COMMITTEE A

PROVISIONAL SUMMARY RECORD OF THE FOURTH MEETING

Palais des Nations, Geneva
Tuesday, 14 May 1974, at 2.30 p.m.

CHAIRMAN: Professor J. TIGYI (Hungary)

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Professor ALIHOU (Dahomey) recalled the statement made by the head of his delegation in plenary meeting on the subject of biomedical research. He emphasized that, although research was clearly an important factor in development, for it to benefit the developing countries it must fulfil two conditions: first, the subject for investigation must be studied on the spot at a high level institute, but it did not have to be directed exclusively to the needs of the developing countries; secondly, the facilities offered by a research centre should be integrated with the country's development plan and be bound up with the life of the region. WHO's assistance would be necessary in determining priorities, but it should have the help of national research workers, who would work in close collaboration with their foreign counterparts.

The delegation of Dahomey strongly supported the report before the Committee and appealed to the better equipped countries to show their confidence in the developing countries, and in WHO, by granting them funds and facilitating the exchange of research workers and experts. Greater responsibility should be given to the research workers of the developing countries as regards biomedical research in their own region and country.

Dr ARNAUDOV (Bulgaria) said that the proposals contained in the Director-General's Report deserved careful consideration; priority had been given to the most urgent problems, and the way in which the programme was to be implemented - by international collaboration in research - had already proved its worth. One shortcoming of the Report was that it lacked complete information on the results of certain tasks already carried out, which made it impossible to evaluate how effectively resources had been utilized and to draw the necessary conclusions.

Moreover, in the proposed programme insufficient account had been taken of the conditions in which it would be implemented; the "cold war" had given place to peaceful coexistence, which required WHO's activities in biomedical research to be carried out on a wider scale and with different approaches. Successful control of widespread diseases, such as cardiovascular diseases and cancer, required correctly oriented, systematic and detailed medical, biomedical and medicosocial research, in which hundreds of large scientific institutions should take part. No one country could elucidate the problems of their etiology, pathogenesis, treatment and prophylaxis, but it was not impossible to accomplish that by a global effort.

In his delegation's opinion, the biomedical research programme might include, first, short-term tasks, intended to solve the most urgent problems such as those posed by infectious and parasitic diseases; secondly, some wide international programmes to cover important medical problems (cardiovascular diseases, malignant neoplasms, etc.); thirdly, a long-term programme on problems of growing importance, such as the aging of populations, medical genetics, conservation of the environment, allergic diseases; and fourthly, the establishment of more effective forms of international collaboration.

The Director-General's Report called upon Member States to assist in determining the research institutions that could take part in the programme. In Bulgaria there were a number of such institutions with considerable experience in carrying out research and putting its achievements into practice. They could successfully cooperate in the programme and assist in training research workers from other countries.

Mr CAMARA (Guinea) said that, among the subjects of research that were of importance to the developing countries, the Report before the meeting rightly laid stress on the strengthening of health services, health manpower development, communicable disease control, malnutrition and environmental health. His delegation shared the views of the Director-General, but had some reservations as to the limits imposed on such research, since the solutions proposed concerned only a restricted aspect of morbidity in developing countries.

As regards reciprocal assistance between developed and developing countries, it was the priority needs of each region that should govern assistance. In the developing
countries, for example, the problem was not to limit the number of births, but to create favourable conditions for survival and development of the child.

Regarding the responsibilities of the Executive Board in medical research, he suggested that there should be a fair distribution of tasks: one member of the Board might be responsible for coordination at international level and should visit countries where research was being undertaken. WHO should not merely wait for the results of research to come in but should centralize the carrying out of such research through its regional offices, which at all times should know what research was being carried out in the area.

The report advocated the training of scientific health personnel in national institutions in countries which most needed such assistance; his delegation was in favour of such training. As for his own country, Guinea had a Ministry of Scientific Research, to which were attached three institutes dealing with (1) the traditional pharmacopoeia, (2) fruit and nutrition, and (3) applied biology.

Dr SAMBA (Gambia) said that he was encouraged by the favourable reaction of the Committee to WHO's role in the development and coordination of biomedical research. The valuable suggestions made by previous speakers prompted him to offer his own country as an ideal setting for one of the world centres on biomedical research.

