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WORKING PAPERS

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

Janet Nassim

This highly regarded organization is one of the few engaged in contraceptive research and development that focuses on the needs of the developing world. The Special Programme of Research, Development and Research Training in Human Reproduction (HRP) merits the Bank's continued and expanded support.

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This paper — a product of the Population, Health and Nutrition Division, Population and Human Resources Department — is part of a larger effort in PRE to provide information on activities in population, health, and nutrition assisted by the Bank under its Special Grants Program. Special Grants Programs support multi-country activities, complementing the Bank's direct lending operations. Copies are available free from the World Bank, 1818 H Street NW, Washington DC 20433. Please contact Otilia Nadora, room S6-065, extension 31019 (13 pages). October 1991.

The Special Programme of Research, Development and Research Training in Human Reproduction (HRP)— which began as a special program of the World Health Organization — is one of the few organizations engaged in contraceptive research and development that focuses on the needs of the developing world.

Nassim reviews the factors that led the World Bank to begin providing the organization with financial support in FY88 and examines the program's accomplishments and present direction.

Major evaluations of HRP strongly endorse the program, concluding that the program has had a major impact — the principal, if not the only impact, in many areas (such as coordinating world research efforts and developing new methods for regulating fertility).

The Bank's cosponsorship of HRP has strengthened the program's links with governments and facilitated its access to ministries outside the health field. The Bank's role is important to policy coordination and to sustaining donor commitment to the program.

The Bank's commitment of $2 million a year represents 10 percent of HRP's total funding. HRP has gained international respect, and its solid record of achievement justify the Bank's continued — and expanded — support.



Produced by the PRE Dissemination Center

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

by
Janet Nassim

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SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION (HRP)

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1. The Special Programme of Research, Development and Research Training in Human Reproduction is one of the few organizations engaged in contraceptive research and development that focusses on the needs of the developing world. Its scope has widened since its inception to include broader issues of reproductive health, and it has recently increased attention to developing national capacity to identify and address country needs. The establishment of a worldwide network of centers collaborating in research, simultaneously contributing to fertility research and institutional development; documentation of the risks and benefits of developing country use of the most widely available contraceptives; and the introduction of two new contraceptive methods, have been its main achievements to date. This paper provides a brief overview of the factors which led the World Bank to begin providing financial support in FY1988, and of the progam's accomplishments and present directions.

## BACKGROUND

2. HRP was established in 1972 as a Special Program of the World Health Organization (WHO) with a mandate "to promote, coordinate, support, conduct and evaluate research on human reproduction, with particular reference to the needs of developing countries". Funding came mainly from European donors and the United Nations Population Fund (UNFPA). The World Bank was involved in an advisory capacity.

3. The World Bank's decision to provide financial support to the program resulted from concern over adverse changes in the financial, political and legal environment of reproductive research in the 1980s. The grounds for concern were summed up by World Bank management in this way: "The combination of increased need and reduced prospects of an appropriate response to that need by the existing mechanisms amounts to a potential crisis that could, unless corrective action is taken, eventually threaten the effectiveness of population policies and the success of family planning programs in the developing countries. .... the present technological

base is inadequate to attract the hundreds of millions of new couples that must use contraception if fertility levels in developing countries are to be reduced to approximately those prevailing in most industrialized countries."[1] These conclusions were based on the following factors:

