week no. 15 ending April 13, 1985

Texas Preventable Disease NEWS

contents:

BUREAU OF EPIDEMIOLOGY 1100 West 49th Street, Austin, Texas 78756 (512-458-7207)

PERTUSSIS AND THE VACCINE

The following material is adapted from a talk paper released by the Food and Drug Administration on February 13, 1985.

Whooping cough remains a highly contagious, serious disease with a course of about six weeks, beginning with symptoms like those of a bad cold. As the disease progresses, coughing comes in spasms interspersed with a characteristic "whoop" sound -- a deep, noisy, inhalation of air. It may be complicated by convulsions, emphysema and other bronchial conditions, middle ear infections, pneumonia, weight loss, and encephalopathy. Deaths that occur generally result from pneumonia.

The disease is of greatest danger to infants. For example, of 15 deaths from whooping cough reported in the United States in 1982-83, 13 were in infants under six months of age. In the 1940s, before a vaccine was available in the United States, as many as 265,000 cases and 7,000 deaths from whooping cough occurred annually.

The vaccine is effective, but even with its use and the availability of antibiotics for treating resultant pneumonia, some 1,000 to 3,000 cases occur in the US each year with five to 20 deaths. Without an immunization program, it is estimated there could be a 70-fold increase in cases and a four-fold increase in deaths. If US immunization should decline to 30% to 40% from its current 90%, the US could experience 380,000 cases of whooping cough, 18,500 hospital admissions, 7,400 cases of pneumonia, 307 cases of convulsions, 184 cases of encephalopathy, and 104 deaths. (These data are extrapolated from the United Kingdom epidemic of 1977-79.) (See PDN Editorial Note.)

Though they pale in comparison to the disease, the vaccine does have adverse effects of its own. Local discomfort at the site of injection is most common -- with local swelling in 40% and local pain in 50% of children in a study of the DTP vaccine (diphtheria, tetanus, and pertussis) sponsored by the Food and Drug Administration (FDA) and conducted at the University of California at Los Angeles (UCLA). Fever is common. Seizures also occur which are frightening but not generally damaging to the child. Other studies have shown that in rare cases, there can be encephalopathy or death. Since such serious problems occur spontaneously in the same age group as is given the vaccine, it is difficult to sort out what is a reaction and what is coincidental. The 1981 UCLA study examined children receiving more than 15,000 injections of the vaccine. Nine children experienced convulsions, and nine more had shock reactions or collapsed; all 18 recovered without lingering problems.

The Japanese currently use an acellular vaccine which the National Institute of Allergy and Infectious Diseases is testing in the US. Much of the FDA work, however, has been aimed at studying the immunochemistry of Bordetella pertussis -- the

bacterium -- and identifying, via animal models, elements of the vaccine that provoke immunity. This work, under Doctor Charles R. Manclark, appears promising and may lead to a tailored vaccine providing long immunity with fewer adverse effects. In addition, other studies are being supported by the National Institute of Allergy and Infectious Diseases and the National Institute of Child Health and Human Development, both parts of the National Institutes of Health (NIH).

The bacterium that causes whooping cough may be carried and spread by: 1) symptom-free adults and older children and 2) adults with mild respiratory disease unrecognized as pertussis or passed off by the adult as "a virus going around." Improved, longer-lasting immunity might eliminate this pool of whooping cough and potentially lead to the end of the disease itself.

OTHER ISSUES:

Q. Is Sudden Infant Death Syndrome (SIDS) caused by the vaccine?

A. Some studies initially suggested a link, but these studies were flawed. Most experts accept the conclusions of a comprehensive, case-controlled study by NIH that found no relationship between cases of SIDS and prior whooping cough vaccination.

Q. Is reporting of the vaccine's adverse effects required?

A. Efforts to require physicians and hospitals by law to report all suspected adverse effects to the FDA have failed not only for vaccines but also for drugs and other medical products. Manufacturers, however, must report all adverse effects involving drugs and keep on file, accessible to the FDA, any reports of vaccine effects. In addition, all commercial manufacturers of DTP have voluntarily provided the FDA with reports of reactions to vaccines and periodic summaries.

Q. If the FDA currently can isolate immunity-producing elements of the bacteria from adverse reaction-producing elements, why hasn't it been doing so all along?

