

REPORT
ON
POLIOMYELITIS VACCINE
PRODUCED BY THE
CUTTER LABORATORIES

AUGUST 25, 1955
U.S. DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE
PUBLIC HEALTH SERVICE.

I
The Study.

Six cases of poliomyelitis were reported as having occurred by April 26 among children who had received vaccine manufactured and distributed by the Cutter Laboratories. Because of the possibility that some of these cases might be attributable to the presence of infective amounts of live virus in some of the lots of vaccine, the Public Health Service requested the Cutter Laboratories to recall the unused portions of the vaccine they had distributed and to suspend the distribution of new lots.

An investigation was begun on April 27. It included:

1. Statistical study of the occurrence of poliomyelitis in the United States with special attention to vaccination as a possible source of infection.
2. Study of Cutter plant facilities, their production practices and the vaccine they produced.
3. Study of vaccine production in the industry as a whole.

The general problem of vaccine production was the subject of the Public Health Service's Report on Salk Poliomyelitis Vaccine published in June 1955. Those findings of the study with general relevance to the entire industry led to the May 26, 1955 revised minimum requirements which the Public Health Service believes provide adequate safeguards for the routine production and use of poliomyelitis vaccine. Those aspects of the study with primary relevance to Cutter vaccine and production methods are the subject of this report.

II
Epidemiology

The Poliomyelitis Surveillance Unit, established April 28, 1955, in the Public Health Service Communicable Disease Center

Atlanta, Georgia, has collected detailed information on the occurrence of poliomyelitis with special attention to vaccine as a possible source of infection. State and local health officials throughout the United States have cooperated in obtaining needed information.

Poliomyelitis in Individuals Receiving Cutter Vaccine.

An estimated 401,000 children were reported to have been vaccinated with vaccine from 17 distribution lots of Cutter vaccine. Poliomyelitis was reported to have occurred in 79 of these individuals within 90 days following the administration of vaccine. Of the 79 cases 73 occurred within a period of 3 to 31 days (the generally recognised incubation period) following vaccination. The majority of these cases were associated with a limited number of distribution lots of Cutter vaccine. Of the 73 cases, 46 cases were reported among individuals injected with vaccine from 6 distribution lots, and 18 cases among those injected with vaccine from the remaining 11 of the 17 distribution lots. The distribution lots of vaccine received by the remaining 9 cases could not be identified.

The attack rate of poliomyelitis in all individuals receiving vaccine from the six lots referred to above was 47 per 100,000 children vaccinated; the lowest attack rate for any one of these lots was 20. The combined attack rate observed for the remaining eleven lots used was 6 per 100,000 and the highest attack rate associated with any one lot was 10.

The number of confirmed cases (46) observed in the 6 lots with the high attack rate of poliomyelitis, was larger than the number of cases (5 to 10) expected to have occurred naturally. During the 90-day period of study 46 of the 49 cases associated with the 6 lots occurred within the incubation period of the disease following vaccination. The site of injection was the site of first paralysis in a high proportion of the cases. These facts warrant a presumption that the cause of the disease in some of the individuals who received vaccine from these 6 lots was infection with poliomyelitis virus contained in these lots of vaccine produced by the Cutter Laboratories.

Attack rates of the disease in individuals receiving vaccine from the remaining 11 of the 17 lots were not higher than could be expected nor did the other data relating to the character of the disease suggest a causal relation between vaccination with material from these lots and the occurrence of poliomyelitis.

Poliomyelitis in close associates of vaccinated children.

There were 90 cases of poliomyelitis in household contacts occurring within 49 days after vaccination of a household associate with Cutter vaccine. In 71 of these cases the occurrence of the disease could be associated with specific distribution lots of vaccine. Among the 71 cases, 57 were associates of persons who had been vaccinated with material from the 6 distribution lots, while 14 cases were associates of persons who had been vaccinated with material from the remaining 11 lots. These data support the initial presumption that infective amounts of live virus were contained in the six lots.

Isolation of Poliomyelitis virus.

Type 1 poliomyelitis virus was isolated from three of the six lots of vaccine by Public Health Service or other laboratories over the 90-day period of study.

Within the study period poliomyelitis virus was isolated from the stools of 28 cases who had been vaccinated with Cutter vaccine from the six lots, and from the stools of 32 cases developing in household contacts of persons vaccinated from these six lots. Type 1 virus was identified from 59 of these 60 individuals; however, this finding by itself would not ordinarily be significant, because it is not unusual to isolate Type I virus from a high percentage of cases of poliomyelitis and their contacts in natural outbreaks. The significance of the laboratory identification of Type I virus lies in the correspondence between the type virus found in the three lots of vaccine and in the stools of the 59 individuals.

