



WHO SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT,
AND RESEARCH TRAINING IN HUMAN REPRODUCTION

Meeting of the Policy and Coordination Advisory Committee (PCAC)
Geneva, 20-22 May 1987

REPORT

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SUMMARY OF ACTIONS

At its May 1987 meeting PCAC:

- APPROVED the report of its November 1986 meeting.
- NOTED the Director's report; and REQUESTED that in subsequent reports a list of ongoing projects funded by the Programme should be annexed.
- ADOPTED the February 1987 report of STAG.
- WELCOMED the close collaboration between HRP and the Special Programme on AIDS and the appointment of a focal point in HRP to coordinate the Programme's activities in this area; RECOMMENDED that the Programme should not deviate from its research mandate in this collaboration; and REQUESTED a report on the Programme's involvement in AIDS-related research, which would include a report on the planned technical consultation, for presentation at the 1988 meeting of the Committee.
- TOOK NOTE of the Programme's proposal for involvement in services research on new approaches to improve reproductive health; and REQUESTED that the Programme should submit, through STAG, for its 1988 meeting, a clearly defined proposal for its role in health services research taking account of other activities in this field.
- ENDORSED the proposal to appoint Dr Banoo Coyaji as a member of STAG; and REQUESTED the Secretariat to continue its search for well-qualified young candidates in the disciplines required with due regard to geographical distribution and maintaining a proper balance between men and women.
- RECOGNIZED the important role STAG played in acting as an effective in-built mechanism for independent external evaluation of the Programme's activities; CONSIDERED nevertheless that it would be timely to review the Programme's impact on the sector, define its role in relation to the responsibilities of other WHO Programmes and organizations active in the field; and therefore RECOMMENDED an independent external assessment of research needs against which priorities and goals for the Programme could be set; and REQUESTED the WHO Director-General to commission, in partnership with other interested bodies, an overall independent assessment of research in reproductive health in developing countries designed to examine needs, assess the institutional and financial resources available to meet them, identify gaps and suggest priorities for future assistance. In addition, PCAC DECIDED that an impact evaluation of HRP activities, particularly in developing countries, would link well with the overall independent assessment exercise by providing guidance on the future role and orientation of the Programme; UNDERLINED that such an evaluation should proceed whether or not the overall assessment was conducted; NOTED the implications in terms of staff time and resources of such an evaluation; REQUESTED that terms of reference, including cost estimates and a time schedule, should be developed by the Secretariat in consultation with interested parties and presented, together with a report on criteria to be used for measuring the Programme's impact on developing countries, to the 1988 meeting of the Committee; ENCOURAGED members to submit names of possible members of the evaluation team to the Director; and NOTED the usefulness that the draft long-term strategic plan for family planning research and the proposals for the Programme's involvement in reproductive health services research would provide as background documents for the evaluation.

- NOTED the paper on HRP's role in post-Phase III activities presented to the meeting; ACCEPTED the need for HRP involvement in post-Phase III work; SUPPORTED the Director's intention to maintain contact with other interested agencies and parties to accelerate work in this area; and ASKED the Director to report to the Committee annually on progress made with an indication of the financial, managerial and legal commitments of the Programme.
- NOTED the present financial situation of the Programme.
- RECOMMENDED approval of the proposed co-sponsorship arrangement; NOTED that it represented a helpful extension of the Programme; EMPHASIZED the paramount importance of the relationship between family planning and health and the necessity for the Programme to continue functioning under the aegis of WHO; RECOMMENDED that the membership of PCAC as outlined in the draft Memorandum of Understanding presented to the meeting should be revised to reflect: a decrease in the number of largest financial contributors from 12 to 11 in category (a) with the term of office of this category being for two years rather than one year, as was the case at present, to accord with the biennial financial reporting system under which the Programme operated; increased membership, from two to four, of the African region in category (b); a decrease in the number of other interested cooperating parties from three to two in category (c); and inclusion of IPPF as a permanent member under category (d); NOTED that this revised membership would become effective on 1 March 1988. In addition, PCAC REQUESTED the Secretariat to prepare guidelines setting out the responsibility of the Standing Committee with respect to reallocation of resources for review at the 1988 meeting of the Committee.
- APPROVED the Programme Budget for the biennium 1988-1989 and the estimates for 1990-1991; and COMMENDED the Secretariat on the clarity and instructiveness of its presentations.
- ELECTED Egypt and Thailand to category (c) membership of the Committee for a three year term of office starting 1 January 1988.

1. Opening of meeting, adoption of agenda and appointment of Rapporteur

Mrs Kelly, Chairman PCAC, welcomed participants and asked Dr Mahler, the WHO Director-General, to open the meeting.

Dr Mahler emphasized the increasing interest being expressed worldwide on issues relating to fertility regulation and noted the importance of family planning in the Organization's target of Health for All by the Year 2000. He commented on the discussions of the recently concluded World Health Assembly and the imperative of supporting important programmes at an appropriate level of funding. Although the previous meeting of PCAC had taken place only six months ago, there were a number of very important items on the agenda. One was the proposed co-sponsorship of the Programme by UNDP/UNFPA/WHO/World Bank, with WHO acting as Executing Agency. PCAC would, as a result of this co-sponsorship, no longer act in an advisory capacity but would assume the responsibility of a governing body and would thus change its title to Policy and Coordination Committee (PCC). It was hoped that co-sponsorship would provide a broader financial base, and thus a better opportunity for continued and increased funding, better access to governments, and better access to expertise within the multilateral development system.

Other important agenda items included a review of Programme Budget proposals for the biennium 1988-1989 and the proposed external evaluation of the Programme's activities. Dr Mahler stressed the usefulness that the external and internal evaluation mechanisms could play as managerial tools for the Programme. In addition, he noted that a number of HRP products were reaching the final stage of development and that decisions were now required by the Committee on the extent of the Programme's future involvement with these products. He emphasized the Programme's considerable achievement in arriving at a prototype vaccine in the field of human reproduction. He also noted the collaboration between the AIDS and Human Reproduction Special Programmes in the global strategy for AIDS prevention and control.

The increasing interest of Member States in the HRP Programme was recorded: the Programme was on the agenda of three of the WHO Regional Committees in 1987, as well as the agenda of the Executive Board in January 1988. In addition, 14 countries had expressed interest in being elected to category (c) of this Committee; members would be asked to vote on this later in this meeting.

Dr Mahler concluded by expressing his appreciation to members both collectively as a Committee and as individuals, for assisting the Programme in the achievement of the common goal of fertility regulation within the context of primary health care.

The draft agenda was approved and adopted.

Dr R. Boukhris was appointed Rapporteur of the meeting.

The Chairman suggested some structural rearrangements of the agenda which were agreed upon.

The agenda and list of participants are provided in Annexes 1 and 2.

2. Report of the November 1986 PCAC meeting

A typographical error relating to the Federal Republic of Germany's pledges for 1987 and 1988 (totalling DM 2.4 million rather than DM 4 million) was noted.

The representative of the Federal Republic of Germany referred to the subject of monitoring of the Programme's activities which he had raised at the previous meeting. He drew attention to the sensitivity in his country of policies related to population issues and for the consequent need by the Programme to monitor its research results and their application in the field, including ethical aspects. His government wished to be kept fully informed of the research institutions and industrial companies with which the Programme was collaborating in the Federal Republic of Germany as well as any financial contributions received from interested companies. He requested that the Programme should provide information on all its collaborating institutions and urged more systematic coordination and feedback on population projects funded by different agencies. He stressed that accountability for the use of public funds was of prime importance in dealing with increased sensitivity about such issues in his country.

Dr Barzelatto responded by stating that most of the points covered by the previous speaker would be dealt with in his report under agenda item 3. The Programme was now systematically coordinating its activities with those of other UN agencies and this would be further strengthened under the proposed co-sponsorship of the Programme. He drew attention to the fact that the Programme gave technical advice to both UNFPA and IPPF, two agencies which were heavily involved in global distribution of contraceptive methods. The Programme's collaboration with industry did not extend to receiving contributions from that source and the Programme had, in fact, refused to carry advertisements by pharmaceutical companies in its publications even though this might have reduced their cost.

PCAC:

- Approved the report of the November 1986 meeting.

3. Report of the Director

Dr Barzelatto stated that the main objectives of the Programme since its inception in 1972 were the development of new methods of fertility regulation and strengthening the research capabilities of developing countries. He affirmed that his overall concern on assuming the directorship of the Programme was to improve its involvement with developing countries. This had been attempted in three ways: reorienting the Programme's activities; increasing its accountability; and assuming a major responsibility for coordinating activities globally in this field.

Reorientation of the Programme was being achieved in several ways. A review of its objectives and mandate had been submitted to an earlier meeting of PCAC and a long-term strategic plan was being prepared in an attempt to establish an optimal role for the Programme with due regard to the global situation and to the needs of developing countries. The Programme's mandate covered monitoring of the safety and efficacy of available methods of fertility control and the Programme had taken a leadership role in this area. In this connection a scientific group meeting on Mechanisms of Action, Safety and Efficacy of Intrauterine Devices had been convened in December 1986 to establish an official WHO position on this method of contraception as a result of the confusion resulting largely from legal rather than scientific problems. The report of this Scientific Group would be distributed to all governments.

To respond to the need for updated guidelines for safety requirements for new methods of contraception, as recommended by the World Population Conference in Mexico, the Programme organized in February of this year a Symposium on Improving Safety Requirements of Contraceptive Steroids. Participants included representatives of drug regulatory agencies, the pharmaceutical industry, consumer groups and experts in the field. Both the guidelines and the proceedings of the Symposium would be published in the near future. Dr Barzelatto noted the consensus reached at the meeting between drug regulatory agencies on the need to update their safety requirements and reported that the European regulatory agencies were proposing to submit the WHO guidelines to the European Commission for Europe for ratification and that, in the light of the discussions and guidelines, the US Federal Drug Administration was also considering amending its regulatory requirements. As a politically neutral agency WHO was in a position to take such initiatives to protect the interests of developing countries.

As already noted by the representative from the Federal Republic of Germany, ethical issues were the subject of increasing concern throughout the world. For this reason the Programme was planning to convene in 1988 an International Conference on Ethics and Human Values in Family Planning which would be organized jointly with CIOMS and co-sponsored by WHO, UNFPA, World Bank, International Planned Parenthood Federation and International Federation of Gynecology and Obstetrics. The conference would bring together representatives from a wide range of disciplines in an attempt to highlight cultural, religious and other values in the field of family planning. The conference would provide a forum for dialogue; no attempt would be made to formulate recommendations.

The first in a series of annual basic science symposia, which had been brought to the attention of PCAC in November 1986, had been held in Mexico in March. Dr Barzelatto noted that although the Programme did not fund basic science research except in some very well defined areas, such as male contraception, it was important for it to be kept up to date on the progress made in basic science.

Accountability was being addressed by the Programme in several ways. The meeting of this Committee had changed from being a meeting of interested parties, attended almost entirely by financial contributors, to a meeting where both financial contributors and developing countries could discuss in a broader context the policies of the Programme. He noted that developing countries were now in a majority in this meeting.

The Programme was attempting to make its Programme Budget, as presented to the Committee at this meeting, as explicit as possible by itemizing budget lines for each activity as well as summarizing the main lines of research in each of the Task Forces.

The Scientific and Technical Advisory Group (STAG) was functioning as an independent body and there was no overlap in membership with other committees of the Programme. In-depth reviews of the various Programme components were carried out on a cyclical basis by the Group. The regulations governing the Programme's activities, such as terms of reference of Steering Committee members and authorship policies, were formally drawn up for eventual incorporation into a handbook. The first biennial report of the Programme's activities would be prepared at the end of 1987 and would pay greater attention than in past annual reports to accountability.

