

B. C. G. VACCINATION Why I Oppose It C. RAJAGOPALACHARI

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G. VACCINATION

hy I Oppose It

THE more I examine this subject, the more firmly am I continued that this B.C.G. mass campaign lacks true scientific basis and is no more than a form of gaackery. It is of no use whatsoever in the vast majority of cases and harmful in quite a few. B. C. G. s based on a weak and undemonstrated theory that artificially produced allergy not supported bv which is that quantity of confirmation which the method of scien- tific induction demands before acceptance. sought to be guarded and buttressed by admissions that meet every case of proof against it. B.C.G. is of no potency, it is admitted, where the re-infection is strong and this can be an explanation for every failure. In cases where it leads to harm, it is explained by 'low resistance' in the victim. Every circumstance of quackery attends this mass campaign that has been started in India, despite the caution observed in civilized countries abroad wherever it is tried. Indian children are being offered for mass experimentation on the same plan as was put in operation among the people in the warravaged areas and uncivilized dependent communities.

Not only is the basis of the B. C. G. scheme scientifically inadequate, but the propaganda employed for its rapid furtherance on a mass scale smacks of the methods of quackery. It has been often officially stated and repeated in the press that so many lakhs of children have been immunised this year against Tuberculosis and so many millions will have been immunized by the end of the next two years and so on. Any one who remembers the nature of the very limited claims put forward on behalf of B.C.G. Vaccination can discover that the public propaganda in this respect is misleading. because the alleged immunity is not claimed to last more than a couple of years after the child is vaccinated and during even that period it is not potent enough against severe infection, and because there is no scheme for re-vaccination for extending the period of immunity. In fact medical opinion is clear that repeated vaccinations with B.C.G. would be dangerous.

This is an issue of general national importance and not a matter to be left for disposal according to the majority opinion among them when experts differ. In the adventures of science opinions may vary. Where it is a matter that does not affect the bulk of the people, the difference of opinion may be left to be solved by the scientists: not so, when on the basis of a theory, men's persons are touched for good or evil.

I am certain that one day in the future this B.C.G. will be declared as of no value and given up by the world of scientists and forgotten. As the Health Department of the Government of India is throwing its great weight on the side of this unscientific adventure, the rejection will take time.

Meanwhile the children and the finest section of them all over the land are being deliberately infected on a mass scale with a variety of one of the deadliest living bacilli known to man. Some among the most eminent men of science have expressed their grave doubts as to what the bacilli introduced in the human system may be capable of becoming and doing in the course of time if not at once. The risk is aggravated by the immense number of persons thus affected and by the unavoidable chances of contamination in a hurricane mass campaign.

The stated object of the mass campaign is to prevent the occurrence of clinical tuberculosis among children. In the first place, the statistical data generally given for mortality among young people from tuberculosis in India are not real statistics but only inferentially deduced conclusions. In the next place, the disease never has occurred or will occur in an epidemic form, so as to justify mass injection with a poison not by any means fully proved to be harmless. Again, the claim put forward for the vaccine is an admittedly undependable immunity and that, too, only for a couple of years. Taking all these into account, one must come to the conclusion that the campaign is thoroughly unjustifiable.

One of the worst incidents of a mass campaign is the ceaseless effort by men whose words carry weight, to rouse a dread of the disease in the vast majority of people. Fear considerably reduces the power of resistance among those who have hitherto

coped with dormant infection. Another general consequence of the campaign is the neglect of other measures such as would go far towards real control of tuberculosis.

I am not against modern 'western' therapy or modern science. B. C. G. has nothing to do with modern western medicine. In fact, it is more akin to the principle of Homoeopathy than to what is generally known as modern medicine. Tt. proceeds on a creed very similar to that of homoeopathy, namely, that diseases are to be dealt with by the administration in mild forms of the very things that produce the disease. The difference is that the homoeopath does not introduce what multiplies in the human body, but the B.C.G. man introduces a large body of living multiplying organisms, which never leave but are intended to remain for ever in the body of the person vaccinated.

Informed readers have to forgive me for devoting even a little space to this, namely to point out that the B. C. G. vaccine is not a cure for anything. The claim is that it may serve as a preventive in some cases and for a brief period of time. I need not have had to say this but for the fact that I have met quite a few respectably educated men who ask why I oppose something that is proposed to relieve sickness! B. C. G. does not relieve any sickness. It is not intended for it.

Quackery is bad whether it be modern or of the time-honoured variety. It is easy to deal with the latter type but modern quackery is difficult to cope

with, as it absorbs for its purposes modern medical terminology and methods of procedure.

"A lie which is all a lie may be met and fought with outright

But a lie which is part a truth is a harder matter to fight.",

A principle is discovered which is not universal but it is sought to apply it to cases, where it cannot applied, and exposure of error is resisted. B.·C. G. is an extension of the principle of immunity underlying the artificial introduction of the very same virus or bacilli that cause the disease, with the object that the human body may be stimulated to produce a defence, as it is observed to do when catching the infection in the normal way. tension of this principle to tuberculosis is wrong because it is known that tuberculosis infection does. not lead to the creation of any defensive antibody in the system. But struggling against this hard fact and insurmountable objection to the application of the pasteurian method of producing immunity, the B. C. G. protagonist proceeds depend the allergy on mere or by the introduction sensitivity created the poison, as a substantial defence against infection and asks us to accept all the unknown risks of the injection for the sake of this allergy, even which admittedly lasts only for a couple of years. The ultimate argument is merely statistical which. according to the best appraisers, as will be seen, is inconclusive. Mere figures of inoculation done, without any well-confirmed observation of results

as regards immunity, do not form a valid statistical argument, beyond proving the energy and resources at the back of the operating organization.

respectfully say, is what I This involved in B. C. G. I am not quackery my conclusions But medical expert. merely on my a priori fears and not based doubts, but on the definite pronouncements of most eminent and illustrious medical men of the civi-The Indian medical men that have lized world. been recruited by the Health Ministry to conduct and speak for this campaign, the biggest among them, are not as eminent as any of the medical men, on the basis of whose observations and opinions, I have come to the conclusion that this mass campaign of inoculation with live tubercle bacilli is wrong and must be given up.

