The Controversy of the Latent Period following Immunizations

by Harold E Buttram, MD

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Introduction:

In 1986 the U.S. Congress passed the National Childhood Vaccine Injury Act, which set up a system whereby the families of vaccine-injured children could be compensated for such injuries. Based on personal experience and observation, there has been much criticism of this system and question whether not it is serving its intended purpose. (1) One of the major areas of controversy surrounding the act involves its limitations in the latent periods, whereby certain defined reactions following vaccines must be identified within a certain time period to qualify for compensation by the childhood vaccine injury act. For the complication of encephalitis, the time limitation for the DTP or DTaP vaccine is 3 days; for the measles-mumps-rubella (MMR) vaccine it is 5 to 15 days.

The limitations in latent periods following vaccines have been generally accepted by our medical-legal system as guidelines in other areas as well. Prominent among these is the "shaken baby syndrome" (SBS) in which a parent or caretaker is accused of injuring or murdering an infant by violent shaking and causing a triad of findings now commonly accepted as diagnostic of SBS: retinal hemorrhages, subdural hematomas, and diffuse axonal injury. (2-5)

However, it has been observed that many cases attributed to the SBS have occurred in a time-related fashion following routine childhood vaccines, especially in compromised children that had been born from medically complicated pregnancies. (6) Consequently there are valid reasons for questioning whether or not some or many cases that have been accused of SBS were not the result of mistaken diagnoses, the true causes of death or injury of the child having been vaccines.

Since questions surrounding the latent period play a prominent role in many of these cases, it is timely and appropriate to review the background of this issue.

Are Current Guidelines in the Latent Period Artifactual?

(A) The DTP (diphtheria-tetanus-pertussis) Vaccine:

If we think in terms of a vaccine-induced encephalitis, most of the earlier literature

deals with the pertussis vaccine. Flexner (1930) noted a strong tendency for the nervous system manifestations to declare themselves between the 10th and 13th days. (7) In a review of 108 cases recorded before 1929 by Gorter (1933) , the onset of encephalitis was "strikingly constant," usually observed between the 10th and 12th days following vaccination, commonly with a febrile period on the 7th and 8th days, followed by recovery until onset of the encephalitis. (8) In 1929 an editorial in the Journal of the American Medical Association reported on an increase in severe neurological complications following infections and inoculations occurring on about the 11th day after vaccines. (9) Over 50 years later Munoz, (1984) in a mice study of experimental encephalomyelitis elicited by injection of pertussigen, found the same latent period of 11 to 13 days. (10)

In contrast, some of the literature since the 1970s has reported an entirely different pattern, with the onset of encephalopathy largely falling within a 3-day period following vaccines. (11-13) We can only speculate as to the reasons for this changing pattern. Perhaps it can be attributed to the fact that, in those early years, children were given very limited numbers of vaccines in comparison with more recent years during which they have routinely received the hepatitis B, H influenza, and polio vaccines in addition to the DTP, all given at the same time. The hepatitis B vaccine has been implicated in neurological disorders, autoimmune disorders, various forms of vasculitis and cutaneous reactions, as well as hemorrhagic complications. (See below, page 6) Both the pertussis and H influenza vaccines have been shown to have unusually high hyper-sensitizing properties. (14) In many vaccines thimerosal, which contains ethyl mercury, has been added as a preservative. (In some vaccines its use dates back to the 1930s.) Thimerosal has also been found to have sensitizing properties. (15) Consequently there are valid reasons for believing that the pertussis and H influenza vaccines, some of which contain mercury, may be acting in a three-way synergy in causing hypersensitivity reactions.

In the text, Vaccinations and Behavioral Disorders, by Greg Wilson, the author made the following comment in regards to the latent period:

"Today the latent period is rarely mentioned in connection with neurological complications of immunizationation. Contemporary studies on the pertussis vaccine select an arbitrary time limit in which reactions have to occur to be considered as vaccine related. This time limit is usually 3 to 7 days.

"Perhaps the only study which explores the dynamics of post DPT reactions is an independent Australian study by Karlsson and Scheibner which, with a monitor which followed breathing volumes, found particular times of stress-induced breathing following DPT injections." (16) "Of special importance (for stress) are days 2,5,6, and

8,11,13-16 and 18-21. (17)

By way of explanation, the above study involved the use of a Cotwatch breathing monitor controlled by a micro-processor and designed to provoke alarms with breathing delays (apnea of hypopnea with 5% or less of normal breathing patterns) following DTP immunizations. It was found in the study that these periods of stressed breathing occurred in clusters of 15 minutes at a time on the post-vaccine days listed above, varying greatly from child to child. From our point of view, the important feature of the study is not so much the specific post-vaccine days on which the stressed breathing occurred but the fact that the clusters continued for 21 days following the vaccines, (18) which would tend to discredit the current medical-legal limitation for DPT reactions to 3 days.

