

B.C.G. PILOT STATION:

UNICEF, when it embarked on its great world-wide campaign of B.C.G. anti-tubercular vaccination, was fully aware of the great responsibilities it would incur. It was decided to establish two "pilot stations", one in Denmark and one in France for purposes of supervision. Both stations are under the supervision of the W.H.O. Standardisation Commission and their work is governed by its general directives. The B.C.G. vaccination campaign in Europe will shortly come to an end, and the various countries will soon be called upon to prepare their own vaccine; it will thus be helpful for them to be able to compare the different vaccines, and to call on the services of the two pilot stations.

There are many points about the B.C.G. Vaccine which require clarification. It is nearly thirty years since B.C.G. vaccination was first carried out in France; since that time, after various vicissitudes, the use of B.C.G. has spread to many countries, and millions of children have been vaccinated.

Despite this, however, it has not yet been possible to adopt a final theory on such important questions as the method of administration of the vaccine, or the dose to be given. Each country has in fact its own method, which it considers the best; and sometimes even its own special method of preparing the vaccine.

It is obvious that, in these conditions, no really scientific conclusions can be drawn from the numerous separate experiments being made. And there is no doubt that the indifference and even hostility of doctors in many countries is due mainly to the fact that no coherent theory has ever been submitted to them.

Yet there is surely no question of greater importance than that of world health.

With this method it is possible (as has now been well established) to protect children against tubercular infection. It had been in use for 27 years. It is not applied universally, neither is it applied in the same way in different countries; but there is no doubt that for this vaccination as for all other preventive or therapeutic medicines there must be a certain dose, a certain method of administration and a certain method of preparing and storing the vaccine which gives the best results.

The International Children's Emergency Fund established the Pilot Station in Paris for the purpose of carrying out methodical research on all questions connected with the B.C.G. vaccine with a view to ultimate standardisation; it was realised that the spread of the use of this vaccine made its standardisation essential.

In addition to this essential short-term task, the Pilot Station is also to make a study of the effectiveness of B.C.G. This latter is a very difficult piece of research, involving years of work; and moreover, in view of the numerous factors involved, no absolute scientific certainty is yet possible, though preliminary approximate conclusions may in time be drawn from the study of allergia.

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The B.C.G. Pilot Station at 166 rue Blomet, Paris XV has been working since June 21st 1948. It has been helped in its work by the fact that there already existed in France a number of centres and organisations providing a wide field of observation.

CENTRES OF ACTIVITY OF THE PILOT STATION

Providing homes in families for infants

This organisation was founded in April 1920 by Leon Bernard and Robert Debre for the purpose of protecting infants born of tubercular parents from contagion. These children are entrusted, on birth, to the care of qualified foster-mothers, with whom they live in hygienic conditions calculated to build up their health. These homes are supervised by a clinic with qualified child nurses, who prepare feeding-bottles with the necessary diet and distribute the milk. The infants are examined regularly by a doctor, and there is a hospital where the children can be kept under observation if necessary. There are at present eight of these centres in Sologne. Children stay there until they are four and are protected, during that period, from all tubercular contact. It has proved possible for twenty-five years to maintain conditions of absolute non-contamination.

This organisation has provided the Pilot Station with accommodation, and enabled it to work in proper scientific condition.

Research into allergia in children after vaccination with B.C.G. has been carried out in absolutely perfect conditions, such as, as far as we know, exist nowhere else. The results obtained at this Training Centre are thus of great value.

More than 400 children have provided material for first-hand study.

After leaving the centres in Sologne, the children continue to be kept under observation by the central organisation in Paris, to which they are summoned at regular intervals for a check on their allergia.

The results of research on the modifications of allergia in children who have returned to normal life are very interesting; they provide data for an attempt to differentiate between post-vaccinal allergia and allergia following an infection by virulent bacilli. (This is one of the new tasks the Pilot Station is proposing to undertake during the next few months).

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In addition to this centre, we have gradually organised further groups of children and adolescents, but have purposely limited the number of such groups in order to ensure that the tests, which require great care and detailed surveillance are always accurately

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carried out; and that every case is examined and checked at regular intervals.