The data on the development of poliomyelitis among individuals who received Cutter vaccine from 6 to 17 distribution lots, on the development of the disease among close associates of those who received that vaccine, and on the isolation of Type I poliomyelitis virus both from individuals who may have been infected and from some of the 6 distribution lots, indicate that infective amounts of live virus were contained in some distribution lots of Cutter vaccine.

III
Plant Production.

The plant study dealt with the two possible sources of infective amounts of live poliomyelitis virus in the vaccine -- contamination and inadequate inactivation. Distribution of vaccine containing infective amounts of live virus could have occurred if the vaccine was inadequately inactivated or if contamination occurred before withdrawal of vaccine for the final safety tests, but in either case only if the final safety tests

failed to demonstrate the presence of live virus. If contamination with virus occurred after the vaccine had been sampled for the safety tests, then the presence of live virus would have gone undetected.

The possibility of contamination.

The equipment, the physical arrangements and the routine handling procedures of the Cutter Laboratories were checked in detail to determine if deficiencies in them might have led to contamination. Nothing was found to indicate that the infective amounts of live virus in Cutter vaccine were attributable to contamination.

The possibility of inadequate inactivation.

In the production process the final safety tests on the trivalent pool (a mixture of the three types of virus) constituted the final check against the release and distribution of an individual lot of vaccine which might have contained an infective amount of live virus if inactivation had been inadequate. Prior to May 27, inadequacy of inactivation was not unusual in the experience of several of the manufacturers. In addition, there were then fundamental weaknesses in the safety testing procedures which failed to assure what is now believed to be a satisfactory degree of sensitivity.

A consideration of the detailed processing data made available to the Public Health Service by the Cutter Laboratories warrants the presumption that a combination of inadequate inactivation and failure of the safety tests permitted the presence of undetected infective amounts of live virus in some lots of the vaccine.

IV.

Comment and Summary.

1. A study of poliomyelitis in children subsequent to the administration of vaccine produced and distributed by the Cutter Laboratories has been made. It is concluded from that study that the development of the disease in some of these patients was the result of the presence, in infective amounts, of live poliomyelitis virus in some distribution lots of Cutter vaccine. Laboratory studies support this conclusion.

2. The exact reasons for the presence of infective amounts of live virus in some lots of Cutter vaccine could not be found. The study produced nothing which pointed to contamination as a source of the live virus but it did produce data suggesting the combination of inadequacy of virus inactivation and failure of the safety tests as responsible for live virus remaining

undetected in the finished vaccine.

3. Study of the Cutter data against the background of general experience of the industry during the same time period strengthens the probability that the cause of the trouble was inadequate inactivation coupled with failure of the safety tests to demonstrate the presence of virus.

Federal Law (18 U.S.C. 1905) prohibits public disclosure, not authorized by law, by officers or employees of the United States of information concerning business processes or operations obtained by them in the course of investigations.

THE ARCHIVE COLLECTION

THIS LITERATURE WAS COLLECTED
FROM VARIOUS SOURCES
OVER THE YEARS OF MY RESEARCH
ON VACCINATION
WHICH STARTED IN SEPTEMBER 1991.

FORTUNATELY I RECEIVED
SEVERAL DOCUMENTS
AND BOOKS FROM INDIVIDUALS
WHO HAD BEEN INVOLVED IN
THE ANTI-VACCINATION LEAGUE OF GREAT BRITAIN
DURING THEIR LIFE TIME.

THE LATE DR GORDON LATTO, WHO SERVED AS THE MEDICAL
VICE PRESIDENT OF THE LEAGUE DURING THE MID 1900s.
ALSO, IAN & MONIQUE STIRLING TO NAME A FEW.

ALSO THANKS TO JOHN WANTLING, AN INDEPENDENT
RESEARCHER, FOR PATIENTLY PHOTOCOPYING
NUMEROUS ARCHIVE PUBLICATIONS & FORWARDING
COPIES TO ME BACK IN THE MID-NINETIES.

I HAVE SCANNED THESE PUBLICATIONS & LITERATURE
TO PRESERVE THE WEALTH OF INFORMATION
CONTAINED WITHIN THESE DOCUMENTS
IN THE HOPE THAT THEY WILL BE CIRCULATED
& MADE AVAILABLE TO ANYONE WHO WISHES
TO STUDY THE HISTORICAL DATA
SURROUNDING THIS SUBJECT.

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• 2017 •