

## Oxford Study--No Evidence Flu Vaccine works in infants

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USA and Canada's influenza vaccination programmes for children based on little evidence: The Lancet review of all relevant trials published last winter by Dr. Jefferson and colleagues found no evidence to support the CDC position.

<http://www.admin.ox.ac.uk/po/050225a.shtml>

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Children in the USA and Canada are being vaccinated against influenza without adequate proof that it will work, concludes a study by researchers in Oxford and Italy published in this week's issue of The Lancet.

Most immunisation campaigns target people aged 65 years or older. However, the USA and Canada have recently started vaccinating children, including those aged 6&ndash;24 months.

In their review of the evidence, the researchers found that there are no published trials supporting the view that vaccination offers protection against influenza to healthy children under two years old. 'We just cannot understand how you can vaccinate millions of small children in the absence of convincing scientific evidence that the vaccines make any difference,' commented Dr Tom Jefferson of Cochrane Vaccines Field, Italy, lead author of the review.

The aim of the USA and Canada in vaccinating children is to reduce disease spread; admissions and visits to hospitals; deaths of elderly relatives; complications (such as ear infections and pneumonia); absences from school; parental loss of workdays; and over-prescribing of antibiotics. However, there is no evidence that vaccinating children can achieve these goals.

Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present there is no convincing data to suggest that vaccines can reduce mortality, hospital admissions, serious complications and community transmission of influenza. There was some evidence suggesting vaccines can reduce school absences.

Sue Smith and Anthony Harnden in the Department of Primary Health Care in Oxford and colleagues in Italy identified and assessed 25 comparative studies that evaluated the efficacy (reduction in laboratory-confirmed cases) and effectiveness (reduction in symptomatic cases) on influenza vaccines in healthy children aged 16 years or younger. Vaccines of live viruses with weakened infectivity had 79% efficacy and 38% effectiveness in children older than two years compared with placebo or no immunisation. Inactivated vaccines had a lower efficacy (65%) than live weakened vaccines, and in children aged two years or younger they had similar effects to placebo. Effectiveness of inactivated vaccines was about 28% in children older than two years.

Vaccines were effective in reducing long school absences, but had little effect on other outcomes such as hospital stays and lower respiratory tract disease, when compared with placebo or no intervention. However, the authors note that these conclusions are based on a small number of studies.

Dr Jefferson concludes: 'We have identified a large dataset showing reasonable quality evidence of efficacy of influenza vaccines in children age two years or older, especially for two-dose live attenuated vaccines. However, we noted a striking difference between efficacy and effectiveness of vaccines, because of the large proportion of influenza-like illness caused by agents other than influenza viruses. This is an important point in the decision to immunise whole populations.

'Immunisation of very young children is not lent support by our findings. Although a growing body of evidence shows effect of influenza on admissions and deaths of children, we recorded no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications and community transmission of influenza.'

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\* 'Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review', by T Jefferson, S Smith, V Demicheli, A Harnden, A Rivetti, Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, and C Di Pietrantonj appears in The Lancet on 25 February 2005.

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<http://www.medicalconsumers.org/pages/SafetyofFlueVaccineinKids.html>

## Safety of Flu Vaccine in Kids in Doubt

Last winter, researchers found that influenza vaccines provide no benefit to babies under age two years. In children over the age of two, vaccines showed a modest reduction in cases of influenza. But there is no evidence that vaccines can prevent the serious complications that are the primary justification for vaccinating children. That was the conclusion of a review of all relevant studies published last February in the British journal, *Lancet*.

The authors of this review, Tom Jefferson, MD, and colleagues at the Cochrane Collaboration, recently wrote a follow-up in a letter to the editor of *The Lancet*. They reported that the safety of influenza vaccines given to babies and children is unknown. Incredibly, most of the trials they reviewed were not designed to assess serious adverse reactions.

Given the fact that the U.S. and Canada now recommend flu vaccines for all children older than six months, this news is extremely disturbing. The review published last winter focused solely on the question of how well flu vaccines work for children over six months. After the review was published, Dr. Jefferson and colleagues took on the equally important question of vaccine safety.