Newspapers are not all of them very willing to oblige one who opposes a government-sponsored campaign with large space, even though the subject be of utmost general importance and though the object be to reach truth and not the furtherance of a particular administrative or political policy. Even when they are generous and willing to publish written criticisms or the reports of speeches dealing with the subject, they are necessarily unable to find space for publishing all the authorities that may be quoted or referred to. This booklet is intended to make up for this. I have here collected and present to readers a few important statements of eminent medical men. I have reduced my own remarks to the minimum that is necessary to explain the relevance of the extracts.

Prof. Heaf is a strong protagonist of B. C. G. Answering Prof. Heaf's remarks in an earlier issue of the Lancet, Dr. R. C. Webster writes in the Lancet of March 5, 1955, a letter which is as instructive as it is interesting. Two points are forcefully brought out in this letter: (1) That even in March, 1955, after over twenty five years of trials, "statistical proof of increased resistance produced by B. C. G is difficult to obtain" and that the advantages of the vaccine are still under question and many authorities of high standing are sceptical about B. C. G., and (2) that the positive skin reaction produced by B. C. G injection is not considered by some eminent experts as a proof of any immunity to Tuberculosis.

From "The Lancet" March 5, 1955 — Page 511

B. C. G. Vaccination

Sir.

Prof. Heaf (Feb. 12) says that "there is strong evidence that B. C. G. increases resistance against tuberculous infection, although statistical proof is difficult to obtain." He admits our ignorance of allergy and immunity in tuberculosis, but he also says "these acknowledged advantages of the vaccine are sufficient to justify its use." Are these advantages so generally acknowledged? The fact that the vaccine is readily administered and cheap is not so very important: the fundamental question to which we do not know the answer is whether a positive skin reaction is really very important in immunity to tuberculosis. After all, we have other diseases in which positive skin reactions occur, but I do not know that it has been suggested that they mean immunity. For example, does a positive Frei test indicate any immunity to lymphogranuloma inguinale and does cason's reaction indicate any immunity? ARE WE REALLY JUSTIFIED IN ASKING PARENTS TO SUBMIT THEIR CHILDREN TO INJECTIONS WHICH MAY, IN A SIGNIFICANT PROPORTION OF CASES, PRODUCE UNPLEASANT LOCAL REACTIONS, AND HAVE A RISK, HOWEVER SLIGHT, OF CAUSING GENERAL DISEASE, WHEN WE HAVE REALLY NO SOUND KNOWLEDGE OF ITS GOOD EFFECTS?

Some of us in the older group are perhaps overanxious. We remember previous campaigns for the use of B. C. G. We remember also the movement for immunisation against scarlet fever some 20 years ago. now I think completely discarded, and we remember earlier attempts (with much enthusiasm) to use vaccine against whooping-cough whose value is now known to have been nil.

I write because I want to be convinced. If B. C. G. is a good thing, then by all means let us use it: But I would like to know more about the "acknowledged advantages of

the vaccine." We do know of the solid advantages of immunisation against diphtheria and therefore some of us are extremely hesitant about any profedure which might prejudice that immunisation. IT IS ADMITTED THAT MANY AUTHORITIES OF HIGH STANDING ARE SCEPTICAL ABOUT B. C. G. AND THAT INDEED IN RECENT YEARS THE SCEPTICS HAVE BECOME MORE VOCAL. IS THERE ANY ANSWER TO THIS? It has been pointed out by Dr. McIntosh, senior chest physician in Dundee, that in that city there was a very considerable decline in tuberculosis mortality in 1947-51 and he points out that if B.C.G. had been used on a wide scale in 1947 there would nave been a strong temptation to credit it with the good result. Can Professor Heaf convince those of us who hesitate on the brink? . . .

Acrington.

R. C. WEBSTER.

The following letter from Dr. G. E. Loxton in the Lancet, March 19, 1955, confirms what Dr. Webster has pointed out.

From "The Lancet" March 19, 1955 — Page 619

B. C. G. Vaccination

Sir,

Dr. Webster (March 5) hits the nail on the head when he says that "the fundamental question to which we do not know the answer is whether a positive skin reaction is really very important in immunity to tuberculosis."

A positive skin reaction is a measure of hypersensitivity and not of immunity, though of course immunity and hypersensitivity may be related. Brownlee has emphasised that the characteristic widespread tissue destruction of tuberculosis follows the conditioned hypersensitivity. Hypersensitivity without immunity is clearly undesirable.

Prof. Heaf (Feb. 12) points out that the evidence is that B. C. G. vaccination does offer considerable protection against the development of primary tuberculosis but exerts little control over the development of post-primary lesions. Whether primary or post-primary tuberculosis is the more lethal or crippling disease in this age of chemotherapy is undecided. But the wisdom of protecting the population against primary tuberculosis is doubtful. As Prof. Heaf so rightly says, "Perhaps the greatest disadvantage associated with B. C. G. vaccination is the unwarranted confidence that it has inspired in laymen in many countries."

We can measure hypersensitivity by the skin reaction in a single human being, but we have as yet no ethical method of measuring individual immunity; consequently we have to rely on current statistical estimates of immunity, and we should therefore not confuse ourselves by thinking that immunity and hypersensitivity must have something in common.

Flimwell. Wadhurst, Sussex.

G. E. LOXTON.

The following extracts further confirm the view that the matter is a subject of doubt and controversy among most eminent authorities;

From "The Lancet" May 16, 1952 — Page 935.

"But nowadays there is considerable disagreement, even among tuberculosis specialists, as to just what a positive or a negative tuberculosis reaction really is. In fact, our knowledge is so incomplete that much of the effort of our office has been devoted to investigating this problem, especially the interpretation of B.C.G.-induced allergy."

(Dr. Carroll E. Palmer, M.D, Head of the Copenhagen T.B. Research Team—Malthe lecture of the Norwegian Medical Society, Oslo. on November 14, 1951).

"Certainly it is evident that much of what we have accepted as common knowledge about B.C.G. vaccine and vaccination is not well-founded, and if so much of what we thought we knew of the simpler facts be untrue, what can we safely believe about those aspects of vaccination which are more difficult to study and to prove?"

"We must seek more dependable information about B.C.C? and tuberculosis immunisation. And this may mean discarding many of our traditional concepts."

(Dr. Carroll E. Palmer—LANCET, May 16, 1952, page 940).

"Scientifically, it cannot be disputed that from every point of view the injection of a virus capable of multiplying in the body of the individual is bad. When multiplication of the virus occurs, then there is no possibility of estimating the dose to which the patient has been subjected. Thus the effect cannot be controlled, and in susceptible individuals this may lead to unforeseen results."

