

Flu Secrets You Should Know

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Flu Secrets You Should Know

By Kelly Patricia O Meara

Early in the 20th century an influenza known as the "Spanish Flu" claimed the lives of an estimated 20 million to 40 million people worldwide. It has been called the pandemic of 1918–1919, one of the most devastating in recorded history, claiming more lives than the "Great War" of 1914–1918, and even topping the death toll of the Black Death, or bubonic plague, that swept from far China in the 1330s across the face of Europe well into 1352.

Given the deadly history of the highly contagious flu virus, it comes as little surprise that governments and their public-health agencies pay keen attention to influenzalike illnesses arising even in the most remote corners of the world, or that news organizations cover the topic with a virulence rivaling that of the bug itself.

In fact the 2003–2004 flu season has been remarkable in that it hit earlier than in recent years and forced government health officials publicly to acknowledge that the influenza vaccine produced to protect against the virus doesn't protect against the strain of flu making its way across the country, leaving the Centers for Disease Control and Prevention (CDC) to cavil that, after all, the vaccine "may provide some protection or lessen the symptoms." The operative words being "may" and "some." Another CDC spokesman has said

that "the vaccine doesn't offer foolproof protection." What "may" and "some" and "foolproof" mean in this context apparently is as difficult to divine as it is for health officials accurately to predict the influenza strains circulating from year to year.

The identification of the virus that is the target of inoculation from year to year is based on reported influenzalike illnesses throughout the world that a handful of international and government health agencies, including the World Health Organization (WHO) and the CDC, monitor. Periodically a group of doctors and experts, known as the Vaccines and Related Biological Products Advisory Committee of the Food and Drug Administration, meet to discuss the ambient cases. Usually by May of each year, they vote on the strain of influenza virus from which to formulate the year's vaccine. Some years the advisory committee picks the right virus, and sometimes (like this year) it guesses wrong.

During voting for the 2003–2004 formulation a majority of participants believed that the influenza A Fujian (H3N2) would be the appropriate strain. But apparently due to complications with isolating the A Fujian strain, and additional manufacturing concerns, the committee decided to stay with the influenza A Panama (H3N2) strain that has been used since the 2000–2001 flu season.

Attempting to make sense of what "may" and "some" and "foolproof" mean, Roland A. Levandowski, a doctor with the FDA's Medical Center for Biologics and a member of the advisory committee, tells *Insight* that "the inactivated influenza vaccines – the protective efficacy of vaccine – is never 100 percent. We know from previous experiences with inactivated influenza vaccines that the best efficacy – the highest level of efficacy – is between 70 and 90 percent in healthy adults, and this occurs when there is a perfect match between the vaccine component and the circulating influenza virus."

Levandowski euphemizes, "This year the strain that is in the vaccine is not a perfect match, but the Fujian strain is represented in this class of virus [H3N2] and it's not so far off that we wouldn't expect to see some protection. If I had to guess, I'd say there is a 50 percent [chance] of protection, but even any guess depends on the outcome and what's happening out there in the real world." So this year the level of protection the vaccine offers is in doubt.

Indeed, by Jan. 15, the CDC issued a press release admitting that ongoing testing showed that this year's vaccine "was not effective or had very low effectiveness" in the test subjects.

Yet up to that time the official edict from federal health agencies had been to charge ahead and vaccinate anyway. Then, as most now are aware, there wasn't enough of the "wrong" vaccine to meet the hysteria–induced demand. So the CDC turned to the recently approved Washington–based MedImmune's FluMist, an influenza live–virus intranasal spray that is not approved for use on children younger than 5 or adults older than 49 – two of the at–risk groups for whom vaccination is recommended.

So with the reported shortage of inactive influenza vaccine and a limited use of the live intranasal spray, large portions of the population remain unprotected. How serious a problem is that? By Dec. 20, 2003, CDC Director Julie L. Gerberding replied: "I think when you look at a map that shows wide-spread influenza activity in 36 states that we can regard it, from a commonsense perspective, as an epidemic." Although the flu was widespread, according to the CDC the actual number of flu cases did not surpass the "epidemic" threshold until week 52 of the flu season.