The British Medical Association had been operating for many years in the Gambia in the fields of nutrition and communicable diseases, but recently the Governments of Nigeria, Ghana, Liberia, Sierra Leone and the Gambia had decided to establish a West African postgraduate medical college in which some of the French-speaking countries of Africa had also shown interest. The Government of the Gambia had approached the British Medical Research Council concerning the setting up of a biomedical research laboratory and school but, although the Council was willing to assist, it could not actively contribute to running the school because of stringent financial constraints. However, if the school were set up, the Council would make available all its experience and technical know-how. His delegation was happy to learn that WHO was in a position to assist in establishing the school of biomedical research, which would be open to students from all parts of the world.

Dr SPANDER (Netherlands) drew attention to the criteria for WHO's role in the development of medical research (page 14 of document A27/11). He stressed the importance of recommendation 2 - establishment, maintenance and extension of working relationships between WHO and individual scientists and collaboration with regional and national institutions. Priority should also be given to recommendation 4, namely that the research programme of WHO should be directed mainly towards the solution of problems neglected by national efforts, particularly those that cut across national boundaries and that could not be investigated without international cooperation or assistance. As regards recommendation 5 - the principle of maximum utility - he said that present-day governments increasingly tended to do a great deal of basic research, and that the resultant large amount of data should be made available to others. He also stressed recommendation 7 - promotion of research through meetings of scientific and other working groups and expert committees, scientific missions to areas of special interest, travel grants, fellowships and publications.

Dr FAKHRO (Bahrain) said that very little attention had been given during the discussion on the biomedical research programme to its financial implications. In view of the fact that only about 10% of the research that was carried out achieved outstanding results, it would seem that much more discussion of financial implications was warranted, as well as more information from the Secretariat, since neither the Executive Board nor the Director-General in his Report had dealt fully with the financial aspect. What was needed was a study of the financial resources available and of the financial implications of the programme.

He wondered whether it would be possible to subdivide the list of priorities given in the Director-General's Report according to their greater or lesser urgency.

If the central theme of the programme of biomedical research was essentially to solve great and urgent problems, then many of the suggestions made by members of the
Committee had to be considered with caution. In that case, operational and clinical research became secondary in importance to the very basic biochemical and molecular research which, if successful, would result in a real breakthrough, and the undertaking of marginal research projects became a luxury that WHO could not afford.

He emphasized the importance of the institutional and cultural atmosphere in the education and training of research workers from the developing countries, and suggested that a follow-up study would be advisable in order to determine the results of their training, in terms of scientific achievement and productivity, under different approaches and in different types of institutions.

From the list of priorities given in the Report he understood that the main criteria for the initiation of research projects by WHO would be, first, the extent of the problem and therefore the number of persons involved; and, second, whether significant research could be carried out through national efforts. The application of such criteria should constitute the "take-off" point from any project. The availability of technical resources, the expected yield, especially of the first efforts, and declared national interest were details that had to be worked out; but they should not constitute criteria which, if not met, would prevent a badly needed research project from being undertaken.

The issue was not only a scientific one - it was basically a moral one. It was a question of whether WHO had an obligation towards the millions of children and young adults who were dying unnecessarily because of lack of research, while billions of dollars were being spent to solve much less urgent health problems. Countries that were able to carry out extensive research on their own health problems had to try to understand the health problems of the poor and undeveloped world.

Professor HALBACH (International Union of Pharmacology), speaking at the invitation of the Chairman, recalled that several Presidents of the Union had served on the Advisory Committee on Medical Research and had contributed to the development of WHO's programme on drug safety and efficacy. They had also taken part in discussions on biomedical research, especially laboratory research coordinated at world level in the areas of carcinogenicity, mutagenicity, teratogenicity and other toxic effects of environmental substances, including drugs and food additives.

Referring to the collation of the large amount of information available on biomedical research and the mobilizing of the results of such research in the interests of the present WHO research programme, he suggested that this could well be facilitated by the establishment within the Union of a section on toxicology.

