

Effectiveness of the Flu Vaccine against Influenza?

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Global Research, December 05, 2014

Vaccine Council 15 October 2013

Region: <u>USA</u>
Theme: Science and Medicine

The great enemy of the truth is very often not the lie—deliberate, contrived and dishonest, but the myth, persistent, persuasive, and unrealistic. Belief in myths allows the comfort of opinion without the discomfort of thought. – John Fitzgerald Kennedy (1917–1963)

Just take a walk or drive around this time of year and you can't help noticing signs for the flu vaccine. They're pretty much everywhere, lining entire parking lots and walkways into markets. They encourage everyone to get the shot – telling you to "walk in anytime" and of course accepting insurance. Some even offer incentives to get the vaccine such as a giving a 20% off shopping pass with every flu shot. At workplaces across the country notices are sent out offering shots at flu clinics. It's a full court press promoting the vaccine everywhere for everyone.

I called my local pharmacy to find out who could get the shot. They told me I didn't even need a doctor's note. I asked if a pregnant woman could get the shot and they said that it wasn't contraindicated, but some people ask for preservative free shots. I asked if I was feeling under the weather if I could still get the shot and the answer was "sure no problem."

So it's easy. No doctor's note. All you need is insurance and if you don't have it just \$31.99 per shot – at least that's the price at my local pharmacy. It didn't even matter if you were sick you're ready for your shot. It couldn't be any simpler.

But a couple of things were missing – science and information. Of course there is no debate when questioning vaccination in general and so it goes with the flu vaccine. Simply blindly accept, roll up your sleeve and get the injection that will supposedly protect you from getting sick. It has to be true doesn't it? The government and medical organizations have all signed on and each year there is more and more push for everyone young and old to get vaccinated. But let's do something you're never supposed to do – ask questions and look for answers.

One of the most obvious questions is "did the flu vaccine reduce deaths?"

Looking at the Vital Statistics of the United States you can get all sorts of interesting information. Some of that information is the deaths from various infectious diseases. The statistics usually group influenza and pneumonia together with data for the United States starting in the year 1900 to the present. What it shows is that the death rate for influenza and pneumonia was at 200 per 100,000 and that slowly declined over the years. Aside from the 1918 flu pandemic the death rate continued to decline and reached about 20 to 25 per 100,000 by the early 1970s when there was the initial push for flu vaccines. You can see this decline in this graph



Deaths from influenza and pneumonia had decreased by 90% before there was an idea to push for widespread vaccination. This isn't surprising at all since infectious disease death rates had declined well before there were vaccines. Measles deaths had declined by almost 100%



and whooping cough deaths by over 99%



before either of their perspective vaccines. Other infectious disease such as scarlet fever, typhoid, typhus, cholera, and others all decrease to virtually zero without any widespread use of any vaccine.

It is quite amazing that there was a 90% decrease in deaths before the use of any flu vaccine. What caused this massive decrease in deaths from infectious disease? What lessons have we learned? When you go get your flu shot do they share any of this information with you? Chances are probably not.

Even if we hadn't learned any lessons as to why there was such a decrease in deaths, there were still people dying of the flu and pneumonia. With a vaccine the idea is of course to reduce those deaths. The question is how well has it done?

Let's look at the data again. This time let's examine the mortality rate and vaccine coverage. You would expect that with an increasing vaccine coverage that the death rate would decline. After all, vaccines are supposed to protect the population from the disease that they target. When we look at that data we find something surprising – we find that as the coverage rate for vaccination improved the death rate actually increased not decreased.



The data shows that influenza and pneumonia deaths were 20-25 per 100,000 in the mid to yearly 1970s and increases to about 30 per 100,000 with a much greater flu vaccine coverage.

This phenomenon was reported by the CDC epidemiologists in 2003 as reported in an article in the journal Vaccine.

...national influenza-related mortality rates among seniors increased in the 1980s and 1990s as the senior vaccination coverage quadrupled. [1]

What's more is that same article reported that only approximately 5% of winter deaths are related to influenza. The often stated 50% of senior deaths could be prevented by vaccination are incorrect and that belief has arisen out of a selection bias in previous studies.

