

How Effective is the Flu Vaccine?

Thousands of elderly Americans are lining up for hours to receive a flu shot. And the media are filled with stories about the inadequacy of the flu vaccine supply now that one of the only two suppliers had to be shut down due to contamination. Nearly half the nation's expected supply of influenza vaccine has been wiped out.

In recent years, the federal government has been promoting the flu vaccine for everyone, not just for the elderly and the sick; but now it has had to do a complete about-face. Because the supply is so limited, the public has been told that influenza vaccines should be reserved for the elderly, the chronically ill, health care workers, babies 6-23 months old, pregnant women and women who plan to become pregnant in the next four months. The public trust was shaken soon after this announcement with the news that members of Congress and at least one football team got flu shots.

Understandably, a certain amount of hysteria has erupted because flu vaccines have not reached many of the people in the government's high-risk category. Now *everyone* seems to want the flu vaccine. It's time to step back and look at the big picture. Time to look at the question of how effective vaccines have been in preventing the flu. More importantly, how effective have vaccines been in reducing the deaths and severe complications sometimes associated with influenza?

As is commonly known, the vaccine formulation changes each year. The three different flu strains are usually chosen in the spring, and the choice is based on a combination of guesswork, flu outbreaks in Asia , and the recommendations of the World Health Organization.

What is *not* commonly known is this: Researchers divide influenza into two types, and the yearly flu vaccine is more likely to be effective against the type that afflicts fewer than 15% of all who appear to have influenza—this is the one caused by influenza A or B. Researchers refer to all other forms of influenza as *influenza-like illness* . Both types produce exactly the same symptoms—headache, fever, muscle aches, cough and runny nose.

All Influenza Looks Alike

In a telephone interview, vaccine researcher Tom Jefferson, MD, explained, “The flu is not caused by a single ‘bug’—about one-third of all influenza is caused by an unknown agent; about one-third are caused by rhinoviruses, the

same viruses that cause the common cold; and the remainder are a mixed bag of other agents including influenza A and B viruses and members of the coronavirus family.”

What makes things complicated, according to Dr. Jefferson, is that they all appear to be the same illness. Moreover, one cannot forecast how much of the influenza viruses in the upcoming flu season will be influenza A or B, he explained, “yet the public is never told this.”

Dr. Jefferson co-authored the first review of all clinical trials in which healthy people under age 60 were randomly assigned to receive a flu vaccination or a placebo vaccine. (More on that later.) And he recently wrote an editorial entitled, “How to deal with Influenza?” for the British medical journal, BMJ. Vaccination successes are largely confined to influenza A and B, the type that accounts for only a small percentage of all influenza cases, he wrote. What’s more, public health officials are not good at predicting how much influenza A and B to expect in the next flu season. Putting these concerns together, Dr. Jefferson expressed reservations about mass vaccination, given the costs and variable benefits. “Before committing scarce resources to deal with influenza we need better proof that what we see is influenza and not an influenza-like illness.”

How good was last year's vaccine?

The panic over flu shots this season is an even more extreme version of what occurred in November 2003 when influenza broke out earlier than usual in some parts of the country. The public was warned that the flu season was going to be much worse than previous years. Reports of flu-related deaths among previously healthy young children sent thousands of people to stand in line for the flu vaccine.

But we are far enough away from last year's crisis to learn that the flu vaccine of the 2003-2004 season was a flop. It was the first time the federal government ever looked at the effectiveness of the flu vaccine in the midst of the flu season. The U.S. Centers for Disease Control (CDC) and Prevention funded this study which followed health care workers in Colorado , where the 2003-04 flu season started with a vengeance.

Lab tests were given to the vaccinated as well as the unvaccinated health care workers. Results showed that last year's vaccine “was not effective or had very low effectiveness against influenza-like illness.” Still, the CDC managed to put a positive spin on these pitiful findings, stating that its study did not prove that last year's vaccine was totally ineffective.

CDC pushed vaccine known to be ineffective

Here is how the CDC explained the poor performance of the 2003-04 vaccine. “Last year, the U.S. public health officials and the companies that make vaccines miscalculated and failed to predict that a new strain called the Fujian influenza A would be the most common cause of infection and left it out of the mix.” The CDC explanation is more than a bit disingenuous to consumer advocate Barbara Loe Fisher, president of the National Vaccine Information Center in Virginia .

As the consumer voting member of the FDA's advisory committee on vaccines, Fisher participated in the discussions regarding the Fujian strain and why it was not included in the 2003-04 flu shot. As early as March 18, 2003, Fisher said the advisory committee knew that Fujian strain was the most important virus for the upcoming flu season. “Federal officials were prevented from replacing the A/Panama strain with the Fujian strain emerging out of Asia and being detected in Europe and the U.S. last spring,” according to Fisher, “because scientists in labs around the world were unable to isolate and grow the virus in a way that would allow vaccine production.”

