

Pneumococcal Vaccine

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A new pneumococcal vaccine has been released recently called Prevnar, which is designed to be given to the under 2 years age group. This should not be confused with Pneumovax, which is a pneumococcal vaccine for children over age 2 years and adults, which has been around for some years.

The Pneumococcus, or otherwise known as Streptococcus pneumoniae is a bacteria that in the USA, is claimed to cause 3,000 cases of meningitis, 50,000 cases of bacteraemia, 500,000 cases of pneumonia and 7 million cases of ear infection. A significant feature of the pneumococcus is that there are over 90 different serotypes, classified according to the antigens in the outer capsule.

There is no one common vaccine that covers all the pneumococci; the vaccine is a mixture of many vaccines against the individual serotypes that are considered clinically relevant. Prevnar covers only 7 serotypes (and is in reality 7 vaccines in one) while the adult pneumonia vaccine, Pneumovax, covers 23 types (23 vaccines in one). This is why they are so expensive. This is why some say that the manufacturer is pushing the vaccine because of the enormous profit that is expected to be made.

Here again, like the meningococcus, this bacteria is found as a commensal in the nasopharynx of about 30% healthy people. (Medical Microbiology Churchill Livingstone 1973). Most of the infections at the extremes of life seem to be endogenous infections, while those in older children and healthy adults are exogenous. In both of these instances, we can say that the breakdown of immune system function is the most likely cause of infection. (i.e. the soil not the seed.)

We have already discussed the reasons for immune system breakdown in a previous article. Here is another vaccine introduced recently and is being considered to be included into the schedule of "Routine Childhood Immunisations". Whereas in the USA immunisations have been made compulsory, Australia is still a free country, at least as far as the ability of parents to choose whether they want their children to be immunised.

What exactly is this vaccine supposed to prevent? I did mention earlier that the bacteria can cause meningitis, septicaemia, pneumonia and ear infections.

Note that meningitis and possibly the pneumonia is mainly an adult problem. Figures from the CDC Bulletin (Dept of Human Services South Australia May 2002 Vol 11, issue2, no 52) shows that in the first quarter of 2002 there were 16 cases of pneumococcal disease in metropolitan Adelaide. 5 (31% were in under age 1 year and 4 (25%) were in the age over 65.

How likely is your child to develop pneumococcal infection. Data from the manufacturer shows that in the over age 2 years the chance is about 1 in 5,000 of being diagnosed with pneumococcal infection. In the under age 2 years the figure is 7.5 in 5,000. The death rate is quoted as 1 in 178,571 children.

The Red Book Report on Infectious Diseases published by the American Academy of Pediatrics states that children with certain predisposing factors are prone to pneumococcus. These predisposing factors are immunoglobulin deficiencies, Hodgkin's disease, congenital or acquired immunodeficiency, nephrotic syndrome, some viral upper respiratory tract infections, splenic dysfunction, splenectomy and organ transplantation. Those with these conditions certainly cannot be considered normal healthy children, so why should normal healthy children be given the vaccine?

On one hand they say that the vaccine is needed to protect chronically ill children from pneumococcus, yet there is very little evidence that it is safe to use in that category of children.

Prevenar has only been about for a short time and therefore there are no long term studies. As a matter of fact, there are no long term studies of any of the vaccines. Most of the data that has been released is from the manufacturer and was done in conjunction with researchers with close financial ties with the manufacturer. There are few, if any independent studies. This situation reeks of conflict of interest.

The manufacturer has been encouraging the use of the vaccine to prevent ear infection. They try to justify this by saying that ear infections are common, yes, so far so good, and with the increasing incidence of bacterial resistance it is better to prevent ear infection with a vaccine than by treating it with stronger and stronger antibiotics. One quoted study (Kaiser Permanente News Release May 4 1999) showed only a 7% reduction! Yes 7%, nothing to really to jump up and down about! Another study published in NEJM 2001;344(6):403-9 says that the vaccine reduced the incidence of all causes of ear infection by 6%. Not really a great result. You must realise that not all ear infections are caused by pneumococcus. According to Dr Erdem Cantekin, Professor of Otolaryngology at the University of Pittsburg, 60% of all ear infections are viral and perhaps only 25% are due to the pneumococcus...and he says also that most ear infection settle down without antibiotics anyway.

The FDA in USA have only approved the vaccine for invasive cases but not for ear infections. So we can see that the indication the vaccine is approved for, i.e. invasive infection is principally an adult problem, not a childhood problem.

Even the adult version of the pneumococcus vaccine has doubtful efficacy. A study published in Lancet 1998 Feb 7;351(9100):399-403 concluded that the 23-valent pneumococcal polysaccharide vaccine did not prevent pneumonia overall or pneumococcal pneumonia in middle aged and elderly individuals.

The principle study that the FDA used to approve Prevenar was done by the manufacturer in conjunction with a HMO (Kaiser Permanente). The manufacturer, the principle investigators and the HMO all had financial ties and there would be a great risk of conflict of interest. The study had no placebo group and the control group was given another experimental meningococcal vaccine. So here we have a situation where one group of children vaccinated with an experimental vaccine was compared with another group of children vaccinated with another experimental vaccine.

The safety of this vaccine and, in fact, any vaccine has to be a major concern. According to the American Academy of Pediatrics, it is one of the most reacrogenic of vaccines, causing excessive numbers of local reactions. Prof Erdem Cantekin, says that the benefits are greatly exaggerated and the risks are significant. He says in one trial, the children who recieved the vaccine were 4 times more likely to have seizures and 4 times more likely to have stomach problems. He also says that more children in the Prevenar group developed asthma and there was 1 death in the Prevenar group. (Abstracted from a lecture by Prof Cantekin, Second International Vaccine Information Centre Conference Sep 9 2000, Washington DC). There is an added problem called Serotype drift which is the ability of the bacteria to shift and change its antigens. So if a large proportion of people are immunised, then the bacteria change, or even less clinically relevant serotypes now become more prominent and cause infections.

There is enough evidence, or should I say, lack of suitable evidence to show that the use of this vaccine in children is premature. The studies were inadequate, done by researchers with a conflict of interest and there have been little or no independant done by researchers with a conflict of interest and there have been little or no independant studies. If there be a vaccine that you don't give your child, let this be the one!!studies. If there be a vaccine that you don't give your child, let this be the one!!