GOVERNING COUNCIL
Special Meeting
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Agenda item 3(f)

COUNTRY AND INTERCOUNTRY PROGRAMMES AND PROJECTS

CONSIDERATION AND APPROVAL OF GLOBAL AND INTERREGIONAL
PROGRAMMES AND PROJECTS

Project Recommendation of the Administrator

Assistance for a Global Project

Diarrhoeal Diseases Control Programme:
Research in Vaccine and Drug Development (Phase II) (CLO/81/011)

Estimated UNDP contribution: $US 4,260,000
Duration: Three years
Executing Agency: World Health Organization (WHO)

I. Background

1. National health administrations around the world have increasingly recognized the extent, severity and deleterious effects of diarrhoeal diseases which are a public health problem demanding priority attention. In most developing countries, acute diarrhoeal diseases are among the leading causes of death and morbidity in children under five years of age. It is estimated that every year from 4 to 5 million children in this age group die of the diseases. Mortality and morbidity among adults is also high, exacting a tragic toll in human suffering, family disruption and economic productivity. The prevalence of acute diarrhoeal diseases also places a serious burden on health facilities in developing countries, often accounting for 30 per cent or more of admissions to children's hospitals as well as a high proportion of visits to out-patient facilities. This represents a serious financial burden on already strained Government health budgets.

1/ The previous UNDP project recommendations were issued under the symbols DP/PROJECTS/R.1/Add. 1-3 through DP/PROJECTS/R.14/Add. 1-6.
2. Against this background, the World Health Organization (WHO), in collaboration with UNDP and other United Nations system organizations, established in 1978 a Global Diarrhoeal Diseases Control Programme. The broad objective of the programme is to reduce mortality and morbidity, caused by acute diarrhoeal diseases, while simultaneously strengthening the countries' own capacities for dealing with the diseases. The programme aims at improving the primary health care services and treatment methods, through a variety of training and other activities, while carrying out, at the same time, the basic research required to develop more effective tools for the treatment and prevention of the diseases. It was realized from the outset of the programme that such research must form an essential complement to field-oriented activities if any basic solutions to this world-wide problem were to be found.

3. At the twenty-sixth session of the Governing Council in June 1979, the Administrator recommended and the Council approved a UNDP contribution of $5,200,400 from the global IPF (Indicative Planning Figure) in support of the research component of the programme. The specific objective of this contribution was to support immunological and other types of research needed for the development of new and improved vaccines and drugs for the treatment and prevention of diarrhoea. This assistance, provided under global project GLO/78/005, has made possible, over the past three years, the establishment of a major research programme in this area. Following an extensive review of available knowledge, carried out through the convening of nine ad hoc groups involving the participation of 64 scientists from 27 countries, three global Scientific Working Groups (SWGs) were established in 1980 to manage biomedical research in the following areas: bacterial enteric infections; viral diarrhoeas; and drug development and management of acute diarrhoeas. Each Group has developed a five-year research plan and established research priorities in each area. Within the management framework provided by these SWGs, research proposals submitted by scientists around the world are assessed and selected for support. As a collateral activity, but not as part of the UNDP project as such, regional SWGs are being established to manage health services research, closely linked to national diarrhoeal disease control programmes. This programme is financially supported by a number of multilateral and bilateral agencies. By the end of 1981, 49 biomedical research projects in 20 countries had received support under the global project: 15 of these are developing countries. Highlights of the research currently under way are as described below.

4. In the area of Bacterial Enteric Infections, 26 projects were active at 31 December 1981. The main activities of this SWG are directed towards the development of new vaccines for the prevention of diarrhoeal diseases due to bacterial pathogens; the elucidation of their epidemiology; and the development of simplified methods for their laboratory diagnosis. An early important breakthrough has been the development of a new, live, oral typhoid vaccine which has been shown to be 95 per cent effective in its initial evaluation in a field trial in Egypt. Some success has also been achieved in developing vaccines for E. coli diarrhoea in animals, which may be useful in developing a vaccine for man. Progress is being made in the development of simpler diagnostic laboratory techniques.