In connexion with the suggestion in Section B (11) on page 4 of the Report that research on pharmacotoxicological problems, particularly at the molecular level, should be intensified, he pointed out that much had been achieved but that more was to be done in this area in order to further the rationale of therapeutics as well as preventive measures against intoxication. As for certain other problems mentioned in the Report, such as atherosclerosis, degenerative diseases, reproduction problems and aging, he emphasized that the randomized controlled trial was a method which should be applied not only to the evaluation of drugs but to all measures of health care in order to evaluate their efficiency and effectiveness.

Dr WONE (Senegal) said that the Report before the Committee on WHO's role in the development and coordination of biomedical research was an excellent one, since it dealt with the problems that had been of concern to the developing countries for many years. Moreover, the proposals for research contained therein appeared well adapted to the situation in those countries.

His delegation was struck by the contrast between the resources available or potentially available for research and the small amount of research that had been carried out in certain fields - for example, in parasitic diseases such as onchocerciasis, as the Minister of Health of Senegal had pointed out during a plenary meeting of the Health Assembly. If the means available for research were brought to bear on the problem of parasitic diseases in the developing countries, those diseases could rapidly be controlled, and perhaps even eradicated.

Sections E and F of the Director-General's Report clearly diagnosed the research problems of the developing countries and he could only hope that everything possible
would be done to solve the special problems connected with biomedical research in those
countries.

He had listened attentively to the statement made at an earlier meeting by the
Deputy Director-General and had read the extracts from the meetings of the Executive
Board attached to the Director-General's Report. He hoped that the recommendations
made in that Report would be carried out as rapidly as possible, since the welfare of
millions of human beings was at stake.

Dr LEIKIE (Zaire) pointed out that the training of research workers was a problem
mainly in the developing countries. However, even if those countries lacked funds, it
was generally possible for them to attract resources from outside, depending on the way
in which their research programmes were presented. WHO should play a more active role
in the developing countries, where the shortage of research workers was particularly
acute. A regular census of national research workers should be undertaken in order to
follow progress, not only in the numbers of such workers but also in their quality.
The only real solution to the problem of the brain drain was to improve the material
conditions - and especially the working conditions - of research workers in the countries
concerned. However, as long as there was liberty of movement in the world, the brain
drain would no doubt continue.

Dr HAN Hong-Sop (Democratic People's Republic of Korea) noted that a high priority
for research on communicable diseases was called for in the Report. It was to be hoped
that WHO would continue its efforts in that field at both regional and international
level; otherwise, it would be difficult to find a solution to the problem, even if
preventive measures were taken at the national level.

Japanese encephalitis and cholera were particularly rife in Korea. Epidemics of
all types had ceased to occur in the northern half of the country thanks to the con-
certed preventive efforts of the Government of the People's Republic. However, the
dangers of communicable diseases - especially Japanese encephalitis and cholera - still
persisted, since the two parts of the country were closely linked and flies and mosquitos
could not be prevented from crossing the frontier from south to north Korea. It was
therefore necessary to make great efforts every year to protect the population of the
northern half of the country from epidemics of those diseases. WHO should take
appropriate measures, as proposed in the document. His country would lend its assis-
tance to that effect.

Dr VENEDIKTOV (Union of Soviet Socialist Republics) said that the discussion had
shown that all delegations were in agreement regarding the importance of WHO's role in
the development and coordination of biomedical research. The work should be continued
and the Executive Board and the Director-General should be requested to intensify it
within the framework of the Organization's long-term programme. In that connexion his
delegation, jointly with those of Poland, Turkey and the United Kingdom, was presenting
the following draft resolution for the consideration of the Committee:

The Twenty-seventh World Health Assembly,
Reaffirming resolution WHA25.60 on the need to intensify WHO activities in the
field of biomedical research, particularly in regard to the development of its
long-term programmes,
REQUESTS the Executive Board and the Director-General to intensify work on the
preparation of proposals for the development of the Organization's long-term
activities in the field of biomedical research, to enlist the active participation
of the Advisory Committee on Medical Research and expert committees, and to report
regularly to the World Health Assembly on the progress achieved.

