Louisiana

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
OFFICE OF HEALTH SERVICES AND ENVIRONMENTAL QUALITY
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MONTHLY MORBIDITY REPORT

Provisional Statistics

from

EPIDEMIOLOGY UNIT AND PUBLIC HEALTH STATISTICS

Reported Morbidity
January, 1981

HEPATITIS B VACCINE EFFICACY TRIAL

A new vaccine against hepatitis B has been developed. Szmuness, et. al. have reported the results in the *New England Journal of Medicine* (Oct. 9, 1980).

BACKGROUND:

Development of a vaccine against hepatitis B has been delayed because of the difficulty in culturing the hepatitis virus in vitro. However, in 1970-73 Krugman, et. al. laid some of the ground work for active immunization against hepatitis B by determining that hepatitis B infective serum boiled to inactivate the virus prevented or modified the infection in 70% of subjects vaccinated with this material.

The new vaccine is a purified, concentrated preparation of formalin – inactivated HB_SAg (hepatitis B surface antigen) particles derived from the plasma of chronic carriers of HB_SAg. The trial of its efficacy is summarized below.

STUDY METHODS:

This study was a placebo-controlled, randomized, double-blind clinical trial of the vaccine in 1083 homosexual men in New York City. Previous baseline studies on the same population (more than 10,000 men included) showed that its members are at high risk of infection by hepatitis B virus (HBV). The prevalence of HBV markers (HB_SAg, anti-HB_S, or anti-HB_C) in this population was 68% or ten times that found in male volunteer blood donors.

Criteria for enrollment in this study included evidence of freedom from past and present hepatitis B infection. All subjects had to be negative for the above HBV markers and had to have alanine aminotransferase levels (ALT, also called SGPT) below 50 I.U.

Each subject was assigned at random either to the vaccine or to the placebo groups for the duration of the study. Each I.M. dose of vaccine contained 40 micrograms of formalin-activated, purified HB_SAg. The vaccine, or placebo, was administered as 3 injections: the first dose as soon as the lab results were available, the second dose one month later, and the third dose six months after the first.

Follow-up visits were scheduled for two years after the last injection: one per month for three months, then one each three months thereafter. The subjects were tested for all HBV markers at each visit.

The vaccine group had 549 subjects, of whom 473 completed their injection (86%). The placebo group had 534 subjects, of whom 455 completed their injections (85%). Ninety-one percent of the scheduled follow-up visits were completed.

ANTIBODY RESPONSE TO THE VACCINE:

All of the subjects were anti-HB_S negative at the beginning of the study. Ninety-six percent of the vaccine group developed anti-HB_S antibodies whereas, only 5% of the placebo group developed anti-HB_S.

CLINICAL RESULTS:

For the first 18 months of follow-up, clinical hepatitis B (symptoms of hepatitis, ALT$\geqslant$ 90 I.U. and serological evidence of hepatitis B) developed in only 1.4% of the vaccine recipients as compared to 18.1% of the placebo group, a significent difference ($p < 0.0001$). If all cases of hepatitis B infection (clinical hepatitis B, mild cases with ALT $\geqslant$ 45 I.U., and cases with HB_SAg or anti-HB_C) are included, the vaccine group had an infection rate of 7.6% and the placebo group had a rate of 35%. If one only counts those clinical hepatitis B cases which occurred after the 3 vaccine or placebo injections were complete, the rate in vaccine recipients was 0.42% (2 of 473) and that in placebo recipients was 7.03% (32 of 455).

EDITORIAL COMMENT:

The development of hepatitis B vaccine and the demonstration that such a vaccine prevents HBV infection represent major advances in the control of this serious, widespread disease. The number of cases of acute hepatitis B in the United States has been estimated to be at least 80,000 to 100,000 per year with a fatality rate of 1 to 2%. It is estimated that the total number of HBV carriers is close to 0.8 million in this country. A substantial number of these carriers do eventually develop chronic active hepatitis and cirrhosis. In Asia and Africa there is evidence that HBV is the single most important causative factor of hepatocellular carcinoma; an extremely widespread cancer among middle-aged men. Thus, future immunization programs against HBV infection may ultimately affect not only the incidence of acute hepatitis B and the pool of chronic carriers but may also reduce morbidity and mortality from related diseases.

It is projected that the hepatitis B vaccine will be available in 1982.

TOXOCARA LARVA MIGRANS – SURVEILLANCE

The larvae of *Toxocara* species, the common roundworms of dogs *(T. canis)* and cats *(T. cati),* are capable of infecting human beings who ingest fertile infective eggs. Between one-third and one-half of households in the United States have one or more dogs and essentially 100% of puppies under three months of age are infected with and shed *T. canis.* Because eggs are not immediately infective and require at least 10 days of soil incubation, humans are infected by ingesting embryonated eggs in soil where puppies have defecated (dooryards, public parks).

