## Acellular Whooping Cough Vaccine: Is it safe and effective?

In 1975, after a spate of 37 crib deaths linked to vaccination, Japanese doctors in one prefecture boycotted vaccination. The Japanese Government responded by lifting the vaccination age to 2 years. However, because there was continued concern about the safety of the whole-cell vaccine, they also developed a new, acellular vaccine which was hoped to be less reactogenic than the standard, whole-cell vaccine.

In 1981 Japan introduced a series of acellular vaccines (Kimura et al. 1991. AJDC; 145: 734) which were supposed to be less reactogenic. However, trials with 115 children ranging in age from about 3 to 23 months showed that local adverse reactions started about 7 days after the first, and 48 hours after the second, third and booster DPT injections containing the acellular pertussis vaccines. Practically every child had some form of local reaction. Noble et al. (Jama 1987; 257 (10): 1351) concluded that the incidence of more serious local reactions and high temperature may be more common after vaccination with acellular vaccines. They hoped that some questions regarding product-specific and age-specific efficacy may be answered by the then ongoing field trials of Japanese acellular vaccines begun in 1986 in Sweden.

In Japan, the acellular vaccines were quickly introduced into widespread use before characterization of pertussis antigen contained in the vaccine was completely known. At the time of their introduction, the only requirement of efficacy for Japanese acellular vaccines was their potency, determined by the intracerebral mouse protection test.

The 1986/1987 Swedish trial of two Japanese acellular vaccines ended in a fiasco: the efficacy of one vaccine was only 69% and of the other only 54%; Swedish health authorities withdrew their license application (Lancet 1989: 814).

In the meantime, other countries, including the United States continued the use of the whole-cell whooping cough vaccine. However, Pichichero et al. (1992. Pediatrics; 89(5): 882) published an evaluation of immunogenicity of and adverse reactions to a two-component acellular pertussis vaccine when given as a primary immunization series at 2, 4 and 6 months of age. They concluded that this acellular vaccine produced greater immunogenicity and fewer adverse effects than the currently licensed whole-cell vaccine. However, one only had to look at the number of withdrawals and the reasons for withdrawals of babies from the trial, to see that this statement was overly optimistic. 31 of the 380 children withdrew from the study and there was a high incidence of drowsiness and irritability in the recipients of both whole-cell and acellular vaccines and a higher than expected rate of unusual 'high-pitched' or 'cerebral cry' indicates great pain due to brain

inflammation. The total oblivion of these researchers to the encephalitogenic effects of the acellular vaccines administered to such young babies is quite incredible.

On the basis of this trial, the acellular vaccine was licensed in the US as a booster in older babies, after the 3 primary shots. The way pro-vaccinators advertising the acellular whooping cough vaccines write about them is quite astonishing and certainly revealing: "The National Institute of Child Health and Human Development said...that the new vaccine was about 71% effective in preventing whooping cough among 1,700 infants who were inoculated. A whooping cough, or pertussis vaccine, used in the United States since the 1940s contains a dead pertussis cell...But the vaccine also contains a toxin that in some infants can cause serious side effects...Some doctors claimed that the vaccine can cause brain damage and even death....More that \$487 million has been paid in compensation awards through the vaccine injury program" (Washington Press 1994).

In Australia the new acellular vaccine was tested on 5 and 6 year old children in Geelong (Victoria). Parents were told that it is a new formula, but side effects would only be mild. In reality half the recipients were absent from school for several days, and many were admitted in hospitals. Parents were outraged that their children were used as guinea pigs, so the Victora' Chief Health Officer published that it was not a new vaccine,"...it was in fact the same vaccine that has been given for a decade to younger children from the age of two months...reaction to the vaccine reported by parents was expected and the National Health and Medical Research Council's 1994 Immunization Handbook sent to all doctors (Note: not to parents, and, the doctors who got the handbook did not warn parents) throughout Australia listed possible side effects. These side effects which are listed on the consent form sent home with children by schools prior to vaccination, include localized pain, redness and swelling at the injection site and mild fever (38 degrees Celsius). Other possible side effects are that the child may become grizzly, unsettled and generally unhappy for 24 hours, plus also becoming drowsy." Commenting on high number of children becoming sick, the officer said: "This figure, we believe could reflect a parent's inexperience with this vaccine in this age child, who tends to make his feelings known more forcible than babies."

The reader should ask themselves what sort of reasoning is this. Just because tiny babies can not talk, their vaccine reactions are more acceptable than in the children who can talk and tell their parents how lousy they feel after being injected with?

Science News (1995; 48: 54) published an article "New pertussis vaccines safer, more effective". Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, which cosponsored the new vaccine trials, hailed the acellular

vaccine as "truly effective". "Current vaccines used in the United States contain whole, but inactive, bacteria that cause fever, swelling, fussiness and - very rarely neurological damage...some countries including Sweden and Italy don't require a pertussis vaccination." And "In the Swedish study, infants received a five-component or a two-component acellular vaccine, the standard whole-cell vaccine, or no vaccine. The five-component acellular vaccine gave 85% protection, while the two-component vaccine gave 58% protection. The Italian study tested two kinds of three-component acellular vaccines against the standard vaccine or no vaccine. Both acellular vaccines offered 84% protection. Surprisingly, the whole-cell vaccine offered no better than 48% protection. Fauci speculates that it performed poorly because the trials omitted boosters." Fauci advised parents to continue with the standard immunization schedule.

Get the picture? No country which considers itself to be democratic should ever force any medical procedure on its citizens. This is especially valid of vaccines, which are neither safe nor effective, but most of all, quite unnecessary. Infectious diseases of childhood are beneficial for children. They prime and mature the immune system of children and represent developmental milestones. Who with of a sound mind would try, no matter how unsuccessfully, to prevent children from developing normal immunological responses and reach developmental milestones?

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