- declining funding for contraceptive research and development, (amounting to a 20 percent reduction in real terms between 1975 and 1983), mainly the result of industry withdrawal from the field due to product liability concerns, and dissatisfaction with the restrictive and prolonged regulatory approval process
- concern about the repercussions of the adverse developments in the U.S., the source at the time of 75 percent of worldwide funding. For example, the greatly increased cost of insurance following a successful liability suit against one company caused the withdrawal of all but one IUD from the U.S. market, a move that could be, and indeed was, interpreted in many parts of the world as a judgement on the safety of all IUDs, rather than as the commercial decision it was in most cases
- the need to develop a wider range of contraceptive methods, in particular those potentially more appropriate and acceptable to developing country users--for example, longer acting or cheaper methods, male methods, and methods less dependent on well developed health systems for their delivery
- the need for safe, effective methods, adequately tested under developing country conditions
- concern at rapid population growth and recognition that a wider range of contraceptive methods is generally associated with increased contraceptive use
- the need for an organization that could coordinate all the complex steps and different agencies involved in the process of bringing a contraceptive from the point of an idea, to use: the work of basic research; testing and development to the point of production; guiding the product through the trials necessary for regulatory approval; manufacturing and packaging the drug or device; marketing it, and finally, conducting post-marketing surveillance
- the need for leadership in the field from an organization which would receive widespread support, both financial and political, given the increasingly controversial nature of contraceptive research

4. HRP's emerging preeminence in the field, and, in particular, its emphasis on the needs of the developing world, made it the logical choice to lead a new international initiative. However, its status as a program within WHO and responsible only to it, aroused concern that it would not attract the necessary support. The Bank

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[1] Memo of October 14, 1986, from Mr. John North, Director, PHND, to Mr. Ernest Stern, SVPOP, through Mr. S. Shahid Husain VPOPS.

engaged in extensive discussions with other agencies of the U.N. system, with donor governments, and with many of the other organizations active in the field of international family planning and contraceptive research, and it was decided to restructure HRP along lines similar to the Tropical Diseases Research (TDR) Programme. Following this agreement, the World Bank joined with WHO, the United Nations Development Progamme (UNDP), and the United Nations Population Fund in becoming co-sponsors of the program, with WHO as the Executing Agency.

## PROGRAM ORGANIZATION

5. HRP carries out two inter-dependent types of operation in fulfilling its mandate: first, the coordination of a worldwide research and development effort in fertility regulation, and second, the strengthening of developing countries' national capacity and resources for research in reproductive health. The first type of operation is the responsibility of the Research and Development component of the Special Programme, the second the responsibility of the Resources for Research component. Administrative responsibility, with technical support, is vested in a Secretariat under the Director of the Programme. The program receives scientific review and evaluation from the Scientific And Technical Advisory Group (STAG), a committee of independent experts in the field of reproductive research. Policy is the responsibility of the Policy and Coordination Committee (PCC), the governing body of HRP. Its 32 members, most of whom represent developing country governments, meet at least once a year. The Bank is a member of the PCC, as are the other co-sponsors. A sub-group of this committee, the Standing Committee, comprised only of the co-sponsors, meets three to four times a year to provide more continuous program oversight and direction. This organizational structure is presented in Figure 1.

6. Research and Development. Research and development activities are conducted through Task Forces, each with a specific focus. The Task Forces change over time as different needs take priority. There are currently eight, (shown in Figure 1), each advised and directed by a Steering Committee. Their activities fall

