MEDICAL INNOVATION: CHICKENPOX VACCINE (PHARMACEUTICAL: BIOLOGICALS)

Physician: Michiaki Takahashi, M.D., D.M.Sc., professor emeritus of Osaka University Organization: National Institute of Allergy and Infectious Diseases (NIAID) Industry: Merck

Situation

Four million cases each year

Chickenpox (Varicella) is an infection caused by the varicella-zoster virus (VZV). The infection usually starts as a rash on the face that spreads to the rest of the body, beginning as red bumps that eventually become blisters. A child will often get 300 to 500 blisters during the infection, which crust over and fall off in one to two weeks. The virus can be spread in the fluid from the blisters or droplets from an infected person's nose or throat.

Chickenpox is most often a mild disease, especially for children. Prior to the introduction of vaccine in 1995 in the U.S., <u>there were around 4,000,000 cases per year nationally</u>, mostly children, with typically 100 or fewer deaths. Though mostly children caught it, the majority of deaths (by as much as 80%) were among adults. Additionally, <u>chickenpox involved the hospitalization of about 10,000 people each year</u>.

Physician-Industry Collaboration

Convening a workshop of scientists toward a cure

<u>According to the VZV Foundation</u>: In 1964, during his research fellowship at Baylor Medical College in Houston, Michiaki Takahashi, M.D., D.M.Sc., recalls that his three-year-old son was suffering from a severe case of chickenpox. He remembers asking himself, 'What if chickenpox could be prevented by a vaccine?" Eight years later, Dr. Takahashi began development of a live chickenpox vaccine.

After serving as a Research Fellow at Baylor and, later, Temple University in Philadelphia, he returned to Osaka University to study cellular transformation in a number of viruses. In conjunction with these studies, he collaborated on the development of a live mumps and rubella vaccine. He then began working on a vaccine for chickenpox, one of the most difficult viruses to study because of its poor virus yield and susceptibility to heat. However, Dr. Takahashi overcame these difficulties and developed a preliminary vaccine in 1974, with the collaboration of many pediatric researchers in Japan.

In the late 1970s, development and use of the vaccine in the U.S. was controversial. However, after a number of subsequent favorable studies were produced in Japan, leaders of the National Institute of Allergy and Infectious Diseases (NIAID) decided to convene a workshop of scientists and vaccine producers from the U.S., Japan and Europe in February 1979 to study its mass production and fielding in the U.S., principally working with Merck and Co.

This led to Merck's production and fielding of a live attenuated chickenpox vaccine known by the trade name Varivax, which was submitted to the U.S. Food and Drug Administration for approval in 1990 and approved in 1995. Since then, it has been added to the recommended vaccination schedules for children in the U.S., Australia and several other countries. Vaccine coverage among children in the U.S now stands at over 90%.

Innovation Benefits

A 66% decrease in hospital visits

<u>Currently, over 40 states require immunization for children attending government-run schools,</u> and, as a result, outbreaks of chickenpox are virtually unheard of in the U.S. – <u>down to the tens</u> of thousands from 4 million before the prevalence of the vaccine. <u>Chickenpox-related hospital</u> visits have decreased by as much as 66% since before the vaccine was available, as well.

Also, cost-benefit studies of the chickenpox vaccine that include both direct medical costs and the indirect cost of a parent's lost wages in caring for a sick child, show that there would be a return of <u>\$5.40 in benefits for every dollar spent on the preventive measure</u>.

Patient Benefits

"The vaccine was a godsend"

Mary F. from San Antonio had a terrible case of chickenpox when she was young, requiring hospitalization for several days. Given her experience, she feared a similar reaction would happen with her two sons, and dreaded their catching it from their classmates once they began going to school.

With the vaccine coming on the market in the late 1990s, Mary was able to vaccinate her young sons before they ever caught it, possibly preventing them from experiencing a reaction as bad as hers.

"The development of the vaccine was a godsend," she said. "I am so glad my sons won't have to go through what I did...I just wish we had the vaccine when I was growing up!"