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P O L I C Y

UNITED NATIONS FUND FOR POPULATION ACTIVITIES

Report of the Executive Director

on UNFPA strategy for support of contraceptive research

Summary

This report is submitted to the Governing Council in response to decision 83/17, II, paragraph 4, in which the Governing Council decided that the level of contributions to the WHO/HRP would be subject to an annual review by the Council, taking into account available resources, priority research needs and a concise report on UNFPA strategy for support of contraceptive research through all appropriate organizations. This report presents for policy decision a number of general principles to be followed by UNFPA in supporting contraceptive research, a recommendation for approval of a funding level for WHO/HRP for 1985 and a strategy for increasing funding to contraceptive research.

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INTRODUCTION

1. This policy paper is submitted in response to decision 83/17, II, paragraph 4, of the Governing Council at its thirtieth session. It (a) proposes the strategy to be followed by UNFPA in its continued support of contraceptive research; and (b) recommends a contribution level by UNFPA to the World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP) for the year 1985.
2. UNFPA has previously submitted two documents to the Governing Council on contraceptive research needs. The first-DP/1982/36 and Addendum 1 - submitted to the Governing Council at its twenty-ninth session in June 1982 was prepared after a review of the work in the field of contraceptive research by an advisory group of experts and a canvassing of the contraceptive needs of developing countries. The second - DP/1983/21 and Addendum 1 - submitted to the Governing Council at its thirtieth session in June 1983 was prepared jointly with WHO, in consultation with the International Planned Parenthood Federation, and concerned family planning research including contraceptive research and development. After consideration of the latter document, the Governing Council in decision 83/17, II, paragraph 1, endorsed the priority areas for family planning research recommended by UNFPA, i.e., of first priority, programme research, then biomedical research and next, social research. The Governing Council in the same decision also endorsed the Fund's recommendation that priority should be given to expansion of research training and the strengthening of national capabilities for research in programme, biomedical and social research. The Council approved a four-year UNFPA funding commitment (1984-1987) to the WHO/HRP, and decided that the levels of contributions to the WHO/HRP would be subject to an annual review by the Council, taking into account available resources, priority research needs and "a concise report on UNFPA strategy for support of contraceptive research through all appropriate organizations," which the Council requested that UNFPA submit to it at its thirty-first session.
3. In planning and allocating its assistance in support of contraceptive research, UNFPA is guided by the directions of the Governing Council in decision 82/20, I, 6 (a), that the Fund take action to increase the level of its financial contribution and effectiveness of its support by "(i) stimulating research on new and existing contraceptive methods, fully taking into account the national policies of developing countries in this field and the needs expressed by those concerned; (ii) taking a more active role in deliberations of research organizations receiving UNFPA support, with respect to UNFPA-supported programmes and projects; (iii) closely co-ordinating its assistance in this area with support provided by other organizations." The Council also endorsed (82/20, I, 6 (b)) the need for increasing and long-term support by UNFPA to this activity through the WHO/HRP as well as appropriate international and non-governmental organizations and through national institutions.
4. As stressed by many Governments and reiterated at several international meetings, family planning programmes would be helped greatly by new and improved contraceptive technology. The process of development of a new contraceptive from basic research through testing in animals and humans and, finally, after appropriate

government approval and registration, its introduction and adaptation in national programmes, was described in paragraphs 8 through 10 of DP/1982/36/Add.1. The Council will recall that for a single contraceptive this process may take more than fifteen years and may require an investment of more than \$50 million over that period of time. Governments of developing countries place great weight upon the certification of new contraceptives by the drug-approval authorities of industrialized countries and this approval necessarily requires extensive and time-consuming domestic testing. It is obvious that UNFPA's contribution to this process can only have a limited effect because of the many other demands requiring UNFPA financing. The relatively modest funding that UNFPA can provide must be strategically applied for best effect.

I. GENERAL PRINCIPLES FOR UNFPA ASSISTANCE

5. As was noted in paragraph 4 of DP/1982/36, within the wide range of activities required for improvement or development of a contraceptive, UNFPA should concentrate upon development of only those methods of fertility regulation that are sufficiently advanced to permit widespread clinical evaluation, and, among these, only those particularly suited to the needs of developing countries. As discussed in paragraph 5 of DP/1982/36, UNFPA should not fund basic fundamental research on human reproductive processes nor should it directly provide continuing administrative or overhead core support for research institutions. UNFPA should encourage Governments of developing countries to mobilize additional scientists and institutions to address the many questions concerning contraceptive technology and should respond to requests for country programme funds to meet government needs in clinical testing and evaluation, acceptability studies or operational research in their own family planning programmes.