The CDC Website (www.CDC.gov) offers weekly reports on the number of influenza cases. For the week ending Dec. 27, 2003, or week 52, the CDC reported that "since Sept. 28, WHO and NREVSS [National Respirator Enteric Virus Surveillance System] laboratories have tested a total of 50,743 specimens for influenza viruses and 14,942 were positive with 9.0 percent of all deaths reported by vital-statistics offices of 122 cities due to pneumonia and influenza." The epidemic threshold is 7.9 percent.

According to the CDC, influenza is the most frequent cause of death from a vaccine-preventable disease in this country. From 1990 through 1998, an average of 36,000 flu-related pulmonary and circulatory deaths occurred each season in the United States.

But how does the CDC arrive at its numbers of deaths related to influenza? "Tracking the flu is done through sentinel physicians who test cases for the influenza virus," CDC spokesman Curtis Allen tells Insight. "But in most cases a person would go to their physician and the doctor would make a clinical diagnosis based on the influenza symptoms. The number of reported deaths [due to complications of the influenza virus] is based on a mathematical model and not actual swabbing of the nasal cavity."

Allen continues, "The CDC gets the information from the sentinel physicians, which basically is a random sampling where there are physicians in a community or health department who will be seeing patients and will swab their noses. There are a couple problems with determining the number of deaths related to the flu because most people don't die from influenza – they die from complications of influenza – so the numbers are based on mathematical formulas. We don't know exactly how many people get the flu each year because it's not a reportable disease and most physicians don't do the test [nasal swab] to indicate whether it's influenza."

Thus the reported average of 36,000 deaths annually associated with influenza is based on estimates rather than actual figures. But what about the growing number of people concerned about the amount of mercury (thimerosal) in the inactive influenza vaccine?

It turns out that, at the very time government health officials were warning of the influenza epidemic, they also were putting out unrelated warnings about the quantities of tuna and other fish that could be ingested safely in view of the high levels of mercury in their flesh. The Environmental Protection Agency (EPA) recommends ingesting no more than 0.1 micrograms of mercury, while the FDA recommends no more than 0.4 micrograms per kilogram

per day. What this amounts to is a recommendation by the EPA and the FDA that women and small children eat no more than 12 ounces of tuna or other fish or shellfish per week. This is because, according to the EPA, "mercury consumed by a pregnant or nursing woman or by a young child can harm the developing brain and nervous system."

Yet the Advisory Committee for Immunization Practices has issued a warning, passed along by the CDC, that "all children aged 6 [months] to 23 months and pregnant women in their second and third trimester" receive the inactive influenza vaccine – which contains a full 25 micrograms of mercury – 250 times the limit the EPA recommends for tuna-lovers.

Nevertheless, the CDC Website says, "the benefits of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, of thimerosal," which is of course the source of the mercury. The CDC Website also states: "Based on guidelines established by the FDA, the EPA and the Agency for Toxic Substances and Disease Registry, no child will receive excessive mercury from childhood vaccines regardless of whether or not their flu shot contains thimerosal as a preservative."

Is there a disconnect in communications between federal agencies? Certainly the EPA and the FDA don't think the risk from exposure of children to high levels of mercury is "theoretical." Does mercury injected directly into the bloodstream of a small child stop at the neck, whereas mercury ingested from a tuna-fish sandwich does not? If EPA and FDA mercury limits are 0.1 and 0.4 micrograms, how can the CDC believe the 25 micrograms contained in the influenza vaccine is not "excessive mercury"?

According to Raymond Strikas, a spokesman for the CDC National Immunization Program, "At this point there is no confirmed proof that anyone has been harmed by mercury in vaccines. I'm not arguing that mercury isn't a neurotoxin – you're right. No one argues that point. It's got to do with the amount in vaccines – it's very small and has been eliminated in the vast majority of childhood vaccines. There is thimerosal-free or reduced-thimerosal influenza vaccine available." Then the "commonsense" factor cited by CDC Director Gerberding about influenza being at epidemic levels kicks in to point out that if you ingest mercury and it causes neurological problems, then it's just common sense that when you inject it into the bloodstream it will do the same.

Thimerosal is a preservative that has been used in multi-dose vials of vaccines. It contains 49 percent ethylmercury. The CDC says "there is no convincing evidence of harm caused by low doses of thimerosal." However, in July 1999, the Public Health Service and the American Academy of Pediatrics agreed thimerosal should be eliminated "as a precautionary measure." And Strikas is correct when he advises that there is a thimerosal-free influenza vaccine. The problem, critics say, is that of the 85 million doses produced for this flu season only 3.2 million were thimerosal-free. Which lucky kids, they ask, weren't exposed to potential mercury risks?