On the third point of coordination, Dr Barzelatto emphasized that effective collaboration was required by all agencies working in the field to ensure the optimal use of limited resources. Over the past two years the Programme had actively promoted collaboration with different agencies in order to coordinate activities and avoid duplication. Collaborating programme scientists were invited to attend Task Force meetings and this was reciprocated. Meetings of the directors of collaborating programmes were held whenever the opportunity arose.

Dr Barzelatto then commented on his recent attendance at the International Conference on Bioethics held in Toronto in early April which had been referred to earlier by the representative from the Federal Republic of Germany. At this meeting he had presented a full review of the Programme's ethical requirements. He noted that participation by institutions in the Programme's activities involving research on human subjects was contingent upon receipt by the Programme of ethical approval from the institution concerned. This had stimulated the establishment of institutional ethical committees as well as, in some cases, the creation of a national system for ethical review of research projects. He stressed the importance of not imposing on developing countries research that was not of interest to them and noted that the major involvement of these countries in the Programme's activities provided a guarantee to this effect. He emphasized that ethical concerns were of prime importance to the Programme since the field of fertility regulation necessitated giving drugs to healthy people for a substantial part of their productive life.

A subject raised in previous meetings by the Federal Republic of Germany related to the Programme's involvement in services research on new approaches to improve reproductive health to ensure that results of the Programme's research entered into use in family planning services. Extension of the Programme's activities into this area would complement its ongoing activities and would give it the comprehensiveness of an international programme. Detailed discussion of this issue would take place at a later stage in the meeting.

Dr Barzelatto concluded his report by referring to the Programme's Newsletter "Progress". The first issue had appeared in February and the second issue had just come off the press. It was hoped that the Newsletter would prove a useful tool in disseminating information about the Programme's activities to scientists and policy-makers alike.

The representative of the Federal Republic of Germany reiterated his request for his country to be kept informed of all the Programme's activities in countries, centres, and collaborating institutions to enable it to respond effectively to questions raised at the national level. He was reassured by Dr Barzelatto that this would be provided on an annual basis to this meeting, apart from the information available in biennial reports of the Programme. It was emphasized however that the Programme could not be aware of all activities carried out by an institution in fields other than fertility regulation.

The representative of the USA complimented the Programme on its Newsletter and offered to ensure its distribution to key persons on AIDS' mailing list.

PCAC:

- Noted the Director's report; and

Requested that in subsequent reports a list of ongoing projects funded by the Programme should be annexed.

4. Scientific and Technical Advisory Group (STAG)

4.1 Report of February 1987 meeting

Professor Bergstrom, the Chairman of STAG, commenced his report by giving two examples of the impact of the Programme's activities in developing countries. The first related to HRP's network of clinical research centres established in the early 1970s as a result of which the quality of research in the developing world reached a very high level; secondly, the establishment of Task Forces and a network of clinics by the Indian Council of Medical Research modelled on those set up by the HRP Programme. He noted the unique qualifications that WHO possessed which enabled it to carry out research in different countries and commented that activities by industry in this field continued to diminish.

He drew attention to the expected future closer involvement of HRP in the later stages of drug development and market introduction and stressed the necessity for each new drug to be dealt with on a case-by-case basis since the field had become too complicated for general guidelines to be of use. He noted that countries which had no drug regulatory agency often sought WHO's advice on the safety of fertility regulating agents and anticipated that this fact, together with clinical trials carried out in these countries, might hasten their acceptance of the drugs in question. He hoped that the evolving role of the Programme in the field of fertility control would be assessed by the proposed external evaluation.

Professor Bergstrom noted that PCAC approval was required for STAG's recommendation for a long-term strategic plan to evaluate the present position of research in the field, identify promising leads and establish a time schedule against which to measure achievements.

He drew attention to the collaboration between the Programme, its newly-named Task Force on Prevention and Management of Infertility and other Task Forces and the AIDS Special Programme; the useful toxicology work carried out by the US National Institute of Health for the Task Force on Long-Acting Systemic Agents and the reorganization of the Programme for Standardization and Quality Control of Laboratory Procedures. He noted the proposed designation as a collaborating centre of a unit of clinical chemistry which, although funded entirely by national means, would implement projects proposed and approved by the Programme and commented that such an arrangement might serve as a model for future Programme activities. The importance of the Programme in obtaining a reasonable price for its products in the public sector was stressed. Professor Bergstrom concluded his presentation by stating that by 1989 STAG would have carried out its first cycle of in-depth reviews of all the Programme's components.

PCAC:

- Adopted the February 1987 report of STAG.

4.1.1 The Programme's involvement in research on AIDS

Dr M. Carballo, a staff member of the Special Programme on AIDS, was asked to address the meeting and to inform the Committee of areas of joint collaboration with HRP.

Dr Carballo emphasized that the collaboration between HRP and SPA lay in two main areas. He noted first the possible interaction between different forms of contraception and HIV transmission, and the prophylactic role of other forms of contraception in prevention and control of HIV transmission. Barrier methods, such as the condom, and the better use of spermicides in conjunction with the condom, were to be evaluated extensively. A consultation was being organized in June 1987 to examine possible interactions not highlighted to date and to propose areas where research could be undertaken.

The second important area of collaboration concerned family planning service infrastructures and the way in which these could assist in counselling and exchange of information in the better use of family planning in the prevention and control of HIV transmission, particularly in reducing the risk of HIV transmission to an infant. HRP and SPA, together with the Division of Family Health, had also recently organized the first of a series of meetings of family planning international agencies to discuss the optimum manner of coordinating, under WHO's auspices, international research and service development in the area of family planning with specific respect to AIDS and HIV infection.

Dr Fathalla commented that he would discuss in length the collaborative activities of the Task Forces and the AIDS Programme under the item on Programme Budget. He stated however that the Programme had designated a staff member to act as a focal point for coordination of all its activities on AIDS.

The representative of the UK emphasized her government's view that collaboration between HRP and AIDS was vital; she requested that a copy of the report of the consultation should be made available to the next meeting of the Committee. This was endorsed by the representative of Zimbabwe who also emphasized the importance of guidelines on counselling for health workers. She requested that these should be distributed as soon as possible for utilization in countries after adaptation, if necessary, to the cultural context.

The Chairman confirmed the importance of rapid dissemination of information to countries to keep them abreast of developments and expressed the hope that steps were being taken to ensure that guidelines and other information generated by these activities would reach the appropriate personnel.

The representative of the USA commented that although the Programme's collaborative activities with the AIDS Programme were very necessary there should be no deviation from the primary mandate of the Programme.

The representative of Norway commended the designation of an HRP focal point on AIDS and hoped that higher priority might be accorded to the promotion and further development of barrier methods.

PCAC:

- Welcomed the close collaboration between HRP and the Special Programme on AIDS and the appointment of a focal point in HRP to coordinate the Programme's activities in this area;
- Recommended that the Programme should not deviate from its research mandate in this collaboration; and
- Requested a report on the Programme's involvement in AIDS-related research, which would include a report on the planned technical consultation, for presentation at the 1988 meeting of the Committee.

4.1.2 The Programme's involvement in Services Research on New Approaches to Improve Reproductive Health

Dr Barzelatto outlined the reasons for the submission of this paper to the meeting: the reorganization of the Task Force on Behavioural and Social Determinants of Fertility Regulation; lack of technical competence and financial resources in the Regional Offices to organize operational research activities in countries along the lines envisaged; requests for assistance by developing countries to improve their reproductive health services, and also PCAC requests for information on the action the Programme was taking to ensure an optimal balance of methods available in health services.

A new Task Force was being proposed since the disciplines required were different from those of the Behavioural and Social Determinants Task Force. The Safe Motherhood Initiative launched in Nairobi in February 1987 could be seen as a complementary activity and joint activities with the Family Health Division were expected as a result. He noted that the Secretariat would present to STAG for review in February 1988 proposed lines of activity on research in reproductive health which would complement the long-term strategic plan also to be discussed by STAG.

Dr Fathalla underlined that, although a research-oriented Programme, HRP's ultimate objective was to improve reproductive health; it had until now relied extensively on dissemination of the results of its research through publications to achieve this. It was recognized however that research for application in a particular health system required health services research for its appropriate adaptation to the country in question. Although not included in its mandate, the Programme's impact on services had been frequently raised at this meeting. The issue was now being presented to PCAC for discussion and for eventually a policy decision to be made on the extent of the Programme's involvement.

The representative of the USA emphasized the two points that required clarification on this issue; the necessity for the Programme to become involved in operations research in service delivery systems, and the parameters for the Programme's work in this area.

The representative of Zimbabwe requested clarification as to why operations research was considered separate from general HRP research since the integrated activities of MCH/FP were of paramount importance at the primary and district levels.

The representative of Sweden confirmed the necessity of HRP becoming involved in health services research and commented on the proposed collaboration with the Divisions of Strengthening of Health Services and Family Health.

The representative of IPPF also commented on the importance of HRP entering into this field since, as a programme developing new methods, it would be well placed to ensure they reached a given population in an acceptable way.

Chairman STAG reiterated the important role the regions could play in such an activity and suggested that one or two regions should first be involved to act as models for other regions.

The representative of Singapore underlined the importance of health services research but questioned the priority this should be accorded by HRP since the Division of Family Health had traditionally been responsible for advice to governments in this field.

The Chairman questioned what priority should be accorded to such work by a busy Programme and whether it would not be preferable for such research to be undertaken as a collaborative effort with other programmes.

Dr Fathalla emphasized that the paper before the Committee was for information and discussion only. After feedback from both STAG and PCAC a paper outlining an optimal role for HRP in these activities would be presented. He clarified for the representative of the USA that the primary focus of HRP would be on fertility regulation. However, as emphasized by the representative of Zimbabwe, in practice family planning was usually integrated in maternal and child health services and the Programme's research activities in this area would consequently be in a broader context.

PCAC:

- Took note of the Programme's proposal for involvement in services research on new approaches to improve reproductive health; and
- Requested that the Programme should submit, through STAG, for its 1988 meeting, a clearly defined proposal for its role in health services research taking account of other activities in this field.

4.2 Membership of STAG

Dr Barzelatto reminded those present that appointment of members to STAG now required the Committee's endorsement. It was now proposed that Dr Banoo Coyaji of India should replace Dr Devi, who died last year. This suggestion was endorsed by the Committee.

PCAC:

- Endorsed the proposal to appoint Dr Banoo Coyaji as a member of STAG; and

- Requested the Secretariat to continue its search for well-qualified young candidates in the disciplines required with due regard to geographical distribution and maintaining a proper balance between men and women.

5. Matters arising out of the November 1986 PCAC meeting

5.1 External evaluation of the Programme

The Chairman summarized the discussions that had taken place at the November 1986 meeting of the Committee on this issue and noted that, as requested at that time, the Secretariat had prepared a paper setting out the internal evaluation mechanisms in the Programme. She noted that STAG had been requested to review this item and to suggest possible areas for evaluation as well as an optimum timing. She drew attention to the terms of reference for the proposed external evaluation, prepared by the Swedish delegation, which had been circulated to members for review.

Chairman STAG outlined the discussions that had taken place at the Group's February 1987 meeting on this subject. He commented that at the last three meetings the Group had devoted a considerable proportion of its time to discussing the preparation of a long-term strategic plan. A cycle of in-depth evaluations of Programme components would be completed by STAG in 1989. Since the Group considered that completion of the present cycle of internal evaluations could facilitate an external evaluation, it had recommended postponement of an evaluation until this was complete in order to avoid a duplication of technical assessments. Professor Bergstrom noted that the terms of reference prepared by the Swedish delegation addressed more the impact of the Programme in developing countries than a technical assessment of its activities.

The representative of Sweden gave in broad outline the background and contents of the terms of reference. The Swedish Government was proposing an external evaluation of the Programme based on its past role and performance, with particular emphasis on the impact of the Programme in developing countries, as well as a review of its mandate and objectives in relation to overall research needs and priorities within the broad field of human reproduction.

