MEDICAL INNOVATION: HAEMOPHILUS INFLUENZA TYPE B (HIB) VACCINE (PHARMACEUTICAL: BIOLOGICALS)

Physicians: Porter Warren Anderson, David Hamilton Smith, John Robbins, Rachel Schneerson Industry: Praxis Biologics

Situation

A principal cause of meningitis and pneumonia in children

Haemophilus Influenza Type B, or Hib, is a bacterium that historically has been one of the principal causes of bacterial meningitis and pneumonia in children under five years of age. Spread through exhaled droplets, <u>Hib is responsible for some 3 million serious illnesses, and over 375,000 deaths</u>, in children each year worldwide <u>according to the World Health</u> <u>Organization (WHO)</u>.

Before a vaccine was developed, Hib was responsible for 20,000 serious illnesses in children annually in the U.S., 1,000 of whom would die from their condition, and another 6,000 of whom would be left with long-term disabilities such as mental retardation, deafness and learning disabilities. <u>Hib was the leading cause of acquired mental retardation nationally, and the treatment of Hib-related illnesses cost the U.S. health care system over \$2 billion each year.</u>

Physician-Industry Collaboration

An independent but collaborative pursuit of a vaccine

Beginning in 1968, two teams of researchers worked independently to leverage modern approaches to bacterial vaccine development toward developing an effective vaccine against Hib. Porter Warren Anderson and David Hamilton Smith of Harvard, and John Robbins and Rachel Schneerson of the National Institute of Child Health and Human Development (NICHD) independently but often collaboratively studied the biology and epidemiology of Hib and how it worked in the body to produce serious diseases in children.

Both teams zeroed in on the goal of producing a vaccine that would target a simple sugar molecule on the Hib bacterium, and, ultimately, on bringing such a vaccine to market. To that end, after a series of promising research successes on the part of both groups, Dr. Smith decided to form a company, Praxis Biologics, for the purposes of building on the scientific formulas for a sugar-targeting vaccine. <u>Two years later, in 1985, they received approval from the FDA to market the first Hib vaccine for adults and children over the age of two.</u>

As effective as the so-called polysaccharide vaccine was in these two groups, it did not work well in infants and very young children, who were especially vulnerable to Hib-related diseases. Fortunately, <u>Dr. Robbins and Dr. Schneerson were able to solve that problem by linking a "weak" polysaccharide to a simple protein to form an effective so-called "conjugate" vaccine that was more easily recognized by the bodies of infants and younger children.</u>

In recognition of their collective breakthroughs in cracking the code behind Hib, all four doctors were jointly awarded the prestigious <u>Albert Lasker Award for Clinical Research in 1996</u>.

Innovation Benefits

Hib-related infections rarely seen today

Very soon after its development and licensing in the U.S., the Hib vaccine became an important addition to the standard regimen of vaccines for infants and children in the U.S., Canada, Western Europe and elsewhere in the developed world, virtually eliminating the instance of Hib-related meningitis in those countries.

In the United States alone, the instance of Hib-related meningitis and other diseases has been reduced by 99%, such that Hib-related infections are rarely seen today. Though appreciably more expensive than other childhood vaccinations, the conjugate Hib vaccine is now recommended by the WHO for universal use in its Expanded Program on Immunization.

Patient Benefits

A near brush with the death of their son

The advocacy group <u>Parents of Kids with Infectious Diseases</u> relates a moving <u>testimonial</u> about an anonymous family's near brush with the death of their son, as told by his parents:

"A few years ago, our son Matthew — he was three-years-old at the time — complained that he had a pain in his neck. We thought maybe he was developing strep. He had a really high fever and he was sort of like hunched over, and at that point we took him just to the local hospital.

"The pediatric doctor that we were able to get was an older doctor who had been around, and he asked us a really important question: 'Was your son vaccinated?' And at the time, he wasn't.

"[The doctor] thought he knew what it was. He said he wasn't positive, but he would know within minutes. He then ordered some x-rays. The x-rays confirmed that he did have Hib disease. Matthew's windpipe was closing up quickly."

"<u>He said that your son is going to die within minutes</u>. And he said 'Quite honestly, we're not in a situation —in this particular hospital— that we're prepared to help him.'

"They had prepared two separate rooms with crash carts, and he was telling the nurses and the staff there that we need to be prepared: 'This child, you know, more than likely, is going to die.'

"Matthew was put into a slight coma, and it was touch-and-go for a few days. Each day, they would bring teams of physicians through to show them what kids were contracting without having vaccinations.

"<u>He spent six days in the hospital and then when we got him home from the hospital, we</u> definitely got him fully vaccinated.

"We had made a conscious decision not to vaccinate based on some information that we had at the time thinking that we were doing, you know, our best for Matthew. We didn't realize these diseases are still out there. We're very thankful to still have our son."