(Prof. James McIntosh, Professor of Pathology, London University—Before the Royal Society of Medicine on October 19, 1926—LANCET, October 30, 1926, page 889).

"The tubercle bacillus can establish itself in the organism through the Calmette system and the result cannot be foretold. Such a dangerous process cannot be approved ortolerated."

(Late Professor Von Pirquet, a great medical authority of his time thus declared in 1930).

"The reintroduction of the use of an attenuated living virus in tuberculosis was described by Professor McIntosh as a retrograde step. Who knows, he said, for how long an attenuated bacillus can be dormant and then assume its former virulence."

(Editor, LANCET, May 24, 1930-page 1,138).

"It was thought that B.C.G. might be the answer, but in the medical section of TIME it was stated recently on high American authority that B.C.G. also was found to have its unmeasured and uncontrolled dangers."

(J. W. Rainey, Dept. of Agriculture, Derby, Tasmania —Veterinary Record, August 4, 1951).

Here is a very fair summary of the position which cannot be controverted by those who claim to be experts and are advising the Health Ministry in India:

From TUBERCULOSIS by John B. McDougall — Pp. 417-418.

In the United States of America, most criticism has come from Myers* (* Myers J.A., Amer, Rev. Tubercl. 1948, 57, 107). He is enthusiastic about the use of B.C.G. so long as it is used in accordance with the controlled programme laid down by the Tuberculosis Control Division of the United States Public Health Service. Until such time however as there is more definite evidence of its efficacy, Myers will not recommend its use for the following reasons:

- 1. The immunity given by B.C.G. is not dependable. It is only persons who have had primary tuberculosis, demonstrated by the tuberculin reaction or at the post mortem table, who develop clinical destructive forms of the disease; he finds no premises from which to start artificial immunisation with a living organism of reduced virulence.
- 2. B.C.G. has failed to immunise adequately animals against tuberculosis and the veterinarians of the U.S.A., after adequate trial, found B.C.G. inefficacious in controlling tuberculosis in cattle.
- 3. If B.C.G. were highly efficacious, abundance of convincing proof should be available after more than a quarter of a century of use, and having been administered to approximately seven million people. In the nations where it has

been used most extensively Myers had failed to find evidence of its effectivenes on tuberculosis morbidity and mortality. Far greater reductions in these rates have occurred in parts of the world where B.C.G. has not been introduced.

- 4. It has not been proved to his satisfaction that B.C.G. is harmless. No one has yet proved that the organisms may not survive in the bodies of some persons for many years, or decades, and gradually regain virulence.
- 5. Deductions as to the efficacy of the vaccine in the past have been drawn from unlike comparisms and controls.
- 6. B. C. G. enthusiasts have, like others before them, started with the same shaky premise that an actual attack of tuberculosis does not produce dependable immunity.
- 7. Since tuberculin testing is the most potent weapon in tuberculosis control, it follows that if B. C. G. were to be administered to a considerable number of children and young adults, thus sensitising their tissues, the tuberculin test as we now use it would be nullified, and our present effective programme would have to be abandoned. There are now large areas in Minnesota in which tuberculous infection has been completely eradicated at the grade—school age level, and this has been done without B. C. G. vaccination. This has been accomplished by standard, thoroughly tried and unfailing methods.
 - 8. There is a danger that, by over-emphasising the value of B. C. G. vaccination, a false sense of security may develop and that people may come to regard B. C. G. vaccination in the same category as vaccination against smallpox. To date there is no reason for even hinting such security from the use of B. C. G.

Conclusion of the author, Dr. J. B. McDougall.

"We would cordially agree with the remarks made by Sweany to the effect that it seems clear that B.C.G. has a definite place in anti-tuberculosis work if rigidly supervised; and that there can be little doubt that it raises the threshold of infectability in the vaccinated so that nurses, attendants, internees and others exposed to tuberculous infection are better protected than the unvaccinated. There may be a limited and temporary use, in badly contaminated regions, especially in war-torn countries, to protect infants and young adults against infection where public health facilities have completely collapsed. In such circumstances it should be used only as an emergency measure and supervised competently."

Dr. J. Arthur Myers, has made a devastating attack on B. C. G. in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION of August 18th, 1951. His main argument is that a primary attack of tuberculosis does not give protection against subsequent attacks, and it cannot therefore be expected that the vaccination, which is supposed to give

some kind of equivalent of a primary attack will do so. Dr. Myers particularly referred to two dangers. One is that the assumption that B. C. G. is effective would lead to neglect, of other measures against tuberculosis. The other is the special danger of administering B. C. G. to under-nourished children.

The following extracts disclose reasons to fear extensive contamination in the mass campaign of B. C. G. inoculation conducted in our country:

From a publication of the Glaxo Laboratories Ltd., England, 1955.

"Obviously, the greatest care must be taken in the preparation of a living vaccine to ensure that it is kept free of contaminating organisms, and more especially to exclude the possibility that B.C.G. vaccine is contaminated with virulent tubercle bacilli. This at once creates a difficulty, because the slow growth of the tubercle bacillus, whether in the test-tube or in animal tissues, means that tests of innocuity take 6 to 12 weeks to complete, whereas the vaccine itself must be used within 2 to 3 weeks of its completed preparation."

From the Journal of the American Medical Association, Feb. 19, 1955, page 678.

Prevention of Bacterial Contamination of B.C.G.:—Since Oct. 18, 1954, the B.C.G. laboratory in Gothenburgh has changed the containers of the B.C.G. vaccine it issues substituting small ampules, with a capacity of 2 ml. for the larger flasks that encourage multiple vaccinations with one and the same sample at different intervals. Dr. O. Sievers, who is in charge of the laboratory, stated (Svenska lakartidningen for Dec. 3, 1954) that this change was prompted by complaints of severe local reactions and even general reactions to vaccination with certain samples. Most of these complaints concerned flasks that had been already used on earlier occasions. A bacteriological examination of 525 such suspect flasks showed that as many as 138 of them were bacteriologically contaminated. No such contamination was demonstrable in any flask that had not been opened earlier. Were it not that B.C.G. is a living vaccine, a preservative such as formaldehyde solution might have been added."

From the monograph on B. C. G. from the BRITISH PHARMACOPOEIA (1953).