6. In addition to the programme of the WHO/HRP, research in contraceptive development is carried out by a small number of non-governmental organizations. Those organizations, concentrating on the needs of developing countries, have gradually become more international in character, guided by boards of directors who come from developing as well as developed countries. The number of sources of funds has increased for a few of these non-government organizations, though all of them have only modest annual budgets compared to their needs. They carry out contraceptive trials in a large number of developing countries as well as developed countries under the supervision of local organizations. The most effective method of contraceptive research which is to benefit developing countries requires the joining of efforts of the best scientists of developed and developing countries with the laboratory facilities usually found only in developed countries. This support, if it is made available to the programme of a non-governmental organization, is almost always "intercountry funding" as defined in UNFPA terms, and it, therefore, continues to fall within the 25 per cent limitation on allocations by UNFPA to intercountry activities. Thus the total amount available for these research programmes is likely to remain small compared to the requirement for funds. Some of the funding for these activities can be channelled through country projects upon receipt of government requests, but intercountry funds should be made available for contraceptive research programmes of appropriate non-governmental organizations. However funded, arrangements for assistance should be fixed for as long a term as possible to give the research institutions assurance of the continuing support that is necessary for their programmes.

7. As was stated in DP/1982/36, III, several major scientific leads are currently sufficiently advanced to justify UNFPA support. These include improved oral methods; injectables and implants; improved IUDs; male and female sterilization; postcoital agents; natural family planning methods; vaginal rings and barrier methods. Male methods, LHRH analogs and vaccines, while potentially important, will require more time to develop to the point of field application. In appraising a project request for an institution or organization pursuing one of these scientific leads, UNFPA should consider whether there is a good chance that the contraceptive being developed will be deliverable at a reasonable cost, will be acceptable to clients and health care providers, and will require minimal supporting health care services and low frequency of application.

II. ORGANIZATIONS IN THE FIELD AND CURRENT UNFPA ASSISTANCE

8. The list of organizations in the field of contraceptive research and development is little changed since submission of document DP/1982/36 and Add.1. Involvement of private pharmaceutical firms in this research has not substantially increased in recent years. There are a number of individual researchers in universities, in private sector companies and in government institutes around the world but very few programmes organized to concentrate on the applied research on contraceptives needed in developing countries. The largest programme is that of the Center for Population Research (CPR) of the U.S. National Institute for Child Health and Human Development. Of its present annual budget of approximately \$100 million, about one-half is utilized for basic fundamental research and about \$8-10 million for research in contraceptives. While the results of CPR's research may prove to be of great value to developing countries, its programme is primarily related to the needs of the United States. Similarly, though on a smaller financial scale, the Indian Council for Medical Research conducts fundamental research and contraceptive development directed towards fertility regulation and contraceptive clinical trials required for regulatory approval in India. The Government of China has substantial research programmes in the use of IUDs, sterilization, long-acting methods such as pills, injectables, vaginal rings, and spermicides and male methods such as the use of gossypol.

9. UNFPA assists only two organizations with their programmes of contraceptive development. Allocations are made from intercountry funds for the WHO/HRP and for the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT). From 1976 through 1984, UNFPA will have contributed a cumulative total of \$12,150,000 to the WHO/HRP. In its Twelfth Annual Report for the year 1983, WHO/HRP estimated obligations of \$13.3 million of which approximately \$8.9 million was for research and development. Of this amount, \$7.1 million is for research and development of current methods and new methods of contraception. Another \$3.2 million of the WHO/HRP budget is expended on institution-strengthening and \$1.2 million is required for programme management. The \$13.3 million of estimated obligations includes \$3.3 from UNFPA (\$2 million as a general contribution to the HRP; \$1.3 million for country projects for which WHO is executing agency).

10. PIACT is a non-profit, non-governmental organization with headquarters in Seattle, Washington, U.S.A. Its Board of Directors is drawn from Bangladesh, Botswana, Egypt, India, Mexico, Nepal and the Philippines. It maintains field associates in five developing countries and affiliated organizations in ten developing countries. Its organizational goal is to improve the availability, effectiveness, safety and continued use of family planning products and methods in developing countries. PIACT provides technical backstopping for local production, product introduction and technology transfer. It assists Governments with commodity procurement and publishes product information and facilitates field trials of PIACT-developed product accessories or modifications. UNFPA is the largest single funder of PIACT and provides approximately 16 per cent of PIACT's revenues which were about \$2.6 million in 1983. PIACT funding is also received from the Governments of Canada and the United States and a large number of foundations. UNFPA support for PIACT for the period 1984-1987 will be as follows: 1984, \$412,500; 1985, \$433,400; 1986, \$454,000; and 1987, \$477,700.

11. UNFPA has allocated funds for country projects designed to increase capacity for biomedical research in China and Indonesia and is considering such a project for Malaysia. WHO/HRP acts as executing agency for these projects, which will require \$4.5 million for China for the period 1980-1984 and \$358,000 for Indonesia for the period 1984-1986. Additional amounts are expected to be provided to China over the next four-year programme. Country project funds have also supported projects related to contraceptive production and executed by PIACT in China, Cuba and Viet Nam.