Dr KAPLAN, Director, Office of Science and Technology, said that a number of
deliberations had referred to the exchange of biomedical research information, which was
generally agreed to be an extremely important aspect of the matter. WHO had been
investigating such exchange for some time and was still studying the problems involved.
Document A27/11 referred to the increased activities of the WHO library service, and he
drew attention to the MEDLINE Service - based on the former MEDLARS - which was being extended to the regions and to Member States. Such a costly service could never be matched by the resources of WHO, but the Organization was taking full advantage of it and passing its benefits on to Member States and institutions. The analysis of individual research papers presented enormous problems. Information handling had advanced to such a degree that vast amounts of information could be compressed and synthesized. Elaborate organizations had been set up in different parts of the world to deal with biological and chemical abstracts, and it would be foolhardy for WHO to attempt to duplicate such activities. WHO's approach to the problem was therefore to try to take advantage of what those organizations were doing from the standpoint of analysing specific research work in different fields, and to transmit such information to Member States.

Furthermore, in order to fulfil its function of coordinating research, WHO held meetings, working groups, organized task forces, and brought together expert committees, seminars, and workshops. WHO was also approaching the medical research councils and analogous institutions of Member States with a view to convening a small group to determine how it might better fulfil its coordinating function, in what respects it could increase its collaborative efforts, and how the exchange of biomedical research information might be improved. Within the limits of its financial resources, WHO was investigating who was doing what in the main areas of medical research; how to transmit that information to the important institutions and medical research policy makers in all countries; and what emphasis was being given to various subjects in different places. The library services and information analysis to which he had referred, as well as the increasing collaboration with medical research councils and the main medical research policy-making bodies in the various Member States, represented a substantial return for the limited resources invested by WHO.

The DEPUTY DIRECTOR-GENERAL said that the Director-General attached considerable importance to the biomedical research programme, and thanked the delegates for their illuminating and positive statements. Note had been taken of their warnings and of the need for a cautious and modest approach. The Director-General had asked for frank and effective dialogue with the Health Assembly, the Executive Board, and the Member States - and it was clear from the discussion that had taken place that the Member States intended to respond in that manner.

One of the most significant facts was the way in which bilateral relationships representing a formidable network of international institutions had been set up, especially between the privileged countries; and the way in which a solid community of international research workers had emerged - also limited to the orbit of the developed countries. A few months previously, WHO had begun to study the geographical distribution of its collaborating institutions and the strategic approach to medical research that had been the basis of the Organization for twenty-five years. It had been discovered that 60-70% of those institutions were located in the developed countries. In other words, where there had been an infrastructure in the past, a superstructure had been grafted on to it. It was hoped to enlarge the network in order that the existing resources of the USSR, the European and North American countries, and other privileged countries, should gradually begin to flow into the developing countries.

During his visits to various institutions he had observed that there were young, enthusiastic scientists all over the world who were anxious to see new things in other countries. He agreed with the delegate of Bahrain that the issue was not merely a scientific question but also moral. From the point of view of the philosophy of biomedical science in general, it was strongly felt that WHO should continue to explore new ideas. It was a commonplace that hypotheses were indispensable for scientific activity and that they should be judged by their heuristic as well as by their veridical importance. WHO had succeeded in avoiding two failures - of courage and of imagination - and it had to be able to take up new challenges. It could not refuse to act in what it judged to be the most helpful way for some of its Member States in acute need, even though the immediate benefits of its strategies might be uncertain. A craving for certainty could lead not
only to immobilization and fossilization, but also to atrophy of the creative instinct—though clearly with regard to the problems of biomedical research, certainty was still a long way off.

He hoped that the resolution to be adopted would reflect the thinking of both developing and developed countries and would enable WHO to go forward with courage and productiveness, as well as with aggressiveness tempered by modesty.

In connexion with the question raised by the delegate of Argentina with regard to WHO's programme of research in human reproduction, he said that note had been taken of the various proposals made. The human reproduction programme had been developed in response to the resolutions of past Health Assemblies and it dealt with a large number of questions, including fertility regulation. It had involved the collaboration of numerous scientists in many countries working on different aspects and with different approaches—biological, clinical, epidemiological, and operational. WHO's activities were closely coordinated with national efforts. The specific research projects supported by WHO in any country adhered strictly to the medical, social, and cultural context and to the practices prevalent in that country. The programme was monitored continuously and was closely evaluated. Its aim was the improvement of reproductive health in accordance with national policies.