"The vaccine (B.C.G.) deteriorates rapidly and is not suitable for use after 14 days from the completion of its manufacture. For this reason tests for sterility, virulence, toxicity and skin sensitising potency cannot be completed until and after the vaccine has been issued for use. When

a batch of vaccine is proved after issue to have failed a prescribed test, every effort is made to stop further use of that batch of the vaccine; and subsequent manufacture of the vaccine is carefully revised in the light of the failure.

The vaccine is suitable for use if all the tests are negative after two days, but the tests for sterility are carried out in full and the vaccine as far as possible withdrawn from use if the tests become positive on the third, fourth or fifth day.

Dr. Webster asked in his letter of 5th March, 1955, page 6 ante, "Are we really justified in asking parents to submit their children to injections which may in a significant proportion of cases produce unpleasant local reactions and have a risk however slight of causing general disease when we have really no sound knowledge of its good effects?"

The following extracts from leading medical journals of 1954 and 1955 are important in this connection:

The JOURNAL of the American Medical Association—Novr. 27, 1954—page 1281.

B.C.G. Vaccination.

Fatal case of tuberculosis produced by B.C.G.: Meyer. Am. Rev. Tuberc. 70: 402-412 (Sept.) 1954, (New York).

A case of extremely malignant tuberculosis of the lymphatic system occurred in a young boy of Western Zealand. Denmark. He was vaccinated at the age of 5 with B.C.G. and two weeks later the illness that brought about his death after two years began. The first symptom was an enlarged node in the left axilla evolving to an abscess. Progressive involvement of the lymph nodes throughout the body was characteristic of the course of the disease in this patient. Serologic investigations showed that the organisms taken from the patient were of the B.C.G. type only.

IN CONCLUSION, THIS CASE JUSTIFIES THE STATE-MENT THAT THE BACILLUS CALMETTE-GOERIN INTRO-DUCED BY B.C.G. VACCINATION CAN PRODUCE A FATAL TUBERCULOSIS IN MAN.

Extracts from the LANCET—April 23, 1955—p. 869. B.C.G. OTITIS.

Sir,

In your annotation of April 9, you discuss various complications associated with B.C.G. vaccination. May I draw attention to an unusual complication of oral B.C.G. vaccination reported from Holland?

It would be interesting to know whether the Dutch experience was an isolated incident. This might be difficult to ascertain, for even 'true' tuberculous otitis media masquerading as chronic suppurating otitis media, may remain long undiagnosed. In the course of a systematic investigation of bone chips from 216 mastoidectamies in 1954, we recognised 3 cases of unsuspected tuberculous otitis media by histological and cultural methods.

I. Friedmann.

Institute of Laryngology and Otology, London, W.C. 1.

- 1. Hammelburg, E., M.D. thesis, Utrecht, 1953.
- Friedmann, I. J. Larving, 1955, 69,27.

The JOURNAL of the American Medical Association—Novr. 13—1954—p. 1123.

B.C.G.—VACCINE.

GENERALIZED B. C. G. INFECTION IN MAN: III. Autopsy Findings.—E. Waaler and P. Oeding, Acta tuberc. scandinav. 29: 188-192 (No. 3) 1954 (In English) (Copenhagen, Denmark).

A 24½-year-old man who had an increased erythrocyte sedimentation rate for many years, the reason for which was not known, was given B.C.G. vaccination in the right arm. The tuberculin reaction turned from negative to positive. One year after the vaccination he had an abscess of a lymph node in the right axilla. It was incised, but the pus was not examined. In the course of the next 4½ years, the patient had a painful swelling in the left hand, pain in the left hip, subcutaneous swelling on the thorax, thoracic fistulas, serous meningitis, abscesses in the cervical lymph nodes, pulmonary infiltration, pleuritis, destructive foci in the left patella and the left trochanter, and spastic paraparesis. Acid-fast bacilli were found in culture from gastric lavage, several abscesses, pleural exudate, and urine. The morphology and virulence of these bacilli were identical with B.C.G. He died 51 years after the vaccination and 4½ years after the occurrence of the first complication after vaccination. Necropsy revealed multiple destructive foci, particularly in the bones, lymph nodes and lungs. Samples from the left lung, spleen, mesenteric and cervical lymph nodes were cultivated. In the microcultures where the same process were cultivated. tures, unorganized colonies characteristic of B.C.G. were seen, and the virulence appeared to be unchanged. Histologically there was a diffuse inflammatory reaction without formation of tubercles. There was a pronounced general immunity reaction with many pyrominophilic plasma cells and an increase in gamma globulins. The patient's tissue reaction to B.C.G. appeared to be abnormal, but the lowered resistance could not be explained. B.C.G. vaccine can apparently cause lymphogenous or hematogenous spread and a fatal disease with multiple destructive foci.

The following three letters must be read together. They are taken from the official organ of the American Medical Association of different dates in the year 1954:

From the Journal of the American Medical Association, July 3, 1954—page 949.

B. C. G. Vaccine.

To the Editor,

Is it advisable to use B.C.G. vaccine to raise immunity against tuberculosis in a young adult who has a negative skin test? He has had a negative chest roentgenogram and is in apparently normal health but is very tall and thin. What preparations are advisable, and where are they obtained?

M. D. Pennsylvania.

Editor's Answer:

The question of advisability in use of B.C.G. vaccine is dependent altogether on the circumstances. If the person is an ordinary citizen and is going about his way of life without any unusual contacts with tuberculosis, B.C.G. vaccine is not necessary, although it would do no particular harm. If the person has negative tuberculin and has tuberculosis contacts, such as cases of tuberculosis within the family circle, immediate or remote, or any work or association that brings him into immediate contact with tuberculosis patients. B.C.G. vaccine would be recommended.

From the Journal of the American Medical Association, September 4, 1954—page 94.

B. C. G. Vaccine.

To the Editor,

In the Journal, July 3, 1954, page 949, is a query on B.C.G. vaccine. The reply contains a statement to the effect that this vaccine would do no particular harm. Such a statement has long been challenged by many physicians. I believe the readers should know some of the reasons for this challenge.