Among the post-treatment cases, some inevitably live in contaminated surroundings. Such cases are subjected to thorough medical-welfare examination by a specialist welfare worker. This had led to the discovery of 6 cases of a contaminator being in close contact with a vaccinee.

These research centres, the number of which is increasing, are as follows:

CHILD WELFARE CENTRE OF THE FACULTY OF MEDICINE

Children are sent to the clinic by out-patient departments (chiefly those of the Public Health Service) doctors or welfare services. The clinic is not confined to infants; school children, adolescents and young adults also go there to be vaccinated (nurses in particular). It is generally a case of whole families who fully understand the benefits of vaccination. This weekly clinic has been working for ten years; it has been at the disposal of the Director of the Pilot Station since February 1949. We have vaccinated 242 cases.

MEDICAL CLINIC FOR SICK CHILDREN

The clinic is open three times a week. Children are tested, vaccinated and kept under medical supervision. The age of the patients varies - they include infants, young children, medical students, nurses and even a few apprentices.

The number of vaccinations performed at this centre up to the end of May 1949 was 309.

FRENCH NATIONAL RAILWAY COMPANY

Since October 1948 the "Pilot Station" has been in charge of the B.C.G. service in two of the main clinics, where soon all the pupils of the Apprenticeship Schools will be tested and vaccinated by us.

Since no person who is allergic is eligible for appointment on the staff of the French National Railways, we have arranged for persons vaccinated to be admitted on the same basis as cases of natural allergia. The B.C.G. service of course operate in close cooperation with the anti-tubercular service.

Special interest attaches to cooperation between the Pilot Stations and the French National Railway Company. In addition to reserach on the variations of allergia corresponding to the different vaccines used, (which is carried out here in the same way as in other countries), there is the possibility of conducting highly effective propaganda in favour of this vaccination through the medium of the

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railway company medical officers who stay at the Pilot Station.

SAINT-MAURICE PROFESSIONAL REEDUCATION SCHOOL

(At La Motte Beuvron, Loire et Cher)

This school is attended by 250 boys, aged from 15 to 21 years. The Pilot Station has been responsible for the B.C.G. service in this school since October 1948; supplementary examinations (X-ray, etc.) are supervised by the school's medical officer.

We have vaccinated 119 adolescents to date.

VILLEPATOUR FRENCH RED CROSS CENTRE

In this centre, which comprises 60 young cripples aged from 5 to 20, the Pilot Station is responsible for B.C.G. vaccination; 29 cases have been vaccinated since May 1949.

S.N.E.C.M.A. INSTRUCTION SCHOOL

(At Argenteuil, S. and O.)

At this school, where the boys are aged from 11 to 17, experiments with B.C.G. have been under way for two years. We have been responsible for the service since January 1949; and had vaccinated 48 cases by the end of May 1949.

GOODRICH FACTORIES

The Pilot Station has likewise been responsible for the B.C.G. service at the Goodrich factories since March 1949, as regards:

- 1) the workers
- 2) workers' children registered at holiday camps.

We work in cooperation with the factory's medical officer, who completes the exploratory examinations (X-ray, rate of sedimentation, etc.).

The factory employs 2,500 persons; we have performed 102 vaccinations.

Since February 1949, our work has also included an infant clinic and a clinic for children under school age, held at the BAGNEUX HOSPITAL twice a week. Children are subjected to regular examination, where necessary in their homes. We have vaccinated 90 children.

We engage in similar work at the MONTREUIL HOSPITAL, but here B.C.G. experiments are of one year's standing only. 162 cases have been vaccinated since March 1949.

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At the PUTEAUX MUNICIPAL HOSPITAL (Infants and Maternity Clinics) the work of the Pilot Station is limited to making a start with vaccination in this milieu. We vaccinated 61 children there from December 1948 to April 1949.

Finally, at the POOR PEOPLES DAY NURSERY at Antony, we have been responsible for the B.C.G. service since January 1949 (about 200 beds).