A. The scientific knowledge has not been available until recently, and some elements still require additional study. Many of the virulence factors from Bordetella pertussis are toxins. Methods must be developed to inactivate the toxicity of such molecules without adversely affecting their power to provoke immunity. This research is in progress. In addition, the elements required in a vaccine will require clinical trials in children to demonstrate safety and efficacy before such vaccines can be approved for general use. Such trials involve some risk and difficulty.

Q. Some contend that the so-called "mouse-weight-gain test" for toxicity does not rule out serious reactions to the vaccine -- and a better test should have been developed.

A. There is no test that can rule out rare reactions to this or other vaccines. The mouse test is designed to make sure that the product is acceptably free of toxicity. The FDA research noted above has developed new assays and attempts are being made to relate the assay results in a meaningful way to reactions seen in chidren.

In Holland, data on adverse reactions show shock and convulsions occur in one per 2,700 children within three days of the DTP-polio vaccine, but serious, permanent neurological damage occurs in only one child per 400,000. In an editorial, Professor R.J. Robinson, Department of Pediatrics, Guy's Hospital Medical School in London, made this comparison between the damage caused by the disease itself in England and the adverse reactions to the vaccine: "There were at least 28 deaths from whooping cough during the (1977-79) epidemic, which may be compared to two deaths from neurological disease after DTP — of which one was probably unrelated to immunization -- in the three years of the National Childhood Encephalopathy study." A study in England showed one case of brain damage per 310,000 immunizations. Although this is the largest to date, it is not strictly comparable to the US experience since immunization practices differ somewhat.

Although these occurrences are far below the human cost of an epidemic, they are tragic and can sometimes be avoided. Some experts suggest that parents tell physicians administering the vaccine of any family history of epilepsy or seizures, though this would not be an automatic contraindication for the vaccine's use. After the vaccination, parents should watch children for signs of problems such as convulsions, shock, persistent screaming episodes, or fever over 105°F in the first couple of days following a DTP shot. When a serious problem occurs, parents should not only get prompt medical care but should also tell the attending physician or responsible clinic about these episodes so that they can be evaluated. If immunization with DTP is contraindicated, the remainder of the series can be given with DT vaccine only.

Except in children having previous, serious reactions, the vaccine is recommended for infants and small children as a far lesser risk than the disease. Pertussis has not disappeared in the way smallpox has, but resides in reservoirs in the population. It can appear in the un-immunized and can rise to epidemic levels if immunization drops significantly. Immunization is recommended by the American Academy of Pediatrics, the United States Public Health Service Advisory Committee on Immunization Practices, and the World Health Organization Immunization Program. Except under special circumstances, it is required in most states before entering school or day-care programs.

The vaccine is made from inactivated cells of the bacteria which cause pertussis. This is a whole cell vaccine. Improved vaccines have been sought for several decades, but progress has been slow.

Eli Lilly produced an acellular vaccine -- a simple extract of the whole cell or bacterium -- from 1962 to 1977, and some physicians felt it produced fewer reactions such as local inflammation. Wyeth Laboratories produced similar experimental vaccines. However, there are no strong data to indicate that either provided the long-sought advantage of effectiveness with fewer serious side effects.

PDN Editorial Note:

The Texas Department of Health does not concur in the belief that a 70-fold increase in cases will result in only a four-fold increase in deaths. Case-fatality rates in the United States and Texas have consistently been reported to be around 0.4% to 0.5%. At a case-fatality rate of 0.4%, 1,520 deaths would be predicted from 380,000 cases. This may represent an overestimate; but in Texas in 1984, three deaths from pertussis occurred among the 60 reported cases. In view of this situation and the pathogenesis of the infection, we feel it unreasonable to assume that 380,000 cases would result in only 104 deaths, a case-fatality rate of 0.027%, or nearly 15 times lower than the case-fatality rates presently being reported.