Dr. Scheibner's findings do have some support in a study which showed a fairly high incidence of cardio-respiratory complications in premature infants following vaccinations. (19) Unfortunately, this study was of limited duration. Another study throwing light on the latent period is one coming from Japan, from which it was found that increased histamine sensitivity in mice, brought about by the pertussis vaccine, showed two peaks, one on the 4th day following vaccination, and a second on the 12th day. (20) In the same vein, in a letter to the British Medical Journal, Rosemary Fox, secretary of Parents of Vaccine Damaged Children, made the following comments:

"Two years ago we started to collect details from parents of serious reactions suffered by their children to immunizations of all kinds. In 65% of the cases referred to us, reactions followed the triple vaccine (diphtheria-pertussis-tetanus). The children in this group total 182 to date; all are severely brain damaged, some are also paralyzed, and 5 have died. Approximately 60% of reactions occurred within 24 hours of vaccination, 80% within 3 days, and all within 12 days." (21)

It is important to point out in the above-survey that 20% of reactions occurred beyond the current 3 day medical-legal limitation for the DPT vaccine.

Another important study throwing light on the latent period involves an unpublished series of 25 cases with accusations or convictions of parents or caretakers for the shaken baby syndrome, a series collected by attorney Toni Blake of San Diego, California (personal communication, 2000) which have the following features: 1) All occurred in fragile infants born from complicated pregnancies. Problems included prematurity, low birth weights, drug/alcohol problems, diabetic mothers, or other maternal complications. 2) All infants were 6 months age or less. 3) Onset of signs and symptoms occurred at about 2,4, or 6 months of age, WITHIN 12 DAYS OF VACCINES, 4) All infants had subdural hematomas. 5) Some had multiple

fractures.

In addition to the work of Dr Viera Scheibner and attorney Toni Blake, another enlightening area of study for the latent period is the federal Vaccine Adverse Events Reporting System (VAERS). In her book, What Your Doctor May Not Tell You About Children's Vaccinations, (22) Dr. Stephanie Cave makes the following observations about VAERS: "It is common knowledge that less than 10% of all adverse events following vaccinations are reported to VAERS, which means that instead of the 12,000 to 14,000 reports of hospitalizations, injuries, and deaths made every year, there may be as many as 120,000 to 140,000."

Even a cursory examination of the VAERS database for DTP/DTaP vaccines will reveal that the latent periods for many vaccine reactions extend into the 7 to 13 day periods, some extending beyond 14 days. (23)

No review of the latent period would be complete without pointing out an almost insuperable difficulty in getting dependable data on these reactions due to the extreme reluctance of doctors to report on vaccine reactions, a pattern which has existed since the earliest days of childhood vaccines. There are a number of reasons for this. From their earliest years of training, medical doctors have been taught to look upon vaccines as one of the greatest achievements in medical science, and any question about the vaccines is often looked upon as disloyalty to the profession. In addressing this issue in the classic text, Shot in the Dark, by Coulter and Fisher, the authors quoted an attorney specializing in vaccine-damaged children. In commenting on the deficiency in doctors' reporting of vaccine reactions, the attorney commented, "As is the case with many pertussis-vaccine-injured children, none of the treating physicians would commit themselves to a final etiological diagnosis. It is strange that parents of pertussis-vaccine-damaged children often can only get an etiological diagnosis by hiring an attorney and seeing one of the few recognized experts in the U.S. on post-pertussis vaccine encephalopathy." (25)

As a result of this physician-reluctance to report vaccine reactions, large numbers of reactions may be taking place beyond the currently established time limits of the latent period, unrecognized as to their true nature.

(B) The Hemophilus influenza (HiB) vaccine:

In one of the largest, if not the largest randomized epidemiological trial ever conducted, the effect of the Hemophilus vaccine on the development of insulin dependent diabetes mellitus (IDDM) was studied in Finland. (26) All children born in Finland between October 1st, 1985 and August 31st, 1987, approximately 116,000,

were randomized to receive 4 doses of the HiB vaccine (PPR-D, Connaught) starting at 3 months of life or one dose starting at 24 months of life. An intent to treat method was used to calculate the incidence of IDDM in both treatment groups until age 10. The incidence of IDDM was also calculated in a control group of 128,500 children which did not receive the HiB vaccine. (27) The results demonstrated a rise in IDDM which was specific for the vaccinated cohort. (28) However, the important point for our purposes was that there was a consistent delay of 3.5 years between vaccination and onset of IDDM. (It should be pointed out that IDDM is considered an autoimmune disease.)