Infection in man may be one of two distinct forms of illness, visceral and ocular. Visceral larva migrans (V.L.M.) is typically a disease of toddlers (1–5 years) with a history of pica and is characterized by fever, hepatomegaly, leukocytosis, persistant eosinophilia, hypergammaglobulinemia and elevated isohemagglutinins. Other symptoms include cough, wheezing, diarrhea, malaise, irritability, weight loss, skin lesions and seizures. Mild pulmonary involvement is common and is accompanied by transient pulmonary infiltrates in approximately half the cases. Ova and parasites are not formed in man and, therefore, stool exams are not helpful in the diagnosis of V.L.M. Ocular larva migrans (O.L.M.) tends to occur in older children and adults without a history of pica and requires a much smaller infective dose. The retinal lesion is a granuloma, usually solitary, situated posteriorly near the optic disk and macula. Common complaints at presentation include visual loss, strabismus and, more rarely, eye pain. Less than 1% of patients have a history of concurrent or antecedent V.L.M.; however, the association with recent exposure to puppies is significant. Eosinophilia is not prominant and anti-*Toxocara* titers are rarely as high as those in children with V.L.M. It is felt that O.L.M. results from ingestion of a small number of eggs and a subsequently prolonged incubation period as the larva migrate toward the eye, unrestrained in the tissues by the host's immune defense. Clinically, O.L.M. is difficult to differentiate from retinoblastoma, the most common eye tumor in children. The recent serologic test for *Toxocara* antibodies (found in high titer in the vitreous humor of O.L.M. patients) has improved diagnostic capabilities.

The relatively new ELISA (Enzyme-linked immunosorbent assay) for *Toxocara* larval antibody now used routinely by C.D.C. has a sensitivity of 78% and a specificity of 92% and can, therefore, differentiate toxocaraiasis from other helminthiases. The predictive value of the ELISA using a titer of greater than or equal to 1:32 is higher than 85%. Previous serologic tests lack such sensitivity and specificity. As toxocariasis is not a reportable disease and the diagnosis prior to development of the ELISA was difficult, the true magnitude of T.L.M. *(Toxocara* larva migrans, both V.L.M. and O.L.M.) is unknown. Of 2500 sera submitted to CDC in 1978 for ELISA testing, most positive results were from southern states. In an 18 month period, a pediatric ophthalmologist in Atlanta diagnosed 41 cases of seropositive O.L.M. representing 37% of the retinal disease in his referral population. Retrospective seroprevalance surveys using the ELISA method in the United States yield a prevalance among the general population of 3.5%; the rate is higher in younger age groups, males and blacks (up to 25% in young black males). An estimated 5½ million people in the United States are infected with *T. canis.* It is not known what proportion of these develop clinical disease. Prospective studies must be conducted to determine the incidence of infection, to asscess pathogenicity and to distinguish simple associations from actual cause.

To document incidence and morbidity associated with toxocaral infections and to elucidate more clearly the epidemiologic risk factors, the Louisiana Division of Disease Control (DHHR), with the cooperation of the Centers for Disease Control, has begun a toxocaral surveillance project. We encourage all physicians to consider the diagnosis of *Toxocara* larva migrans (either V.L.M. or O.L.M.) in children with a compatable systemic or ocular illness, particularly if such a patient has a history of pica and/or lives in a household with a dog. We invite you to submit serum specimens from these individuals to the State Health Laboratory for toxocaral antibody testing by the ELISA method. We will be pleased to discuss cases or answer questions you may have. Our number is 504-568-5005.

SUGGESTED REFERENCES:

1. Glickman LT, Schantz PM and Cypress RH: Canine and Human Toxocariasis: Review of Transmission, Pathogenesis, and Clinical Disease. *JAVMA* 175: 1265–1269, 1979.
2. Achantz PM and Glickman LT: Current Concepts in Parasitology: Toxocaral Visceral Larva Migrans. *NEJM* 298: 436–439, 1978.
3. Schantz PM, Weis PE, Pollad ZF, et. al.: Risk Factors for Toxocaral Ocular Larva Migrans: A Case–Control Study. *Am. J. Public Health* 70: 1269–1272, 1980.

