

# Combining Childhood Vaccines at One Visit Is Not Safe

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## ABSTRACT

Although health authorities including the Centers for Disease Control and Prevention (CDC) claim that childhood vaccines are safe and recommend combining multiple vaccines during one visit, a review of data from the Vaccine Adverse Event Reporting System (VAERS) shows a dose-dependent association between the number of vaccines administered simultaneously and the likelihood of hospitalization or death for an adverse reaction. Additionally, younger age at the time of the adverse reaction is associated with a higher risk of hospitalization or death.

## Background

In the 1980s vaccine manufacturers were frequently sued by the parents of children who were permanently disabled or died following vaccination. After paying out millions of dollars in these lawsuits, vaccine manufacturers were prepared to stop producing vaccines unless the federal government provided them with immunity from jury verdicts.

In response to pharmaceutical manufacturers' threat to close their own vaccine factories, in 1986 Congress passed the National Childhood Vaccine Injury Act (NCVIA), protecting vaccine manufacturers from most financial liability associated with their products. Under NCVIA, the National Vaccine Injury Compensation Program (VICP) was created to provide cost-effective arbitration for vaccine injury claims. Vaccine manufacturers can no longer be sued in a state or federal court for damages arising from a vaccine-related injury or death unless a petition for compensation under the new program is filed and denied.

Compensation under the program is paid for by a 75-cent excise tax on every vaccine purchased. (MMR contains three vaccines, so the tax is \$2.25.) The money goes into a Trust Fund managed by the U.S. Department of the Treasury. As of Mar 1, 2016, more than \$3.2 billion had already been paid out, most of it to compensate parents whose children were severely disabled or died after receiving vaccines.<sup>1</sup> Today, vaccine manufacturers not only make millions of dollars annually from their lucrative business, but they have been disincentivized from producing safer vaccines, since they are shielded from liability when their mandatory products harm consumers.

## Vaccine Adverse Event Reporting System (VAERS)

The new federal law also required medical workers to report suspected vaccine reactions to a centralized reporting system. As a result, the Vaccine Adverse Event Reporting System (VAERS), jointly operated by CDC and the U.S. Food and Drug Administration (FDA), was established in 1990. VAERS is a national vaccine safety surveillance program that collects information about possible adverse reactions to vaccines. This large database is accessible to the general public, including independent researchers who may use it to look for patterns in the data that might indicate vaccine safety concerns or problems.<sup>2</sup>

VAERS is a passive surveillance system, which means that reports about adverse events are not automatically collected. VAERS relies on doctors and nurses to voluntarily submit reports, although vaccine recipients and parents may also file reports. Vaccine manufacturers are required to report all adverse events of which they become aware. Since 1990, the VAERS database has received more than 500,000 reports of suspected adverse reactions to vaccines. Although this represents a large number of people who may have been hurt by vaccines, under-reporting is a known limitation of passive surveillance systems. This means that VAERS only captures a small fraction of actual adverse events. In fact, shortly after VAERS was established, a large vaccine manufacturer, Connaught Laboratories, estimated "about a 50-fold under-reporting of adverse events in the passive reporting system."<sup>3</sup> Perhaps 98% of all adverse reactions to vaccines are not included in the VAERS database, and up to 25 million U.S. citizens could have been adversely affected by vaccines in the past 25 years. This well-known disadvantage of a passive reporting system, as opposed to an active surveillance system in which medical workers are trained to systematically collect all cases of suspected adverse vaccine reactions, is rarely acknowledged by health authorities when vaccine safety is discussed.

Although VAERS collects information about adverse events that occur after vaccines are administered, it should be noted that a report is not a confirmation that a vaccine caused the event. Health authorities like to emphasize this point whenever VAERS data are used in a study with findings that are critical of vaccines. The implication is that studies using VAERS are unreliable and should be disregarded. However, CDC considers VAERS an important vaccine safety assessment tool and regularly conducts its own studies using VAERS data, often to justify maintaining national vaccination campaigns.

## CDC Studies Utilizing VAERS

In May 2015, the CDC published a study in *Clinical Infectious Diseases* that analyzed the VAERS database for reports of serious adverse events after MMR vaccination in adults. CDC researchers found that the vaccine was often administered to pregnant women, a group in whom the vaccine is contraindicated, "suggesting the need for continued provider education on vaccine recommendations and screening." Although 5% of reports were serious, including several deaths, CDC researchers concluded that "in our review of VAERS data, we did not detect any new or unexpected safety concerns for MMR vaccination in adults."<sup>4</sup>

In November 2014, CDC published a study in the journal *Vaccine* that analyzed VAERS reports associated with the live attenuated influenza vaccine (LAIV3). Although 8.9% of reports were classified as serious (e.g., cardiovascular events, neurological debilities, and fatalities) CDC researchers concluded that "review of VAERS reports are reassuring, the only unexpected safety concern for LAIV3 identified was a higher than expected number of Guillain-Barré syndrome reports in the Department of Defense population, which is being investigated [*sic*]."<sup>5</sup>