

Press Release

Rise in shingles cases linked to universal varicella vaccination program

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The results of a new study published in the October 1, 2003, issue of the European journal *Vaccine* indicate that a higher than expected number of shingles cases was reported among children with a previous history of chickenpox. The rates observed approach those normally seen only in older adults. Results of the study suggest mass vaccination with varicella (chickenpox) vaccine may be responsible for this adverse effect. Complications from shingles, which is caused by the reactivation of the chickenpox virus that lies dormant in the body, result in about three times the number of hospitalizations and five times the number of deaths than those from chickenpox disease itself. Shingles, usually mild in children, can be severe in adults.

On March 17, 1995, the U.S. Food and Drug Administration (FDA) approved the live varicella vaccine, and shortly thereafter 38 states mandated that every infant be inoculated at twelve months of age. The CDC-funded Varicella Active Surveillance Project (VASP) of the Los Angeles County Department of Health Services was established to study trends in varicella disease among the 300,000 residents in the Antelope Valley health district. Because this high desert community, including the primary cities of Lancaster and Palmdale, is geographically distinct with few individuals seeking healthcare outside the region, it is nearly ideal for scientists to detect preliminary disease trends.

Because the vaccine is eliminating chickenpox disease, children and adults no longer receive the natural boost to their immune systems that they used to receive from periodic exposures to the disease. Due to the dramatic decline in chickenpox, children that have had a previous history of natural chickenpox are now experiencing a higher incidence of shingles.

To compensate for this, vaccine manufacturers plan to license a booster "shingles" vaccine to substitute for the natural boost in immunity that occurred when chickenpox disease was previously circulating in the population. There are serious doubts about the effectiveness of this approach to the impending problem. Universal varicella vaccination will likely lead to endless disease-and-cure cycles and would have been less problematic if all healthy children had the opportunity to gain natural immunity—with only those still susceptible at twelve years-of-age targeted for vaccination.

Previous research shows that Japanese pediatricians who were exposed to patients with chickenpox demonstrated shingles incidence rates that were one-half to one-eighth the rates

of the general population. In 2002, researchers in England and Wales also found a lower incidence of shingles among adults living with children compared to those living without children.

According to a spokesperson from the FDA, "There is no legal precedent requiring a vaccine manufacturer to perform studies on individuals who have not received their product." However, to assess the safety of chickenpox vaccine, continued study of the effect of widespread vaccination on increasing shingles incidence is critical. It is hoped that this new study will encourage other investigators to examine shingles rates not only among vaccine recipients, but also among adults who have not received varicella vaccine.

If a clear vaccine-associated increase in shingles is confirmed in further studies in broader populations, this should be considered by public health authorities in evaluating vaccine use strategies.

For more information on the current study, see the three reports published on 18 consecutive pages in *Vaccine* (Volume 21, Issue 27-30).

Manuscripts authored by Gary S. Goldman contribute these important ideas:

- Exogenous (outside) re-exposures to natural varicella play a significant role in boosting CMI to VZV to help suppress the reactivation of HZ (shingles) in children with a previous history of natural varicella.
- Children aged <10 years may be more sensitive to exogenous boosting than older individuals and adults.
- Since HZ increased by 18.6% from 2000 to 2001 in adults in every age category (20 to 29; 30 to 39; 40 to 49, through 60 to 69) in the Antelope Valley (population approximately 300,000), with the greatest increase among young adults who previously received the most exogenous boosts, HZ incidence may be increasing as CMI to VZV wanes due to universal varicella vaccination of children. Additional years of observation and data from broader populations are necessary.
- Health departments that (1) analyze HZ data without taking into account reporting completeness of cases and (2) present HZ incidence rates as an average or mean rate among vaccinated and unvaccinated cohorts, derive results that mask the deleterious effects of vaccination—giving a false impression HZ incidence has been decreasing when, in fact, incidence among chil-

dren with a previous history of natural disease is approaching the high rates seen among older adults.

- The high crude HZ incidence rate among children aged <10 years seven years post-licensure will resolve shortly and will be less of an issue—especially as children with natural varicella are replaced by vaccinated children.
- There is a question of ethics when universal vaccination of healthy children causes increased HZ incidence among adults who have not been informed of the outcome of increased shingles, nor have they agreed to suffer the increased burden of shingles disease.
- Other studies corroborate an increase in shingles among adults that will last 30 to 50 years, until the adult population dies out. Since 76% of Varicella Zoster Virus (VZV) disease is attributed to shingles (not varicella), instead of the savings projected for universal varicella vaccination, there will be a large deficit of medical and societal costs for many years.
- An intervention consisting of supplying a booster vaccine to adults 60 years and older may reduce incidence of HZ in the elderly. This does not ameliorate the increase that will occur among individuals aged 10 to 59. Medical costs to vaccinate the entire adult population are approximately five times the cost of treating the natural disease in the prelicensure era.
- It may be too late to revert back to the boosting that occurred naturally when wild-type varicella was prevalent in the community.
- Vaccinating children that are still susceptible at the age of 12 years would have been less problematic.
- Shingles disease tends to be mild in children and increases in severity with age.
- Shingles results in three times the number of hospitalizations and five times the number of fatalities as varicella.