The representative of Singapore commented that the terms of reference prepared by the Swedish delegation required amplification to define exactly what sort of impact evaluation was required. He did not consider that technical aspects could be divorced from the question of impact and emphasized that behavioural, social and cultural factors also had to be taken into account.

The representative of the USA expressed his continued reservations about an evaluation of this magnitude, as outlined at the previous meeting of the Committee. He considered it could effectively be delayed several years since the existing evaluation mechanisms were being effectively implemented. The question of whether the Programme covered the important leads in the field could probably be well documented. The cost of such an evaluation to the Programme's staff in terms of time and resources might have a counterproductive effect on its efficiency. Since results generated from an evaluation such as proposed by the Swedish delegation would be difficult to interpret, he proposed that the focus of the evaluation should be more on training, contraceptive development, and social science research related to contraceptive development, rather than spin-off effects from these activities.

The representatives from the Netherlands, Australia and Finland supported the ideas put forward in the Swedish paper. The suggestion by the representative of Australia that a small committee should be established to review the terms of reference under discussion was supported by the representative of the United Kingdom.

The representative of Indonesia noted the new type of indicators to be used in the proposed evaluation, the expectations that would arise following such an evaluation, and the subsequent effect on the activities of the Programme.

The representative of Zimbabwe emphasized the importance that publications by developing country scientists would serve as a reference source in such an evaluation and stressed the importance of analysing factors that determined the acceptability and impact of contraceptive technology in developing countries.

The representative of the UNFPA suggested the possibility of making the internal evaluation mechanisms compatible with those of an external evaluation both from the point of view of content and timing. He noted that in the Committee's discussions in November 1986 the evaluation was clearly determined as the responsibility of PCAC whereas in the present discussions a large responsibility was now placed on the Secretariat. This would indeed place a heavy burden on staff resources.

The representative of the World Bank agreed with the principle of having an external evaluation but considered it should be narrower in scope than that proposed so that attribution to the Programme of concrete results could be correctly identified. He was concerned lest the proposed evaluation should play into the hands of critics and for this reason requested that the objectives and scope of the evaluation should be clearly defined.

The representative of Gabon stressed that the evaluation should be appropriately focused and noted that, even if constraints and difficulties were identified as a result of the evaluation, these could subsequently be used constructively. He read out a telegram from Dr Mavoungou who had been the representative of Gabon at the November 1986 meeting of the Committee and who, although unable to attend on this occasion, wished to appraise the Committee of activities taking place in Central Africa in the area of human reproduction research.

The representatives of Mexico, China and Argentina confirmed their support for an external evaluation that was complementary rather than a duplication of the internal HRP evaluation procedures and stressed that criteria for impact should be more clearly defined in the terms of reference. The representative of China also suggested inclusion of evaluation procedures at the national level.

The representative of the USA noted the complexity and scope of the Programme's activities which would require experts to evaluate the different areas. He noted that intermediate variables, rather than impact, resulted from many of the Programme's activities. He also recommended establishment of an intersessional group to develop a work plan for the evaluation.

The Chairman summarized the various points raised in the discussions and proposed that a small working group comprising representatives from the delegations of Sweden, Mexico, Ethiopia, Singapore and UNFPA together with herself should meet to prepare a report on an external evaluation of the Programme to clarify various issues such as scope and timing and to report back to the meeting.

The Working Group met twice outside the working hours of PCAC, and concluded its deliberations in a written report. The UNFPA representative, who was appointed Chairman of the Working Group, introduced the report which he considered covered most of the issues raised in the earlier discussions. The recommendation was to have a two-tier exercise: firstly an independent external assessment, which would review the whole field of reproductive health, and the second, an external evaluation exercise which would review the role and impact of the Programme in developing countries. The terms of reference of the evaluation would be prepared by HRP and presented to the 1988 meeting of the Committee.

The representative of Zimbabwe noted that the Programme's impact in developing countries was at different stages and that this was a variable to be taken into account in the evaluation.

The Chairman responded that the terms of reference to be presented to the Committee by the Secretariat in 1988 would provide criteria for measuring impact which would also take country variations into account. She confirmed for the World Bank representative that cost estimates and a time schedule had also been requested. The discussions in the Working Group had emphasized that there should be adequate representation by developing countries on the assessment team. She noted that three important papers would be presented to the Committee in 1988 for review: a draft strategic long-term plan, a proposal for health services research, and a criteria paper for the evaluation, all of which would provide a good basis for the broader assessment that was proposed. She confirmed for the representative of the USA that the Secretariat would be preparing the terms of reference for the evaluation.

The representative of Australia commented that the proposed broader scope of the assessment went beyond the mandate of the Programme and of PCAC and queried the size of the budget resources that would be required.

Dr Barzelatto clarified that several members of PCAC considered a broad assessment of the field to be timely. It was therefore suggested in the proposal that it might be appropriate for the Director-General, in collaboration with other interested agencies, to take such an initiative. The assessment and the external evaluation would together provide a good basis for a decision on the future orientation of the Programme's activities.

The representative of Tunisia suggested that an evaluation of the impact should first be carried out at the country level. This proposal was corroborated by the representatives of China, Gabon and the Netherlands and the suggestion was made that the evaluation team should comprise representatives of nationals in the countries being evaluated. The representative of the Netherlands also requested assurance that the assessment would commence in 1988.

Dr Barzelatto confirmed that selected countries would be requested to evaluate the Programme's activities at the national level and that their reports would form the basic documentation for the evaluation.

The representatives of both the World Bank and the USA were concerned that the proposed assessment of the worldwide situation in fertility regulation research would pose problems, particularly in relation to the assessment of other programmes' activities.

The representative of UNFPA emphasized that the focus on the HRP Programme would automatically limit the scope of the broad-based evaluation exercise. He noted that after completion of the assessment and evaluation exercises, the Committee would be required to define the activities of the Programme in a broader context.

The representatives of Singapore and Sweden confirmed that the proposed evaluation and assessment would assist the Committee in assessing priority areas and the optimal role of the Programme in the broad field of fertility control.

The report of the working group was modified in the light of these discussions. The amended report is attached as Annex 3.

PCAC:

- Recognized the important role STAG played in acting as an effective in-built mechanism for independent external evaluation of the Programme's activities;
- Considered nevertheless that it would be timely to review the Programme's activities against the broader needs of the reproductive health field to quantify the Programme's impact on the sector, define its role in relation to the responsibilities of other WHO Programmes and organizations active in the field; and therefore
- Recommended an independent external assessment of research needs against which priorities and goals for the Programme could be set; and
- Requested the WHO Director-General to commission, in partnership with other interested bodies, an overall independent assessment of research in reproductive health in developing countries designed to examine needs, assess the institutional and financial resources available to meet them, identify gaps and suggest priorities for future assistance.

In addition, PCAC:

- Decided that an impact evaluation of HRP activities, particularly in developing countries, would link well with the overall independent assessment exercise by providing guidance on the future role and orientation of the Programme;
- Underlined that such an evaluation should proceed whether or not the overall assessment was conducted;
- Noted the implications in terms of staff time and resources of such an evaluation;

- Requested that terms of reference, including cost estimates and a time schedule, should be developed by the Secretariat in consultation with interested parties and presented, together with a report on criteria to be used for measuring the Programme's impact in developing countries, to the 1988 meeting of the Committee;
- Encouraged members to submit names of possible members of the evaluation team to the Director; and
- Noted the usefulness that the draft long-term strategic plan for family planning research and the proposals for the Programme's involvement in reproductive health services research would provide as background documents for the evaluation.

5.2 HRP's role in post-Phase III activities

Mr Hall introduced this item which had been briefly discussed at the November 1986 meeting of the Committee. He outlined the various stages in preparation of a product prior to introduction into family planning programmes: Phases I, II and III, testing in field situations; registration; introduction into family planning programmes and long-term surveillance. Two HRP products were now ready for testing in field conditions: once-a-month injectable preparations and a levonorgestrel releasing vaginal ring. He listed the HRP and other agency products that were expected to reach a similar stage of development over the next 10 years. He stressed the collaborative nature of post-Phase III activities which involved working with Member States to identify requirements for introductory studies of such new methods, and underlined the increasing role public sector agencies would play as a result of the growing reluctance of pharmaceutical companies to be involved in drug development.

The levonorgestrel releasing vaginal ring, a new method, would require field trials in a number of countries to assess its acceptability whereas the once-a-month injectable was a superior model of a currently available method of fertility control in some countries. Development and evaluation of user/provider materials, training, information for programme managers, visual and oral publicity material would all be required in the case of the vaginal ring but would be developed in conjunction with other specialized organizations such as PIACT. For the once-a-month injectable, service requirements at the district, provincial and national levels would have to be examined. He noted that the Programme's Task Force on Safety and Efficacy would be closely involved in the long-term surveillance of these new products after field testing.

The representative of the USA asked for clarification of the role of HRP in post-Phase III activities since, although the Programme anticipated contracting out a lot of activities, staff resources might have been underestimated. He commended the potentially important role WHO would play in these activities, which he compared to that of a regulatory agency.

Chairman, STAG commented that the Swedish International Development Agency (SIDA) was considering involvement in Phase IV activities and that this would have important implications for the Programme.

The representative of Sweden confirmed that the Swedish Agency for Research Cooperation in Developing Countries (SAREC) support was restricted to research development and that if post-Phase III activities were envisaged, combined SIDA/SAREC funding would be required.

The representative of Australia noted his government's commendation and approval for the activities outlined provided there was effective cooperation between the Task Forces, continued monitoring of progress, and liability and legal aspects were kept under constant review.

Dr Barzelatto confirmed that WHO would permit the Programme to proceed as far as registration of a product since, until that stage, research was still involved under controlled conditions. However, it would then be necessary to look at other options such as finding a commercial partner, transferring the technology to countries wishing to manufacture their own product, or handing over to an organization like IPPF responsibility for distribution to the public sector. Liability was a difficult issue and a major stumbling block but the co-sponsorship arrangement might assist by enabling the Programme to address the issue on an international rather than country basis. After registration involvement would continue through the Programme's Task Forces on Safety and Efficacy and Behavioural and Social Determinants.

On the question of resources, the Programme had reallocated a post to this activity from another Programme component so that a staff member could be recruited to assist with the necessary contacts with governments. Adequate financial resources had been budgeted to ensure reasonably rapid introduction of these methods into family planning services. It was hoped that, as with Norplant, there might be other programmes and countries that could assist in accelerating the introduction process by providing additional resources.

The representative of the Netherlands stressed that, although post-Phase III work would start on an experimental basis and with annual reporting to the Committee on progress, the Programme's activities should be confined to the field of research.

PCAC:

- Noted the paper presented to the meeting;
- Accepted the need for HRP involvement in post-Phase III work;
- Supported the Director's intention to maintain contact with other interested agencies and parties to accelerate work in this area; and
- Asked the Director to report to the Committee annually on progress made with an indication of the financial, managerial and legal commitments of the Programme.

6. Funding Situation

Mr Roëd gave an overview of the financial situation of the Programme. He noted that the total funds available for the biennium 1986-1987 were estimated at US\$ 37.6 million, which was approximately US\$ 3 million below the total budget approved by PCAC for the biennium in 1985, but which was very close to the revised budget presented to both STAG and PCAC in 1986.

The representative of the USA commended the use of graphic presentations in the Programme Budget document and hoped that they might feature more extensively in the documentation in future.

PCAC:

- Noted the present financial situation of the Programme.

7. Technical Presentation: Immunological Approaches to Contraception

Mr Griffin, the Manager of the Task Force on Vaccines for Fertility Regulation, introduced the presentation. He noted that vaccine development was an area of high technology where great advances were being made in recent years. The presentation would, in addition to illustrating the work carried out by the Task Force, also exemplify the potential scope for work in this field.

The presentation was given by Mr D. Griffin, Professor V. Stevens of the USA, and Professor W. Jones of Australia. A summary of the presentation is attached as Annex 4. The presentation summed up the efforts of a decade of research, outlined the status of the now ongoing Phase I clinical trial and highlighted the need for further work to bring up a second generation of vaccines for large scale use.