The delegate of Thailand had asked whether WHO had engaged in any research into the attitudes of the public towards health policy, especially in so far as they affected the preference for a curative as opposed to a preventive approach. No research work of any scientific merit had been done in that field by WHO, but much work had been done in a number of countries of North America and Europe, and also in Brazil, in fields closely related to the subject. Note had been taken of the proposal that WHO should nevertheless encourage young behavioural scientists in the developing countries to include the topic in their research activities.

The CHAIRMAN said that the draft resolution prepared by the delegates of the USSR, Poland, the United Kingdom, and Turkey, would be circulated for discussion at a subsequent meeting.

Dr GARCIA (Argentina) wished to clarify his reference to an experiment in birth control carried out in the Province of Entre Ríos by a private group. He regretted not having stressed sufficiently that no responsibility for that programme devolved upon WHO, PAHO, or other international agencies. The Argentinian Government was making a thorough investigation in order to determine the responsibilities.

Dr MORA (Colombia) recalled his earlier as yet unanswered, question: whether there was any criterion for defining when research agreements should be established directly with the countries concerned (or occasionally with institutions in certain countries) and when they should be made through the regional offices.

Dr KAPLAN, Director, Office of Science and Technology, replied that the designation of a WHO collaborating centre was usually cleared through the government concerned. The regional office was always informed and often assisted WHO headquarters with its negotiations, including those for research agreements. A study was in progress to see how regional offices could be involved to a greater extent in the research programme of WHO, to define their better relationship with collaborating institutions, and to determine when communications with those institutions should proceed direct from headquarters, through regional offices, or by some other means.

2. STANDARDIZATION OF DIAGNOSTIC MATERIALS: Item 2.5 of the Agenda (Resolution WHA25.47; Document A27/12)

Dr CHANG, Assistant Director-General, introducing document A27/12, said that at the Twenty-fifth World Health Assembly several delegates had stressed the increasing use of the laboratory in the diagnosis and prevention of disease, and the consequent increased importance of diagnostic substances and laboratory methodology. After further discussions, during which attention had been drawn to the increasing need for the standardization of these reagents and to the lack of international coordination of such activities, resolution
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WHA25.47 had been adopted. In that resolution the Director-General had been requested to study methods of extending the work of WHO in the development of standards for diagnostic laboratory work, including an estimate of the costs.

After a brief introduction explaining why the report had been prepared, Part II of the document outlined the main reasons for the standardization of diagnostic materials. In Part III, the general aims of the programme were defined; it also included a clear definition of "standardization". Part IV briefly described the existing activities in WHO, and Part V summarized similar activities carried out by international scientific organizations. Part VI gave a summary and the conclusions of the International Conference on Standardization of Diagnostic Materials, held in Atlanta in June 1973, and co-sponsored by WHO and the United States Department of Health, Education and Welfare, Center for Disease Control, Atlanta, Georgia. Part VII described the proposed future programme of WHO in that area, its three main aspects being: (1) programme planning and coordination; (2) services to Member countries, and (3) the promotion of research and development. It also described the programme development in two stages - immediate and long-term - and considered the different scientific areas of standardization, such as microbiology, clinical chemistry, immunology, and haematology. Part VIII considered the cost of standardization in general terms. And Part IX indicated how WHO would organize a long-term programme on a practical basis and considered the staff requirements (in terms of WHO staff and consultants), the creation of a special advisory panel, the organization of meetings, the development of training and assistance to research activities.

It was estimated that the programme would involve fairly high expenditure over the first five years, and it was likely that the programme would be needed for a much longer period.

Dr SENCER (United States of America) said that the need for improved standardization of diagnostic materials was amply demonstrated in the Appendix to the document, in which it was indicated that a blood glucose specimen with a known value could give widely diverging results. Such results could lead to misdiagnosis or unnecessary hospitalization - either of which was unacceptable to the patient and added to the cost of health care. In the United States of America, the cost of clinical laboratory services amounted to 15% of health care costs. The urgent need for ensuring high quality diagnostic materials was therefore evident. The problem was one requiring international recognition, and concerned not only countries that produced diagnostic materials but also those that imported them. Diagnostic materials that did not meet the standards in the United States of America had been known to appear on the market in other countries. Only through international coordination could such occurrences be prevented. WHO was ideally suited for such a coordinating role.