These are new born infants, admitted as a rule when their mothers leave the maternity hospitals, and they stay a few months only. They comprise orphanage children, children receiving public assistance, and children in custody. We have already vaccinated 232 cases.

There are plans for enabling us to continue the treatment of these children after they leave the day nursery - at least in the case of those sent to the provinces - and it appears that the Public Assistance Administration Authorities intend in future to make us responsible for the B.C.G. service amongst their children.

By the end of May 1949, in all these centres, we had vaccinated a total of 1918 cases, the results of the vaccination having been checked in 1300 cases. The rest of the cases were too recent for results to have been checked. We also supervised 511 cases of vaccination not performed by our service.

We must further stress the fact that the specially favourable conditions of work of the specialised staff of the Pilot Station make the results they obtain of particular value.

The vaccination centres have been established in a number of different milieux, and young cases can be attended at all stages of development, from new-born babies to factory apprentices.

We are thus able to make a study of the conditions peculiar to every age group; and it is possible that the methods of vaccination may have to be varied slightly for the different age groups.

Comparative Study of the allergia obtained after vaccination by cutaneous scarification and by intradermic injections.

In France, the most widely used method is that of scarification; we thought it would be instructive to compare this method with the intradermic method, the favourite Scandinavian method.

The vaccine used for scarification is B.C.G. † - S.P. prepared by the Pasteur Institute in Paris (75 mgr per cc); the vaccine used for the intradermic method is that of the Serum Institute, Copenhagen (‡ mgr. per cc), with an injection of 1/10 c.c.

From our study of about 1500 children it may be concluded that.

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- a) the immediate results given by the two methods are roughly identical; we cannot yet speak of the long-term results, as our observation period was too short to judge in the case of the intradermic injection method,
- b) the fact that it has been easier to administer and more accurate undoubtedly make the intradermic method more suitable for purposes of mass vaccination.

Experiments with and comparison of the various different types of vaccine for obtaining allergia.

Fresh Vaccine

After comparing fresh B.C.G. vaccine prepared by the Pasteur Institute for scarification (concentration 75 mgr. of B.C.G. per cc) with the vaccine prepared for intradermic injection by the Serum Institute (the results of which we gave above) the Pilot Station carried out experiments on various vaccines.

We asked the Pasteur Institute to prepare us a vaccine of the same concentration as that provided by the Serum Institute, i.e. 1/4 mgr. of B.C.G. per cc. for injection of one tenth, or 1/40th mgr. of B.C.G.

On the whole the results are very similar; local reactions are very similar, allergic reactions appear at the same time. All that remains to be discovered is the duration of the allergia; this demands a long period of observation, which cannot be completed at present.

Dried Vaccine

Since fresh vaccine only remains effective for a fortnight, we attempted to determine the conditions of use of dried vaccine. If it were in fact possible to codify these conditions, the problem of supplying vaccine to remote centres and its use in hot or tropical countries would be considerably simplified.

Until a few months ago, the Pasteur Institute used to prepare this vaccine for cutaneous scarification only.

We asked the Pasteur Institute to prepare us some dried vaccine for intradermic injection; the ampullae contain 2.5 mgr of B.C.G., but we add, at the moment of use, the necessary quantity of physiological serum, varying according to the concentration required. We have experimented with doses of one tenth, one twentieth and one fortieth. The twentieth gave good results, with allergia appearing in 86.17% cases after about six weeks.

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We are continuing this work using vaccines dried for two months and more, with a view to determining the optimum dilution in each case. We also vary the storage conditions, using different temperatures.

In all this research work, close contact is maintained with the Pasteur Institute. This cooperation is highly advantageous, as the excellent conditions in which the experiments and checks are carried out, enable the Pilot Station to furnish valuable information. It is interesting to note that the Pilot Station in its study of the various different types of vaccine and tuberculin has already exercised a beneficial effect on the production centres, inducing them to modify or improve their methods of preparation of the products.