12. The International Committee for Contraception Research (ICCR) was organized by The Population Council in 1971 to identify the areas of special promise in contraceptive research, to determine whether these leads will require special attention in order to be properly and rapidly evaluated and, if so, to carry forward these investigations. This is achieved by research in the clinics and laboratories of ICCR members and by the award of grants and contracts to other investigators for specified projects. At present the seven individual members of the ICCR are from Brazil, Canada, Chile, Finland, India, Sweden and the United States. The ICCR has been successful in its development of the Lippes Loop Copper T intrauterine device and its sub-dermal implant method is at a very promising stage, having recently been approved for use and manufacture by the Government of Finland. ICCR is pursuing other leads such as the contraceptive ring, progestin-releasing IUD, pregnancy vaccine, and LHRH analogs for female and male contraception. From 1971 through 1982, the ICCR received its largest amount of financial support from The Ford Foundation and The Rockefeller Foundation and the Canadian International Development Research Centre (IDRC), some 70 per cent of the total of \$30.4 million received over this twelve-year period. Both The Ford Foundation and the IDRC are now shifting their attention to areas other than family planning and contraceptive research and, while ICCR hopes to receive increased funding from the U.S. Agency for International Development (U.S.AID) in the future, its estimated budget for 1983 is only \$3 million and there is a definite need for additional funds to expand and accelerate its programme.

13. Family Health International (formerly called International Fertility Research Programme) concentrates on contraceptive prototype development and Phase III and IV clinical trials of contraceptive technologies through a network of institutions in several countries, especially developing countries. Its budget for 1984 for this work is about \$6 million, of which 80-90 per cent is provided by U.S. AID.
14. The Programme for Applied Research on Fertility Regulation (PARFR) of Northwestern University, U.S.A., funds promising early leads through grants to private investigators for applied research and conducts early clinical trials, Phases I and II, of promising new products. Its budget is approximately \$2.5 million and is provided mostly by U.S. AID.
15. The International Organization for Chemical Sciences in Development (IOCD) is an international non-governmental organization established in 1981 to enlist the expertise of the chemical sciences in solving problems of developing countries. Through its community of scientists, IOCD provides a mechanism by which chemists in both developing and industrialized countries can collaborate in strengthening the chemical sciences in developing countries, particularly those problems related to population, health and food. Having already commenced work in treatment of tropical diseases, IOCD is now turning its attention to fertility regulation. A joint IOCD/WHO Consultative Meeting in July 1984 will consider a male fertility regulation programme starting with a project for chemical synthesis of agents for sperm function regulation.
16. WHO, the non-governmental organizations described above and national institutions in developing countries such as the Indian Centre for Medical Research are all appropriate entities to receive UNFPA funds for intercountry or country projects in applied contraceptive research.

III. UNFPA STRATEGY FOR 1984-1987

17. In response to the Council's decision 82/20, I, 6 (a) UNFPA has taken a more active role in the deliberations of research organizations receiving UNFPA support. UNFPA serves on the Policy and Co-ordinating Advisory Committee (PCAC) of the WHO/HRP, an advisory body whose formation was recommended to the Director-General of WHO by the December 1983 Meeting of Interested Agencies of the WHO/HRP. UNFPA is also represented on the Preparatory Intersessional Committee that will prepare a report to the PCAC concerning the appropriate balance among various activities within the WHO/HRP, the time-scale which WHO/HRP envisages for the fulfillment of the objectives of each of its programme areas and the possibilities and problems of integrating its activities into the regular programme of WHO as the objectives are met, and other policy issues concerning WHO/HRP. UNFPA will take an equally interested role in the activities of other research organizations with respect to UNFPA-supported programmes and projects.
18. In determining the level of the UNFPA contribution to the WHO/HRP for 1985, the Governing Council should consider that the Policy and Co-ordination Committee of WHO/HRP at its annual meeting in late 1984 will make a number of recommendations to the Director-General of WHO on the subjects covered by the Preparatory

Intersessional Committee report. These recommendations, if accepted, will have an important effect on the future structure and activities of the WHO/HRP. For example, some projects in the area of service and psycho-social research currently part of the WHO/HRP programme may be supported by UNFPA in the future as country projects. If so, a level of funding at \$2 million for 1985 would represent an actual increase of UNFPA general support to WHO/HRP. UNFPA should contribute \$2 million to WHO/HRP for 1985 and should present to the Governing Council at its thirty-second session a brief report on the results of the recommendations of the 1984 PCAC meeting together with a recommendation for the level of UNFPA funding for the WHO/HRP for 1986.

19. As its immediate strategy for funding contraceptive research and in accordance with the general principles above, UNFPA, in its programming activities, should consult with Governments of developing countries and non-governmental organizations active in the field to ascertain their needs for funds for projects designed to introduce new or improved contraceptives to existing family planning programmes. UNFPA should continue to make available country programme funds for projects to improve the existing capacity of developing countries to carry out their own biomedical research on contraceptives. In addition to its general contribution of \$2 million to the WHO/HRP for 1985, UNFPA should, within the limitations on funding intercountry activities and subject to availability of funds for individual country programmes, increase its assistance during 1985-1987 to contraceptive research, development, introduction and adaptation.

IV. RECOMMENDATIONS

20. The Executive Director recommends that the Governing Council:
- a) Approve the general principles in Part I, above;
 - b) Fix the level of UNFPA funding for WHO/HRP for 1985 at \$2 million;
 - c) Approve the strategy for increasing funding to contraceptive research through intercountry and country projects with the assistance of WHO, non-governmental organizations and national institutions of developing countries.

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