...there was no evidence that the vaccine prevented more deaths in the influenza period than in surround time periods... But much of the evidence for vaccine effectiveness from observational studies in seniors over 70 years of age is unreliable, and the remaining evidence suggests that vaccination is far less effective than previously thought... there are only a few well-controlled observational studies at this point; these studies suggest low vaccine benefits for seniors, with point estimates ranging from 0% to 29%.[2]

It's important to note that 90% of influenza and pneumonia related deaths occur in seniors older than 70 years of age. Data from the National Vital Statistics[3] in 2001 shows the death rate per 100,000 for all age groups with clearly the biggest problem in seniors over 75 and over 85 at 148 and 685 rate per 100K respectively. Also, if you're between the ages of 1 and 65 when you look at other causes of death (some are listed in the TABLE) the flu and pneumonia are not as nearly as high as a lot of other risks in life.



So a less than stellar 0 to 29% effectiveness in seniors isn't all that we are led to believe in advertisements and public announcements. The authors of this study harshly conclude:

...the idea that influenza vaccine can prevent up to 50% of ALL winter deaths is preposterous.[4]

A 2009 review by the Cochrane Collaboration identified, retrieved, and assessed all studies evaluating the effects (efficacy, effectiveness and harm) of vaccines against influenza in healthy adults. This study also came to the conclusion that there was insufficient evidence for the use of widespread vaccination for the flu.

There is not enough evidence to decide whether routine vaccination to prevent influenza in healthy adults is effective... The results of this review seem to discourage the utilisation of vaccination against influenza in healthy adults as a routine public health measure.[5]

A February 14, 2005 study published in the Archives of Internal Medicine examined the influenza related deaths in the entire US elderly population. The authors expected that since influenza vaccination had greatly increased over the last 25 years that there should be a reduction in mortality by about 35% to 40%. What they found instead was no reduction in death despite increased vaccination.

...the 50-percentage-point increase in vaccination coverage among the elderly after 1980 should have reduced both excess P&I [Pneumonia and Influenza] and excess all-cause mortality by about 35% to 40%. We found no evidence to indicate that such a reduction had occurred in excess P&I or excess all-cause mortality in any elderly age group.[6]

Again, the authors conclude that previous observational studies must have been biased to overestimate the benefits of the flu vaccine.

...these estimates, which provide the best available national estimates of the

fraction of all winter deaths that are specifically attributable to influenza, show that the observational studies must overstate the mortality benefits of the vaccine.[7]

In a recent article Peter Doshi, Ph.D reiterated this position. He declared that:

The vaccine may be less beneficial and less safe than has been claimed, and the threat of influenza seems to be overstated... This means that influenza vaccines are approved for use in older people despite any clinical trials demonstrating a reduction in serious outcomes.[8]

He also stated that public officials only need to claim that the vaccine saves lives and that most people, including doctors, assume there is solid research behind the claim and unfortunately that is not the case. So in seniors – the group that has the greatest need – there really isn't any good science to backup the use of the flu vaccine.

What about in children under 1 year of age where there is also a higher mortality rate? After all, the CDC currently recommends children 6 months and older get a flu vaccine. A 2008 study found no evidence as to the benefits of flu vaccination in children under two years of age.

...vaccine effectiveness was not clearly shown in children under 2 years of age. Further studies using different methods, in different locations, and in different seasons, are needed to clarify the effectiveness of influenza vaccine among young children.[9]

In 2012 a comprehensive review of 75 randomized control studies in healthy children under 16 years of age was published.

Inactivated vaccines in children aged two years or younger are not significantly more efficacious than placebo... little evidence is available for children younger than two years of age... No safety comparisons could be carried out, emphasising the need for standardisation of methods and presentation of vaccine safety data in future studies. In specific cases, influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions. It was surprising to find only one study of inactivated vaccine in children under two years, given current recommendations to vaccinate healthy children from six months of age in the USA, Canada, parts of Europe and Australia. If immunisation in children is to be recommended as a public health policy, large-scale studies assessing important outcomes, and directly comparing vaccine types are urgently required.[10]

What's surprising is not only was an evaluation of all the available studies showing that there was no benefit for vaccinating children under 2 years of age, but that there was only 1 study at all in children in that age group. The authors also note that serious problems such as narcolepsy and convulsions were also associated with the vaccine.

In yet another study examining the flu vaccine in children under 5 years old for two seasons the authors found no benefit. The vaccine did not prevent emergency room visits or inpatient/outpatient visits during the years 2003-2005.

Each year, US children aged 6 to 59 months experience high rates of hospitalizations, ED [Emergency Department] visits, and outpatient visits due to influenza. Despite this, we were unable across 3 large communities to demonstrate that influenza vaccination was effective in preventing influenza-related inpatient/ED visits or outpatient visits during 2 consecutive seasons (2003-2004 and 2004-2005) among 6- to 23-month-olds, 24- to 59-month-olds, or the entire age span.[11]

So why are we vaccinating children as young as 6 month old?