INFLUENZA

As of the week ending January 24, 1981 influenza activity as measured by the Immunization Division's active surveillance program was elevated above expected. The surveillance system consists of weekly reports from most Charity hospital emergency rooms, several schools and some nursing homes throughout the state regarding the incidence of both total illness and illness due to upper respiratory infection. Three of ten emergency rooms (Shreveport, Alexandria, Lake Charles) have documented an increase in total visits and visits for URI; schools in northeastern parishes and, more recently, in Orleans and Jefferson parishes have reported large increases in absenteeism. One nursing home in New Orleans experienced a small outbreak of influenza. Eight cases have been confirmed by laboratory methods including two by viral isolation (A/Bangkok/79) and six by seroconversion. Thus, Louisiana is presently experiencing an excess of influenza A, particularly in the northern parishes. As expected, the attack rate is highest among children and young adults and is characterized by fever, cough, sore throat, myalgias and headache lasting 3 to 5 days. We expect the "flu season" to continue through February and suspect that disease activity will increase in southern Louisiana.

On the national level, as of January 10, 1981, nine states have experienced widespread outbreaks of influenza and 17 states, primarily in the Northeast and Midwest, have reported regional outbreaks. At least 23 states have isolated A/Bangkok/79 (H_3N_2) virus; in addition, both Massachusettes and Texas have isolated H_1N_1 strains. No isolations of Influenza B have been reported. Deaths due to pneumonia and influenza (P and I), recorded in 121 cities, were elevated for the sixth consecutive week since December 13, 1980. Outbreaks of influenza produced by both H_1N_1 and H_3N_2 strains have occurred in several countries worldwide.

Fortunately, most individuals who contract influenza are not at risk of developing complications and only supportive care is indicated. This year's vaccine provides protection against the currently prevalent strains (A/Bangkok/79 and A/Brazil/78) as well as B/Singapore/79 and is indicated for high risk individuals (elderly and those with underlying disease as outlined in the August, 1980 edition of this publication). Nearly 50,000 vaccinations have been administered by parish health units. We continue to recommend that those individuals at risk of adverse consequences from infections of the lower respiratory tract receive influenza now. Amantadine hydrochloride (Symmetrel) is an effective chemoprophylactic agent for these high-risk individuals who are unvaccinated and exposed to influenza. Its administration should be considered concomitant with vaccination in these exposed patients until serum antibodies have time to develop (2 to 6 weeks). We encourage health care practitioners to submit throat cultures for viral isolation and paired serum samples for serology from suspected cases of influenza. Such specimens should be obtained during the febrile episode and sent to the State Health Laboratory. The Division of Disease Control will continue to recommend annual influenza vaccination for individuals at risk of complications. The documentation of current viral strains will guide the preparation of next year's vaccine.

SELECTED REPORTABLE DISEASES
(By Place of Residence)

STATE AND PARISH TOTALS SUPPLEMENT DECEMBER, 1980	VACCINE PREVENTABLE DISEASES					ASEPTIC MENINGITIS	HEPATITIS A AND UNSPECIFIED	HEPATITIS B	LEGIONNAIRES DISEASE	MALARIA**	MENINGOCOCCAL INFECTIONS	SHIGELLOSIS	TUBERCULOSIS, PULMONARY	TYPHOID FEVER	OTHER SALMONELLOSIS	UNDERNUTRITION SEVERE	GONORRHEA	SYPHILIS, PRIMARY AND SECONDARY	RABIES IN ANIMALS (PARISH TOTALS CUMULATIVE, 1980)
	MEASLES	RUBELLA*	MUMPS	PERTUSSIS	TETANUS														
TOTAL TO DATE 1979	268	32	32	18	4	106	873	303	7	6	151	123	509	5	196	10	23990	1130	43
TOTAL TO DATE 1980	15	13	69	38	5	83	927	313	5	60	98	233	478	2	214	7	22754	1424	19
TOTAL in SUPPLEMENT	0	0	0	3	0	1	25	5	0	9	6	5	0	0	2	0	0	0	0
ACADIA												2							
ALLEN																			
ASCENSION																			
ASSUMPTION																			
AVOYELLES																			
BEAUREGARD																			
BIENVILLE																			
BOSSIER							1												
CADDO																			
CALCASIEU							1												
CALDWELL																			
CAMERON																			
CATAHOULA																			
CLAIBORNE																			
CONCORDIA																			
DESOTO																			
EAST BATON ROUGE							1	1											
EAST CARROLL																			
EAST FELICIANA																			
EVANGELINE							1												
FRANKLIN																			
GRANT																			
IBERIA																			
IBERVILLE																			
JACKSON																			
JEFFERSON							11			1	2	1							
JEFFERSON DAVIS																			
LAFAYETTE																			
LAFOURCHE							1												
LASALLE																			
LINCOLN																			
LIVINGSTON																			
MADISON							1												
MOREHOUSE																			
NATCHITOCHES																			
ORLEANS										8	3								
OUACHITA							1	1											
PLAQUEMINES				1															
POINTE COUPEE																			
RAPIDES							2												
RED RIVER																			
RICHLAND																			
SABINE																			
ST. BERNARD											1								
ST. CHARLES																			
ST. HELENA																			
ST. JAMES																			
ST. JOHN																			
ST. LANDRY				2															
ST. MARTIN								1							1				
ST. MARY																			
ST. TAMMANY							1												
TANGIPAHOA							1												
TENSAS																			
TERREBONNE							2					2			1				
UNION																			
VERMILION																			
VERNON																			
WASHINGTON							1	1											
WEBSTER								1											
WEST BATON ROUGE							1												
WEST CARROLL																			
WEST FELICIANA																			
WINN																			
OUT OF STATE																			

* Includes Rubella, Congenital Syndrome.

