First US research was in '78, halted early

Fresno Bee DPT report 1984

Reports of brain damage and death are found in the following DPT inoculation medical literature as far back as 1933, but it was 45 years before the federal government decided to take a closer look.

In 1978-79, the Food and Drug Administration financed a study of adverse reactions to DPT within 48 hours of immunization. Research work was done at the University of California at Los Angeles by Drs. James D. Cherry, Larry J. Baraff, Charles R. Manclark, Christopher Cody and S. Michael Marcy.

When their first article appeared in the journal Pediatrics in November 1981, adverse reaction rates reported were unexpectedly high. The incidence of convulsions was one in 1,750 shots. Incidence of shock also was one in 1,750 shots.

Typically, the number of shots is converted into the number of children by dividing by three primary shots. That would make the incidence rate one in about 600 children. However, Cherry said last month he could not calculate the number of children because they had differing numbers of shots.

The statistics marked a tremendous leap in the previous figures — one in 7,000 children or one in 21,000 immunizations —used by the national Centers for Disease Control and accepted by physicians as the best data available in 1978.

However, it was March 1, 1983, before UCLA's data was added to what the CDC calls the Important Information Statement which is given to parents at every public health clinic in the country.

Early in the UCLA study, adverse reactions were 5,000 percent higher than expected. That prompted Baraff to contact Wyeth Laboratories, the primary Source of DPT vaccine used in the study. He met with Dr. Marc W. Deitch of Wyeth on Sept. 6, 1978.

In a report that has been produced in lawsuits against the manufacturers Deitch reported to eight other Wyeth doctors that Baraff was studying reactions to DPT vaccine and that "far from the expected incidence of one in 15,000 immunizations,

there have been five out of 1,500 or an incidence of one in 300 of generalized seizures" Deitch said all the reactions had occurred in infants less than 6 months old.

Deitch said Baraff called the reaction rate unacceptable and that Baraff's feelings "are reinforced by phone calls and letters he receives constantly from Practitioners, clinic directors and pediatricians in California"

Also during the UCLA study, two deaths occurred following DPT vaccinations The Los Angeles County Coroner's Office recorded both as apparent crib deaths.

The deaths were disclosed in the researchers' final report to the FDA in March 1980, but they were not included in published articles. The UCLA researchers' articles appeared in the journal Pediatrics in late 1981 and in January 1984.

Manclark who was on the UCLA team and now directs the FDA's pertussis branch, said the deaths were not reported because "they were outside the study." They occurred at 88 and 90 hours after the DPT shot, but the study was limited to reactions within 48 hours.

Cherry said: "They weren't part of the study. Those deaths were no more frequent than by chance. It's like saying children who had a shot, then were hit by a car, should be included."

Why were the deaths reported to the FDA but not to physicians in the Pediatrics articles? "There were tons of things not included in the journal," Cherry said. "That information was actually presented at a national meeting in 1981 at the Society for Pediatric Research."

Although money was provided for 50,000 doses, the study was stopped after fewer than 16,000 doses were given. The reason is unclear.

"The FDA was going in to prove their figure — one in 310,000 — was right, maybe even optimistic," said Ed Hodges of California's Dissatisfied Parents Together. "They say they ran out of money, but what really happened is the reactions there too high. It blew up in their faces, and they aborted the study."

Cherry denies that. "Actually there was too little money to do it, anyway. The reason we didn't do more was that it took forever to get going.

"We had to get permission through three human-subject protection committees. .. Consent forms were so crazy, trying to cover every single thing. That was at least a three-month delay.

Manclark disclaimed a link between the reaction rate and the study's curtailment. He said a considerable amount of time and money had been spent in preparation, creating forms for parents to use and then following up on parents to see they filled them out accurately.

"All the money was used and the study was extended to get as many of the patients into the study as possible," Manclark said.

Vital medical data might have been obtained from children who had convulsions and shock if follow-ups had been done, but the study time was limited to 48 hours.

Five years after the study ended, Manclark said "Dr. Baraff is trying to find the kids now. We said we [at the FDA] would find him some support money to find those kids."

[Vaccination] [Fresno Bee report]