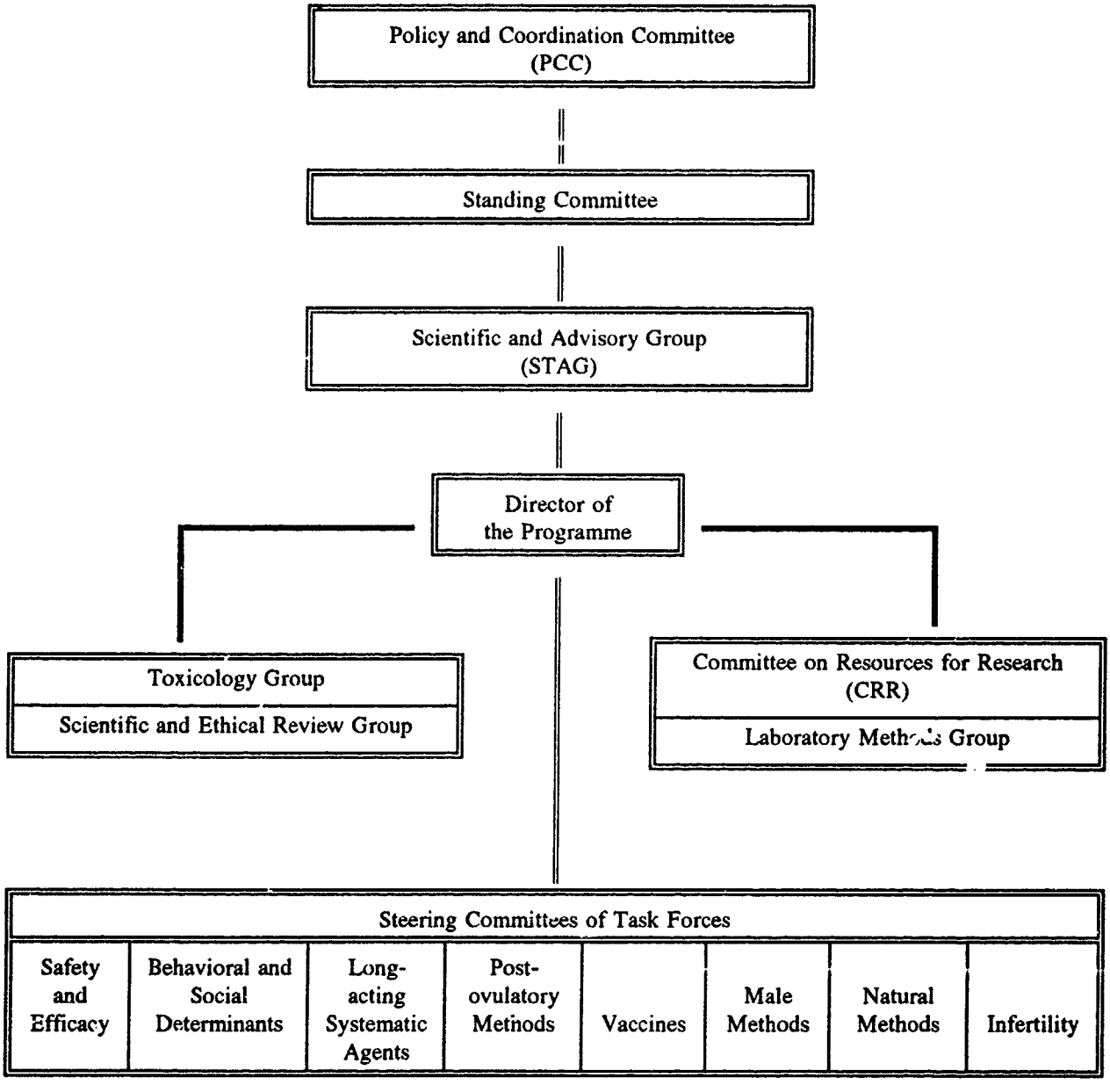


Figure 1. Governing and advisory bodies of the Programme.

Source: WHO. 1990. Research in Human Reproduction: Biennial Report 1988-89. Special Programme of Research, Development and Research Training in Human Reproduction, Geneva.

under the following main headings: evaluation of the safety and efficacy of existing methods of fertility regulation; development of new and improved methods, and research into the behavioral and social aspects of reproductive behavior, as well as investigation of the extent and causes of infertility.

7. In addition to the overall scientific direction provided by STAG, the research and development program is guided by scientific and technical review committees, and by experts called in for ad hoc consultations. The program makes a special effort to include scientists from developing countries and women scientists in all the advisory committees. Stringent ethical standards are set and promoted by the program - essential in work that often involves human subjects, and in the sensitive area of human reproduction research especially. The Scientific and Ethical Review Group provides an independent ethical and technical assessment of all Task Force projects, and research proposals. The Toxicology Group reviews projects involving the use of new drugs and devices in human subjects, and the Steering Committees review all projects in their Task Force area. All projects submitted to the program must show evidence of approval by institutional and national ethical review mechanisms. (This requirement has often led to the establishment and strengthening of these ethical review committees). In addition, projects which involve human subjects must be approved by a special WHO ethical reivew committee to ensure that such projects comply with WHO requirements.