The report specifically pointed out that standardization did not mean the imposition of a single method or reagent as the standard. It was rather intended to determine the accuracy and precision of performance of materials when used with a particular method. It was emphasized that WHO should not attempt to establish a standardization programme itself, but should build up the institutions already concerned with standardization in the Member States. As a result of the WHO programme of regional and national laboratories dealing with influenza - which currently numbered 95 - the typing of an influenza virus was the same in Rabat as it was in Bombay. The system had been developed not by constructing a large central reference laboratory, but by coordinating the efforts of a number of laboratories.

It was clear from the report that the standardization of high quality reagents, rather than increasing the cost of health care was actually of financial advantage to the health services. The programme outlined was a modest one designed to achieve results not to create a large superstructure overnight. The United States Government was prepared to give financial assistance in the initial stages of the programme, and scientific institutions in the United States were ready to collaborate in standardization work if they were coordinated by WHO. The term "chaotic" was used in the report to describe the situation, and the number of international professional societies involved might lead to further chaos if they all became involved in standardization efforts. It was therefore incumbent upon the Organization to assume the leadership in that field.
Dr JAROCKIJ (Union of Soviet Socialist Republics) said that the choice of subjects for WHO's future programme in the standardization of diagnostic materials given in the Director-General's Report was a good one. The subjects were those most closely related to public health practice and to the development of laboratory services, and reflected concern for the health of the most gravely affected patients. His delegation considered that the report provided an acceptable basis for future work. Unfortunately, it had been distributed only a few days before the Health Assembly and the experts on standardization in many countries had not had the opportunity to study it thoroughly.

The report contained no information on what had already been done by many national and international scientific institutions, whereas all achievements in the world had to be taken into account when a long-term programme was drawn up. Moreover, the programme should reflect the qualitative and quantitative requirements of various countries with different ecological conditions and different patterns of local pathology.

It would be desirable to provide the WHO expert groups that would consider the programme with additional information and proposals from as many countries as possible, so that the programme would have a more nearly universal character. The programme should also be taken into account when the Sixth General Programme of Work Covering a Specific Period was drawn up.

As the delegate of the USSR to the Twenty-sixth World Health Assembly had stated, the research institutions in the Soviet Union were prepared to participate in the programme.

Dr ZAMFIRESCU (Romania) said that standardization of diagnostic materials was of prime importance for the progress of medical science and it was therefore essential for all countries to participate in WHO's programme. The meeting at Atlanta, Georgia, in June 1973, under the auspices of the Center for Disease Control had proposed a vast and ambitious programme of work covering practically all aspects of the standardization of diagnostic materials, including nomenclature, recommendations on quality control, evaluation and comparison of methods, and even instruments and apparatus required for the methods considered, as well as training of personnel.

Clinical biochemistry had become a vast subject covering thousands of different methods, tests and reagents. His delegation would be interested to hear the views of other delegations on the need for a special unit of clinical pathology, or clinical biochemistry, headed by a pathologist, to develop an effective and comprehensive programme, covering all WHO's work in standardization, including biological and pharmaceutical substances, and diagnostic materials, as well as the organization of health laboratory services. That work was at present spread over several units in WHO and his delegation considered that it might be advisable to group it in a single service.

Dr DEL REY CALERO (Spain) said that standardization of diagnostic materials was of fundamental importance for (i) the development of research in the medical sciences and (ii) studies in epidemiology, and (iii) at the clinical level in relation to hospitalization of patients. For such standardization it was important to establish international reference centres and to promote the exchange of information between research workers. When screening tests were used it was essential to know the limitations of the tests employed, and information on the reliability and reproducibility of the tests was essential. Studies in one field might have far-reaching repercussions in other fields, for example, standards developed for work in radioimmunology could be used in several different fields.

Extension of work on the standardization of diagnostic materials would enable workers involved in pure and applied research to use the same language, knowing that they were using comparable materials. One of WHO's functions should be to facilitate communication between research workers in different countries.