** Acquired outside United States unless otherwise stated.

From January 1, 1980, through December 31, 1980, the following cases were also reported: 7-Leptospirosis; 4-Brucellosis 1-Blastomyocosis; 1-Cryptococcosis; 28-Trichinosis; 1-Poliomyelitis; non-paralytic; 4-Rocky Mountain Spotted Fever; 12-Encephalitis, Anthropod-Borne.
5-Reyes Syndrome

SELECTED REPORTABLE DISEASES
(By Place of Residence)

STATE AND PARISH TOTALS REPORTED MORBIDITY JANUARY, 1981	VACCINE PREVENTABLE DISEASES					ASEPTIC MENINGITIS	HEPATITIS A AND UNSPECIFIED	HEPATITIS B	LEGIONNAIRES DISEASE	MALARIA**	MENINGOCOCCAL INFECTIONS	SHIGELLOSIS	TUBERCULOSIS, PULMONARY	TYPHOID FEVER	OTHER SALMONELLOSIS	UNDERNUTRITION SEVERE	GONORRHEA	SYPHILIS, PRIMARY AND SECONDARY	RABIES IN ANIMALS (PARISH TOTALS CUMULATIVE, 1981
	MEASLES	RUBELLA*	MUMPS	PERTUSSIS	TETANUS														
TOTAL TO DATE 19 80	0	0	1	0	0	1	55	11	0	0	4	6	32	0	5	0	1560	101	1
TOTAL TO DATE 19 81	0	0	0	0	0	2	31	12	0	1	2	1	21	0	6	0	1672	108	5
TOTAL THIS MONTH	0	0	0	0	0	2	31	12	0	1	2	1	21	0	6	0	1672	108	5
ACADIA															1		16		
ALLEN																	1		
ASCENSION																	5	1	
ASSUMPTION													1						
AVOYELLES																	2	1	
BEAUREGARD																	2		
BIENVILLE																	2		2
BOSSIER							1										20		
CADDO								1					2				174		
CALCASIEU													1				90	4	
CALDWELL																	5		
CAMERON																	3		
CATAHOULA																	4		
CLAIBORNE																	3		
CONCORDIA																	3	1	
DESOTO																	6		
EAST BATON ROUGE							1						3				126	11	
EAST CARROLL													2				7	2	
EAST FELICIANA																		1	
EVANGELINE							2	1									4		
FRANKLIN																	7		
GRANT																	3		
IBERIA																	19	1	
IBERVILLE																	5		
JACKSON																	2		
JEFFERSON						1	4						2		2		111	6	
JEFFERSON DAVIS																	10		
LAFAYETTE											1						53		
LAFOURCHE													1				3		
LASALLE																	1		
LINCOLN																	21	4	
LIVINGSTON							1										3	1	
MADISON																	6		
MOREHOUSE																	7		
NATCHITOCHES																			2
ORLEANS							6	5		1			2				703	52	
OUACHITA							4										63	4	
PLAQUEMINES																	6	2	
POINTE COUPEE																	1	1	
RAPIDES															1		50	2	
RED RIVER													1					2	
RICHLAND																	8		
SABINE													1				1		
ST. BERNARD																	9		
ST. CHARLES												1					6		
ST. HELENA																			
ST. JAMES																	1		
ST. JOHN																	2		
ST. LANDRY							1						1				11	1	
ST. MARTIN							1	2					1				10		
ST. MARY																	2		
ST. TAMMANY							1	1					2				12		
TANGIPAHOA											1				1		25	5	
TENSAS																			
TERREBONNE						1	7	1									1		
UNION																	1		
VERMILION							1								1		9		
VERNON								1									2	3	
WASHINGTON																	4		
WEBSTER													1				4		1
WEST BATON ROUGE																		1	
WEST CARROLL																	2		
WEST FELICIANA																		2	
WINN							1										6		
OUT OF STATE																	9		

* Includes Rubella, Congenital Syndrome.
** Acquired outside United States unless otherwise stated.

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This public document was published at a cost of $.27 per copy by the Office of Health Services and Environmental Quality to inform Physicians, Hospitals, and the Public of current Louisiana morbidity status under authority of R.S. 40:36. This material was printed in accordance with the standards for printing by state agencies established pursuant to R.S. 43:31.