When Calmette and Goerin gave this bacillus their names in 1921 and declared it a virus fixed in 1924, it was so reduced in virulence that it would not produce tubercles in animal tissues. However, since that time significant changes have occurred in the cultures: from several laboratories, including the two mentioned in this reply. They found no two alike even on gross culture appearance, and they found that each culture examined was composed of multiple bacterial forms instead of the single bacterial form in the B.C.G. produced by Calmette. This leaves no doubt that B.C.G. cultures have undergone marked changes since Calmette designated his original one a virus fixe. Apparently no two cultures examined have undergone the same changes. These changes probably account for the alarming occurrences following administration of B.C.G. to persons and animals during the last 25 years. In

so many persons who received B.C.G. subcutaneously, abscesses and ulcers developed at the sites of administration and disease of regional lymph nodes broke down and discharged pus for months so that scarification and puncture methods of administration were recommended. Although, this reduced the incidence, there are still many such cases reported each year. These are clinical lesions that behave like those from natural infections. Some of them require treatment including surgery and antimicrobial drugs.

Many persons who have received B.C.G. have later had clinical tuberculosis, and a considerable number have died from this disease. Attempts to determine the type of bacilli causing illness and death have been far too few. In the Journal, May 1, 1954, page 61, attention is called to seven cases of lupus vulgaris having developed from B.C.G. In the June 19, 1954 issue of the Journal, page 773, a well_documented case of tuberculosis resulting fatally from B.C.G. is reported. B.C.G. was administered when the man was 20 years old. This resulted in a reaction to tuberculin within six weeks. first clinical lesion appeared about a year later. From then on numerous clinical lesions developed in various parts of the body including the lungs and kidneys. He died from tuber-culosis in December, 1953 and B.C.G. was recovered from the númerous lesions. Such cases make one strongly suspect that in the past some clinical and some fatal cases of tubercuosis in those who previously received B.C.G. were due to the B.C.G. itself rather than its failure to protect against natural infec-In any event, the well-documented evidence regarding B.C.G. cultures and the disease it produces in animals and persons is cause for alarm and justifies challenging the statement in this reply, or wherever it is made, that B.C.G. does no particular harm.

> J. A. Myers, M.D., 111, Millard Hall, University of Minnesota, Minneapolis 14.

To the Editor,

I am concerned regarding the answer in the July 3, 1954 issue of THE JOURNAL, page 949, to a question on B.C.G. vaccine. I feel that the reader would have the impression that this so-called vaccine could do no harm. In recent years an impressive amount of information has been gathered in studies on cultures, animals and human beings that forces one to challenge a statement to the effect that B.C.G. is without harm. After approximately 40 years of use. B.C.G. remains a controversial question in all parts of the world. Most certainly great caution is justified.

Seymour M. Farber, M.D., University of California Tuberculosis Service, San Francisco Hospital, 22nd St. and Potrero Ave., San Francisco. On the value or rather valuelessness of European statistics often quoted in the course of this controversy and blindly relied on, the following views of very eminent doctors whose opinions are entitled to respect will be found instructive:

"One of the greatest difficulties in assessing the efficacy of B. C. G. vaccination is that generally speaking tuberculosis morbidity and mortality, has been decreasing in most parts of the world for the last 50 years.

"In this respect it is interesting to note that in the U.S.A. when some States introduced B.C.G. vaccination, while others did not, the most marked drop both in the morbidity and mortality occurred in some of the States without B.C.G. Vaccination."

(F. Kellermann, M.D., L.R.C.P., L.R.C.S., Edin.), Chest Physician, North-East Metropolitan Regional Hospital Board, stated in an article in the MEDICAL PRESS—Sept. 15, 1954. page 240).

It should also be borne in mind that in New York City between 1924 and 1944 there was a fall in the death-rate from tuberculosis of nearly 95 per cent, without the use of B.C.G. vaccine.

(J. Arthus Myers, M.D.: Jour. Amer. Med. Assoc. Vol. 146, No. 16, Aug. 18, 1951—page 1492).

Extracts from Topley and Wilson's Principles of Bacteriology and Immunity—Third Edition.

This vaccine has now been tried out on an extensive scale with results that are extremely difficult to assess.

The reproduction, even if it were possible, of the immense pile of data that has been accumulated on this subject in France and French-speaking countries, would serve no useful purpose, since from a statistical point of view it is practically worthless.

The realisation of these fallacies has now led to the institution by other workers of a few experiments in which an attempt has been made to provide a control group with which the vaccinated group can be more strictly compared. It must be noted that the difficulties of obtaining an absolutely identical control group are almost insuperable, and some allowance has therefore got to be made when considering the results. Neither of these investigations yielded very striking results, but both of them afford some evidence that B. C. G. vaccination may bring about a slight increase in resistance to tuberculosis. How far even this conclusion is justifiable, however, may be questioned.

Even if we admitted the beneficial effect of B. C. G. vaccination, which we are not prepared to do, we should still have to decide what value it is likely to be in practice.

... Calmette himself advised re-vaccination at 3, 7 and 15 years of age. If re-vaccination is not performed, the immunity—if any—resulting from the primary vaccination will probably wear off in a year or two. If, on the other hand, it is performed, there is a danger of setting up in a tuberculin_positive patient an acute allergic reaction, which may have serious results.

Here is an extract from a 1953 memorandum of the U. K. Health Ministry:

B. C. G. Vaccine.

In spite of the vast number of vaccinations that have been performed with either fresh liquid or freeze-dried vaccine during the past twenty years, there is no scientific evidence of its true value.

(Ministry of Health, U.K.—Memorandum No. $324 \mid BCG$ dated Nov. 1953 issued to Medical Officers of Health).

The following extracts from a letter received from the U. K. Health Ministry about Dr. Benjamin's statement that there was compulsory inoculation of B. C. G. in U. K., France and Sweden, will show over and above the gross inaccuracy of which Dr. Benjamin was guilty, the great precautions and cautious pace associated with B. C. G. trials in Great Britain.

Extracts from the letter dated 24th May 1955 of Dr. D. Thomson, Ministry of Health, Savile Row, London.

"In the past six years, the use of B. C. G. has been gradually extended in this country until now vaccination is advocated for the following three groups, if members of them are found to be tuberculin negative: (a) contacts of cases; (b) classes especially liable to exposure, e.g. nurses, dental and medical students; and (c) those of around 13 years who are shortly to leave school. Vaccination of the last class was only introduced two years ago and by no means all local authorities carry it out. In addition, in no part of the country, and for no class, is vaccination compulsory. . . . As you will see, we have gradually extended the scope of our B. C. G. vaccination scheme, but until the present Medical Research Council trials to test its efficiency are completed—and an interim report may be published in the near future—we will have no accurate estimation of its value. We have no intention of expanding our vaccination programme at the moment.