* * *

ROCKY MOUNTAIN SPOTTED FEVER

Rocky Mountain spotted fever (RMSF) is a rickettsial infection caused by Rickettsia rickettsii. The organism is primarily a parasite of ticks and is passed through unending generations of ticks by transovarial transmission. Man contracts RMSF either through the bite of an infected tick or by contamination of the skin with crushed tissues or feces of infected ticks. The tick species most commonly associated with human infection in Texas are the Lone Star tick (Amblyomma americanum), the dog tick (Dermacentor variabilis), and the brown dog tick (Rhipicephalus sanguineus).

In 1984, 53 confirmed cases of RMSF were reported in Texas. This was a 51% decrease from the 108 cases reported in 1983 and a 17% decrease from the 64 cases reported in 1982. Adverse environmental conditions affecting tick populations may be responsible for the decreased number of cases. The states of Arkansas and Oklahoma also experienced a decrease in the number of RMSF cases from 1983 to 1984.

The 1984 incidence rate for RMSF was 0.33 cases per 100,000 Texas residents. The counties of residence of cases are illustrated in Figure 1. The majority of cases in 1984 resided in north central Texas. Public Health Regions 5 and 7 reported incidence rates of 0.76 per 100,000 and 1.2 per 100,000, respectively. Rocky Mountain spotted fever was responsible for three deaths in 1984 -- one each in Grayson, Red River, and Tarrant Counties.

Thirty-six cases were male, and 17 were female. Twenty-nine cases (55%) were 9 years of age or younger. The ages of the three RMSF cases who died were 10, 44, and 50 years.

Cases had onset of symptoms from January through September. Thirty-two cases (60%) had onset of symptoms in the months of April, May, or June. Thirty-one cases remembered a recent tick attachment prior to the onset of symptoms.

Clinical symptoms were noted with the following frequencies: fever -- 96%; rash -- 81%; headache -- 79%; malaise -- 51%; myalgia -- 49%; anorexia -- 38%; conjunctivitis -- 30%; lymphadenopatny -- 15%; and photophobia -- 15%. The associated rash was most frequently observed on the trunk (81%), followed by the arms (77%), and the legs (74%). A generalized rash appearing on the trunk, arms, legs, face, soles, and palms was observed in 18 (42%) of those case having a rash. The rash appeared, on the average, three days after onset of fever, the range being from zero to 18 days. Ten cases developed their rashes on the same day as the onset of fever.