A discussion followed with participation by the representatives of Norway, the People's Republic of China, Sweden, Zimbabwe, France, Federal Republic of Germany, USA, and Viet Nam. Questions were raised about the anticipated duration of effect and potential for reversibility. Concerns were raised about spread of AIDS and logistics in developing countries. Emphasis was made on assessment of effectiveness, safety and acceptability. In response to a question on when the vaccine might become available, the answer was given that much depended on the availability of funding and on progress. Given ideal circumstances, it could be available for general use by the mid-1990s. Ethical concerns were also raised and addressed.

The Chairman expressed the thanks of the Committee to Mr Griffin and Professor Stevens and Professor Jones for an interesting presentation.

8. Co-sponsorship of the Programme

Dr Barzelatto noted the changes that would result from the Programme becoming an inter-agency programme sponsored by UNDP/UNFPA/WHO/World Bank, with WHO acting as Executing Agency. As an inter-agency Programme it was hoped that its collaboration with governments and Member States would increase and that its funding would rest on a more secure base. The PCAC would then, instead of its present advisory role, become the governing body of the Programme empowered with responsibility for policy matters, for directing and coordinating the Programme's activities and for approval of its Programme Budget. One additional body would be created, a Standing Committee, comprising representatives of the four agencies who would meet periodically to review matters, either at PCC's request or on its own initiative, and to make recommendations to the Committee. The Standing Committee would, in particular, assist PCC in reviewing budgetary and financial matters. The Scientific and Technical Advisory Group would maintain its central role in technically guiding the Programme and advising PCC on the implementation of the Programme's activities, extending its overall view of the Programme to a global perspective when required.

The representative of the Federal Republic of Germany asked if, under this arrangement, the World Bank would receive financial contributions for the Programme. In response, the representative of the World Bank stated that a special fund had been created at The Bank in the case of two other Special Programmes in order for some potential contributors, under their legislative arrangements, to fund these Programmes in addition to their regular contributions to WHO. However, in the case of HRP, no particular advantages could be seen to accrue from the establishment of such a fund.

The representative from Sweden expressed concern about the HRP being taken out of the WHO context since much of its success to date could be attributed to the fact that family planning was seen in the context of health. She considered that the functions of the Standing Committee should be clearly linked to financial assistance and planning with no management or executive functions. She was particularly concerned that, with regard to paragraph 3.2.3 of the Memorandum of Understanding, the Standing Committee should not approve reallocation of resources since this was a policy matter. She queried whether the representation on PCC of developing countries was adequate and stated that the costs of their representation should be covered. She noted that the size of the group representing the largest financial contributors was considerable (12 members) and that in TDR elections were carried out among this group to enable even the smaller donors to have an opportunity of being elected. Whilst it might have been admissible for PCAC to be seen as a donor group in its advisory capacity, in its new role as a governing body this was not an optimum situation. She requested clarification as to whether a decision on co-sponsorship could be taken by this Committee or whether it would be subject to the approval of the WHO Executive Board and World Health Assembly.

The representative of Norway stated that her government agreed that adjustments to the structure of the Programme might be required to increase its financial resources and foresaw no problems provided that the direction and management of its activities were not impeded under the new management. It was essential, though, for the terms of reference of the different committees in the Programme to be clearly defined and for this reason her government would appreciate formulation of terms of reference for the Standing Committee. Human reproduction was a sensitive area and should remain closely linked to the health sector; adjustments to the Programme's structure should not tamper with its independence or impartial role.

The representative of Zimbabwe reiterated that, from a developing country point of view, the issues raised by Sweden were important. The field of human reproduction was of major interest to developing countries and the change in status of the Committee to a decision-making body was important.

The representative of the Netherlands welcomed the proposed co-sponsorship of the Programme and commented that participation by the World Bank and UNDP indicated increased awareness globally in matters related to population and family planning. Co-sponsorship would, in addition, increase cooperation between the different agencies working in these fields as well as the possibility of further disseminating the results of research. He hoped that, in addition, particular attention would be paid to social and psychological aspects of fertility control.

The representative of IPPF also welcomed the proposed co-sponsorship of the Programme and drew attention to other WHO Programmes which had benefited from such an arrangement. She noted that IPPF's present status as a permanent member of PCAC took account of its role as the largest international family planning organization. IPPF did not however feature under the proposed membership of PCC and she requested that consideration be given to membership of IPPF on PCC.

The representative of Australia confirmed his country's support for the co-sponsorship of the Programme which it was hoped would provide a sounder funding structure and increased recognition for its achievements and thus, in turn, attract other financial contributors.

Dr Mahler, Director-General, who was present during the meeting for part of the discussion on this agenda item, clarified for the representative of Sweden that, in order for policy decisions not to contradict existing overall strategies formulated by the World Health Assembly, any change in role of the HRP Programme would require the approval of the Executive Board and the World Health Assembly. He stressed the importance of co-sponsorship being seen as a positive arrangement by all parties concerned. He emphasized that the co-sponsorship arrangement would assist in coordinating policies and would facilitate research and development in developing countries with the result that the widest possible array of scientifically sound, socially acceptable and economically feasible contraceptive technology would be available.

The representatives of Indonesia and the Federal Republic of Germany both affirmed their governments' support of the proposed co-sponsorship arrangement. The representative of Indonesia also indicated the desirability of Programme activities being broad-based and not limited to a few countries.

In response to the various questions raised, Dr Barzelatto stated that the composition of PCC was exactly the same as that established for PCAC in 1985 and that considerable embarrassment was incurred in some programmes as a result of election procedures among financial contributors. He commented that some of the smaller financial contributors were represented on PCAC and that there was in fact also, in his opinion, healthy competition among the smaller contributors to remain members. He noted that a similar co-sponsorship arrangement existed in the TDR Programme and that in both HRP and TDR there was a majority of developing countries on the governing bodies. He detailed the various functions of the Standing Committee, which were advisory to PCC, and emphasized that the Standing Committee in no way had any executive powers. He noted also the role that the Standing Committee would play in assisting the Programme in its fund-raising activities.

The World Bank representative seriously doubted the suggestion made that the Programme was in any way moving out of the health context and preferred to regard The Bank's involvement as a step for The Bank into the health field. He emphasized the role WHO would play both as an executing agency and a sponsor to the Programme. He confirmed the nature of the work to be carried out by the Standing Committee between PCC meetings and stated that, since PCC was only in session once a year, a mechanism such as the Standing Committee was required to ensure that Programme activities proceeded in conformity with PCC's expressed wishes throughout the year. He emphasized that costs of the Standing Committee were borne by the co-sponsors and not transferred to the Programme and that co-sponsorship very much strengthened the case for a World Bank contribution to the Programme.

The representative of Singapore confirmed his support for the view expressed that the Standing Committee should not approve reallocation of resources.

The representative of the Netherlands underlined the importance of clarifying exactly which body under the proposed arrangements would be responsible for establishing policies and making decisions.

The representative of UNFPA drew attention to the fact that the Standing Committee was in fact part of PCC and represented PCC in between sessions.

Mr Furth corroborated the advisory role that the Standing Committee provided to TDR's governing body and noted the assistance the sponsors would provide in widening the Programme's present access to Ministries of Health to include Ministries of Finance, Planning and Development. He pointed out that in TDR there were guidelines governing the

responsibility of its Standing Committee with respect to reallocation of resources. He proposed that the Director of the Programme should submit similar guidelines for the HRP Standing Committee to its 1988 meeting. He confirmed the similarity between the governing bodies of TDR and PCC and stated that, although in TDR the category for financial contributors was not specified as it was in HRP by "largest", it was invariably the largest contributors who were elected to this category. Since the elections had sometimes proved an embarrassing formality, it was hoped to avoid this in HRP by clearly specifying "largest financial contributors". Smaller contributors who did not qualify under this category had the opportunity of participating in the Committee through elections by the Regional Committees under category (b) or through elections by PCC under category (c).

The representative of Sweden requested a review of PCC's membership to ensure strong representation by developing countries in its new role as a decision-making rather than advisory body.

The Director-General commented on the indispensability of increased African representation on PCC as well as possible revisions in the representation on PCC accorded to other regions.

The representative of Zimbabwe agreed wholeheartedly that the focus of HRP was in developing countries. The co-sponsorship of the Programme was welcomed. The results of the Programme's research would be most evident in developing countries, some of which would require assistance in promoting the sensitive issue of fertility regulation in order to make any impact on health. She requested that favourable consideration be given to Dr Mahler's point about increased membership by Africa on PCC. She was supported in this request by the representative of Nigeria.

The representative of the Netherlands supported the point made by the Director-General but did not wish to see the issue of membership feature annually as an item for discussion, since the present membership arrangement functioned well. However, the Chairman responded that even if the question of membership did not form a specific agenda item members were nevertheless free at any time to raise it.

The representative of Australia expressed concern that the solution to such a problem was always to increase the size of a committee without regard to its optimum size and suggested decreasing the number of members in the category reserved for financial contributors.

The World Bank representative commented that the Committee should attempt to establish membership on a lasting basis; he did, in fact, consider the present membership reasonably well balanced. He noted that the Arab countries were among those with the fastest growing populations and which consequently could be better represented on the Committee.

Mr Furth commented that in the TDR Programme observers outnumbered members and that perhaps observer status had been overlooked as a means by which countries could participate in the discussions of the Committee. Observers participated fully in all the deliberations and were excluded only from voting procedures. Dr Mahler, however, noted the political importance of membership compared to observer status.

Dr Barzelatto commented that increased membership of PCC was basically no problem but that any decrease in the numbers of those elected by the Regional Committees for fixed terms would cause considerable complications.

Based on the PCAC's discussions the Chairman then proposed the revised membership for PCAC as set out in the Memorandum of Understanding attached to this report as Annex 5 and this was approved by the Committee.

Dr Barzelatto detailed other revisions that were incorporated in the Memorandum of Understanding relating to PCC and these were noted and also approved.

The representative from Gabon noted that there were very few members on the Committee who spoke French exclusively. He wished to participate actively in the discussions and wondered whether, in future, more documents might be provided in the French language. This request was endorsed by the representative of France. Dr Barzelatto reassured the two

speakers that in future meetings documentation would be available in both French and English to facilitate the Committee's new decision-making responsibilities.

PCAC:

- Recommended approval of the proposed co-sponsorship arrangement;
- Noted that it represented a helpful extension of the Programme;
- Emphasized the paramount importance of the relationship between family planning and health and the necessity for the Programme to continue functioning under the aegis of WHO;
- Recommended that the membership of PCAC as outlined in the draft Memorandum of Understanding presented to the meeting should be revised to reflect: a decrease in the number of largest financial contributors from 12 to 11 in category (a) with the term of office of this category being for two years rather than one year, as was the case at present, to accord with the biennial financial reporting system under which the Programme operated; increased membership, from two to four, of the African region in category (b); a decrease in the number of other interested cooperating parties from three to two in category (c); and inclusion of IPPF as a permanent member under category (d); and
- Noted that this revised membership would become effective on 1 March 1988.

In addition, PCAC:

- Requested the Secretariat to prepare guidelines setting out the responsibility of the Standing Committee with respect to reallocation of resources for review at the 1988 meeting of the Committee.

9. Proposed Programme Budget 1988-1989 and estimates for 1990-1991

Dr Barzelatto introduced the Programme Budget document. He described the Secretariat process for its preparation and noted the fixed ratio of expenditures of 2:1 between Research and Development and Resources for Research. A consolidated budget of US\$ 48.3 million for the biennium had been submitted to STAG which had been reduced by the Group to approximately US\$ 46 million. The increase for the biennium of approximately 10% over estimated income and expenditures in 1987 covered new activities, such as post-Phase III work, small increases in current Task Force activities, and inflation. Dr Barzelatto noted that the devaluation of the dollar had increased the Programme's fixed costs on salaries, meetings and Programme support.