At a presentation this past spring in Nashville, Tennessee sponsored by the American College for the Advancement of Medicine, (29) Dr. John Classen reviewed 32 publications in the medical literature showing a similar increases in diabetes mellitus in a number of countries with the MMR and hepatitis B as well as the HiB vaccine, again with latent periods up to three years or more, according to graphs that were provided. (Copies of references will be provided on request). Rather than being specific to any one vaccine, Dr. Classen offered his opinion that the general immune stimulation from the vaccines was the cause of a rise in autoimmunity. As an interesting sidelight, Dr. Classen mentioned that personnel in the U.S. navy are more heavily immunized than their European counterparts, and that the U.S. navy personnel have five times more diabetes than their European counterparts.

(C) The MMR (measles-mumps-rubella) vaccine:

Whereas DTP and Hib vaccine-related encephalopathy may be the result of interactions between endotoxin and mercury, (the latter in the form of the additive, thimerosal), the primary mechanism of viral vaccines in causing encephalopathy may be related to the propensity of viruses (and viral vaccines) in bringing about autoimmune reactions. (30)

In order to provide an overview of the latent period, there are two basic classes of immune systems, the humoral or antibody producing system, which tends to produce immediate-type reactions, and cellular immunity, in which reactions are delayed. Either class is capable of producing autoimmunity. (31) Obviously, the usual 15 day limitation for the MMR vaccine excludes a recognition of the delayed-type autoimmune reactions and, by inference, even denies their existence. In an article by Cohen and Shoenfeld dealing with questions of vaccine-induced autoimmunity, the authors pointed out that it is a subject about which relatively little is known, due to the paucity of clinical and laboratory studies. (32) In point of fact a more recent review on this subject cites a temporal relationship of 2 to 3 months between vaccines and autoimmune reactions. (33)

Recently the subject of the latent periods for the MMR vaccine came sharply into focus in an article published in Adverse Drug Reaction & Toxicology Review, (34) in which researchers Andrew Wakefield and Scott Montgomery, who have been investigating a possible causal relationship between the MMR vaccine and the autism-enterocolitis syndrome, carefully reviewed deficiencies in the early pre-licensing trials of the MMR vaccine. In the article they pointed out that follow up periods following the vaccine were a maximum of 28 days and in some studies even shorter periods. They stressed that such short periods of observations following the vaccine were totally inadequate to detect delayed reactions, including pervasive developmental delay (autism), immune deficiencies, and inflammatory bowel disease, which are known from earlier published reports to occur following both the natural measles infection and the measles vaccine.

The most interesting feature of the Wakefield/Montgomery article was that it was reviewed by four leading British authorities, all of whom had previously held positions in the regulation and licensing of medicines in the United Kingdom. (35) Taken as a whole, the reviewers were supportive of the article, three highly so. Peter Fletcher, formerly a senior professional medical officer for the Department of Health wrote, "being extremely generous, evidence of safety (of the MMR vaccine) was very thin." Noting that single vaccines for measles, mumps, and rubella already existed, he argued, "caution should have ruled the day granting of a product license was definitely premature." Professor Duncan Vere, former member of the Committee on the Safety of Medicines, agreed that the periods for tests were too short. "In almost every case," he wrote, "observation periods were too short to include the onset of delayed neurological or other adverse events."

(D) The Hepatitis B vaccine:

Other than the references provided by John Classen, M.D. on the findings of increased diabetes from the hepatitis B vaccine with a latent period of 3 years, I am not aware of additional information bearing on the latent periods between hepatitis B vaccine and other forms of reactions, which reflects the sheer lack of data on the subject.

However, many reactions to hepatitis B vaccine may be taking place unrecognized, for two reasons: Reason one, I have in my possession a list of 109 references of published articles reporting on complications from the hepatitis B vaccine including autoimmune disorders, neurological disorders, vasculitis and cutaneous reactions. This list will be provided on request.

For reason two, in 1994 a special committee of the national Academy of Sciences

(Institute of Medicine) published a comprehensive review of the safety of the hepatitis B vaccine. When the committee, which carries the responsibility for determining the safety of vaccines by Congressional mandate, investigated five possible and plausible adverse effects, they were unable to come to conclusion for four of them because they found that relevant safety research had not been done. Furthermore, they found that serious "gaps and limitations" exist in both the knowledge and infrastructure needed to study vaccine adverse events. Among the 76 types of vaccine adverse events reviewed by the IOM, the basic scientific evidence was inadequate to assess definitive vaccine causality for 50 (66%). The IOM also noted that "if research" (is) not improved, future reviews of vaccine safety will be similarly handicapped. (36) For this reason, the published reports of hepatitis B vaccine reactions may only be a small portion of those actually taking place, with large numbers of delayed reactions taking place unrecognized.

Conclusion:

Based on published evidence that many vaccine reactions take place beyond current medical-legal time limits that have been established for vaccines, and on overwhelming evidence that large numbers of delayed vaccine reactions may be taking place unrecognized, there are grounds for believing
that these time limitations may be unrealistic and artifactual.

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Francine Yurko (NMW)
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