Dr EL SAVED IMAM (Egypt) said that there was no doubt that standardization of chemical and biochemical substances was of extreme importance in ensuring reliable and comparable results. Standardization was particularly necessary for biochemical
substances such as agglutinating sera and antigenic substances, etc., and for the media used for growing and isolating organisms. His delegation proposed: (1) the organization by WHO of scientific committees to consider the standardization of materials for each branch of laboratory work; (2) the establishment of control laboratories in different parts of the world to examine and license all biochemical reagents; (3) a recommendation from WHO that only licensed products should be used; (4) the extension of proficiency tests for national laboratories; and (5) a mechanism for enabling scientific institutes to submit materials for testing to regional control laboratories.

Professor VON MANGER-KOENIG (Federal Republic of Germany) said that the large increase in health expenditure in Member countries indicated how important it was to rationalize health services, develop an efficient infrastructure, and plan carefully. But this was not sufficient: in order to obtain optimal efficiency and efficacy of diagnosis and therapy, reliable methods and reliable standardized materials were essential. In his country, all doctors undertaking laboratory work were now subject to continuous control of the quality of their work. Standardization of diagnostic materials must be the next step.

In the use of early detection methods and mass screening programmes it was clear that success or failure depended on the reliability of the diagnostic methods and materials. Epidemiological studies were of use only when the clinical chemist had reliable materials available. Developments in kidney transplantation would be possible only if the methods and materials used were comparable.

His delegation welcomed the fact that WHO had collaborated with the health authorities of the United States of America in bringing together representatives of organizations that had already undertaken preliminary work in standardization of diagnostic materials to study further developments. WHO should exercise a coordinating role, the practical work being done by laboratories in the field.

Professor LEOWSKI (Poland) said that the necessity for standardization was evident; it was a first step towards broad international collaboration in laboratory diagnostics. The programme proposed by the Director-General was a move towards solving a very complex problem. In order to be able to compare results internationally it was essential to have standardized materials. In Poland, the procedures concerned with laboratory diagnosis that were subject to standardization were as follows: the sampling procedures, the storage of samples, the analytical procedures, the recording of results, the control of quality testing, and the reporting of results. He thought that priority should be given to standardization of chemical reagents. His country would be willing to join any initiative in that field and to participate in any long-term programme.

Dr VIOLAKIS (Greece) said that there was no doubt that national government laboratories, as well as national and international scientific societies and manufacturing establishments, had an important role to play in standardization of diagnostic materials. Only WHO could coordinate this work and disseminate information to the Member countries. There was an urgent need to establish priorities in the field of standardization of diagnostic materials.

Dr REID (United Kingdom of Great Britain and Northern Ireland) referred to two particular aspects of the standardization of diagnostic materials. First, he drew attention to the proliferation of commercially produced reagents sets and analytical packages and to the rapid increase in expenditure on those items, especially in the field of clinical chemistry. The Appendix to the Director-General's Report showed that some of those kits were not very reliable. He could understand that such kits were very attractive to the developing countries, but his delegation would support WHO involvement in the field of standardization to save developing countries much wasted expenditure.

Second, he referred to laboratory diagnostic materials that were biological materials. WHO and the League of Nations had an excellent record in relation to the biological standardization of substances administered to man and of substances used in laboratory diagnosis. Over the last twenty years there had been increasing interest in laboratory diagnostic materials, many of which had to be assayed by biological methods. He assumed
that many of those biological substances would be established as international standards with defined international units. His delegation thought it was important that the new group of biological substances for quantitative measurement should be included in the programme of biological standardization of the Organization. Such standardization for quantitative measurement was a discipline quite different from that concerned with the vast number of diagnostic chemical substances and reagents, and WHO had developed, through its biological standardization programme, the expertise for dealing with it.

It was important that that expertise should be kept intact and independent of the other aspects of standardization of diagnostic materials, thus avoiding the undesirable situation of having a number of programmes within WHO, each defining international units of biological activity. That suggestion did not, of course, preclude the coordination of the biological standardization programme with other standardization activities within WHO; indeed, it would be advisable to have them all grouped together administratively.

Both individual scientists and institutions such as the National Institute for Biological Standards and Control in the United Kingdom were looking forward to offering their continuing and increasing assistance to WHO in the broad field of the standardization of diagnostic materials covered by the Director-General's Report.