The representative of the Federal Republic of Germany commented on the financial crisis affecting the UN system generally, the decrease in UNFPA's funding of country projects for the biennium, and the possibility of the Programme's budget having to be revised in the light of organizational cutbacks. He queried whether additional funds might be made available by companies which could be expected to profit from HRP's research and development activities at a later stage. He noted that a considerable proportion of the Programme's income was drawn from interest and requested information on any reserve funds it might have. He underlined the extensive role in coordinating activities that would be undertaken by the Programme and requested an explanation as to how they would feature under programme management expenditure.

Dr Barzelatto responded that, for a Programme funded by voluntary contributions, the WHO restrictions on zero limit growth did not apply. The Programme's activities depended entirely on its financial contributors who were encouraged by the Director-General to increase funding both to this and other Special Programmes. Since the Programme wished to maintain its total independence, no contributions from the pharmaceutical industry had been looked for. He clarified that HRP held no funds in reserve; if it did, they would have been reported. He asked Mr Roëd to respond to the question of interest accruing to the Programme.

Mr Roëd clarified that during the financial year the Organization permitted the Programme to take up financial obligations against written pledges. However, there was often a time lag of several months between the taking up of the obligation and disbursement as a result of which the Organization invested these cash balances in the short term for the Programme. He noted that in 1986 interest earned on such short-term investments amounted to US\$ 461 000.

Mr Imbruglia, the Director of the Division of Budget and Finance clarified that at no time throughout the year could WHO provide funds to the Programme which were not guaranteed by written pledges.

Mr Furth highlighted two points. Firstly, that in 1986 there had been a considerable increase in voluntary contributions to WHO which demonstrated the confidence of Member States in the effective implementation of WHO Programmes. Secondly, he noted that the WHO Regular Budget was funded by Member States which were under a legal obligation to pay their contributions. This contrasted with an extra-budgetary Programme, such as HRP, where there was no obligation to fund on the part of any Member State and was an important distinction. It was also the reason why no limitation had ever been placed on the growth of any extra-budgetary programme.

The UNFPA representative clarified a remark made by the representative of the Federal Republic of Germany about the decrease in the size of the UNFPA country budgets by stating that the decrease did not reflect any financial difficulty but was determined only by the size of the projects.

The representative of Sweden noted the increased budget for the biennium. She emphasized that it would be useful to have it costed at different budgetary levels to reflect the priority that the Programme would accord to different lines if there were cutbacks.

Dr Barzelatto noted this request but confirmed his preference for putting forward a budget in which there might be a reasonable expectation of increased funding. He commented that a proposed budget at three different levels would undoubtedly imply funding at the lowest level, as had been the case in the past when this system was adopted. He anticipated, however, that co-sponsorship would increase further the Programme's funding and therefore considered the 10% increase requested in the budget proposals as reasonable.

The five Programme areas listed in the Programme Budget document were then reviewed in sequence. Under Programme Area I (Advisory Bodies) Dr Barzelatto commented that no budget line yet existed for an external evaluation but that this would be included when required. He reminded members that the Swedish delegation had generously offered additional funds to cover some of the costs involved.

Dr Fathalla presented Programme Area II (Research and Development) outlining the lines of activity in the Task Forces, and the priorities accorded to them by STAG.

The two Task Forces that dealt with improving the performance of existing methods for fertility regulation (Safety and Efficacy, Behavioural and Social Determinants) were ranked by STAG as of high priority, because results of research in these two Task Forces were of immediate relevance to services. The Task Forces concerned with the development of new and improved methods were ranked in the following order: Long-acting methods, Post-ovulatory methods, Vaccines, Male methods, Natural methods. This order took into consideration the state of product development in each Task Force. Higher priority was accorded to Task Forces with products at more advanced stages of development and which were more likely to be made available to services in a shorter time. This system of priorities was applied between the Task Forces when budgetary cuts had to be made because of shortcomings in funding. Within each Task Force there was also a system of priorities. In general, existing lines had a higher priority over new lines.

Dr Fathalla then described the three criteria used in combination by Steering Committees and STAG to select research lines within Task Forces: relevance of the research area to the needs of developing countries; the state of the art, and, thirdly, activities by other programmes in the area. He underlined that, since the Programme had a global responsibility for the whole field of fertility regulation, Steering Committees were encouraged by the Programme to be visionary, firstly so as not to inhibit their scientific thinking and, secondly, because their identification of research priorities would be of assistance to other programmes in the event that funding was not available from this Programme. He emphasized the long period of time it took to explore some research lines. He then outlined the activities of the various Task Forces, highlighting the new lines and where an increase in funding was requested, as shown in the proposed Programme Budget for the 1988-1989 biennium and estimates for 1990-1991.

The representatives of Sweden, Netherlands, France, Zimbabwe, Argentina, Norway and Denmark requested clarifications regarding the Safety and Efficacy Task Force and the ways in which priorities were assessed within the Task Force, particularly in relation to HIV infection; the large increase in the budget for cardiovascular diseases; the cross-sectional approach among the Task Forces in the area of sexually transmitted diseases, and the cut in the budget line relating to Pelvic Inflammatory Disease (PID).

The Secretariat responded that, within Task Forces priority was given first of all to continuation of ongoing activities and secondly to new activities. The Safety and Efficacy Task Force was basically an epidemiologically oriented Task Force. The mandate of the Programme did not cover sexually transmitted diseases, which formed the focus of activities in another WHO Programme. However, the three HRP Task Forces on Safety and Efficacy, Infertility, and Behavioural and Social Determinants all had activities related to sexually transmitted diseases which fell within the HRP mandate and which were carried out in collaboration with the AIDS Programme. These activities would doubtless be extended as new areas of collaboration became apparent. The PID study referred to was time-limited, related only to contraceptive use, and, since completed, would require no funding in the coming biennium.

At the request of the representative of the Netherlands clarification was given on the field trials of the once-a-month injectables under the Task Force on Long-Acting Systemic Agents.

The UNFPA representative queried whether the budget of the Male Fertility Task Force reflected the UNFPA contribution to IOCD for the synthesis of drugs and was informed that, although there was close collaboration with IOCD, the Chemical Synthesis Programme was an IOCD activity and therefore not reflected in the budget of the Task Force.

The representatives of Gabon, Norway, Zimbabwe, Sweden and the UNFPA addressed the activities of the Infertility Task Force. The lack of scientific knowledge about condoms was noted as well as the impact of developments in this area and its linkage to the Safe Motherhood Initiative. The need for education and counselling for both men and women in a field hitherto characteristically devoted to women was also noted. It was remarked that the funding level of the Task Force might not be sufficient for the activities specified.

Dr Fathalla drew attention to the fact that research on condoms was not limited to the Infertility Task Force where technical aspects of development and testing of improved condoms were implemented but was covered also by the Safety and Efficacy and Behavioural and Social Determinants Task Forces which dealt with the efficacy of condom use and the individual and social acceptability of condoms respectively. He emphasized that, although the effectiveness and acceptability of condoms were much lower than for other contraceptive methods, the condom ranked very highly in the prevention of sexually transmitted diseases. This, together with an assessment of the disciplines required by the Steering Committee, had prompted STAG to place condom development under the Infertility Task Force rather than the Male Task Force.

The representatives of France, Zimbabwe, USA and UNFPA participated in discussion on the Task Force on Natural Methods. The almost doubling of the budget of this Task Force was noted as well as the considerable funding by the USA to this area. The heavy reliance of developing countries on lactation as a means of contraception was stressed and the possible transmission of HIV infection through breastmilk noted.

The budget increase was clarified by the Task Force Manager. He noted that breastfeeding prevented more pregnancies in developing countries than any other form of contraception and was therefore very important as a birth-spacing method. Since the reason for lactational infertility appeared from the data to be population-related, a pilot study in seven countries was planned which would be developed into a main study in 1988 and was the reason for the increased funding. There was close liaison with the US agencies funding the field and thus no duplication of activities.

Dr Varaganam presented the Programme Budget for Programme Area III (Resources for Research), which was essentially concerned with the strengthening of research capabilities in developing countries. Based on the Strategic Plan drawn up by the Committee on Resources for Research in 1985 he reviewed the different forms of support accorded and gave examples of how institutions in the various regions were developing and strengthening their capabilities in the lines of research relevant to their own country needs. He remarked that a third of

resources available to this component were allocated to the African region. Dr Varagunam noted that the Programme on Standardization and Quality Control of Laboratory Procedures had been evaluated in depth by STAG at its February 1987 meeting and was expected to be reorganized during ensuing years to focus mainly on providing matched reagents and on strengthening the capacities of developing countries to produce their own reagents.

The representative of Bangladesh noted with appreciation the work of the Programme, emphasized the necessity for collaborative research in different countries in view of the wide diversity in size, genetic make-up and attitudes from country to country. He hoped that there would be increased opportunity for involvement in research carried out by the Programme in the countries in his region with appropriate phasing out of support where self-reliance had been achieved.

Dr Ayeni introduced Programme Area IV (Statistics and Data Processing) and stated that this area provided statistics and data processing support for all the research projects carried out by the Programme as well as some institutional strengthening programmes for the Resources for Research component. The number of studies serviced had increased from 62 during the previous biennium to 72 at present.

Programme Area V (Programme Management) required no presentation since it was self-explanatory.

PCAC:

- Approved the Programme Budget for the biennium 1988-1989 and the estimates for 1990-1991; and
 - Commended the Secretariat on the clarity and instructiveness of its presentations.
10. Election of category (c) members to PCAC

After detailed discussion it was agreed that the membership of PCC as outlined in the Memorandum of Understanding and as revised in discussions under agenda item 8 should become effective from 1 March 1988. It was noted that, as a result of revisions to the membership of PCC two, rather than three, members were to be elected to the Committee under category (c) and that their term of office would be for three years rather than one year.

The Committee was required to decide whether to include in the election the candidatures of Kuwait and Lebanon which were received by the Secretariat after the deadline given for submission of applications. The Committee agreed that the deadline should be respected.

Dr Vignes, Legal Counsel, assisted in conducting the procedures to elect two countries out of the 12 countries (Democratic Republic of Afghanistan, Cuba, Egypt, El Salvador, Haiti, Malta, Republic of Panama, Paraguay, Somalia, Sudan, Thailand and Yemen Arab Republic) which had submitted their candidatures by the due date. By secret ballot Egypt and Thailand were elected by majority vote.

PCAC:

- Elected Egypt and Thailand to category (c) membership of the Committee for a three year term of office starting 1 January 1988.

11. Pledging for 1988 and subsequent years

The majority of representatives who spoke on this agenda item indicated that it was too early in the preparation of national budgets for 1988 for them to be able to make firm pledges but indicated that they wished under this agenda item to confirm their support to the Programme.

The representative of Pakistan stated that, although his country's financial resources were limited, his government wished to participate in the Programme and pledged the sum of US\$ 5000.

The representatives of Norway and Finland confirmed their countries' continuing support for the Programme.

The representative of Denmark noted that, subject to parliamentary approval, the Danish contribution to HRP in 1988 would be increased to Danish Crowns 15 million.

The representative of the People's Republic of China noted that population issues were of global concern, and particularly so in developing countries. Family planning formed an integral part of the Constitution of his country, such was the importance and priority accorded to it. He stressed his appreciation of the excellent collaboration between his government and the HRP Programme and indicated that China intended to actively support the Programme in 1988.

The representative of the Netherlands gave assurance that his government would continue its support of the Programme in 1988.

The representative of Australia indicated that a decision on future funding levels of HRP would not be taken until later in the year. He noted, however, that this decision would have to be made against a backdrop of continued budgetary restraint and in the context of a decline in the value of the Australian dollar which had placed additional pressure on the aid component of the budget.

The representative of the United Kingdom indicated that the level of support of her government to the Programme would be indicated later in the year.

