeptical of the CDC's annual influenza death estimates. One reason for the seemingly alarming number of deaths is that pneumonia, influenza, and ILIs are often combined in statistical reporting. The difference between influenza death and flu-associated death is not distinguished by the CDC; the terms are used interchangeably. Furthermore, on death certificates, pneumonia and influenza are grouped together in one category (P&I) as an underlying cause of death.

The problem with lumping these causes together, said David Rosenthal, MD, director of Harvard University Health Services, is that "people don't necessarily die, per se, of the [influenza] virus.... What they die of is a secondary pneumonia. So many of these pneumonias are not viral pneumonias but secondary [pneumonias]."[12] The CDC lists pneumonia and influenza combined as the seventh leading cause of death.

Peter Doshi, PhD, a postdoctoral fellow at Johns Hopkins University's School of Medicine, examined in the *British Medical Journal* the question of whether the relationship between flu and pneumonia is so strong or unique as to warrant characterizing them as a single cause of death.[12] If so, he observed, there should be increased pneumonia mortality during an influenza pandemic. Doshi stated that recorded pneumonia mortality during the 1968-1969 pandemic was almost indistinguishable from mortality in the non-pandemic season preceding it. Writing in another peer-reviewed publication, *American Journal of Public Health*, Doshi commented, "What continually gets lost in discussions like these are the myriad other, far less studied cocirculating pathogens that cause a syndrome clinically indistinguishable from influenza."[13]

Thus, the actual number of deaths that occurred solely from influenza viruses may be drastically lower than what the CDC estimates. Even one of the CDC's own offices acknowledges the disparity. The National Center for Health Statistics (NCHS) stated that influenza and pneumonia killed over 60,000 people in 2001, but only 257 of these deaths were attributed directly to influenza, and the rest to pneumonia. Between 1979 and 2002, NCHS data show an average of only 1,348 influenza deaths per year.[14]

Currently, the only accurate method to determine influenza incidence, according to Jefferson, is to use data from influenza vaccine and antiviral studies. Based on nearly 100 studies in the Cochrane Collaboration's peer-reviewed database, the incidence of influenza is estimated at around seven percent; however, the control arms of the studies only evaluate people with ILI. Therefore, said Jefferson, "seven percent is not the absolute incidence of influenza in the general population, but is rather the portion of ILI that is caused by influenza, making the incidence of influenza itself in the general population much smaller." Exactly how small? Approximately one-half of one percent.[5]

As Doshi stated in his *British Medical Journal* article, "By arbitrarily linking flu with pneumonia, current data are statistically biased. Until corrected and until unbiased statistics are developed, the chances for sound discussion and public health policy are limited."[12]

Perhaps the CDC recognized this conundrum, explaining the discrepancy on its website: "Influenza virus infection may not be identified in many instances because influenza virus is only detectable for a short period of time and/or many people don't seek medical care until after the first few days of acute illness.

"For these and other reasons, statistical modeling strategies have been used to estimate seasonal flu-related deaths for many decades.... Only counting deaths where influenza was included on a death certificate would be a gross underestimation of seasonal influenza's true impact."[9]

Despite this deft explanation, the CDC clearly admits that only 8.5 percent of all pneumonia and influenza deaths are influenza-related.[9]

Doshi told this author in an interview that the problem stems from the CDC's influenza mortality modeling: "As of 2010, the CDC no longer stated 36,000 deaths; the range is now 3,000 to 48,000. The problem with the new range is that it is from a statistical model that also produced estimates for the years in the 1990s which had been previously estimated at

36,000, but now, the new models estimate those same years at 25,000 deaths per year."[15]

"So which is it? Thirty-six thousand, 25,000, or none of the above?" asked Doshi, who added, "These statistics are extremely questionable; there are contradictions in official statistics that are not accurately explained. What we have represented as fact is largely guesswork.... It is irresponsible to promote statistics that are not factually based."

SAFETY OF INFLUENZA VACCINE INGREDIENTS

Equally as controversial as the influenza shot's efficacy, if not more so, is the safety of the vaccine. Physicians who don't question the CDC statistics believe that with extremely rare exceptions, the flu vaccine is safe. Even some of the most prominent medical researchers who have questioned the vaccine's success rate suggest that it is safer than many other vaccines and that the chances of a serious complication are minute, even for children.