Dr ROASHAN (Afghanistan) emphasized the great need for all types of standardization in the field of health in the developing countries, including, of course, the standardization of diagnostic materials. Standards established in the developed countries would not be applicable everywhere in the world and his delegation was therefore pleased to note the importance attached to the standardization of diagnostic materials by WHO and would also like to see standards established for many of the elements of treatment. He also emphasized the necessity for the regional offices to promote the exchange of information in the field of standardization and to help countries to establish the standards most suitable to their environment. Assistance should be made available to the developing countries to carry out their own studies on standardization. Such an investment would bring results that would lead to great savings in the rendering of health services. Efforts along those lines were currently being made in his own country. His delegation fully approved the Director-General's Report.

Dr SHRIVASTAV (India) said that he had been associated with several WHO expert committees dealing with the standardization of diagnostic materials, biological reagents, and pharmaceutical products. It was clear that quality control and testing of those materials had much in common, and it seemed to him, therefore, that there was a need for coordination, by WHO, of the standardization work being carried out in those fields by laboratories, research associations and industrial research centres all over the world. For that reason, his delegation strongly supported the suggestions of the delegations of Romania and the United Kingdom concerning coordination, within the Organization, of the work of the research units dealing with standardization.

Dr LARREA (Ecuador) said that standardization was obviously necessary to enable laboratories to provide reliable information on which to base diagnosis and to permit comparison of laboratory tests carried out in different countries.

In Ecuador the National Institute of Hygiene was responsible for quality control of pharmaceutical and biological products and for fixing the technical standards for their production; the National Institute of Nutrition was responsible for standards for food products, and the Institute of Standardisation had extended its work for products used in industry and commerce.

His delegation supported the proposals outlined in the Director-General's Report and would like to see emphasis placed on nutritional factors. In view of the high cost of the programme, he felt that the costs should be borne by the developed countries and that they should make the results available to the developing countries.

Dr AMMUNDSEN (Denmark) drew attention to the fact that standardization was not a new item in programmes of international public health. In 1921 the Permanent Commission on Standardization of the Health Organisation of the League of Nations had been initiated. Standardization programmes at first had centred on the standardization of therapeutic and
prophylactic substances of biological origin, but the programmes had subsequently been widened to include diagnostic materials. WHO now seemed to have realized that the time had come to launch a comprehensive programme of standardization of in vitro diagnostic reagents. The programme proposed covered products in many different fields, including microbiology, clinical chemistry (including endocrinology), clinical immunology, and clinical haematology. Activities were to be centralized in one unit at headquarters, with an appropriate advisory panel and a network of collaborating laboratories. The Danish delegation wondered whether the proposed programme was not too ambitious and whether priority should not be given at first to studies on diagnostic materials for clinical chemistry.

Dr HIDDLESTONE (New Zealand) said that, with the increasing availability of complex laboratory diagnostic equipment and automation, the purchase of commercial reagents was both attractive and often necessary. Smaller laboratories found the kits of laboratory diagnostic materials very useful, especially for the more unusual tests that were only required infrequently. Referring to the problem of import control of such kits, he said that the ideal arrangement would be for the importers or the manufacturers to submit samples to the central public health laboratory for testing prior to use. However, at present that procedure was impracticable, and in New Zealand only those reagents regarded as suspect were investigated.

The Center for Disease Control, at Atlanta (United States of America) regularly published assessment reports on microbiological reagents and media, and those reports had been very useful to the National Health Institute in New Zealand. It was proposed that WHO could sponsor the extension of that type of service so that countries with limited testing facilities could import diagnostic reagents that met a minimum accepted standard.

His delegation strongly supported the use of international standards and international reference preparations and thought that WHO should encourage suitably accredited laboratories to undertake the preparation and testing of such materials. Manufacturers should be encouraged to refer their products to such reference laboratories and, wherever possible, central public health laboratories should use international reference materials for the preparation of national standards.

Within each country the conduct of proficiency testing programmes by central reference laboratories would assist in raising the standard of laboratory practice. The National Health Institute, as the New Zealand Department of Health reference laboratory, already participated in the United States Public Health Service proficiency testing scheme and would welcome its extension in the South Pacific Region.

The meeting rose at 5.30 p.m.