The Swedish representative commented on the long association between the Programme and her government which, as well as being a major financial contributor, had also been instrumental in its creation. The results of the assessment and impact evaluation were awaited with interest. She applauded the high quality of this PCAC meeting and the excellent presentations by the Secretariat, as well as the competent leadership given by the present Chairman.

The UNFPA representative noted that the Fund would support the Programme in 1988 at the same level as in 1987 of US\$ 2-1/2 million. Depending on the financial situation, this might be increased.

The representative of Mexico indicated that his country would maintain its contribution at the same level as in 1987 which, taking into account the devaluation of the Mexican currency, represented an increase.

The representative of the World Bank indicated that US\$ 2 million were pledged for the period 1 July 1987 - 30 June 1988, this being the period of the Bank's financial year, and emphasized that discussions could take place with the Secretariat on the transfer date to ensure a balanced financial flow.

The Argentinian representative expressed the interest of her country in becoming a financial contributor to the Programme whilst noting that Argentina's economic situation would place limitations on the level of the contribution.

The Chairman emphasized that all financial contributions were appreciated and reminded those present that written confirmation of pledges should be made as soon as possible to enable expenditures to be authorized.

12. Dates of 1988 and 1989 meetings

The dates for the 1988 and 1989 meetings were discussed. Confirmation of the date of the 1988 meeting would be communicated by correspondence.

13. Other business

There was no other business.

The Chairman thanked the members, the Secretariat, and the interpreters, and declared the meeting closed.

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT
AND RESEARCH TRAINING IN HUMAN REPRODUCTION

Meeting of the Policy and Coordination Advisory Committee (PCAC)

Geneva, 20-22 May 1987
Executive Board Room

AGENDA

1. Opening of meeting, adoption of agenda and appointment of Rapporteur
2. Report of the November 1986 PCAC meeting
3. Report of the Director
4. Scientific and Technical Advisory Group (STAG)
 - 4.1 Report of the February 1987 STAG meeting
 - 4.2 Membership of STAG
5. Matters arising out of the November 1986 PCAC meeting:
 - 5.1 External evaluation of the Programme
 - 5.2 HRP's role in post-Phase III activities
6. Funding situation
7. Technical presentation: immunological approaches to contraception
8. Co-sponsorship of the Programme
9. Proposed Programme Budget 1988-1989 and estimates for 1990-1991
10. Election of category (c) members of PCAC for the period 1 January - 31 December 1988
11. Pledging for 1988 and subsequent years
12. Dates of 1988 and 1989 meetings
13. Other business

ANNEX 2

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT
AND RESEARCH TRAINING IN HUMAN REPRODUCTION

MEETING OF THE POLICY AND COORDINATION ADVISORY COMMITTEE (PCAC)

Geneva, 20-22 May 1987
Executive Board Room

List of Participants

MEMBERS

ARGENTINA

Dr M. Bianco
Directora Nacional
de Relaciones Internacionales
Secretaria de Salud
Ministerio de Salud y Accion Social
Defensa, 120 (Piso 4°)
C.P. 1345
Bucnos Aires

AUSTRALIA

Mr M.P.F. Smith
Counsellor
Permanent Mission of Australia to the
United Nations Office at Geneva
Case postale 172
1211 Genève 19

BANGLADESH

Dr T.A. Chowdhury
Director and Professor of Obstetrics
and Gynaecology
Institute of Postgraduate
Medicine and Research
Shahbagh Avenue
Dhaka 2

CHINA, PEOPLE'S REPUBLIC OF

Dr Liu Hailin
Deputy Director
Department of Science and Education
Ministry of Public Health
Beijing

Alternates

Mr Shen Yu-long
Programme Officer
Division of International Organizations
Bureau of Foreign Affairs
Ministry of Public Health
Beijing

Dr Du Xiangjin
Division of Foreign Affairs
State Family Planning Commission
2 Nanshuncheng Street
Xizhimen
Beijing

DENMARK

Dr J. Fog
Medical Adviser
Ministry of Foreign Affairs
Danida D.3
Asiatisk Plads 2
DK - 1448 Copenhagen K

Alternate

Ms A. Meldgaard
Deputy Head of Section
Ministry of Foreign Affairs
Danida D.3
Asiatisk Plads 2
DK - 1448 Copenhagen K

ETHIOPIA

Professor N. Tafari
Department of Pediatrics and Child Health
Faculty of Medicine
P.O. Box 1768
Addis Ababa

FINLAND

Ms A. Liedes
 Programme Officer, Health
 Finnish International Development
 Agency (FINNIDA)
 Ministry for Foreign Affairs
 Mannerheimintie 15 C
SF - 00260 Helsinki 29

Alternate

Professor R. Vihko
 Department of Clinical Chemistry
 University of Oulu
SF - 90220 Oulu

FRANCE

Mr H. Ladsous
 Conseiller
 Permanent Mission of France to the
 United Nations Office at Geneva and
 Specialized Agencies in Switzerland
 Villa "Les Ormeaux"
 36, route de Pregny
1292 Chambésy

Alternate

Mme M. Saliou
 Attachée
 The Permanent Mission of France to the
 United Nations Office at Geneva and
 Specialized Agencies in Switzerland
 Villa "Les Ormeaux"
 36, route de Pregny
1292 Chambésy

GABON

Dr L. Adandé Menest
 Inspecteur Générale de la Santé publique
 et de la Population
 Ministère de la Santé publique et de la
 Population
 B.P. 50
Libreville

Alternate

Dr D. Mavoungou (unable to attend)
 Senior Endocrinologist
 International Medical Research Centre
 B.P. 769
Franceville

GERMANY, THE FEDERAL REPUBLIC OF

Mr H. Müllers
 Assistant Head, International Division
 Ministry of Economic Co-operation
 Karl-Marx Strasse 4-6
D-5300 Bonn 12

Alternate

Mr B. von Alvensleben
 Counsellor
 Permanent Mission of the Federal
 Republic of Germany to the United
 Nations Office and Other Specialized
 Agencies at Geneva
 Case postale 171
1211 Genève 19

INDONESIA

Dr Haryono Suyono
 Chairman
 National Family Planning Coordinating
 Board (BKKBN)
 P.O. Box 186 JKT
Jakarta

Alternate

Dr Abdul Rachman Surono
 Secretary
 Directorate General of
 Community Health
 Ministry of Health
 Parapattan 10
Jakarta

KENYA

Dr F.M. Mueke
 Deputy Director
 Medical Services
 Ministry of Health
 P.O. Box 30016
Nairobi

Alternate

Dr D.K. Mepukori
 Second Secretary
 Permanent Mission of the Republic
 of Kenya to the United Nations Office
 at Geneva and the Specialized Agencies
 in Switzerland
 80, rue de Lausanne
1202 Genève

KORFA, THE REPUBLIC OF

Mr Tae-chul Chung
Second Secretary
Permanent Mission of the Republic of Korea
to International Organizations at Geneva
75, rue de Lyon
1203 Genève

MEXICO

Dr G. Pérez Palacios
Professor and Chairman
Department of Reproductive Biology
National Institute of Nutrition
Calle Vasco de Quiroga No. 15
Tlalpan
Mexico D.F. CP 14000

NEPAL

Dr M.R. Beral
Medical Superintendent
Kanti Hospital
P.O. Box 2668
Maharajgunj
Kathmandu

NETHERLANDS

Mr J.E. van den Berg
First Secretary
Permanent Mission of the Kingdom of the
Netherlands to the United Nations Office
and International Organizations at Geneva
Case postale 273
1211 Genève 19

Alternate

Mr B.J.M. van Bolhuis
OMP/UM
Ministry of Foreign Affairs
Bezuidenhoutseweg 67
Postbus 20061
NL - 2500 EB The Hague

NIGERIA

Mr B.O. Tonwe
Ambassador
Permanent Mission of the Federal
Republic of Nigeria to the United
Nations Office and the International
Organizations at Geneva
1, rue Richard-Wagner
1211 Genève 2

Alternate

Mr U.A. Baraya
Second Secretary
Permanent Mission of the Federal
Republic of Nigeria to the United
Nations Office and the International
Organizations at Geneva
1, rue Richard-Wagner
1211 Genève 2

NORWAY

Ms I. Eidheim
Senior Executive Officer/Acting Head
of Office
Norwegian Directorate of Health
P.O. Box 8128 Dep.
0032 Oslo 1

Alternate

Dr B.I. Nesheim
Consultant Gynaecologist
Akershus Central Hospital
N-1474 Nordbyhagen

PAKISTAN

Dr Zaheer Uddin Khan
Director-General
National Research Institute of
Reproductive Physiology (NRIRP)
National Institute of Health Complex
Islamabad

SINGAPORE

Dr S.S. Ratnam
Department of Obstetrics and Gynaecology
National University Hospital of Singapore
Lower Kent Ridge Road
Singapore 0511

SWEDEN

Dr B. Olsson
Research Officer
Swedish Agency for Research Cooperation
with Developing Countries (SAREC)
Saltmätargatan 8
S 105 25 Stockholm 61

Alternates

Dr K.-G. Nygren
Consultant
Swedish Agency for Research Cooperation
with Developing Countries (SAREC)
Saltmätargatan 8
S 105 25 Stockholm 61

Mr L. Danielsson
First Secretary
Permanent Mission of Sweden to the United
Nations Office and other International
Organizations at Geneva
Case postale 190
1211 Genève 20

TUNISIA

Dr R. Boukhris
Director
Centre de Recherches
19, rue des Jasmins
2080 Nouvelle Ariana
Tunis

TURKEY

Dr C. Ozcan
Deputy Director-General
Maternal and Child Health Care
and Family Planning
Ministry of Health and Social Welfare
Mihat Pasa Cad. Sihhiye
Ankara

Alternate

Mr A. Algan
Conseiller
Permanent Mission of Turkey to the
United Nations Office at Geneva and
other International Organizations
in Switzerland
Case postale
1211 Genève 19

UNITED KINGDOM

Mrs B.M. Kelly (Chairman)
Health and Population Division
Overseas Development Administration
Foreign and Commonwealth Office
Eland House, Stag Place
London, SW1E 5DH

Alternate

Ms I. Doig
Assistant Administrator
Health and Population Division
Overseas Development Administration
Foreign and Commonwealth Office
Eland House, Stag Place
London, SW1E 5DH

UNITED STATES OF AMERICA

Dr D.G. Gillespie
Director
Office of Population
Agency for International Development
Washington, D.C. 20523

VIET NAM

Dr Duong Thi Cuong
Deputy Director
Central Institute of Gynaecology
and Obstetrics
Hanoi

ZIMBABWE

Mrs J.C. Kadandara
Director of Nursing Services
Ministry of Health
P.O. Box 8204
Causeway
Harare

INTERNATIONAL PLANNED PARENTHOOD
FEDERATION (IPPF)

Dr P. Senanayake
Assistant Secretary General
International Planned Parenthood
Federation
Regent's College
Inner Circle
Regent's Park
London, NW1 4NS
United Kingdom

UNITED NATIONS FUND FOR POPULATION
ACTIVITIES (UNFPA)

Dr J. Donayre
Deputy Chief
Policy and Evaluation Division
United Nations Fund for
Population Activities
220 E. 42nd Street
New York N.Y. 10017
USA

THE WORLD BANK

Dr F.T. Sai
Senior Population Adviser
Population, Health and Nutrition
Department
The World Bank
1818 H. Street, N.W.
Washington, D.C. 20433
USA

Alternate

Mr J. North
Director
Population, Health and Nutrition
Department
The World Bank
1818 H. Street, N.W.
Washington, D.C. 20433
USA

OBSERVERS

CANADA

Mr P. Mackinnon
Counsellor
Permanent Mission of Canada to the United
Nations Office and International
Organizations at Geneva
10-A, avenue de Budé
1202 Genève

SECRETARIAT

Mr W. Furth, Assistant Director-General

Special Programme of Research, Development and Research Training in Human Reproduction

