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Leprosy and the Community

The World Health Organisation and Leprosy

The inclusion of leprosy in the World Health Organisation Special Programme for Research and Training in Tropical Diseases is a major event in the history of leprosy control and eradication. We are happy to reprint here, with the special permission of WHO, relevant extracts from the Strategy document, including the Summary Report of the First Meeting of IMMLEP, describing the foundation of the leprosy vaccine task force.

LEPROSY

3.1 *Magnitude of the Problem*

Leprosy is a public health problem in more than 70 countries, mostly developing ones. Some 11-12 million cases of leprosy are estimated to exist in the world, with little fluctuation over the past 15 years. In Africa, the estimated number of cases is about 4 million, with more than one million disabled patients. Strong prejudice against leprosy, the long duration of the disease, as well as the frequency of disabilities and their steady aggravation create special problems not found with other communicable diseases.

3.2 *Reasons for Inclusion in the Special Programme*

(a) Need for a specific vaccine (BCG cannot be recommended).
(b) Need for improved methods for the detection of the disease, particularly of its contagious forms in the pre-clinical phase.
(c) Need for improved chemotherapy of established cases. Dapsone, introduced some 30 years ago, is still the drug of choice. It is cheap and well-established, but its action is slow, relapses are frequent in the severe (lepromatous) forms, and resistant strains of *M. leprae* have been demonstrated. No satisfactory alternative drug for mass treatment is at present available.

3.3 *Priorities for Research*

3.3.1 *Short-term* (up to 5 years)

(a) Development of a simple skin test permitting the identification of individuals at high risk of developing the disease, particularly in its severe infectious form.
(b) Development of a more active drug, or combination of drugs, for treatment (including animal screening and short-term trials in man).
(c) Study of the biochemical requirements of *M. leprae,* with a view to achieve mass *in vitro* cultivation of the pathogen.

3.3.2 *Long-term* (over 5 years)

(a) Confirmation of the possible therapeutic effect of new drugs in long-term trials in man.

(b) Development of a vaccine for the prevention of leprosy.

The developments referred to above under 3.3.1 (a) and 3.3.2 (b) can now be envisaged with some reasonable chance of success, mainly because of the availability of large amounts of bacilli from armadillo tissues.

APPENDIX

Summary Report of IMMLEP*

A pure, specific antigen from *M. leprae* would be of inestimable value as a diagnostic and epidemiological tool, as an immunological reagent for incorporation into a vaccine, and as a therapeutic weapon that could perhaps be used to prevent some of the most adverse of the immunological consequences of leprosy, or to restore a state of natural resistance to patients cured of lepromatous leprosy but still at risk of relapse.

Certain logical steps can now be taken towards these goals because of the major contribution made by Kirchheimer and Storrs when they demonstrated that an abundant supply of *M. leprae* could be had from tissues of infected armadillos. Moreover, their generosity in supplying others with infected tissues has permitted the critical first steps to be taken to recover *M. leprae* in preparation for the more exacting task of fractionating the bacillus and purifying its antigenic components. The job of separating the many irrelevant antigens of *M. leprae* from those of diagnostic, immunoprophylactic and therapeutic importance has begun; and from it has come an early indication of what it means to have unprecedented amounts of *M. leprae* with which to plan a concerted attack on this ancient disease.

It was agreed that a plan for developing anti-leprosy tools would have the best chance of success if programmed and implemented in collaboration with the WHO Immunology and Leprosy units and several laboratories and centres in different countries under the Special Programme for Research and Training in Tropical Diseases.

The accompanying chart (the Strategic Plan) depicts a carefully considered approach to the problem of using immunological methods for the control and treatment of leprosy. It can be seen that certain problems must be solved in a logical sequence. For this reason, some aspects of the plan need special emphasis. The first priority is to secure an adequate supply of *M. leprae* from infected armadillos. This is a *sine qua non,* for every phase of the IMMLEP project depends upon the uninterrupted flow of bacilli for the purification, fractionation and antigenic analysis involved in creating the immunological reagents that will be needed at every step of the undertaking.

The rest of the plan, as outlined in the protocols, does not represent merely progression from one problem to the next, since many aspects of the plan can be undertaken concurrently once the supply of *M. leprae* begins to flow. Thus, those charged with responsibility for characterizing the organism antigenically will be preoccupied with its antigenic profile while others are seeking to place *M. leprae* in its proper relation to other mycobacterial species for reasons that are stated

* These plans form the foundation of the leprosy vaccine task force.

elsewhere. At the same time, still other participants in the project will be engaged on the equally important objective of learning how to potentiate the immune response to *M. leprae* and its constituent antigens in ways best calculated to induce resistance. It is not possible to give assurances, however, that an effective vaccine will emerge from all this effort, but there is ample precedent for believing that adjuvants selected for their capacity to modulate the immune response to tumour-associated antigens can do as much and more to enhance the immune response to *M. leprae,* as they have been shown to do with other infectious agents.

There is less uncertainty about other benefit that will soon materialize—a specific skin-test antigen which can provide valuable information. Firstly in the epidemiological field; secondly as an important adjunct to immunological studies; and thirdly in the planning of a vaccination trial and as a preliminary parameter for the measurement of its success.

The protocols, with their crude estimates of cost, provide only a forward-thinking sketch of anticipated problems and suggested solutions. They do, however, open the door to many questions that have engaged the interest of frustrated leprologists for many years. The prospect of analyzing with new-found precision the nature of the defect in lepromatous leprosy, or of devising a rational means of controlling the damage done to nerves in tuberculoid leprosy, are striking examples of the less obvious advantages that deeper immunological insight will bring to the management of this disease.

If the fruits of IMMLEP could be foreseen, the projected costs might seem extremely small. But even in ignorance they are still not large in comparison with what has often been spent on less promising projects. A relatively small investment is needed, however, to bolster budgets that are already committed to one or other aspect of the project by a number of interested agencies. Costs are likely to increase as the project advances, but they will grow only in proportion to its success.

Members of the IMMLEP Task Force at its First Meeting, November 1974

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First Meeting of IMMLEP Task Force
List of Protocols

Number	*Title*
1	Supply of *M. leprae* from the armadillo
2	Purification of *M. leprae* from tissues
3	Antigen fractionation of *M. leprae*
4	Taxonomic studies
5	Induction of cell-mediated immunity to *M. leprae*
6	Resistance to experimental infection
7	Immunopathology
8	Sensitization of human volunteers
9	Development and trial of a specific soluble antigen for skin testing
10	Preliminary considerations for a vaccine field trial