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## EDITORIALS

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### CONCERNING THE STUDY OF THE PROPHYLACTIC ACTION OF BCG VACCINATION AGAINST LEPROSY

The great majority of leprologists recognize that reactivity to lepromin, naturally acquired, may be considered as an indicator of a state of relative immunity against leprosy. The fact that BCG vaccination gives rise to this reactivity in healthy subjects permits one to hope that the Calmette-Guérin method of protection against tuberculosis may possibly play an effective role in the prophylaxis of leprosy.

To throw light on this very important question, many leprologists desire to undertake campaigns of BCG vaccination in regions where leprosy is strongly endemic. Such an experimentation, however, in most of the countries where leprosy is endemic, would be practically possible only if the method of vaccination would not necessitate the frequent assembling of the population. All physicians who have made inquiries of such nature are aware of the difficulties and the loss of time involved in the repeated convocation of numerous individuals. In BCG work these conditions exist in employing the inoculation method, now widely adopted in tuberculosis prophylaxis and officially approved by the World Health Organization, since that method involves preliminary tuberculin testing and the vaccination of only negative reactors.<sup>1</sup>

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<sup>1</sup> It happens that this was the method which Fernandez employed in the first observations on the induction of lepromin reactivity by means of BCG. (See *Rev. argentina Dermatosisif.* **23** (1939) 425-453.)

Without any implications whatever regarding what method is best for anti-tuberculosis work, we hold that the inoculation method is obviously not suitable for the mass application of BCG prophylaxis under the conditions of under-development which exist in regions where leprosy is a problem. In Brazil, where most investigations on lepromin conversion by BCG have been carried out, antituberculosis prophylaxis is being carried on by the oral method of vaccination developed during the past twenty-five years by Arlindo de Assis and collaborators, in which the original method that Calmette and Guérin applied only to newborn children has been modified in certain important ways and extended to other age groups.<sup>2</sup> The oral route is also being used in various other countries, in Europe as well as South America.

Of the several reports on the activating effect of BCG vaccination in persons proved nonreactive to lepromin, a series of studies published by Rosemberg, de Souza Campos and Aun<sup>3</sup> is especially noteworthy. Briefly, these authors have shown that in healthy subjects the oral administration of a single dose of 100 mgm. of BCG prepared by the method of de Assis provokes the appearance of reactivity to lepromin. They have shown also that the BCG vaccine may be given and the lepromin injected at the same time. In this work they confirmed the findings of de Assis that this could be done, with no inconvenience, without preliminary tuberculin testing. On this basis it is possible to undertake large-scale experiments to determine the prophylactic effect of BCG with respect to leprosy, with minimal observation of the people concerned. Nevertheless, based on our personal experience of 18 years in the preparation and application of BCG, we believe it desirable to offer the following remarks.

The dose of 100 mgm. of BCG recommended by the Brazilian workers for oral vaccination, without preliminary tuberculin testing, cannot be adopted everywhere. It is a fact that, al-

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<sup>2</sup> In 1950 de Assis presented, in French, a summary of the work in Brazil to that time at the 11th Conference of the Union Internationale contre la Tuberculose, held in Copenhagen in September (pp. 477-510 of the transactions). This work was also summarized, in English, by José Feldman in the *Rev. Ass. Méd. Minas Gerais* 1 (1949) 147-160. An apparently complete bibliography through 1952 appeared in *O Hospital* (Rio de Janeiro) 41 (1952) 965-971.

<sup>3</sup> ROSEMBERG, J., DE SOUZA CAMPOS, N., and AUN, J. N. *Rev. brasileira Leprol.* 18 (1950) 3-23; 117-127; 128-143; 19 (1951) 8-18; 19-26; 20 (1952) 67-74; 75-83; 84-96; 97-103.

though the vaccine prepared in Rio de Janeiro can be so used in that dose without ill effects, vaccines prepared by other laboratories may, even in doses as small as 30 mgm., give rise to more or less frequent post-vaccination lymphadenitis. The reason for these observed differences in the effects of BCG is not yet known. They may be due to the fact that the different strains of BCG used in different parts of the world are not absolutely identical, and that the techniques employed in the cultivation of the germ and the preparation of the vaccine vary in some respects from one laboratory to another. Be that as it may, it is evident that before undertaking mass vaccination campaigns by the Brazilian method it would be necessary to make a preliminary study, in each country, of the minimal dose of oral BCG which is capable of producing reactivity to lepromin without undesirable side-effects, and that would have to be done for each vaccine produced by different laboratories.

Large-scale vaccination by the buccal route would require very large quantities of BCG, whereas in the various countries where leprosy is widespread there actually exist few laboratories prepared to manufacture the quantities of "fresh" oral BCG that would be needed for a large experiment. Furthermore, the fresh vaccine, even when protected from heat and light, remains active only for a period of some 15 days. Yet the study of the value of the vaccine of Calmette and Guérin in the prophylaxis of leprosy would be undertaken in regions often difficult to reach and generally far from the BCG laboratories, to say nothing of the conditions needed to preserve the activity of the vaccine. An appreciable amount of the vaccine would therefore become unusable, and the resulting increase in the demands for it might exceed the capacities of the centers of production.

On the other hand, it is probable that the use of the lyophilized "dry" BCG, which when kept in the refrigerator maintains its activity for about five months, would permit the undertaking of such vaccination campaigns in a much more economical and practicable manner. The BCG laboratory of the Institut Pasteur of Paris has, since 1947, been making a dry vaccine containing 150 mgm. of BCG per ampule. This concentrated material is intended for vaccinations by the scarification method, but Sayé of Barcelona has been using it for the past 18 months for the oral vaccination of newborn children without the least difficulty.

It seems, therefore, that this dry vaccine could be used by

mouth, without risk of complications, in the campaigns which the leprologists desire to undertake. It is probable, however, that the dose of 150 mgm. would be unnecessarily high. Preliminary experiments with doses of 50, 75 and 100 mgm. might be made in progressive manner in order to determine the minimal dose which would regularly produce reactivity to lepromin. In this way it is probable that vaccination campaigns with dry BCG would be found to be more economical, and more practicable, than with the fresh vaccine.

—R. CHAUSSINAND