Dr J. Barzelatto (Director and Secretary of Meeting)
Dr E. Diezfalusy (Senior Consultant)
Mrs S. Baron (Administrative Assistant)

JAPAN

Mr K. Fukuyama
First Secretary
Permanent Mission of Japan to the United
Nations Office and to the International
Organizations at Geneva
Case postale 114
1211 Genève 19

CHAIRMAN, SCIENTIFIC AND TECHNICAL
ADVISORY GROUP (STAG)

Professor S. Bergstrom
Karolinska Institute
Solnavagen 1
104 01 Stockholm 60
Sweden

TECHNICAL PRESENTATION

Task Force on Vaccines for Fertility
Regulation

Dr W.R. Jones
Department of Obstetrics
and Gynaecology
Flinders Medical Centre
University of South Australia
Bedford Park
S.A. 5042
Australia

Dr V.C. Stevens
Department of Obstetrics & Gynaecology
Ohio State University
1654 Upham Drive
Columbus
Ohio 43210
USA

(1) Research and Development

Dr M. Fathalla (Responsible Officer)
Dr C. d'Arcangues (Assistant Task Force Manager for Long-Acting Systemic Agents)
Dr H. Bathija (Short-term staff member, Task Force on Safety and Efficacy)
Mr D. Griffin (Task Force Manager for Plants and Vaccines)
Mr P. Hall (Task Force Manager for Long-Acting Systemic Agents)
Dr S. Holck (Task Force Manager for Safety and Efficacy)
Dr U. Koch (Assistant Task Force Manager for Behavioural and Social Determinants)
Dr O. Meirik (Project Manager, Norplant)
Dr F. Michal (Secretary of Review and Toxicology Groups)
Dr A. Mundigo (Task Force Manager for Behavioural and Social Determinants)
Dr P. Rowe (Task Force Manager for Infertility; responsible for Coordination with Industry)
Dr I. Shah (Assistant Task Force Manager for Behavioural and Social Determinants)
Dr P. Van Look (Task Force Manager for Post-Ovulatory Methods and Natural Methods)
Dr G. Waites (Task Force Manager for Male Fertility)

(2) Resources for Research

Dr T. Varagunam (Responsible Officer and Programme Manager for Latin America)
Dr J. Kasonde (Programme Manager for Africa)
Dr F.T.G. Webb (Programme Manager for China)
Dr E. Wilson (Programme Manager for Asia)

(3) Statistics and Data Processing

Dr O. Ayeni (Senior Statistician)
Dr E. Belsey (Short-term staff member, Statistician)
Dr T. Farley (Statistician)
Mr A. Pinol (Programmer Analyst)

(4) Administration

Mr E. Røed (Administrative Officer)
Mr J. Khanna (Publications Manager)

Division of Budget and Finance

Mr A. Imbruglia, Director

Division of Family Health

Dr A. Petros-Barvazian, Director
Dr L. Mehra, Senior Medical Officer, Maternal and Child Health

Office of the Legal Counsel

Dr C.-H. Vignes, Director

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Annex 2

Programme for External Coordination

Mrs I. Bruggemann, Director
Dr S. Kingma, Chief, Health Resources Mobilization
Dr Y. Kawaguchi, External Relations Officer

Special Programme for Research and Training in Tropical Diseases

Dr T.C. Nchinda, Medical Officer, Research Capability Strengthening

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT, AND RESEARCH TRAINING
IN HUMAN REPRODUCTION

Meeting of the Policy and Coordination Advisory Committee

Geneva, 20-22 May 1987

Report of PCAC Working Group on an External Evaluation of HRP

After a general discussion the PCAC asked a small working group to consider the question of an external evaluation to clarify various issues such as scope and timing and to report back to the main meeting. The PCAC agreed that the ultimate objective of the Special Programme in Human Reproduction was to help improve reproductive health in developing countries. The Programme sought to meet this objective by initiating, funding and coordinating research on:

- safety and efficacy of current contraceptive methods;
- development of new and improved contraceptive methods (including basic mission-oriented research);
- behavioural and social determinants of fertility; and
- prevention and management of infertility.

In addition, the Programme played an important role in strengthening the research capabilities of developing countries in the field of human reproduction.

The PCAC recognized that STAG acted as an effective in-built internal mechanism for independent external evaluation of the Programme's activities. However, STAG rightly concentrated on evaluating and monitoring the scientific and technical aspects of the Programme, as defined in its mandate. The PCAC felt that it would be timely to step outside this formalized evaluation structure and look at the Programme's achievements against the broader needs of the reproductive health field; to try to quantify the Programme's impact on the sector; to define its role in relation to the responsibilities of other WHO programmes and other organizations active in the field; and in the light of this to offer suggestions for the Programme's future development. However, the Committee acknowledged that reproductive health was a broad and complex field in which many bodies supported research and programme development. PCAC therefore felt that there was a need for an independent external assessment of research needs in reproductive health, against which priorities and goals for programmes such as HRP could be set. Such an assessment would be particularly timely in view of recent international initiatives focusing on specific aspects of reproductive health such as the control and prevention of AIDS; maternal mortality and morbidity; and the fact that HRP was itself having to redefine its role and priorities to take account of work to be done on the introduction and post-marketing surveillance of new methods developed by the Programme.

The PCAC felt that WHO was best placed to initiate and manage such an external assessment because of its global leadership in health issues; its political neutrality; and its technical credibility. It therefore requested the Director-General to consider commissioning, in partnership with other interested bodies, an overall independent assessment of research in reproductive health in developing countries designed to:

- (a) examine needs;
- (b) assess the institutional and financial resources available to meet them;
- (c) identify gaps; and

- (d) suggest priorities for future assistance.

The PCAC would appreciate being informed of the Director-General's decision on this proposal.

External evaluation of HRP

The Committee decided that an impact evaluation of HRP's activities, particularly in developing countries, would link well with this exercise and would provide guidance on the future role and orientation of the Programme. The Committee further considered that the HRP evaluation should not duplicate planned internal evaluation activities such as the in-depth review of the Resources for Research component of the Programme. This evaluation should go ahead whether or not the overall assessment was conducted.

The PCAC suggested that Terms of Reference for the evaluation should be developed over the next 12 months, in consultation with interested parties, and submitted to its 1988 meeting, together with proposed operational details and estimated costs. Representatives of the PCAC were encouraged to submit names of possible members of the evaluation team to the Director. The evaluation team members should have experience related to the scope of the Special Programme and should have suitable professional standing. They should not have received or be receiving financial support from the Programme or be serving as members of STAG. There should be balanced geographical distribution, with members from developed and developing countries.

The Committee felt that a number of reports already planned for the 1988 meeting would be valuable background documents for the evaluation. It requested the Director and STAG to bear this in mind in preparing:

- (a) the draft long-term strategic plan for family planning research; and
- (b) the proposals for the Programme's involvement in reproductive health services research.

The Committee also asked the Director to prepare a report on the criteria which could be used for measuring the Programme's impact in developing countries for consideration at the 1988 meeting, alongside the proposed Terms of Reference for the evaluation.

The Committee acknowledged that the external evaluation would have an effect on the Programme's performance. However, it felt that it would be a useful fund-raising tool and was therefore worth the investment.

IMMUNOLOGICAL APPROACHES TO CONTRACEPTION

A Technical Presentation by

Mr P.D. Griffin, Professor W.R. Jones and Professor V.C Stevens

Summary

In view of the complexity of the subject matter to be reviewed and the specialized terminology used in the fields of immunology and vaccine development, a number of key words and concepts were defined by Mr Griffin to facilitate the presentation which consisted of an introduction to the rationale for, history of, and current research activities of the Task Force on Vaccines for Fertility Regulation, followed by a description of the development of the Task Force's anti-hCG vaccine, the current status of the Phase I clinical evaluation of this vaccine, and the planned future activities of the Task Force.

It is well known that there are molecules specific to, and essential for, the development of the gametes, their fusion in the process of fertilization, and in the subsequent establishment and maintenance of pregnancy. In addition, a large volume of evidence has been gathered over the last few decades to indicate that naturally occurring and experimentally induced immunity to some of these molecules can produce an antifertility effect. Whilst many of these molecules, such as the releasing hormone(s), pituitary gonadotrophins and gonadal steroids, represent unattractive targets for an antifertility vaccine since they are required for maintaining physiological processes and are constantly present in the body, others such as those specific to the gametes and early embryo, represent much more attractive targets. By developing vaccines against one or more of this latter group of molecules, it might prove possible, by immunological means, to safely and effectively interfere with gametogenesis, fertilization, implantation and/or disrupt very early pregnancy. Since its formation in 1974, therefore, the Task Force has carried out studies with a number of sperm-specific, ovum-specific and embryo-specific molecules in order to determine their potential as antifertility immunogens for vaccine development. A summary of the results obtained in these studies was presented.

Professor Stevens introduced the next section of the presentation by explaining that largely as a result of funding constraints, the Task Force has focused its attention over the past seven years exclusively on the development of a vaccine directed against human chorionic gonadotrophin (hCG), a hormone produced by the embryo as early as the pre-implantation stage of its development and necessary for successful implantation and early pregnancy. Vaccines based on whole hCG and on each of its major molecular subunits produce immune responses which cross-react extensively with other hormones, such as pituitary hLH, leading to endocrine disturbances and the risk of auto-immune disease. To avoid these problems, the Task Force has based its anti-hCG vaccine development programme on a synthetic peptide representing a portion of the molecule which does not appear in any normal body constituent apart from hCG. As a result of a large number of comparative evaluations of a number of peptides of different lengths, of a number of carrier molecules to which the hCG peptide could be linked in order to elicit an immune response, of adjuvants to augment the response, and of various vehicles in which the vaccine could be administered, by 1980 the Task Force had selected a prototype anti-hCG vaccine formulation consisting of a 37 amino-acid hCG peptide linked to diphtheria toxoid as the carrier, mixed with a muramyl dipeptide adjuvant and administered in a water in oil emulsion vehicle. This prototype vaccine, when administered to fertile female baboons, elicited an immune response which reduced the fertility of these animals to less than 5%, compared to 70% in a control group of non-immunized baboons, without producing any overt side-effects.

Professor Stevens explained that a vaccine having an antifertility effect of 95% would not be acceptable for clinical application. However, it should be remembered that these data had been obtained in a heterologous immunization situation in which antibodies raised to hCG

cross-react with the endogenous baboon hormone (baboon CG) by approximately 15%. As close to 100% cross-reactivity is anticipated in the homologous clinical situation, where antibodies will be directed at the endogenous hCG, an antifertility effect in excess of 95% is expected.

Mr Griffin provided a summary of the extensive toxicity and immunosafety studies that were carried out with this innovative vaccine, in several animal species and over varying periods of time, in order to assess its safety for initial human testing. These detailed studies, which took almost four years to complete, revealed no adverse side-effects that would preclude the clinical testing of the vaccine. The data generated in these studies were compiled into a four volume investigational New Drug Application which was submitted to the United States Food and Drug Administration and to the Australian Department of Health together with a detailed protocol for the Phase I clinical trial of this vaccine. After a long period of review, necessitated by the novel nature of the preparation and the lack of previous clinical experience with a vaccine of this type, both regulatory authorities had recommended, by late 1985, that the Phase I trial could proceed.

Professor Jones provided an overview of the sequence and nature of the institutional and national approvals that needed to be obtained before the Phase I trial could proceed and of the logistical problems involved in recruiting volunteers and conducting a trial of this novel type of preparation. He explained that the purpose of this study is to determine if the vaccine is safe to use in women. It is not designed to determine efficacy since one of the criteria for admission to the trial is that all volunteers had previously been electively sterilized. However, some indication of potential antifertility efficacy is being obtained by quantifying the level of immunity generated by the vaccine in the women volunteers and comparing these data to the levels of immunity found to be effective in baboons.