TRAINING CENTRE

Apart from the technical results achieved, the Pilot Station constitutes a useful training centre for doctors wishing to learn the technique of this form of vaccination. Already a number of Parisian and provincial doctors and also doctors from abroad came to us to learn about our methods and instruments, our index system etc. Many of them insist on visiting the various vaccination centres. As already said, the medical officers of the Pilot Station have instructions to teach the Railway Company's medical officers the best vaccination methods. This will result in the training of some hundred experts who, in their turn, will disseminate the training they have received in the districts under their control.

The value of the Pilot Station as a teaching centre was again clearly demonstrated when teams had to be trained at a few week's notice, for the B.C.G. campaign in North Africa: it was possible to train 7 medical officers and 18 nurses in this way. They received the fullest possible theoretical instructions, enabling them to answer any questions they might be asked about B.C.G., whilst at the same time having technical training on the various tests and on methods of intradermic vaccination.

These teams are now at work, and, despite the difficult technical conditions, they have made a great success of this first attempt at systematic vaccination in a Moslem country. In one month, they have made tests on more than 150,000 children, and vaccinated 72,000.

The Director of the Health Service in Tonkin recently sent a young woman doctor from Indo-China to learn the technique of B.C.G.

CENTRE OF INTEREST

Amongst those who, since the beginning of the year, have visited the B.C.G. Pilot Station, mention may be made of the following:

Doctor J.A. FAREOR, Chief of Delegation of the World Health

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Organisation in Rome, visited us on January 7th 1949.

He wanted information on the technical, medical and social aspects of our work. We took him to see Professor Robert Debre, and also to the Pasteur Institute, where Mr. Van Deinse showed him round the B.C.G. laboratory. He watched the preparation of the vaccine.

Doctor Irven M. LOURIE, also of the World Health Organisation, came to see us when he was passing through Paris on his way to Geneva. He appeared to take a great interest in our organisation, and we explained many points to him, in particular regarding the intradermic method.

On March 17th 1949, Dr. LELONG of Marrakesh (Morocco) came to us for information on B.C.G. vaccination; he wanted to learn our technique and was present several times when intradermic vaccination was being performed.

On April 6th 1949, Doctor P.Z. KING, medical advisor of UNICEF, New York, visited the Pilot Station, and appeared to be very interested in our work.

On May 9th 1949, Doctor GAUTIER, representing the World Health Organisation, honoured us with a visit to the Pilot Station. Doctor Broca gave him all the information he wanted about the working of the Pilot Station, and he appeared to be very much interested.

Professor LACROIX, of Algeria, also visited us in May 1949.

He wanted to study our methods of work as a preliminary to a projected campaign for B.C.G. vaccination in Algeria. We supplied him with the material necessary for carrying out a partial experiment in Algeria.

Last May also, Doctor BRETEY, head of the Tuberculosis Research Branch at the Pasteur Institute, sent to us Professor de LOUREIRO (of Lisbon) who came several times to see us. He required information on B.C.G. vaccination by the intradermic method, and asked for various details of our technical methods, from both the medical and the social aspect, with a view to establishing a B.C.G. vaccination center in Lisbon.

BIBLIOGRAPHY (see appendix I)

We have organised a bibliography service, and have been able to collect, translate and classify a large number of documents from all over the world. These documents are at the disposal of any one who wishes to consult them.

We are in correspondence with a number of Doctors and Centers, some of them in very remote parts (Upper Katanga, Shanghai) who are interested in this question. They request information, and submit their results.

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Thus the B.C.G. Pilot Station in Paris, thanks both to its valuable technical research and supervisory work, and also to its work as a training and information center, constitutes a very valuable medium for familiarising the public with the properties of B.C.G. vaccination.

Its programme, admittedly a very vast one, is essentially practical in its aims.

Its originality lies in the fact that, unlike official standardisation organs, where control of the individual is frequently lacking, it serves a number of different purposes: it is a center for research and information on B.C.G. vaccine; and it is an effective organ for propagating knowledge on the method of use of the vaccine; and it is a center for training special personnel. At the request of the W.H.O. and in compliance with the directives laid down by the W.H.O. Standardisation Commission it could give valuable aid both to the W.H.O. and to the various countries.

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