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## **FOR IMMEDIATE RELEASE**

### **FEW HEALTH PROBLEMS ARE CAUSED BY VACCINES, IOM REPORT FINDS**

WASHINGTON — An analysis of more than 1,000 research articles concluded that few health problems are caused by or clearly associated with vaccines. A committee of experts convened by the Institute of Medicine to review the scientific literature on possible adverse effects of vaccines found convincing evidence of 14 health outcomes -- including seizures, inflammation of the brain, and fainting -- that can be caused by certain vaccines, although these outcomes occur rarely. It also found indicative though less clear data on associations between specific vaccines and four other effects, such as allergic reactions and temporary joint pain. In addition, the evidence shows there are no links between immunization and some serious conditions that have raised concerns, including Type 1 diabetes and autism. The data were inadequate to reach conclusions about other suggested adverse effects.

The review will help the U.S. Department of Health and Human Services (HHS) administer the Vaccine Injury Compensation Program (VICP). VICP is committed to using science-based evidence to inform its decisions about vaccine-related adverse effects, and HHS turned to IOM to provide a comprehensive review of study results on eight vaccines covered by the program. The report's findings will be useful to all stakeholders involved in vaccine compensation decisions, including VICP staff, people filing claims, special masters that rule on vaccine cases, and others.

Convincing evidence shows that the measles-mumps-rubella (MMR) vaccine can lead to fever-triggered seizures in some individuals, although these effects are almost always without long-term consequences, the report says. The MMR vaccine also can produce a rare form of brain inflammation in some people with severe immune system deficiencies. In a minority of patients, the varicella vaccine against chickenpox can induce brain swelling, pneumonia, hepatitis, meningitis, shingles, and chickenpox in immunocompromised patients as well as some who apparently have competent immune function, the committee found. The majority of these problems have occurred in individuals with immunodeficiencies, which increase individuals' susceptibility to the live viruses used in MMR and varicella. Six vaccines -- MMR, varicella, influenza, hepatitis B, meningococcal, and the tetanus-containing vaccines -- can trigger anaphylaxis, an allergic reaction that appears shortly after injection. And, in general, the injection of vaccines can trigger fainting and inflammation of the shoulder, the committee noted.

The evidence suggests that certain vaccines can lead to four other adverse effects, although the data on these links are not as convincing, the report says. The MMR vaccine appears to trigger short-term joint pain in some women and children. Some people can experience anaphylaxis after receiving the HPV vaccine. And certain influenza vaccines used abroad have resulted in a mild, temporary oculo-respiratory syndrome characterized by conjunctivitis, facial swelling, and mild respiratory symptoms.

The committee's review also concluded that certain vaccines are not linked to four specific conditions. The MMR vaccine and diphtheria-tetanus-acellular pertussis (DTaP) do not cause Type 1 diabetes, and the MMR vaccine does not cause autism, according to the results of several studies. The evidence shows that the flu shot does not cause Bell's palsy or exacerbate asthma. Suggestions that vaccines can lead to these serious health problems have contributed to parental concerns about immunization for their children.

Establishing a cause-and-effect relationship between an agent and a health outcome requires solid evidence. The committee's conclusions are based on the strengths and weaknesses of several types of evidence, including biological, clinical, and epidemiological research. In many cases of suggested vaccine-related adverse outcomes, there is too little evidence, or the available evidence offers conflicting results or is otherwise inadequate to draw conclusions.

"With the start of the new school year, it's time to ensure that children are up to date on their immunizations, making this report's findings about the safety of these eight vaccines particularly timely," said committee chair Ellen Wright Clayton, professor of pediatrics and law, and director, Center for Biomedical Ethics and Society,

Vanderbilt University, Nashville, Tenn. "The findings should be reassuring to parents that few health problems are clearly connected to immunizations, and these effects occur relatively rarely. And repeated study has made clear that some health problems are not caused by vaccines."

In accordance with its charge, the committee focused solely on findings about potential risks of immunizations. It did not examine information that would have allowed it to draw conclusions about the ratio of benefits to risks. However, the committee members noted that deaths and disability due to infectious diseases have been dramatically reduced over the last century since the majority of vaccines were developed and brought into widespread use.

The study was sponsored by the U.S. Department of Health and Human Services. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. For more information, visit <http://national-academies.org> or <http://iom.edu>. A committee roster follows.

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Additional resources:

[Full Report \(http://www.nap.edu/catalog.php?record\\_id=13164\)](http://www.nap.edu/catalog.php?record_id=13164)

[Project Website \(http://www.iom.edu/Activities/Research/VaccineAdvEffectReview.aspx\)](http://www.iom.edu/Activities/Research/VaccineAdvEffectReview.aspx)

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Pre-publication copies of Adverse Effects of Vaccines: Evidence and Causality are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>. Additional information is at <http://www.iom.edu/vaccineadverseeffects>. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above).

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