In presenting the results of the trial to date, Professor Jones indicated that apart from a transient technical problem encountered with the formulation of the emulsion vehicle, the trial has proceeded satisfactorily and is expected to be completed by mid 1987. The trial has a doubling dose design in which six women, in each of five dosage groups, are immunized with the vaccine with the highest dose being the same as that used in the preclinical safety and efficacy studies in baboons. Some minor and transient arthralgia and myalgia, believed to be due to the muramyl dipeptide adjuvant, was experienced by some individuals receiving the highest dose of the vaccine and it is anticipated that the dose of this particular component could be reduced in any future clinical trials of this vaccine formulation. Although all of the data from the two highest vaccine dose groups were not available at the time of the presentation, the results so far are very encouraging in that a dose-response effect has been observed and all groups produce a sufficient level of immunity, demonstrated by antibody titres, to confer an antifertility effect. In the highest dose group the available data indicate that the level of antibodies raised is approximately ten times that estimated to be protective and that the effective level of immunity in this group will extend beyond six months and may reach twelve months. In accordance with the requirements of the Phase I clinical trial protocol, all subjects will be followed up until their anti-hCG antibody levels return to baseline values. It is estimated that all of the data from this study will be collated by the beginning of 1988 and will be compiled into one or more papers for publication by the Task Force.

Mr Griffin briefly described the recent advances in the fields of immunology and molecular genetics that were already having a major impact on vaccine development. In comparison to the classical and more primitive biochemical techniques that had been used in the past, it is now possible, using monoclonal antibodies and recombinant DNA technology, to identify, isolate, characterize and synthesize natural and modified molecules by a number of approaches. This new technology is expected to revolutionize vaccine development by permitting the identification of a large number of previously unknown molecular entities which have not been detected before using classical biochemical methods, because they have been destroyed or lost in the isolation process. The Task Force is actively employing these new technologies in its ongoing and planned research programmes to develop second generation hCG vaccines and vaccines directed against the cell membrane of the very early trophoblast.

MEMORANDUM ON THE ADMINISTRATIVE STRUCTURE OF THE SPECIAL PROGRAMME
OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION

The Special Programme of Research, Development and Research Training in Human Reproduction (hereinafter called the Special Programme) is structured on the basis of co-sponsorship by the United Nations Development Programme (hereinafter called UNDP), the United Nations Fund for Population Activities (hereinafter called UNFPA), the World Health Organization (hereinafter called WHO) and the International Bank for Reconstruction and Development (hereinafter called The Bank), and operates within a broad framework of intergovernmental and inter-agency cooperation and participation.

1. BASIC STRUCTURE

1.1 The Special Programme is a global programme of international technical cooperation initiated by WHO to promote, coordinate, support, conduct and evaluate research in human reproduction with particular reference to the needs of developing countries, by:

- (i) promoting and supporting research aimed at finding and developing safe and effective methods of fertility regulation as well as identifying and eliminating obstacles to such research and development;
- (ii) identifying and evaluating health and safety problems associated with fertility regulation technology, analysing the behavioural and social determinants of fertility regulation, and testing cost-effective interventions to develop improved approaches to fertility regulation within the context of reproductive health services;
- (iii) strengthening the training and research capability of developing countries to conduct research in the field of human reproduction; and
- (iv) establishing a basis for collaboration with other programmes engaged in research and development in human reproduction, including the identification of priorities across the field and the coordination of activities in the light of such priorities.

1.2 The Cooperating Parties are:

1.2.1 Governments contributing to Special Programme Resources; governments providing technical and/or scientific support to the Special Programme; and governments with policies designed to address the needs for fertility regulation and family planning for their populations in the context of their overall plans for health care and social and economic development.

1.2.2 Intergovernmental and other non-profit-making organizations contributing to Special Programme Resources or providing technical and scientific support to the Special Programme.

1.3 The Co-Sponsors are UNDP, UNFPA, WHO and The Bank.

1.4 The Executing Agency is WHO.

1.5 Special Programme Resources are the financial resources made available to the Special Programme by governments and organizations through the WHO Voluntary Fund for Health Promotion.

2. POLICY AND COORDINATION COMMITTEE (PCC)

The PCC is the governing body of the Special Programme.

2.1 Functions

The PCC shall, for the purpose of coordinating the interests and responsibilities of the parties cooperating in the Special Programme, have the following functions:

- 2.1.1 Review and decide upon the planning and execution of the Special Programme. For this purpose it will keep itself informed of all aspects of the development of the Special Programme and consider reports and recommendations submitted to it by the Standing Committee referred to in Section 3 of this Memorandum (hereinafter called the Standing Committee), the Executing Agency and the Scientific and Technical Advisory Group referred to in Section 4 of this Memorandum (hereinafter called STAG).
- 2.1.2 Review and approve the plan of action and budget for the coming financial period prepared by the Executing Agency and reviewed by STAG and the Standing Committee.
- 2.1.3 Review the proposals of the Standing Committee and approve arrangements for the financing of the Special Programme.
- 2.1.4 Review proposed longer-term plans of action and their financial implications.
- 2.1.5 Review the annual financial statements submitted by the Executing Agency, as well as the audit report thereon submitted by the External Auditor of the Executing Agency.
- 2.1.6 Review periodic reports which evaluate the progress of the Special Programme towards the achievement of its objectives.
- 2.1.7 Review and endorse the selection of members of STAG by the Executing Agency in consultation with the Standing Committee.
- 2.1.8 Consider such other matters relating to the Special Programme as may be referred to it by any Cooperating Party.

2.2 Membership

The PCC shall consist of 32 members from among the Cooperating Parties as follows:

- 2.2.1 Largest financial contributors: the 11 government representatives from the countries which were the largest financial contributors to the Special Programme in the previous biennium.
- 2.2.2 Countries elected by WHO Regional Committees: 14 member countries elected by the WHO Regional Committees for three-year terms according to the population distribution and regional needs:

Africa	4
Americas	2
Eastern Mediterranean	1
Europe	1
South-East Asia	3
Western Pacific	3

In these elections due account should be taken of a country's financial and/or technical support to the Special Programme as well as its interest in the fields of family planning, research and development in human reproduction and fertility regulation as demonstrated by national policies and programmes.

- 2.2.3 Other interested Cooperating Parties: Two members elected by the PCC for three-year terms from the remaining Cooperating Parties.

2.2.4 Permanent members: The Co-Sponsors of the Special Programme, and IPPF.

Members of the PCC in categories 2.2.2 and 2.2.3 may be re-elected.

2.3 Observers

Other Cooperating Parties may be represented as observers upon approval of the Executing Agency, after consultation with the Standing Committee. Observers attend sessions of the PCC at their own expense.

2.4 Operation

2.4.1 The PCC will meet at least once a year, and in extraordinary sessions if required, subject to the agreement of the majority of its members. The Executing Agency shall provide the Secretariat.

2.4.2 The PCC shall elect each year from among its members, a Chairman, a Vice-Chairman and a Rapporteur.

2.4.3 The Chairman shall:

- convene and preside over meetings of the PCC; and
- undertake such additional duties as may be assigned to him by the PCC.

2.4.4 Subject to such other special arrangements as may be decided upon by the PCC, members of the PCC shall make their own arrangements to cover the expenses incurred in attending sessions of the PCC.

2.5 Procedures

2.5.1 The PCC shall, in its proceedings be guided mutatis mutandis by the Rules of Procedure of the World Health Assembly.

2.5.2 In consultation with the Chairman, the Secretariat shall prepare an annotated provisional agenda for the meeting.

2.5.3 A report, prepared by the Rapporteur, with the assistance of the Secretariat, shall be circulated as soon as possible after the conclusion of the session for the subsequent approval of participants.

3. THE STANDING COMMITTEE

3.1 Composition

The Standing Committee shall be comprised of representatives of the Co-Sponsors.

3.2 Functions

The Standing Committee shall have the following functions:

3.2.1 Review plans of action and budget for the coming financial periods as prepared by the Executing Agency and reviewed by STAG in time for presentation to the annual session of the PCC.

3.2.2 Make proposals to the PCC for the financing of the Special Programme for the coming financial period.

- 3.2.3 Review reallocation of resources during a financial period upon the recommendation of STAG and the Executing Agency and report to the PCC.
- 3.2.4 Examine the reports submitted to the Executing Agency by STAG and the Executing Agency's comments; make the necessary observations thereon and transmit these, with comments as appropriate, to the PCC.
- 3.2.5 Review particular aspects of the Special Programme, including those which may be referred to it by the PCC, and present findings and recommendations to the PCC.
- 3.2.6 Inform the PCC, as required, regarding Special Programme matters of interest to the PCC.
- 3.2.7 Prepare an annual report of its activities for the PCC.

3.3 Operation

- 3.3.1 The Standing Committee shall usually meet twice a year; once at the time of the PCC meeting, and additionally between sessions of the PCC.
- 3.3.2 The Executing Agency shall arrange for support services and facilities as may be required by the Standing Committee.
- 3.3.3 Members of the Standing Committee shall make their own arrangements to cover the expenses incurred in attending sessions of the Standing Committee.

4. SCIENTIFIC AND TECHNICAL ADVISORY GROUP (STAG)

4.1 Functions

The STAG shall have the following functions:

- 4.1.1 Review, from a scientific and technical standpoint, the content, scope and dimensions of the Special Programme, including the research areas covered and approaches to be adopted.
- 4.1.2 Recommend priorities within the Special Programme, including the establishment and disestablishment of Task Forces, and all scientific and technical activities related to the Programme.
- 4.1.3 Provide PCC and the Standing Committee with a continuous and independent evaluation of the scientific and technical aspects of all activities of the Special Programme.
- 4.1.4 Review the plans of action and budget for financial periods prepared by the Executing Agency and make proposals to the Standing Committee for possible reallocation of resources within the scientific and technical component of the Special Programme during the period concerned.

For these purposes, the STAG may propose and present for consideration such technical documents and recommendations as it may deem necessary to the Executing Agency, the Standing Committee or the PCC, as appropriate.

4.2 Composition

- 4.2.1 The STAG shall be comprised of 15-18 members, who will serve in their personal capacities to represent the broad range of biomedical and other disciplines required for the Special Programme's activities.

- 4.2.2 Members of the STAG, including the Chairman, will be selected on the basis of scientific and technical competence by the Executing Agency in consultation with the Standing Committee and with the endorsement of PCC.
- 4.2.3 Members of the STAG shall not be members of other committees of the Special Programme, principal investigators in studies undertaken by the Special Programme, or Special Programme grantees.
- 4.2.4 Members of the STAG, including the Chairman, shall be appointed to serve for a period of three years, and will be eligible for immediate reappointment only once.

4.3 Operation

- 4.3.1 The STAG shall meet at least once each year.
- 4.3.2 The Executing Agency shall provide the Secretariat to STAG, including sustained scientific, technical and administrative support.
- 4.3.3 The STAG shall elect a Vice-Chairman and a Rapporteur from among its members for each meeting.
- 4.3.4 The STAG shall prepare an annual report on the basis of a full review of all technical and scientific aspects of the Special Programme. This report, containing its findings and recommendations, shall be submitted to the Executing Agency and to the Standing Committee. The Executing Agency shall submit its comments (if any) on the report to the Standing Committee. The Standing Committee shall then transmit the report, including any comments of the Executing Agency, together with its own observations and recommendations, to the PCC. The Chairman of STAG, or in his absence a member of STAG deputized to act for him, shall attend all sessions of the PCC.

5. THE EXECUTING AGENCY

The Executing Agency, after consultations with the Standing Committee and other consultations as it may deem appropriate, shall appoint the Special Programme Director and appoint or assign all other personnel to the Special Programme as specified in the plans of work. Drawing as required upon the administrative resources of the Executing Agency and in cooperation with the Co-Sponsors, the Assistant Director-General, supervising the Director of the Special Programme, will be responsible for the overall management of the Special Programme. Drawing to the full upon the scientific and technical resources of the Executing Agency, the Director of the Special Programme shall be responsible for the overall scientific and technical development and operation of the Special Programme, including the plan of action and budget.

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