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2/ DP/PROJECTS/R.12/Add. 1.
The lack of such techniques has been a major impediment to the more detailed study of the epidemiology of diarrhoeal diseases in developing countries.

5. In the area of Viral Diarrhoeas, 13 projects were active at the end of 1981. The main objectives of this SWG are the development of new vaccines for the prevention of diarrhoeas due to viral pathogens; a better understanding of their epidemiology; and the development of simplified methods for their laboratory diagnosis. Progress is being made towards the development of a vaccine against rotavirus infection, and the successful laboratory growth of human strains of rotavirus in tissue culture has given considerable impetus to research in this area. There is hope that vaccines suitable for wide-scale field trials will be available within the near future. Epidemiological studies currently under way are providing new and significant information on the incidence and importance of rotavirus infections. A new and simple test for the diagnosis of rotavirus infection, which eliminates the need for expensive electron-microscopes, has been developed and is being field-tested.

6. In the area of Drug Development and Management of Acute Diarrhoeas, 10 research projects were under way at the end of 1981. The fields of research receiving the highest priority are the development and testing of new and existing drugs and clinical managements of diarrhoea. In the first area, research is being carried out on the effectiveness of existing anti-diarrhoea drugs as well as on the potentialities of some traditional medicines. Efforts are being made to identify institutions in developing countries that could serve as clinical centres for testing suitable compounds. Five have been identified to date. Discussions are also being held with pharmaceutical companies aimed at enlisting their collaboration in the programme. In the area of clinical management, present work is concentrated chiefly on efforts aimed at improving oral rehydration therapy, including alternative means of packaging and distributing the oral rehydration salts (ORS) recommended by WHO for this therapy.

7. A number of other research activities are under way, including the preparation of guidelines for clinical trials and epidemiological studies to assist investigators in the design of research proposals.

II. The project

8. The above activities and results achieved thus far represent the first stage in building up a world-wide biomedical research programme which holds out the promise of saving many millions of lives in the years ahead. Fundamental research of the type that has been embarked upon is, by its nature, a long and costly effort. It is now necessary to provide the continued support required to carry forward the research currently under way and to extend the work into potentially fruitful new areas.

9. The basic objectives of the programme and research directions remain unchanged. They are:

(a) The development of new and improved vaccines for the prevention of diarrhoeal diseases, and establishing guidelines for their use;

(b) The development of improved drugs for the better treatment of diarrhoeal disease, including drugs that can block or reverse the intestinal secre-
tory process, reduce nausea and vomiting, and the development of better prophylactic drugs;

(c) The improvement of laboratory methods for rapid identification and characterization of microbial agents, and for determining the immune response to the major pathogenic factors in each of the agents.

10. Activities will continue to be carried out within the management framework of the three global SWGs that have been established, appropriately strengthened as may be required to identify new priorities and areas of research, and co-ordinate and monitor an expanding programme. Efforts will be intensified to increase the involvement of developing country scientists and institutions, in line with the programme's objective of strengthening the research capacity of developing countries. In addition, the programme will continue to work closely with other research organizations and institutes known to be carrying out research in diarrhoeal diseases, and will continue to endeavour to enlist the collaboration of the pharmaceutical industries in order to achieve the programme's various goals. Close collaboration with the International Centre for Diarrhoeal Diseases Research in Dacca, Bangladesh, will be continued.

11. The Governing Council is being requested to approve additional funds for the programme to allow WHO and the SWGs to do the required forward planning with the assurance that the necessary support will be available through the current IPF cycle.

12. The expenditure component of the proposed UNDP contribution is as follows:

<table>
<thead>
<tr>
<th>Subcontract</th>
<th>$4,200,000</th>
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<tbody>
<tr>
<td>UNDP direct costs</td>
<td>$60,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$4,260,000</strong></td>
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13. The expenditures under the project will be contained within the IPF available for global projects established by the Governing Council for the third cycle 1982-1986.