At issue are two types of vaccines: inactivated and live attenuated (nasal spray). Where it concerned the inactivated vaccine, the research on safety was pitiful. Only one trial exists; it was small (35 participants) and conducted 30 years ago. All other safety studies of inactivated vaccine were in children three years or older. When the reviewers looked at safety studies of the live attenuated vaccine, Dr. Jefferson explained in an e-mail interview, "We found clear evidence of systematic suppression (non-reporting) of safety data." Worse, he said that the authors of the trials did not have access to safety data from their own trials! "Do U.S. parents know all this?" asked Dr. Jefferson, "I do not think so."

One trial in this review stood out from the rest. With 10,000 participants, it included a chart showing a nearly double number of "medical adverse events" among the vaccinated kids, compared with the unvaccinated. When Dr. Jefferson and colleagues noticed that fewer than half of these events had been adequately identified, they wrote to request the missing data, first from the lead author and then from the final authority, the vaccine manufacturer MedImmune. The company's response: "MedImmune does not provide safety data to outside parties."

Noting that serious omissions like this are common, Dr. Jefferson and colleagues wrote, "An incomplete or fragmented evidence base could hinder identifications of rare and serious adverse events."

The U.S. Centers for Disease Control and Prevention, known as the CDC, is the most influential promoter of vaccinations for children (and everyone else). Presently, flu vaccines for babies and children are recommended; they are not mandated, as are other childhood vaccinations. At the CDC Web site, you will find no cautions regarding the missing information about the safety of vaccines for children. Nor will you find any evidence that the agency is aware of the review published last winter by Dr. Jefferson and colleagues. The CDC Web site's main message: "The single best way to protect against the flu is to get vaccinated each fall." And babies 6-23 months are listed as one of the priority groups for flu vaccines.

"Their rate of influenza-related hospitalization is similar to that of people 65 and older," warned Carolyn Buxton Bridges, MD, medical epidemiologist in the CDC's National Immunization Program. By e-mail, Dr. Bridges was asked for proof that flu vaccines reduce the rate of hospitalization in babies 6-23 months. "I fully acknowledge that the number of randomized studies is very limited and none published to date have evaluated the benefits of the vaccine in terms of preventing influenza hospitalization. However, ample data exists that the vaccine prevents laboratory confirmed influenza in young children 6-23 months. And, if you prevent the initial infection, you would also prevent the complications that would follow the infection."

Consumer advocate Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center, has a different perspective. "Children these days get so many vaccines that they almost always get them together on the same day. Use of the flu vaccine in combination with other childhood vaccines in babies this young amounts to a national medical experiment on American babies. The science should precede the policy and not the other way around."

Dr. Bridges was asked whether the CDC will warn parents about the lack of safety data and the fact that some vaccine companies refused to release their data to Dr. Jefferson and colleagues. She partially addressed only the second half of the e-mailed question. "As to why the researchers [sic: vaccine companies] will not share their data with Dr. Jefferson, I cannot comment."

As for proof of safety Dr. Bridges points to 40 years of vaccine usage and the Vaccine Adverse Event Reporting System, established in 1990, under the joint administration of the CDC and the FDA. (The CDC's own assessment of VAERS in 2003 found, "multiple limitations" to be associated with this "passive surveillance system [in which] reports of events are voluntarily submitted by those who experience them, their caregivers, or others." Underreporting and unconfirmed diagnoses are the major problems. )

Dr. Jefferson identified the problem in using the CDC as a credible source of advice, though it is the one used most frequently by the media. "The CDC, which should have a neutral public health role, is in fact a vaccine advocate, with all the good and bad things that that entails."

#### Bottom Line

The Lancet review of all relevant trials published last winter by Dr. Jefferson and colleagues found no evidence to support the CDC position. Asked to summarize the findings of this review, which was published as the 2004/05 flu season was just about over, Dr. Jefferson responded, "Our review showed that influenza vaccines below the age of two have the same effects as placebo. Beyond the age of two, they may be effective in preventing cases of influenza, but we found no evidence that they could prevent serious outcomes (death, hospitalization, pneumonia etc)."

The CDC's Dr. Bridges conceded that there is, as yet, no proof that flu vaccines will reduce the rate of serious complications in young children. Due to incomplete reporting of adverse reactions to influenza vaccines in clinical trials involving children, safety questions remain unanswered.

Maryann Napoli, Center for Medical Consumers (c), October 2005