Dear Doctor:

The letter sent to you under date of June 11, 1951 on the relationship of elective immunization and poliomyelitis has resulted in a number of inquiries from physicians on this subject. In response to these inquiries, we are presenting in the enclosed summary the scientific data upon which the Department's recommendations were based.

Preliminary reports on this subject were communicated to you in the July, August, and October, 1950 issues of HEALTH NEWS, which goes to every physician in Upstate New York.

It should be emphasized that the recommendations refer only to those injections which the physician can elect to give either before or after the poliomyelitis season. Such injections include immunization against diphtheria, pertussis, tetanus, typhoid fever and smallpox. Restricting the initial immunization of infants to the period under six months of age and postponing booster injections to periods other than the poliomyelitis season will accomplish the desired results.

Certain prophylactic injections cannot, of course, be postponed. The following are examples: Immunization of persons travelling abroad; immunization of student nurses and newly employed nurses in hospitals; tetanus antitoxin or tetanus toxoid following injuries; rabies vaccine following a bite by a rabid animal; diphtheria antitoxin when needed as a prophylactic; gamma globulin for measles and other diseases; and injections of allergens for the testing and treatment of allergic patients.

Most diagnostic and therapeutic injections used in medical practice certainly cannot be considered as elective. Obviously, such injections cannot be postponed. The calculated risk in their use must be taken in view of the known benefits to the patients offered by the antibiotics, insulin, antitoxin and other therapeutic agents.

We are sure you fully appreciate the State Health Department's responsibility to inform the medical profession and the public of hazards to the health of our citizens in advance of the danger. While no one can predict when a poliomyelitis epidemic can occur, we know from past experience that there is an increased hazard during the summer months.

Accordingly, we are giving you the most recent information on this subject as a follow-up report of previous material presented to you in HEALTH NEWS during the past 12 months. We will keep you currently informed of any new developments in this field.

Sincerely yours,

Herman E. Hilleboe, M.D.
Commissioner of Health

(See Enclosures)
The following is a summary of pertinent scientific facts upon which our recommendations were made:

There are five British reports (1-5) (one of these Australian) dealing with the relationship between paralysis in poliomyelitis and injections of diphtheria, tetanus and pertussis antigens. Of these the most extensive and carefully planned is that by Hill & Knowelden (5). They made a detailed study of 410 cases of poliomyelitis under 5 years of age, and of paired controls in 104 of these. This study indicated that in recently inoculated children, the limb of the injection was the site of paralysis much more frequently than was the case with children not recently inoculated. The interval between last injection and the onset of symptoms was no more than a month; most commonly 8-17 days. This study confirmed completely the four other British reports.

In addition, several studies (6)(7)(8) now awaiting publication add conclusive affirmative evidence. The study by Anderson and Skaar (6) in Minnesota, was made available to our epidemiologists in April 1951.

The major basis for our recommendations is a study carried out in 1950 by the staff of the New York State Health Department in cooperation with all the county and city health departments in the State. The study was made by obtaining from each reported case of poliomyelitis (2137 cases) information on all injections received during the two months prior to onset with specification as to the type of material, site of injection, date given, and by whom. Identical information was obtained from each member of the nonenroll (6055 persons) and for the members of three additional control families living on either side and across the street (14,710 persons). The material has been studied with great care and presented to leading epidemiologists throughout the United States. A few of the pertinent facts are summarized below:

A history of an injection during the month before onset was twice as frequent among poliomyelitis patients as among either the household or extra-household controls at every age level. This ratio was about the same for injections of immunizing materials, as for penicillin alone, and a miscellaneous group of other injections including hormones, liver extract, and local anaesthetics. Injections of penicillin given during the week before onset were excluded from the analysis.

By calculating the poliomyelitis attack rate per 1000 injected persons and comparing it with the attack rate per 1000 non-injected persons, the analysis disclosed that the risk of getting paralytic poliomyelitis at each age group is doubled in the injected population.

In addition, the study shows a clear-cut association between site of injection and site of paralysis. For example, of the paralytic poliomyelitis patients without history of recent injection only 34 per cent had arm involvement; of patients with arm injections during the period 8-14 days before onset, 77 per cent had arm paralysis. Of the group with arm injections 15-21 days before onset, 62 per cent had arm paralysis; and those injected 22-28 days before onset, 50 per cent had arm involvement.

The Committee on Research and Standards of the American Public Health Association has set forth its recommendations in the June 1951 issue of the Association Journal. The recommendations read as follows:
"Recent published and unpublished data strongly suggest that an individual who develops poliomyelitis within a month after receipt of an injection of an antigen, or possibly of some other material, shows an increased frequency of paralysis in the extremity into which the injection has been given. * * * * * * the data so far available would suggest that, in the face of an abnormal prevalence of poliomyelitis in a given locality, antigen inoculations may well be postponed until after the subsidence of the abnormal prevalence." (12)

References:


7. Greenberg, Morris - Unpublished investigation by the New York City Health Department.


Discussion on Practical Aspects of Immunization Against Diphtheria, Whooping Cough, etc., During Poliomyelitis Epidemics, by Joseph A. Bell, M.D.