Looking at all this information it's surprising how much time and effort has been invested in vaccinating against the flu. And here is part of the problem – what is the flu anyway? Most people think of the flu as being caused by a single entity – an influenza virus. Is this really the case?

"Flu" is basically defined as a 100°F or higher fever or feeling feverish (not everyone with the flu has a fever), a cough and/or sore throat, a runny or stuffy nose, headaches and/or body aches, chills, and fatigue. So if you have that you think you have the flu. Right? Not so fast. What is often poorly understood is that a person actually has a syndrome (influenzalike illness, or ILI) that can be caused by various agents. Only a proportion of these syndromes is caused by influenza A and B viruses, but differential diagnosis on clinical grounds alone is not possible. So in other words, just because you or your doctor think you have the "flu" doesn't mean you have the influenza virus.

In a 2009 editorial by Thomas Jefferson of the Cochrane Vaccines Field, explained just what the incidence of ILI is and what percentage are actually caused by the influenza virus. Using perspective studies the Cochrane group determined that during the winter season about 7% of people come down with ILI – 93% don't. Of that 7% only a small fraction are from influenza – 11% influenza, 6% RSV [Respiratory syncytial virus], 3% Rhinovirus, 2% PIV [Parainfluenza virus], and a whopping 77% from unknown causes. Based on this the conclusion was:

...evidence presented here points to influenza being a relatively rare cause of ILI and a relatively rare disease. It follows that vaccines may not be appropriate preventive interventions for either influenza or ILI.[12]

So when you're supposed to be protected from the flu you're really getting an injection against a small subset of influenza-like illnesses. It's no small wonder why those looking at the effectiveness of the flu vaccine have seen so little of it.

Although it's often thought as impossible, people sometimes even get sick with the flu after being vaccinated. But, as we just discovered, feeling like you have the flu doesn't mean you have an influenza virus. It could be that you've gotten another type of infection. This is exactly what is discussed in the 2012 research paper by Cowling et al. In a double-blind randomized controlled trial, children aged 6–15 years either received a 2008–2009 seasonal trivalent influenza inactivated vaccine [TIV] or a REAL SALINE placebo (which you don't often see in vaccine trials).

TIV recipients had higher (5 times) risk of confirmed noninfluenza respiratory virus infection. The majority of the noninfluenza respiratory virus detections were rhinoviruses and coxsackie/echoviruses, and the increased risk among TIV

The author's note that the influenza vaccine may have reduced immunity to noninfluenza respiratory viruses by "some unknown biological mechanism." What's worse is what they noticed between the vaccine versus the placebo:

There was no statistically significant difference in the risk of confirmed seasonal influenza infection between recipients of TIV or placebo.[14]

Perhaps that is why a hepatitis A vaccine or another old influenza vaccine is so often used as a placebo in vaccine trials?

The immunity picture that we might have of a vaccine stimulating an antibody to protect us from a specific illness is actually much more complicated. There are multiple infections that can cause us to feel like we have the flu and when we get a shot it can make us more susceptible to another infection. This is exactly what has appeared to have happened with the use of the flu vaccine and susceptibility to the swine flu.

Professor Peter Collignon has called for a review of Australia's flu vaccine... "What was a bit surprising when we looked at some of the data from Canada and Hong Kong in the last year is that people who have been vaccinated in 2008 with the seasonal or ordinary vaccine seemed to have twice the risk of getting swine flu compared to the people who hadn't received that vaccine, Some interesting data has become available which suggests that if you get immunised with the seasonal vaccine, you get less broad protection than if you get a natural infection. It is particularly relevant for children because it is a condition they call original antigenic sin, which basically means if you get infected with a natural virus, that gives you not only protection against that virus but similar viruses or even in fact quite different flu viruses in the next year. We may be perversely setting ourselves up that if something really new and nasty comes along, that people who have been vaccinated may in fact be more susceptible compared to getting this natural infection."[15]

Confused? Don't be upset because diseases are complicated and, moreover, the immune system is very superficially understood by even the most accomplished immunologists today.

