

# STUDIES FAIL TO DEMONSTRATE SAFETY OR EFFECTIVENESS OF INFLUENZA VACCINE

An independent analysis by the internationally renowned Cochrane Collaboration of worldwide influenza vaccine studies, published in the **British Medical Journal on Oct. 28, 2006**, concluded **there is little scientific proof that inactivated influenza vaccine is safe and effective for children and adults.**

Citing the Cochrane Collaboration finding as well as methodological flaws in a child influenza vaccine study published Oct. 25 in the Journal of the American Medical Association (JAMA), the National Vaccine Information Center (NVIC) called on the Centers for Disease Control (CDC) to stop recommending annual flu shots for all infants and children **until methodologically sound studies are conducted.**

"There is a big gap between policies promoting annual influenza vaccinations for most children and adults and supporting scientific evidence," said epidemiologist Tom Jefferson, Cochrane Vaccines Field, Rome, Italy, who coordinated the comprehensive analysis for the prestigious Cochrane Collaboration. "Given the significant resources involved in annual mass influenza campaigns, there is urgent need for re-evaluation of these strategies."

The Cochrane Collaboration analysis found that the majority of published influenza vaccine studies were methodologically flawed with selection biases, confounders and heavy reliance on non-randomized studies. The report points out that **potential confusion between respiratory infections caused by influenza viruses and those caused by non-influenza viruses can result in misdiagnosis and gross overestimation of the true impact of influenza on death and illness in a given influenza season.**

The report concluded that too few clinical trials have been conducted to prove vaccine safety and current evidence indicates that use of inactivated influenza vaccine has only a modest or no effect on preventing influenza in the children and the elderly.

"The CDC has pushed mass use of influenza vaccine in all children without scientific evidence the policy is either necessary or safe," said NVIC President Barbara Loe Fisher. "Where is the good science to back up the policy? **If the recently published CDC-funded influenza vaccine study in JAMA is the kind of flawed science public health officials are using to convince the public the vaccine is safe, it is no wonder that many parents don't trust what public health officials say about vaccination. The CDC should stop recommending annual influenza vaccination of all young children when there is insufficient scientific justification for it.**"

The JAMA study, which was conducted by Kaiser Permanente doctors with CDC funding, was a non-randomized retrospective analysis of the medical records of children 6 to 23 months old who were given influenza vaccine as well as other vaccines between 1991 and 2003.

Vaccines were not randomly administered and unvaccinated controls were not used.

Children's case histories were included in the study only if an HMO doctor had seen them within 14 days of influenza vaccination.

Dozens of convulsions and other adverse events, including brain injury experienced by children after vaccination, were excluded from the study if the children had not been seen by a doctor within 14 days of the adverse event or were sick in the weeks before and after vaccination.

Because of **arbitrarily chosen cut-off periods, adverse events which occurred before and after different observation times cancelled each other out and were not classified as vaccine-related. In some cases,**

**convulsions and cases of Guillain Barre Syndrome were dismissed as "coincidental" or caused by other vaccines the children received by the 19 Kaiser Permanente and CDC authors—nine of whom reported financial ties to flu vaccine manufacturers and all of whom received CDC funding.**

"Vaccine studies are using increasingly complex statistical techniques rather than time-tested research designs," said NVIC Health Policy Analyst Vicky Debold, R.N., Ph.D. "The JAMA study is exactly the type of study criticized by the Cochrane Collaboration. There were so many limitations and exclusions in the study design that it is nearly impossible to interpret or replicate the findings. The true effect of the influenza vaccine on health outcomes cannot be identified in this single, flawed study, which should not be used as evidence that influenza vaccine is safe for infants and toddlers or to justify national vaccine policies."

**The Cochrane Collaboration**, which maintains the Cochrane Library and **is the world's leading producer of systematic reviews of scientific information about health care**, is a UK registered international charity. **Cochrane reviews are considered the gold standard for determining the effectiveness of health care interventions.**

The National Vaccine Information Center ([www.nvic.org](http://www.nvic.org)) is a non-profit, educational organization founded in 1982 and is dedicated to preventing vaccine injuries and deaths through public education and defending the informed consent ethic.