But not every physician agrees. Bob Sears, MD, is a pediatrician and author of the best-seller *The Vaccine Book*. Speaking in the documentary film *The Greater Good*, Sears said that one of his patients asked him several years ago, "Did you know there is mercury in vaccines?"[16] Sears says he was not aware that influenza shots contained mercury (in thimerosol, a preservative) and decided to investigate what other ingredients were in them. He opened the vaccine inserts and discovered that aluminum, formaldehyde, antibiotics, and preservatives such as polysorbate 80 were in it.

"I asked the pediatric resident, 'How does the body process the ingredients?' but she didn't have a clue. Nobody in science can answer that because nobody has looked," said Sears.

Some ardent pro-vaccine experts might say that these ingredients are added in such minimal quantities that the chances of an adverse reaction would be negligible. However, said Sears, until tests are confirmed on the safety of each of the ingredients added to the influenza shot, it should not be automatically and unequivocally assumed that they are safe.

In his interview, Dr. Harper said, "There are detergents in the [influenza] shot. There are antibiotics like Garamycin in the vaccine, as well as chemicals and allergens like polysorbate-80, which can cause infertility. [Influenza] vaccines also contain sugar (sucrose), which causes inflammation and suppresses the immune system; also gelatin from horse serum injections, which are pro-inflammatory."[6]

Harper claimed that 7.5 out of 100 people develop long-term neurological complications from the vaccine. "Only 1.2 people out of 100 get any benefit from the shot, and more than five times as many are harmed as receive benefit," he said.

Adverse reactions to the influenza shot are reported on the Department of Health and Human Services' Vaccine Adverse Event Reporting System (VAERS). Over 60,000 adverse events have been reported thus far. The percentage of adverse reactions reported may indeed be tiny, compared to the number of influenza vaccines that have been administered since the mid-1940s, but it is highly unlikely that the majority of adverse reactions actually get reported. For one thing, says board-certified pediatrician Lawrence Palevsky, MD, in *The Greater Good*, pediatricians often do not recognize a reaction to a vaccine, because they have not been trained to do so.[16]

One of the notable adverse reactions to influenza shots that has been reported on the VAERS database is Guillain-Barré syndrome (GBS), an autoimmune disorder that can cause the immune system to attack the nervous system and possibly result in paralysis. During the "swine flu" scare of 1976—in which a pandemic outbreak of a strain of H1N1 influenza was projected but never materialized—over 1,100 cases of GBS were reported (out of 45 million vaccinations). For the year 2012, as of August 31, over 30 cases of GBS associated with influenza had been reported on VAERS, including five that resulted in death.[17]

During the 2009-2010 flu season, a combination of seasonal influenza vaccinations and swine flu shots, both of which contain mercury, were associated with a 4,250 percent increase in fetal death reports on VAERS, after the vaccines were routinely administered to pregnant woman.[18]

There also exists a plethora of peer-reviewed research and epidemiological reports, originating in various countries, that indicate adverse reactions to influenza vaccines. Reported side effects have included seizures, narcolepsy, and asthma.

In Finland, in 2010, 54 children under the age of 17 who received the Pandemrix H1N1 swine flu shot were diagnosed with narcolepsy, equating to 5.3 cases per 100,000 children. This represented a 17-fold increase in incidence compared with the average for the previous eight years, when the vaccine was not administered. Some 34 of the 54 children diagnosed in 2010 carried a gene variant associated with an increased risk of narcolepsy, according to a study funded by the National Institute for Health and Welfare (THL) and Ministry of Social Affairs and Health, Finland.[19] However, the World Health Organization stated, "The National Institute considers it probable that the Pandemrix vaccine was a contributing factor to this observed increase."[20]

In April 2010, Australia temporarily suspended seasonal influenza vaccinations for children under 5 years old, when 23 children were hospitalized with convulsions and fever after receiving injections of Fluvax and Fluvax Junior, produced by CSL, Australia's largest pharmaceutical company and one of the leading influenza vaccine producers in the world. All cases occurred within 12 hours of receiving vaccine injections. In all, febrile seizures were reported in approximately 1 in 100 in children aged between 6 months to less than 5 years of age after receiving either of the two vaccines during 2010.[21] Over 40 other children around the same time period experienced adverse reactions (such as vomiting) to Fluvax. Since that time, Fluvax has not been licensed for use in children aged five and under, although other influenza vaccines are now permitted for use in this age group.

CONTAMINATION OR AGGREGATION?

