

'Tennessee cluster' stirs inquiries

In Fresno County, Coroner Dr. David Hadden researched records from an unusual cluster of crib deaths in 1981. He said the question about DPT vaccination was not routinely asked of parents. Hadden...said he will add such a question about DPT from now on.

Within 8 days of their DPT inoculation, 11 infants died in Tennessee. Nine of the 11 had received DPT vaccine from Wyeth Laboratories lot 64201. Four of the 11 were dead in 24 hours.

All the deaths, which coroners classified as crib deaths (technically, sudden infant death syndrome), occurred between August 1978 and March 1979.

Nothing of this magnitude had occurred before.

The Tennessee Department of Health notified the national Centers for Disease Control, and the CDC assigned Dr. Roger H. Bernier to investigate. On April 26, 1979, the U.S. surgeon general called a meeting of top DPT researchers, officials from the CDC and the Food and Drug Administration, and representatives of drug manufacturers to discuss Bernier's findings.

Outside consultants came from the University of Colorado, Denver; Duke University Medical Center, Durham, N.C., University of Rochester, N.Y., University of Washington, Seattle; Boston City Hospital; Case Western Reserve University, Cleveland; National Center for Health Statistics, Hyattsville, Md. When the daylong session was over, there were still questions.

Every one of the seven consultants asked for additional information to determine whether there was any connection between DPT and crib deaths: more details, medical histories, data from other states that used lot 64201, further testing on the lot.

Dr. David Brandling-Bennett of the CDC reported on a survey of states that had received 7,500 or more doses of lot 64201. "All said they could identify sudden infant death cases," which are called crib deaths.

The survey also produced a list of 14 more infant deaths — half within 24 hours of a DPT shot. All were classified as crib deaths. However, the children had received vaccine from other lots.

In September 1982, 3½ years after the 1979 surgeon general's meeting, the first major article about the so-called Tennessee cluster appeared in the *Journal of Pediatrics*.

In the article, Bernier said the panel could not find a causal relationship between lot 64201 and crib death although it could not exclude one, either.

Dr. Kevin C. Geraghty of Bay Area Physicians for the Study of Pertussis Vaccines, said Bernier "failed to give physicians the information he had.

"He didn't say the batch was double strength. He didn't say so many of these babies are dying on the first shot, which points to an age vulnerability. He didn't point out that they had no histories on these children. The consultants all said the same thing. 'We would love to have histories on these kids.'"

Dr. John Robbins was the FDA biologics director at the time of the Tennessee cluster and attended the surgeon general's meeting. "Tennessee has an excellent public health system," he said. "That year, they really pushed and immunized everyone they could.

"They had a terrific record, maybe 95 percent of the children were immunized. And that year, in the winter, the SIDS [crib deaths] occurred."

Although it was not certain five years ago, today it is generally accepted among DPT experts that pertussis vaccine does not cause the kind of death typical of crib death.

Several studies, including a large one by the National Institute of Child Health and Human Development, have shown only a coincidental relationship with DPT vaccinations.

Dr. Mortimer B. Lipsett, director of the institute, has written that it's inevitable that health problems that occur early in life occasionally will occur near DPT vaccination because the vaccine is given several times in the first year of life. Thus, he said, a few crib deaths will appear to be associated with the vaccine.

Dr. Kenneth J. Bart, chief of the surveillance investigation research branch of CDC, said that each year, "It's expected that 55 SIDS [crib deaths] will occur within

-24 hours of DPT just by chance alone."

Some people and groups, including Physicians for the Study of Pertussis Vaccines, suggest that some crib deaths might not be crib deaths at all. There are parents like Janet Ciotoll of Endicott, N.Y., who have disputed a coroner's report of crib death.

Ciotoli, a licensed practical nurse, said her 2-month-old son, Richard, died of irreversible shock after his first DPT shot a year and a half ago.

Shocklike deaths following DPT shots were reported in the Journal of the American Medical Association in 1933 and 1946.

Geraghty independently researched the 10 crib deaths in Contra Costa County in the first half of 1983. Three of them showed "disturbing clinical histories not typical of crib deaths," but typical of shock, he said.

"The UCLA study showed one in 600 kids have shock like episodes. That is not controversial," Geraghty said. "My position is that an occasional one of those must result in death.

"There are 9,000 crib deaths a year. If even one in 100 [shock like deaths] were mistakenly called crib death, that would be 90 babies a year.

"There's 3.5 million children born annually, so we're talking about 1 in 35,000 babies die from this reaction.

"Let's drop fills nonsense about crib deaths," Geraghty said. "We don't think they are crib deaths. We think they are shock like deaths that out of incompetency the Centers for Disease Control began to call crib deaths with no proof and the coroners innocently have followed along with this practice.

In Fresno County, Coroner Dr. David Hadden researched records from an unusual cluster of crib deaths in 1981. He said the question about DPT vaccination was not routinely asked of parents. Hadden was shown Geraghty's study and said he will add such a question about DPT from now on.

Based on a British study, the U.S. government says that one in 100,000 children (or one in 310,000 injections) will experience permanent brain damage, usually with profound retardation and hard-to-control seizures. Government statistics do not attribute any deaths to DPT vaccine, except when an occasional brain-damaged child has a vigorous reaction and dies from it or complications.

Dr. James D. Cherry one of the UCLA researchers, was asked if some instances of crib deaths could, instead, be shock like deaths. They could be, he said, "but my guess

is that a particular parent is involved in a lawsuit and Is trying to get some money from a drug company."

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