In a telephone interview, Fisher said that the transcripts of these discussions at the FDA are publicly available (see below). “I called for the federal health officials to be honest with the American public about the effectiveness of the [2003-04] flu vaccine,” she continued. (In mid-January 2004, just as the time to be vaccinated had passed, the CDC issued a press release admitting the ineffectiveness of the current flu vaccine.) The National Vaccine Information Center , which Fisher co-founded in 1982, is a national, non-profit advocacy organization that often points to the lack of scientific evidence to support public policy regarding childhood immunizations.

Efficacy of Vaccines Past for People Under 60

It is, of course, too early to see whether the CDC 2004-05 flu predictions are more accurate, but for the first time a systematic assessment has been conducted of all flu vaccine trials worldwide. The review was conducted by the Cochrane Collaboration* and Dr. Jefferson was one of the four authors. The Cochrane reviewers wanted to answer the question of how effective flu vaccines are for healthy people under the age of 60 years. They also wanted to see whether there were any adverse effects.

They found 25 clinical trials in which healthy people between the ages of 14 and 60 years had been randomly assigned to have a flu vaccine or a placebo (inactive) vaccine. All the trials had been published in medical journals between 1969 and 2002. Altogether they involved 59,566 participants. Here is the Cochrane Review conclusion: Influenza vaccines are effective in reducing influenza A and B, but they do not work against the overwhelming majority of influenza-like illnesses.

When the Cochrane reviewers pooled the results of all 25 trials, they found that only 6% fewer vaccinated people got the flu, compared to the unvaccinated people. The vaccine formulations, which differed each year, were based on the recommendations of the World Health Organization or single governments (the 25 trials took place in eight different countries). No adverse reactions to the vaccines were reported.

The Cochrane review, which was published this year, produced these additional findings: The influenza vaccine did not reduce the number of working days lost, nor did it reduce flu-related complications, deaths or hospitalizations. From a public health standpoint, another disappointing finding was the failure of the vaccines to stop the spread of influenza.

Elderly People

Dr. Jefferson and his colleagues are currently conducting a similar Cochrane Review of all vaccine clinical trials involving the elderly (another one about children is in the works). Surprisingly few randomized trials have been conducted for the elderly and chronically ill. In less well-designed studies (20 in all), the influenza vaccine reduced the risk of pneumonia, hospitalization, and death in people over 65.

People with asthma

Another Cochrane Review focused solely on the benefit of the influenza vaccine to people with asthma. It addressed two important questions: Does the vaccine itself trigger asthma attacks? Does it protect against asthma attacks caused by influenza? Combined results of trials involving adults with asthma and children with asthma came to the same conclusion: Asthma attacks did not increase in the two weeks following a flu vaccination.

As for the question of whether the flu vaccine reduces the rate of asthma attacks following influenza infection (as opposed to the vaccination itself), few trials have looked at this crucial issue. The Cochrane Review, which was published in 2003, concluded, "...uncertainty remains in terms of how much difference vaccination makes to people with asthma."

Children and Babies

A yearly flu shot for healthy babies and children is a relatively new policy in the U.S. As noted, last year's reports of flu-related deaths among healthy children drove many panicked people to line up for flu shots. But the CDC web site (as of October 22, 2004) acknowledges that there is no way of knowing whether more children than usual died of the flu last winter. "Because the number of influenza deaths in children has not been tracked before, it's not possible to compare the number of deaths in children this year with previous

years.”

As far as the CDC knows, 152 children died of influenza in the 2003-04 season. For this article, the CDC officials were asked how many of these children had been severely ill before they got influenza. Answer: “The CDC will report these statistics at the end of this year.” (The agency would not permit direct access to its scientists for this article, so the answers to all questions came via a press officer.) Since CDC had used these deaths to promote flu shots and has since admitted the vaccine was largely ineffective, it is important to know more about the children who died.

One imperfect study supports policy on babies

The basis of the CDC recommendation for babies between 6 and 23 months rests on one rather imperfect study conducted in Colorado during last year's flu season. It was a retrospective study of the nearly 30,000 children enrolled in a Kaiser Permanente health plan. The 6-23 month-olds represented only about one-sixth of all the children in the health plan. The study was funded by the CDC and led by Debra P. Ritzwoller, PhD, research scientist in the Research Unit at Kaiser Permanente, Colorado.

In a telephone interview, Dr. Ritzwoller was asked to explain the results, as they were not described clearly on the CDC Web site. Compared to unvaccinated children, the vaccinated children had 49% fewer cases of influenza, according to Dr. Ritzwoller. This finding, she noted, applied only to the children who had influenza A or B. Whereas, there was a smaller benefit to those with the more common *influenza-like illness*: 25% fewer cases among the vaccinated kids. But the key question is: 49% and 25% of what? Dr. Ritzwoller was not able to provide the answer. Here's why the question is important: If few children in this study got the flu, then these reductions are less than meets the eye. For example, if 10,000 kids belong to a health plan, and only four of the unvaccinated kids and three of the vaccinated kids got an influenza-like illness, that's 25% fewer cases.