B. C. G. vaccination is not compulsory in France nor Sweden. In certain provinces of Norway there is legal power to enforce vaccination of school leavers, but such is never employed and if the child's parents do not wish

vaccination, no action is taken beyond persuasion. Mass campaigns have been carried out in Denmark, Norway, Sweden and Finland but present opinion in these countries is now against such procedures and most faith is put on the vaccination of the same classes as in England."

News has just been received that the British Medical Research Council have decided to abandon the American Salk Vaccine for Polio in spite of the imposing statistical figures repeatedly quoted in support of it. It is stated that the British Medical Research Council await the discovery of a safer vaccine. As was stated above in the U. K. Health Ministry official's letter, the B. C. G. vaccine value is still under examination by the British Medical Research Council.

What for are we carrying on this mass inoculation? The objections apart, what are we offered? Immunity of a very undependable character and even that, only for the very brief period of a couple of years. After that, we are thrown back on natural defence and care and education and improvement of living conditions!

The following extracts are important in connection with Encephalitis diagnosed in many cases in areas where the B. C. G. campaign has been carried out. What is rare in other countries is noticed in a greater number of cases in our country, probably owing to living conditions prevailing here. It is probable that many more cases of complications have been occurring all over the country than are being brought to notice.

Extracts from Topley and Wilson's Principles of Bacteriology and Immunity—Vol. II (third Edn. By G. S. Wilson, M.D., and A. A. Miles, F.R.C.P.—Page 1894.

Variola and Vaccinia.

In recent years, a new complication has been observed, namely, post-vaccinal encephalitis. The first case studied in detail was observed by Turnbull in 1912; but it was not till the publication of Turnbull and McIntosh's report in 1926 that

serious attention was drawn to the subject. Altogether in this country and abroad, some hundreds of cases have been observed, though the disease is now very much less frequent than formerly (Report 1936). Most of them have occurred after late primary vaccination.

Extracts from A Text Book of the Practice of Medicine edited by Frederick W. Price—page 187—Oxford University Press, London, Publication (1950).

A rare sequel, to which special attention has been drawn, is a form of encephalo-myelitis. Its great incidence has been in Holland, Great Britain and Germany, and has varied from 1 in 5.000 to 1 in 100.000 vaccinations. The characteristic lesion is a focal, perivascular demyelinisation of nerve fibres often associated with perivascular cuffing. Its chief incidence is where infantile vaccination is not the rule, i.e., after primary vaccination of children of school age or of adolescents. Very similar to the encephalo-myelitis of small-pox and of measles, it sets in 7 to 12 days after vaccination, with headache, vomiting and paresis. These symptoms become aggravated, and delirium may pass into coma and death. In other cases the symptoms are more suggestive of meningitis, myelitis, lethargic encephalitis, with ocular palsies or of tetanus. The mortality may reach 50 per cent, but when recovery occurs it is usually complete.

Latent infection may be brought into activity and prominence by vaccination; this is the case with congenital syphilis and tuberculosis. Hence the advisability of postponing vaccination until the age of two or three months or should the infant show skin eruptions or signs of ill-health. Acute specific fevers are no bar to vaccination if necessary.

Encephalomyelitis is different from Epidemic Encephalitis, otherwise known as Encephalitis Lethargica or sleeping sickness. The former is a well understood post-vaccinal complication attended with among other things, loss of eye-sght besides being fatal in a majority of cases. The latter named disease has nothing to do with the destruction of the optic nerve which is what has happened in the case of the unfortunate Coimbatore girl. In this connection, the following papers will be interesting reading. No reply was forthcoming to Dr. Anantaraman's letter and the Madras Committee's Report is still unpublished apart from the findings reported in the Government Press Note that the girl's loss of eyesight is not due either to the pox vaccination or to the B. C. G. vaccination (which two

were interposed in the case at a short interval against all principles of due care and caution) but was due to Epidemic Encephalitis; i.e., sleeping sickness!

From Press Note of the Government appointing the Committee dated June 2, 1955.

Preliminary enquiries regarding the case of a child from Coimbatore Municipality, reported in the papers, suggest that her illness had no relation to B. C. G. or small-pox vaccination. However, Government is deputing a panel of senior specialists to study the case in detail and submit a report.

From Press Note giving findings of the Committee:

The Government appointed a Committee consisting of Dr. K. Vasudeva Rao, retired Director of Medical Services, Dr. K. S. Sanjivi, Professor of Medicine, Madras Medical College and Dr. Ramalingam, Acting Superintendent of the Government Ophthalmic Hospital, Madras to enquire into the case of a child Vasantha, in Coimbatore who was alleged to have lost her eye-sight as a result of B. C. G. vaccination.

The Committee visited Coimbatore on June 9, 1955, examined the case and has submit ed a report to the Government. From the report of the Committee, it is clear that in the opinion of the Committee, Vasantha had suffered from "epidemic encephalitis", that this epidemic encephalitis had definitely no relationship to small-pox or B. C. G. Vaccination. The Committee concludes that there must have been sporadic cases of "epidemic encephalitis" in Coimbatore during the cold season of 1954.

The Committee examined another child by name Rukmini, living in the same locality as Vasantha, alleged to have partially lost her eye-sight after tuberculin testing. The Committee found that she had not been vaccinated with B. C. G. In this case also the Committee was of opinion that the child must have suffered from "epidemic encephalitis". The Committee also examined two other persons who came forward with some minor complaints after B. C. G. vaccination. The Committee was of opinion that these two cases had only followed the normal course after vaccination and found that there was nothing wrong with them.

Letter of Dr. Anantaraman to the Editor, "The Hindu".

Sir,

May I request you for permission to make the following remarks through the columns of your esteemed daily on the recent communique issued by the Madras Government on "Inquiry into the loss of eye-sight" published in your issue

cf 22nd June 1955. I am not entering into the controversy myself but certain facts mentioned in the communique pass the comprehension of a student of medicine.