Len Lavenda is a spokesman for Adventis Pasteur, one of three pharmaceutical companies producing this season's influenza vaccine. He tells Insight, "We produce flu vaccines in several different presentations. We have three of these: a 10-dose vial [multidose], single-dose prefilled syringes and the pediatric preservative-free dose. Based on prebooking we determine how many of each will be produced." Lavenda explains that "for the 2003-2004 season Adventis produced 43 million doses of the influenza vaccine." The pharmaceutical spokesman was unsure of how many were free of thimerosal or even of how many thimerosal-free doses might be produced for the next flu season. The FluMist intranasal spray is free of thimerosal, remember, but cannot be given to children younger than 5.

Mark Geier is president of the Genetic Centers of America. He and his son David Geier, president of Medcon Inc., are consultants on vaccine issues and longtime opponents of thimerosal in vaccines. Certainly the Geiers don't accept the concept that mercury somehow is less poisonous to the human body when injected rather than ingested. They are alarmed about the presence of mercury in millions of doses of influenza vaccine being used to fight an epidemic.

"The ethyl mercury in the influenza vaccine," insists Mark Geier, "assuredly does not stop at the neck. Yes, there is something called the blood/brain barrier, which prevents some toxins from entering the brain. But ethyl mercury, which is what is in the influenza vaccine, crosses that barrier. The influenza vaccine has 25 micrograms of mercury, which means that to be at the recommended level of safety, and assuming that you get no mercury from any other source, you'd have to weigh 550 pounds to be safe."

But, Geier says, "that is only one aspect of this influenza virus that concerns us. There is a further risk to the health of this country because the current vaccine doesn't match the current influenza strain. You understand that they have been wrong about the strain about half the time and we've been screaming about this for years. Finally, this year, they even admitted it was the wrong strain. But they say you should continue to get the vaccine because 'it may give you some protection.' The truth is it is unlikely to give you a significant amount of protection because it is the wrong strain."

He continues, "Now let's talk about what can be done. It turns out that this is not going to be a terribly deadly year and the created panic has succeeded in selling the vaccine. But there is no joking about influenza. What if the 1919 strain comes back? Every year we try to make a vaccine, and let's hope the year it comes back we have a good one. In its best year the influenza vaccine is probably about 70 percent efficacious, which means we'd still lose tens of millions of people, so what do we do? The next thing out of their mouths is: 'Well, if it gets really bad we're going to quarantine states.' Wait. This isn't 1919, and we have three FDA-approved drugs that prevent influenza. What happened to them?"

"Tamiflu," Geier says, "is made by Roche [Pharmaceuticals]. Taking one pill a day prevents up to 90 percent of flu. So explain to me why our [Department

of] Homeland Security has stocked millions of doses of Cipro in case we're attacked with anthrax – unlikely on a wide-scale basis – but has not put away Tamiflu for a major outbreak of influenza that could go worldwide? Tamiflu ... can be taken within 48 hours of the onset of flulike symptoms and will shorten the case. Two, it is approved for prophylactic use – taking one pill a day for the flu season – and it will prevent any type of influenza A or B, no matter what strain, and it is graded in the 90 percent range."

Geier insists that "it should be put away for both uses and, God forbid there is a major outbreak, every city should have this stocked. Homeland Security is supposed to protect us not only from terrorists but also natural disasters – and this would be a real natural disaster. Why aren't public-health officials telling people there is an alternative? Instead, what we've got is people fighting to get the wrong vaccine, fully approved by the FDA. What kind of leadership is this?"

"Suppose for a moment," he says, "that there were a 1919 swine-flu outbreak tomorrow. Do you think they could just pass out Tamiflu to everyone then? No. That would mean producing tens of millions of doses. I went to a local pharmacy to get Tamiflu and asked the pharmacist how many he had on the shelf. He had just 20 Tamiflu pills – not even enough to fill my prescription. Look, this is serious. If the 1919 strain should return tens of millions of Americans could die, but our health officials are doing nothing, even though the FDA has approved the antivirals for exactly this use. The vaccine in its wildest dreams never works in the 90 [percent range], so why aren't they actively promoting Tamiflu?"

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