The children had their illness type determined in laboratory tests that were administered in the emergency room. Unlike the well-designed clinical trials that formed the basis of the Cochrane Reviews, the Colorado Kaiser Permanente study had not randomly assigned the children to receive a flu vaccine or a placebo vaccine. This study appeared online last summer in the MMWR (Morbidity & Mortality Weekly Report), but is yet to be published in a peer-reviewed journal. When asked whether the flu vaccine caused any adverse reactions, Dr. Ritzwoller said there were none, but acknowledged some gaps in her study. “Hospital admissions were not tracked, and the parents were not interviewed,” she explained, attributing this to inadequate CDC funding.

The CDC's rationale for its relatively new policy regarding yearly flu shots for babies 6-23 months is also based on their purportedly worse incidence of influenza complications. But consumer advocate Barbara Loe Fisher has her doubts. Giving the flu vaccine to babies under age two who are likely to receive other, standard childhood immunizations at the same doctor visit is a "national experiment," said Fisher.

She faults the CDC for creating hysteria about the dangers of the flu—last year and this year—without warning parents and doctors about the unknowns surrounding the safety of the flu vaccine in combination with other childhood vaccines. The one exception she identified was Prevnar, the pneumonia vaccine which has been studied in combination with the flu vaccine.

Fisher is concerned about public health officials "cavalierly adding yet another vaccine to the childhood regimen without proof of safety or efficacy." A new Japanese study, published in *Pediatrics International*, supports her concerns. Japanese babies, aged 6 to 24 months, had been vaccinated against influenza A and then age-matched to unvaccinated babies.

All the babies were followed for three flu seasons. The study found that the vaccine was ineffective in preventing influenza A. What's more, the research team led by Tao Maeda concluded that influenza vaccination of healthy infants and young children is not justified unless the benefits clearly outweigh the risks. More studies are needed, say the Japanese researchers, before vaccinating children under the age of two becomes public policy.

In conclusion

Most people will not get the flu (only 5-20% come down with it each season, according to the CDC). Influenza does not pose a risk of serious complications to most people who get it. The flu vaccine (which changes formulations each year) does not prevent the type of flu that the overwhelming majority of Americans get each fall/winter season. The flu vaccine will cut the odds of getting influenza A and B by only 25%. This type of influenza, however, represents less than 15% of all cases, and public health officials cannot forecast how much of the influenza viruses expected in the upcoming flu season will be influenza A and B.

Elderly people *may* benefit from a flu vaccination in terms of reduced risk of pneumonia, hospitalizations and death, but the supporting studies are not very good. There is no good evidence to show that the benefits outweigh the risks of vaccinating babies and young children against the flu. Healthy people under age 60 years do not benefit from the flu vaccine, in terms of reduced odds of getting the flu, days lost from work, or stopping the spread of influenza. No adverse reactions to the flu vaccine have been identified, though long-term consequences are unknown.

For more information:

- Visit the CDC Web site (www.cdc.gov/flu), or call the hotline at 1(800) 232-2522. This is *the* vaccine policy-setting government agency, and clearly not an objective source of information. For example, the Web site explains that the current vaccine shortage is due to the fact that the British supplier to the U.S. stopped production at the order of the British version of the FDA, but fails to give the reason (contamination).

- For an entirely different viewpoint, go to the National Vaccine Information Center 's Web site at (www.nvic.org/diseases/influenza.htm), or call 1(703)938-0342. You will get an explanation, for example, about the difference between temporary immunity as delivered by a flu vaccine and natural or permanent immunity as conferred by recovering from the flu. The NVIC offers a free fact sheet and newsletter about influenza. At the Web site, you can read the transcripts of last year's FDA advisory committee meetings mentioned by Barbara Loe Fisher in this article.

- At www.bmj.com, go the 9/18/04 issue of the BMJ to read Dr. Jefferson's editorial, "How to deal with influenza?"

- If you believe that the flu vaccine shortage is due to lawsuits against pharmaceutical companies, go to the Web site of the Washington, DC-based, advocacy organization, Public Citizen (www.citizen.org/documents/ACF7D6.pdf).

***The Cochrane Collaboration is an international organization that conducts systematic reviews of all relevant studies to determine whether or not medical treatments work. The reviews are maintained in a subscription-only "library" online or in a CD ROM format.**

Maryann Napoli November 2004

© 2005 Center for Medical Consumers

The Center for Medical Consumers cannot respond to inquiries regarding individual health concerns.

Our Web site is updated during the first two weeks of each month.

Please send any comments or questions to medconsumers@earthlink.net