

# **Federation of the European Academies of Medicine (FEAM)**

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## **REPORT ON THE SAFETY OF VACCINES SESSION AT THE CONFERENCE HELD BY FEAM IN CAMBRIDGE ON 5 JULY 2003**

### **1. Vaccine scares and vaccine safety** (by Professor Peter Lachmann FRS FMedSci, Emeritus Sheila Joan Smith Professor of Immunology, University of Cambridge)

Vaccination antedates by many years any knowledge of either microbiology or immunology; but most of the currently used vaccines were developed between 1920 and 1985. The impact of vaccination upon human mortality has been second only to that produced by the provision of clean water and adequate sewage disposal. Together they have produced a striking "squaring off" of the death curve so that it is now relatively unusual in western countries for people to die below the age of 60. The effectiveness of the vaccines now routinely used is very high with a reduction in incidence of disease of about 99% (compared to pre-vaccine peak incidence) for pertussis, measles, mumps and congenital rubella syndrome and polio. Vaccine safety is also remarkably high. Reported adverse effects, many of which are minor, amounted to only around 10,600 in 1995 for the whole of the United-States. The risk benefit ratio of all vaccines in current use is therefore enormously favourable. Nevertheless opposition to vaccination on safety grounds has existed since the time of Jenner. Current vaccine scares include:

- the association of pertussis vaccine with brain damage;
- the association of Hepatitis B vaccine with multiple sclerosis;
- the implication of polio vaccine with the origins of HIV;
- the association of MMR with autism and inflammatory bowel disease;
- the association of mercury used as a preservative in vaccines also with autism.

Possible reasons why these vaccine scares occur will be discussed. The factors that I regard as significant include:

- Because vaccine damaged children are real children their story can be told in the media while, on the other hand, vaccine saved children are merely statistics, which do not have a comparable emotional appeal.
- Some parents feel that if all other children are vaccinated the disease will not exist in their community and they therefore can have the benefit of vaccination without the risk.
- There are vocal and well financed groups who oppose vaccination on principle believing it to be an interference with the natural order.
- There is considerable confusion about and misuse of the so-called 'Precautionary Principle' based upon a failure to recognise that to cause harm by omission is not morally different from causing harm by commission.
- There is similar confusion about the distinction between absence of proof and proof of absence with regard to harmful effects.
- Finally, the media in the United Kingdom have a marked obsession with maverick science to which give far more attention than they do to mainstream science. This gives a prominent public platform for outrageous views that are given no credence by serious scientists.

Within Europe the legal requirements for vaccination are variable. In the United Kingdom all compulsory vaccination was abolished in 1948 whereas in France some vaccinations are still required to enter the public school system, as is also the case in the United States.

Special considerations apply to vaccination campaigns which are intended to eradicate disease. This is possible only for diseases where humans are an essential hosts. Vaccine eradicatable diseases include smallpox, polio, measles and malaria. Eradication of disease by vaccination requires whole populations to be vaccinated and this gives rise to significant problems with the requirements for individual consent. A particular example of this is the potential use of transmission blocking vaccines to eradicate malaria. Some people regard these vaccines as not giving individual benefit and it is unclear whether the political will exists to try to eradicate malaria in this way.

**RECOMMENDATIONS** (1) It is very important that the European Union maintains high levels of vaccine uptake for current vaccines and has a high state of preparedness to prepare vaccines for emerging infections. (2) Whether vaccinations should be truly voluntary or encouraged by financial or other sanctions for refusal to vaccinate is controversial and reflects differences between libertarian and utilitarian views of society.

## **2. Hepatitis B: universal vaccination and difficulties in France (by P. Bégué)**

From 1981 to 1994 in France, the Hepatitis B vaccine was recommended for high risk persons only. In 1994 following WHO recommendations, the French Health ministry set up a universal immunisation programme against Hepatitis B for infants and adolescents. A national mass immunisation campaign for 11-13 years old children was implemented in schools in 1995. Between 1995 and 1997, several cases of multiple sclerosis were reported in adults within a few weeks of vaccination. An association for 'victims' was then set up: REVAHB.

Case-control studies started in 1996 and the Agence française de sécurité sanitaire des produits de santé (AFSSAPS) was informed of CNS demyelinating disease cases; the results of the studies were then compared with data produced by REVAHB. In 1998, it was concluded that studies did not support a link between vaccination and CNS demyelinating disease. The studies reported an insignificant increase of relative risk: OR value from 1.4 to 1.7 for an IC 95%. In 2001 the ASCHERIO study in the US found a relative risk of 0.7 (95% CI(0.3-1.8)). In other parts, it was obvious from 1996 that in contrast with the objectives of the French immunisation policy young adults had been immunised on a large scale (17 million people), in a short time and at the peak age for developing multiple sclerosis.

In October 1998, the French Health Minister temporarily suspended the Hepatitis B programme in schools. Yet Hepatitis B immunisation was kept in the vaccination schedule and carried out on an individual basis privately or in hospitals. Doctors were informed of the Ministry's recommendation not to immunise patients with multiple sclerosis and to inquire about possible cases of CNS demyelinating disease in close relatives.

Allegations by the media and patients groups were made and compensation was obtained by some 'victims and healthcare workers' on the basis of the Precautionary Principle.

Other autoimmune diseases such as diabetes, SLE and rheumatic arthritis also attracted attention during this period. Macrophagic myofasciitis, a new disease imputable to vaccines

containing aluminium adjuvant, was also observed in France and could lead to the rejection of the Hepatitis B vaccine.

Consequently, the vaccination level has fallen dramatically in adolescents and remains under 30% for infants in spite of the recommendation by the French Health authorities to immunise infants. Parents are reluctant to immunise their children and a risk of late hepatic complications is expected in the future for those adolescents who have not been immunized. To this day there is no scientifically proven link between multiple sclerosis and Hepatitis B immunisation. Yet the cost/benefit ratio clearly supports vaccination. In France, for 800.000 immunised children and for a period of 20 years – even if the risks exist -, immunisation would avoid 3 fulminating hepatitis, 60 to 150 chronic hepatitis and 12 to 30 hepatocellular carcinomas (D. Lévy-Brühl I.V.S Paris 1998).

**RECOMMENDATIONS** No recent case-control study has shown a link between the Hepatitis B vaccine and neurological demyelinating chronic diseases. Immunisation against Hepatitis B must be continued, especially in infants as there is no risk for them to develop demyelinating diseases (no myelin) and the post immunization protective effect is long lasting (perhaps life). Vaccination of children and adolescents should be recommended to parents, who should receive better information of its benefits. Vaccinovigilance activity should be increased and public information of vaccines and other drugs improved.

August 2003