Swiss pharmaceutical company Novartis, worth more than $50 billion, saw its stock value plummet by four percent in late October 2012, after two of its influenza vaccines were banned in more than half a dozen European countries. Italy was the first country to ban them, barring nearly a half-million influenza injections from entering the marketplace—though only two weeks later, on November 9, the Italian Medicines Agency (AIFA) lifted the ban.[22]

The ban had been enacted after small white particles were spotted in some vials, and possible contamination was suspected. Novartis researchers informed AIFA that these were clumps of protein particles. This type of clumping is better known scientifically as "aggregation," which, Novartis said in a press release after the ban was lifted in most of the European Union, is not that unusual in the manufacturing process of influenza vaccines. "The aggregate proteins are predominantly influenza virus-derived, all normal and necessary components of influenza vaccines," said the statement by Novartis.[23]

However, the aggregate virus antigens in influenza vaccine injections—such as hemagglutinin, which is propagated in fertilized hen's eggs—also contain chemical agents for inactivating the virus and performing other functions. It's these chemical agents, including detergents, formaldehyde, and many others (such as acetyl ethyleneimine, carboxyfullerene [C60], and methylene blue), that have some people concerned. It is not unambiguously clear whether exposure to clumped particles in the influenza vaccine in any given year—or aggregately, over many years—will cause harm at the cellular level.

HOW INFLUENZA VACCINES ARE MADE

Every year, scientists at the World Health Organization, during late winter or early spring in the northern hemisphere, predict which influenza virus strains will become prevalent in what is conventionally regarded as the upcoming flu season. These will be used to make the flu shots for the coming year. The effectiveness of the shots in any given year depends in part on how well the scientists predicted which of the hundreds of possible influenza viruses would be dominant.

Seasonal influenza vaccines are made with three main strains of influenza virus: 2 subtype "A" viruses (H3N2 and H1N1), and a subtype "B" virus). Flu shots are inactivated vaccines, which means that rather than containing live viruses, they contain two proteins extracted from each of the selected strains of virus.

Traditionally, these influenza viruses have been grown in eggs, in a laborious, expensive, and time-intensive endeavor. In this process, a small portion of the top of an egg shell is broken, and the viruses are injected into the egg white when the embryo is 11 days old. Some days later, centrifugal force is used to separate the virus from the chicken blood and tissues, but that process may not be entirely effective. Residual egg protein is found in the final vaccine solution; therefore, those with egg allergies are highly recommended not to receive this type of influenza injection.[24]

The production of just one influenza vaccine line requires up to 500,000 eggs per day, for up to eight months, according to vaccine expert Sherri Tenpenny, DO. Essentially, the millions of eggs become mini-incubators for cultured viruses. In order to produce more influenza vaccines and avoid this time-intensive process, vaccine makers have recently developed a new influenza vaccine production method: cell line technology, which uses animal DNA from sources including canine kidneys and caterpillar eggs.[24]

Though animal cell lines have been used in vaccines for decades, in 2009, Novartis became the first vaccine maker to have a large-scale influenza vaccine manufacturing facility (in Holly Springs, North Carolina) that uses this technology.

Huge vats of these cells are injected with the influenza viruses. The influenza vaccines are harvested every six to eight weeks, unlike the egg-produced viruses, which are harvested only about once per year. Dr. Tenpenny says cell line technology also includes use of DNA from the retinas of aborted fetal tissue and from insects. Concerns have been raised that possible contamination from the animal tissue may cause increased risk of cancer or other diseases.[24]

NASAL MIST INFLUENZA VACCINES

Though most people who get vaccinated for influenza receive injections, a live attenuated (weakened) influenza vaccine is available in the form of a nasal mist. The most popular, at least in the U.S., is FluMist. This vaccine produces "active" immunity against the influenza virus by actually causing an infection. The weakened vaccines normally do not cause full-blown influenza, but the possibility does exist that a virus could reproduce and cause the disease. The virus could also transfer to others in the household who have severely compromised immune systems.

Age group recommendations for the respective vaccines differ. FluMist is approved by the CDC for healthy people aged two to 49 who are not pregnant. They should not be given to people with asthma, as they can exacerbate wheezing, and have not been established as safe for people with certain medical conditions, including heart disease, diabetes, and kidney failure.[25] Like influenza injections, the nasal spray vaccines are mostly grown in eggs, and so should be avoided by those with egg allergies.

MANDATORY FLU SHOTS FOR STUDENTS AND HEALTHCARE WORKERS

In 2008, New Jersey became the first state to require an influenza vaccine for children in preschools and daycare centers. Healthcare workers around the country have been threatened with job termination if they refuse to receive the influenza vaccine.

Mandatory influenza shots are a philosophical, medical, and constitutional powder keg, with laws that vary significantly from state to state. For those who face the controversial mandate to vaccinate, there are a few exemptions that may allow individuals to avoid vaccination, although it is important that people interested in obtaining these exemptions call their state health department, as laws may periodically change.