... "the immune system remains a black box," says Garry Fathman, MD, a professor of immunology and rheumatology and associate director of the Institute for Immunology, Transplantation and Infection . . . "Right now we're still doing the same tests I did when I was a medical student in the late 1960s . . ." It's staggeringly complex, comprising at least 15 different interacting cell types that spew dozens of different molecules into the blood to communicate with one another and to do battle. Within each of those cells sit tens of thousands of genes whose activity can be altered by age, exercise, infection, vaccination status, diet, stress, you name it. . . . That's an awful lot of moving parts. And we don't really know what the vast majority of them do, or should be doing . . . We can't even be sure how to tell when the immune system's not working right, let

alone why not, because we don't have good metrics of what a healthy human immune system looks like. Despite billions spent on immune stimulants in supermarkets and drugstores last year, we don't know what—if anything—those really do, or what "immune stimulant" even means. [16]

There is one more thing you probably have noticed by now – that the statistics almost always lump the flu and pneumonia together. It's assumed that influenza and pneumonia are strongly linked so that's why there are often grouped together for data reporting, but that association is often lost when claims are made that 36,000 people die each year from the flu. For example this is from the American Lung Association:

Many confuse the flu with the common cold, but in actuality, the flu is much more serious. In the United States, the flu is responsible for 226,000 hospitalizations and an average of 36,000 deaths annually.[17]

But what they actually mean is "flu-related" deaths not from the flu itself and that complication is pneumonia.

...according to the CDC's National Center for Health Statistics (NCHS), "influenza and pneumonia" took 62,034 lives in 2001—61,777 of which were attributed to pneumonia and 257 to flu, and in only 18 cases was flu virus positively identified. Between 1979 and 2002, NCHS data show an average 1348 flu deaths per year (range 257 to 3,006).[18]

So in actuality the number of lives lost to the flu by percentage is less than 1%, and only a few were actually positively identified as the flu. So where does this 36,000 flu deaths figure come from? It comes from a model and not actually verified numbers.

CDC's model calculated an average annual 36,155 deaths from influenza associated underlying respiratory and circulatory causes. Less than a quarter of these (8,097) were described as flu or flu associated underlying pneumonia deaths. Thus the much publicized figure of 36,000 is not an estimate of yearly flu deaths, as widely reported in both the lay and scientific press, but an estimate—generated by a model—of flu-associated death.[19]

Remember that the "flu" isn't always caused by the flu virus (7% of ILI is the influenza virus) and since no one is really looking to test for the influenza virus association to pneumonia (the biggest part of the killer statistic) it is just an assumption. So how can the flu vaccine help prevent the lion's share of the deaths when the association is more with ILI? According to Cochrane Reviews when they went to find how well vaccination helped people prevent pneumonia or death – they couldn't find any.

After reviewing more than 40 clinical trials, it is clear that the performance of the vaccines in healthy adults is nothing to get excited about. On average, perhaps 1 adult out of a 100 vaccinated will get influenza symptoms compared to 2 out of 100 in the unvaccinated group. To put it another way we need to vaccinate 100 healthy adults to prevent one set of symptoms. However, our Cochrane review found no credible evidence that there is an effect

So what are we supposed to do to help us not get sick?

In this randomized clinical trial, daily supplementation with 1200 IU vitamin D3 in school children between December and March showed a significant preventive effect against influenza A, although no significant difference was observed for influenza B... daily dietary probiotic supplementation was a safe effective way to reduce fever and other symptoms in small children. Moreover, a significant preventive effect of a product containing echinacea, propolis, and vitamin C on the incidence of respiratory tract infections was observed in children. [21]

We could use vitamin D – you produce this if you get good amount of sunshine – probiotics, vitamin C, and other natural options. We can also be careful to wash our hands properly and even use a face mask when appropriate.

We found a significant reduction in the rate of ILI among participants randomized to the face mask and hand hygiene intervention during the latter half of this study, ranging from 35% to 51% when compared with a control group that did not use face masks. Our results are consistent with a previous review of studies examining the effectiveness of mask use in reducing the transmission of respiratory viruses.[22]

There is plenty you can do to maintain your health and not get sick. If you do get sick then there are ways to help keep you from getting really sick. But is your local pharmacy or your doctor or the CDC going to tell to make sure you wash your hands, get plenty of sunlight, take lots of vitamin C and D, get proper rest, and the many other things to keep you from coming down with the flu or other illness? Don't hold your breath. Right now they believe in and push a mythical magic wand to keep you from getting the flu and that's not going to stop anytime soon.

Roman Bystrianyk is co-author of Dissolving Illusions: Disease, Vaccines and the Forgotten History which is available on <u>AMAZON</u>.

Notes

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