First of all, the Government would have done well if it had appointed a real non-official member to be in the Committee. Secondly, the statement that "Epidemic Encephalitis" has caused blindness in the girl cannot be substantiated. If the Committee means Encephalitis Lethargia by "Epidemic Encephalitis" which text books describe, I have been unable to find blindness mentioned as a complication or a sequel to "Epidemic Encephali is" though other ocular signs are freely mentioned. Also there is no other type of encephalitis described causing blindness. I have referred to standard text books as those of Price, Walsh, Russel Brain and Kinnier Wilson. I shall feel much obliged if the Government will quote the references where blindness is mentioned as a complication or a sequel to "Epidemic Encephalitis" and also its pathogenesis.

L. N. Anantaraman, M.B.

The following correspondence refers to the question of procedure in the mass campaign. The Government has not taken any responsibility through legislation. It is still carried out as a mass campaign of "voluntary" inoculation. When I was informed that the consent of parents of school children was presumed when no objection was lodged, I felt that this was a very illegal procedure in a land of illiterate parents whose young boys are in school and subjected there to B. C. G. The letter of the Madras Health Minister confirms the fear I had:

Extract from the D. O. letter No. 59236. HIV-2|55-3 dated 1st July 1955 from Sri A. B. Shetty, M. L. A., Minister for Health:

The practice followed in the State Mass B. C. G. Vaccination Campaign, with regard to school children, is to send advance intimation through school authorities to parents about the dates of tuberculin testing and B. C. G. Vaccination, stressing the absence of compulsion and asking them to obtain the approval of the parents. The Supervising Public Health Officer, the Publicity Officer or the Team Doctors make it a point to contact Headmasters and teachers of schools either individually or at a meeting of all the teachers and impress upon them the voluntary nature of the scheme and the importance of giving advance intimation to parents. Parents, who object to their children being vaccinated, either keep the children back at home on the day of testing or send a letter of objection to the school authorities.

Extract from the letter of Sri C. Rajagopalachari to the "Indian Express, Madras"—July 12, 1955.

I have received a letter dated July 1, from the Health Minister of Madras fully confirming my impression that consent of guardians of school children is presumed from not receiving any objection from the parents. In fact, the schoolmaster is supposed to be in complete charge of the body and soul of the pupil; this is most illegal and it is a matter for law officers of Government to consider whether they should not advise the Government to desist from indulging in this improper practice.

In the following pages are given the cases that were sent to my notice since it became known that I was interesting myself in this matter. I have drawn public attention in the daily press to most of these cases:

Letter from Mr. G. M. Krishnaraja Chettiar, 22|286 Rengai Gounder Street, Coimbatore.

My female child Vasantha, aged 6 was reading in I Class at the London Mission School, Rengai Gounder St., Coimbatore. She was (B. C. G.) vaccinated on Nov. 18, 1954 and was hale and healthy before that and was also reading well. After the second (small-pox) vaccination (on Dec. 3, 1954) she lost her eyesight. Without my consent the authorities vaccinated my child in the school and due to that my child lost her eyesight. This was brought to the notice of the local municipal authorities and till now there has been no remedy. I am herewith producing the report of the Sanitary Inspector and also the report of the Medical Officer, Coimbatore. I do not know what further to do in the matter. The local doctors say that it will not be possible to effect a cure.

Letter from C. K. Sundararajan, 9 3 Devangapet, Coimbatore.

My two children, a girl aged seven and a boy aged two years, developed boils all over the body three days after the B. C. G. vaccination. For three months they suffered terribly despite all the treatment given. After having several injections, they recovered in the third month. They continue to be very weak still.

Letter from S. Varadaraj, 17|87 Muthannamkulam Street, Coimbatore.

Since the B. C. G. vaccination, I am suffering from severe pain in my left arm, despite treatment of various kinds. I am a young man of 20, and 1 have to support my mother, two brothers and two sisters.

Letter from Bellaswamy Chetty, 17|87 Muthannam-kulam Street, Coimbatore.

On B. C. G. vaccination my six-year old daughter Rukmini, lost her eye-sight and after treatment in the local Government Headquarters hospital, she has regained her sight partially, but she is still very weak in health, and mentally not all right still.

Letter from Rangammal, 14|5 Raja Street, Coimbatore.

My 18-year old daughter, Sarasu, got headache and sore throat on the day she was vaccinated with B. C. G. After treatment by a local doctor for some time, on his suggestion we took the girl to the Eye Surgeon in the Headquarters Hospital. But he said there was nothing wrong with her eyes. Again we went to the old doctor under whose treatment there was some slight improvement though headache and vomiting persisted. Again we went to a Eye Hospital where glasses were prescribed for her. But, on her wearing the glasses, headache and vomiting increased. Later, we took her to the Headquarters Hospital, where she died.

Letter from K. S. Guruvayya Setty, 21|17 Lighthouse Road, Coimbatore.

After my six-year-old son, Somasundaram, was B. C. G. vaccinated, pus formed in the hand and he suffered for three months. Later, he took medicine from a doctor for a month and got cured, but still he continues to be weak.

Letter from Y. R. Narayanaswamy, $14 \mid 33$ Thyagaraya New Street, Coimbatore.

Since my boy, Jayarth, was B. C. G. vaccinated (in November last) pus formed in the spot and it has not yet been cured, despite the use of all kinds of medicine.

Letter from T. N. Ramachari, Range Gounder Street, Coimbatore.

Since my three-year-old daughter, Bhanumathi, got $B.\ C.\ G.$ vaccinated, the festering sore on the spot is still not cured and she is always crying with pain. We

took her to many doctors and then to the Headquarters Hospital and also the Madurai Hospital, but to no purpose.

Letter from Subbanna Goundan, 17|378 Range Gounder St., Coimbatore.

My $1\frac{1}{2}$ year old baby, Ponnammal, developed fever after B. C. G. vaccination. Despite treatment by a doctor she died in a week.

Letter from V. Kuppuswamy, Avinashi Road, Coimbatore.

My $4-\frac{1}{2}$ year old brother, V. Ramakrishnan, who was B. C. G. vaccinated, developed a sore on the spot which could not be cured even after a week of treatment in the Headquarters Hospital. Treatment by another doctor was also of no use. Till today pus is flowing from the festering sore.

Extracts from the letter to the Editor, Hindustan Times (9th July 1955) from R. Sambasiyan, M.B.B.S., Physician and Surgeon, Tiruchi.