Currently, 18 states allow philosophical or personal belief exemptions. (For a full list, visit NVIC.org.) States differ in how they might grant a philosophical exemption; for example, requiring a notarized statement or the signature of both parents, or a personal letter and signed exemption form. (Dr. Tenpenny's website SayingNoToVaccines.com has a downloadable philosophical refusal sample letter.)

West Virginia and Mississippi are the only states that do not specifically grant a religious exemption at this time. In states where such an exemption is available, requirements differ, but the onus is on the parents or individuals to prove that state-forced vaccination would be a violation of their right to exercise their religious beliefs. Some states may have the au-

thority to challenge a religious exemption while others do not. Consumers should also be aware that in some states, after an exemption has been exercised, all future vaccines must be refused.

Medical exemptions are also an option. Every state allows a medical doctor or an osteopathic physician to write a medical exemption, which must explain why a person's health would be compromised if that individual were administered a vaccine. The chances are much lower that one will receive a medical exemption if the letter is written by a chiropractor, naturopath, or doctor of Oriental medicine.

New research on the efficacy and safety of influenza vaccines is constantly emerging. Consumers will need to stay informed in order to make educated decisions on whether vaccination is in their best interest, and whether they wish to seek an exemption from any mandates. An increasing number of studies suggest that across-the-board influenza vaccinations of an entire population may be of limited use, at best. Careful weighing of the risks and benefits of vaccination as they pertain to one's individual situation is clearly the wisest course. 🕮

For additional information, see Dr. Tenpenny's Vaccine Research Library (http://vaccineresearchlibrary.com), a subscription-based website with over 3,400 articles on vaccine efficacy and safety.

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Other Factors That May Have Caused Global Pandemics

There are other factors besides influenza viruses that may be culpable for the deaths of millions during the last few significant influenza pandemics. Perhaps the most notorious of these pandemics occurred in 1918, as the first World War was coming to an end. Commonly known as the "Spanish flu," this major outbreak resulted in the deaths of between 30 and 100 million people.

Sherri Tenpenny, DO, writes in her book *Fowl! Bird Flu: It's Not What You Think,* "The highest mortality rate occurred among those who developed a rapidly progressing pneumonia. Because penicillin was not discovered until 1928, many deaths were most likely due to secondary bacterial infections and could have been preventable today." Even the use of intravenous therapy was rare in the early twentieth century. During that time, the rudimentary care provided included aspirin, oxygen, and, mostly, rest, she explains.[1]

Tenpenny also suggests that malnutrition played a role in the 1918 epidemic. During wartime, limited rations and an absence of clean water led to a global immunocompromised population. She quotes Anthony Fauci, ND, director of the National Institute of Allergy and Infectious Disease, who in 1985 stated, "Malnutrition was the most prevalent cause of immune deficiency diseases throughout the world in humans and undoubtedly played a hefty role in the large number of deaths during the 1918 pandemic."

The Vietnam War was a probable factor during the Hong Kong flu pandemic of 1968-1969. The World Health Organization attributed the outbreak in the U.S. to the return of American troops to California from Southeast Asia. Many of us can imagine how poor hygiene, emotional stress, pre-deployment vaccines, and chemical exposures could have contributed to the weakening of immune systems and the subsequent outbreak of influenza, Tenpenny says.

The underlying health conditions of those who died in these and other pandemics were largely unknown, she adds. Underlying and secondary factors such as bacterial infections or congestive heart failure could have been the prime culprits; there is no definitive proof that the deaths were caused by influenza viruses.

Many voices in the mainstream medical community praise vaccinations of all kinds for exponentially reducing mortality rates. But Lawrence Palevsky, MD, in the documentary *The Greater Good,* says that vaccinations, in general, do not account for the impressive declines in mortality seen in the first half of the twentieth century. Citing an article in the journal *Pediatrics,* he discusses child mortality rates in the U.S. between 1900 and 1998. The death rates from certain diseases were declining significantly before their corresponding vaccines were developed. The DPT (diphtheria, pertussis, and tetanus) vaccine was introduced in 1949, but Palevsky states those diseases were already on their way out, and rates of measles were declining before the measles vaccine was introduced in 1963.[2]

Palevsky credits governments on all levels for facilitating the decline of highly contagious diseases by promoting hygienic consciousness. He also suggests that frequent hand washing and proper sanitation played a bigger role than vaccines in preventing disease.

—Judd Handler

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Editor's note: *FOWL! Bird Flu: It's Not What You Think* is available from PPNF; see page 35 for ordering information.