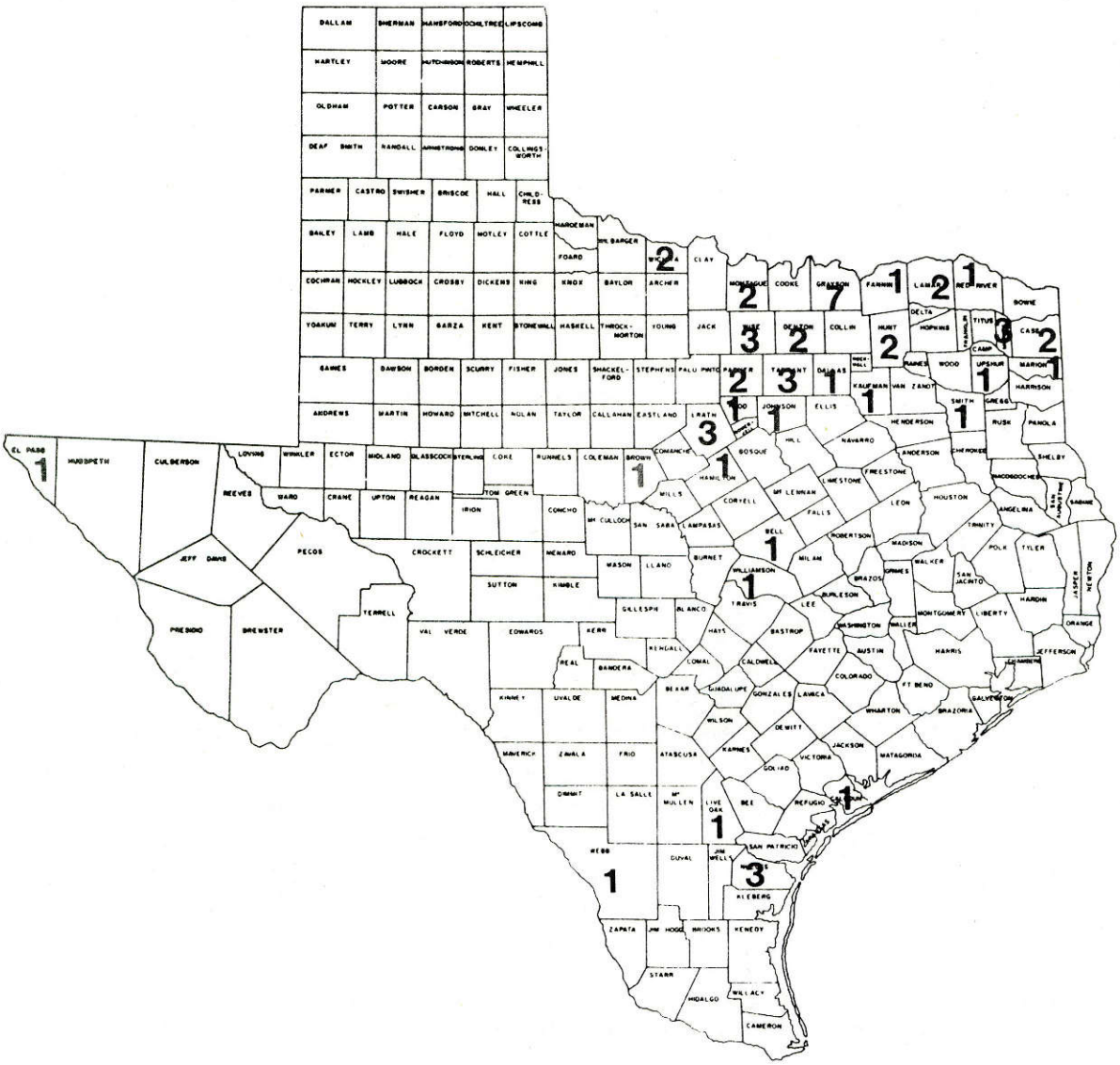
Treatment data were recorded for all the cases. Thirty cases were treated with tetracycline alone; 3 cases were treated with chloramphenicol alone; and two cases were treated with both tetracycline and chloramphenicol. Three cases were treated with antibiotics not recognized as being effective against Rickettsia rickettsii.

The diagnosis was confirmed in all cases. Forty-seven (89%) of the cases were confirmed by the indirect fluorescent antibody test (IFA), five (9%) were confirmed by acute blood inoculation into test animals (Microtus), and one case (2%) was confirmed by fluorescent antibody staining of tissue.

Questions concerning RMSF surveillance should be directed to the Bureau of Epidemiology, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756; telephone (512) 458-7328 or STS 824-9328.

This article was written by Jeff Taylor, MPH, Bureau of Epidemiology, Texas Department of Health.

Figure 1.
County of residence of 53
Rocky Mountain spotted fever cases, Texas, 1984



* * *

MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR)
SUBSCRIPTION RATES

	Dr. V Alexander, Chmn Occ Med, Ochsner Clin 1515 Jefferson Highway New Orleans, LA 70121	Mass Med Society Publications CSPO Box 9120 Waltham, MA 02254	Superintendent/Docs US Governt Prtng Off Washington, DC 20402
52 Weekly Issues & Annual Supplement (1st-Class Mail)	$30	N/A	N/A
52 Weekly Issues & Annual Supplement (3rd-Class Mail)	$25	N/A	N/A
52 Weekly Issues, Annual & 4-6 Periodic Supplements (1st-Class Mail)	$40	$34	Domestic $69 International $86.25
52 Weekly Issues, Annual & 4-6 Periodic Supplements (3rd-Class Mail)	$35	$25	N/A

TEXAS PREVENTABLE DISEASE NEWS ( ) is a free, weekly publication of the Texas Department of Health, 1100 West 49th Street, Austin, TX, 78756-3180. Second-class postage paid at Austin, TX. POSTMASTER: Send address changes to TEXAS PREVENTABLE DISEASE NEWS, 1100 West 49th Street, Austin, TX 78756-3180.

TEXAS PREVENTABLE DISEASE NEWS
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3180

RETURN POSTAGE GUARANTEED

APPLICATION TO MAIL AT
SECOND CLASS POSTAGE RATES
PENDING AT AUSTIN, TX