I have on my hand a shattered child in my grandson aged 14 years. He was B. C. G. vaccinated in 1954. Till the time of vaccination his health was A-1, with very good physique and stamina and resistance to infections. He was very well nourished and playing school games. From the time of vaccination he has developed an allergic state, with eosino-Boils, small and big, crop up intermittently over any part of the body which do not heal in the ordinary way and in the usual time in spite of standard measures. Now a few boils have sloughed out leaving punched and cup-shaped ulcers, slowly granulating. Another feature is the development of easy and quick inflammatory edema for a few inches around each boil, unlike ordinary boils where inflammation is self-limited to the base of the boil only. Anyhow, I am striving my best to rehabilitate him to normal standard fitness and resistance.

Letter from Vigian Prakash, Co Ch. Mansa Ram, Retired Engineer, Dehra Dun.

With reference to your articles and letters to the Editor to the Hindustan Times, regarding harmfulness of B. C. G., I have dared to address to such high position person the case of my son Jai Dev, aged 13 years and student of VIII Class of Sri Sadhuram Higher Secondary School, Dehra Dun, who had been vaccinated with B. C. G. about a year back in the school.

Sir, since he had been vaccinated his health has deterioraied, affecting lungs and poisoning his blood. He caught cough and asthma. Now I fear T. B. He is losing his weight and by now he has lost 12 lbs. in weight. I took him to Chandigarh (Punjab) for treatment and remained there under the treatment of Col. D. Bhatia, O.B.E., F.R.C.S., Chief Medi-Chandigarh for more than a month who was of

Chandigarn for more same spinon.

Sh. I had a shift him to this place as I could not afford to keep him there. He had no relief there. I took him to Civil Surgeon Dena Dun, on the advice of the Head Master with his letter who paid no heed and did not examine. I again approached his through a man and paid him a fee of Rs. 16|- in the Hostal. He gave some prescription without much seeing him am giving him now his medicines. He also told me that the lay be due to B. C. G.

(Hindustan Times, July 20, 1955).

One who has given his name and address in his letter and who holds the position of a district officer under Government, writes to me:

> "It is very good of you to have taken up seriously to oppose and condemn boldly, the indiscriminate mass vaccination with B. C. G. against T. B. I am a father who lost an eleven year old handsome son due to this. My son was studying in a primary school here in 1951. The protagonist campaigners of B. C. G. arranged for vaccination in that school. My boy ran out of the compound saying 'I cannot take this vaccination without the permission of my father who will otherwise beat me'. He was forcibly dragged in and He was then in the incubation period for vaccinated. measles. On the fourth or fifth day he developed measles and with high temperature rising upto 109 degrees with meningitis and pneumonia, died on the second day, i.e. on 4th April, 1951 exactly a year after my wife's death due to other causes. Thus I had a double calamity. The boy who was very healthy before the vaccination and playful. But without consideration to other factors like parents' permission, observation whether the children are in the incubation for any other infectious diseases, etc., these vaccinations are being done. I wish and pray God to give you long life and health to fight against these unwanted and indiscriminate vaccinations on the innocent children."

I do not give the name lest it might lead to a third calamity to this unfortunate father who is a Government servant.

(Published in Indian Express, Madras 12-7-55).

K. Balasubramanian, aged 18. son of N. Krishnaswami Pillai, Malamaiyur Road, Chingleput, had B. C. G. vaccination last March_April campaign at St. Joseph's High School, Chingleput. He was studying in IV Form. His health deteriorated since then and now he often vomits, has severe headache, eye-sight gone bad, feels giddy, sometimes goes unconscious and partially unsound in mind and loses power of speech and going down in weight. Being the only son of his parents, they are extremely anxious. He has been admitted for treatment in the Government Headquarters Hospital on 3rd July.

Michael Anthony, now in the military hospital, Aundh Camp (Poona) vaccinated with B. C. G., attacked by T.B., lost his job and is very ill in hospital. He was vaccinated when he was working in a military establishment in Bangalore. He was in perfect health before this and there was no history of T.B. in his family. He writes a most doleful angry letter to me about the foreign "World Health Experts" in whose presence he was vaccinated.

M. S. Fakir, a beedi worker in Majid Mark Factory in Vincent Road, Fort, Coimbatore: Had his child of 2½ years vaccinated with B. C. G. on 18th Dec. 1954; Eye-sight affected and health deteriorating.

(Letter from Prit Singh, Lodi Colony, Delhi, dated 20th July, 1955).

I give below the full account how the B. C. G. vaccination reacted adversely in the case of my son. My son named UDAI VIR SINGH, then aged about 9½ years and a very healthy boy, was given a B. C. G. vaccination in the school in the month of August, 1953. Unfortunately for us the next day some kind of glands became visible and swelling on the neck. I consulted a Homeopath (Doctor) whose treatment had a soothing and desirable effect upon the child. Just one year later the same thing re-appeared with a greater force and the condition of the child became alarmingly dangerous. The X-ray report, dated 8th September, 1954, of the Radiologist Safdarjung Hospital, New Delhi, read as "Infiltration near left gout (sic) T.B. left lung. Mediastinal glands enlarged." Thereupon the case having been referred to The T.B. Clinic (Irwin Hospital), New Delhi, the necessary investigations were carried out there and their findings dated 18th September, 1954, read as "X-rays chest negative. T.B. glands neck. Advised (i) General tonics & vitamins and (ii) Ultra violet rays exposure."

Thus we were unnecessarily put to so much of trouble and our peace of mind was greatly disturbed solely due to the B. C. G. vaccination. Even though a good deal of treatment has been given to the boy yet his condition has not so farreturned to normal. I may add, that the history of my family is quite negative. Nobody has ever suffered from T.B. in my family.

Actually for some years past this practice is being given effect to in a very indiscriminate manner and without trying to know whether or not it is at all necessary to do so with the result that at times greater harm is done than the contemplated good. Some device to check this is absolutely necessary and it must be brought home to the authorities concerned to value its necessity and urgency.

Postscript: When this booklet was in the press, the following statement was made by Dr. Friedmot-Moller, Superintendent of the Union Mission Tuberculosis Hospital, Madanapalle, in the course of a survey of the work done by the Sanatorium: "As for the effect of the B.C.G. in protecting children against plater infection with virulent tubercle bacilli, they must wait for the results until more time had gone." This guarded statement from one with experience of treatments work is significant and confirms the view that the B.C.G. campaign in India is experimentation on an unjustifiable large scale, rather than a prophylactic measure of proved value.

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