During the last 18 months several medical reports have been published showing retrospective analyses of data collected in the large poliomyelitis epidemics of 1946 in Minnesota and 1949 in England and Australia. In brief, these studies endeavored to see whether there was any relationship between the occurrence, location and severity of paralysis and the history of prior immunization against diphtheria, whooping cough, smallpox, etc. The results show that in the total of the reported poliomyelitis cases studied there was no significant difference in location or severity of paralysis between persons who were immunized and those who were not. However, the comparatively few cases who gave a history of whooping cough or diphtheria immunization within the month prior to onset of illness had a tendency for localization of paralysis in the limb recently injected, and some studies indicate that the paralysis in such cases was more severe. Also a larger percentage of these cases gave a history of such immunization during the month prior to onset than during the second, third, fourth, or fifth month prior to onset.

Medical authorities on poliomyelitis have been pressed for interpretation of these phenomena. In general, most all agree that retrospective studies carried out in this manner cannot give proof that immunizations during polio epidemics increase the risk of attack with paralytic poliomyelitis. Studies of this type cannot make adequate allowance for all the many factors aside from immunization which may account for the observations reported. Among these factors are those which determine exposure
and resistance to infection and disease, those that determine whether a case comes to official recognition, and those which influence memory of prior immunizations. Studies of this type do not determine the comparative risk of poliomyelitis among children who were and were not immunized during an epidemic. Nevertheless the consistent findings of these studies cannot be ignored. Authorities generally concede that if the reported observations are not biased by the unknown factors suggested above, then the observations are consistent with an hypothesis that injections of children with diphtheria toxoid or whooping cough vaccine may tend to precipitate the paralytic disease. It is well known that during a poliomyelitis epidemic in a community many persons are infected but comparatively few develop the paralytic disease. The infection is widespread in many persons of the community whereas only few develop paralytic poliomyelitis and a nearly equal few develop a mild inconsequential illness. What determines whether an infected person develops paralysis is unknown. It is possible that immunization of infected persons may precipitate a paralytic case. Other studies have suggested in a similar way that extreme physical exertion, undue fatigue, severe injuries, and operations particularly of the nose and throat may precipitate paralytic cases in infected persons.

Paralytic poliomyelitis is such a dread disease that we want to do everything practicable and reasonable to prevent it. What is practicable and reasonable depends upon an evaluation of the benefits against the risks involved, and even if we assume the hypothesis to be fact, we do not know the amount of risk. It is obvious that thousands upon thousands
of children have been immunized against diphtheria and whooping cough during poliomyelitis epidemics and extremely few develop paralytic poliomyelitis. It is also obvious that of the many, many cases of poliomyelitis which have occurred, very few have been immunized during the month prior to onset. Thus, even if the hypothesis is correct, we must surmise that the risk of poliomyelitis following such immunization during an epidemic is very small.

Of course it should be added that immunizations per se do not cause poliomyelitis. Polio is caused by a minute, infectious, living virus which can be readily recognized in research laboratories. There is absolutely no risk of poliomyelitis following immunization of any kind when polio infection is not present.

The great benefit of immunization against diphtheria, whooping cough, smallpox, and tetanus is well established. In the absence of immunization against diphtheria, whooping cough, and smallpox, each of these diseases alone would present a greater danger than poliomyelitis. The deaths from whooping cough alone have decreased many fold as immunization has become more extensive, but during the last 8 years for which reported deaths in the United States are available, the deaths from whooping cough alone in little babies less than 1 year of age was approximately twice that of all deaths from poliomyelitis in all persons at all ages. Thus we must keep up and expand our immunization program. It is recommended that, in general, all children should be immunized against smallpox, diphtheria and whooping cough and that tetanus immunization be
given in areas where tetanus germs are likely to cause infection. There being no doubt that children should be immunized, the question arises as to when is the best time to do it. The preferable time for immunization varies with each disease. For example, it is preferable that the first smallpox vaccination be done before a child is 1 year old. There are many good reasons for this but in the event it is not done at this time, then it should be done as soon as practicable thereafter. Similarly, it is preferable to do smallpox vaccination in the cool, dry months of the year because when the vaccination site is kept cool and dry, the local reaction is more discrete and favorable. But if the only opportune time to vaccinate a child is in the summer, then it should be done in the summertime because the most important thing is to get it done. Again, one postpones smallpox immunization in children with eczema, but if a person is exposed to smallpox there are no contraindications to vaccination and no excuse for delay. The same principles apply to other diseases and immunizations. The preferable time for immunization may also vary in different communities and in the same community from time to time. This will depend upon the immunity state of the general population, the prevalence of disease, and the opportunities for exposure to disease. Physicians are the only persons qualified to determine the preferable time for each immunization in each particular circumstance.

With respect to the possible, but not conclusively proven relationship between immunizations carried out during poliomyelitis epidemics and the occurrence of the paralytic disease, the Surgeon General has recommended that, in general, emphasis should be given towards immunization of children during the months from October to May, but immunizations during
the summer months should be done when indicated. Obviously, if the prevalence of diphtheria and whooping cough in a community is very low and if the child is not likely to be exposed to these diseases during June to September, then it makes little difference as far as protection is concerned whether he is immunized in July or whether the immunization is temporarily delayed until October. Thus in instances where it makes little or no difference about protection, it is preferable to temporarily delay immunization when poliomyelitis infection is prevalent in the community. In all, a physician has to evaluate the benefits against the possible hazards of immunization in a particular person in a particular community at a particular time.