8. Resources for Research. The strengthening of national research capabilities has two objectives: to involve developing country research institutions and scientists in the world-wide research effort; and to help countries address their own research needs. The Committee on Resources for Research oversees this program component, and individual program staff scientists have responsibility for managing and coordinating activities which are organized by geographic region.

9. Program Evaluation. The program has established procedures for internal and external evaluation. The scientific committees provide regular evaluations of program activities, and the STAG carries out periodic in-depth reviews of different program components. The Director-General of WHO submits progress reports on HRP to the

WHO Executive Board, and to the World Health Assembly. Three major external reviews of the program have taken place. The most recent, which focused on the program's impact in developing countries, is discussed in paragraph 22 below. This sytem of scientific, technical and ethical review has assured HRP's scientific quality and credibility.

## PROGRAM ACTIVITIES AND ACCOMPLISHMENTS

10. HRP has a substantial record of success. One of its greatest contributions has been its strengthening of the capacity of developing country institutions to participate in the research and development effort, by drawing them into a worldwide network of centers that collaborate in the work of the Task Forces. Centers participating in multicenter studies use standardized protocols and materials, with benefits to both the institution and the program--increased technical expertise in the country, and increased confidence in the results of program studies. There are now collaborating centers in 26 developed and 54 developing countries, a significant achievement.

11. In Research and Development, the program's emphasis on meeting the needs of the developing world has resulted in priority being given to evaluating the safety and performance of currently available methods which were, for the most part, developed and tested in industrialized settings, and, in the development of new methods, to research on methods at an advanced stage of development rather than those at an early or exploratory stage of investigation. In the area of reproductive behavior, increasing attention is being paid to maternal health and to sexually-transmitted disease--AIDS in particular. These latter issues are also becoming very important in the Resources for Research component where recently HRP has reoriented its efforts in order to be more responsive to developing country needs in reproductive health in general, while maintaining its activities in the field of fertility regulation.

Research and Development Activities

12. Safety and Efficacy. More women use contraceptives than any other category of drug or medical device, and many use them for long periods of time. It is, therefore, particularly important for information on the safety and side-effects of different contraceptives to be as complete and accurate as possible. Much of the existing information has been collected from the most developed countries. Relatively little has been obtained from less developed countries, even though the use of contraceptives in the developing world is increasing on a wide scale. In particular, not much is known about the safety of contraceptives when used by women with diseases which are endemic in developing countries, and whether results from studies conducted in developed countries are applicable to other parts of the world where patterns of disease may be very different.

13. An important achievement has been the publication of the first series of results from the large, multicenter study on oral contraceptive use and cancer. The results obtained do not differ markedly from earlier findings in North America and Europe, and confirm the safety of oral contraception for most women. Oral contraceptive use provides some protection against endometrial and ovarian cancer. There is a weak association with a somewhat elevated risk of breast cancer and cervical cancer but it is not determined whether the association is of a causal nature. No link was found between oral contraceptives and liver cancer in developing countries. Studies on cancer and the use of the injectable contraceptive depot-medroxyprogesterone acetate (DMPA), about to be published, have helped to quiet the understandable concern that had arisen over the use of this method of contraception in developing countries when the Food and Drug Administration had withheld approval for its use as a contraceptive in the United States.

14. Several other major multinational safety evaluations are underway. Among them are a 20-center, four-year study on how the use of low dose hormonal contraceptive pills affects the risk of cardiovascular disease. Priority is also being given to studies on: the interaction between different methods of contraception and iron-deficiency anemia--a very common condition among women of reproductive age in a large number of developing countries;

the safety of oral contraceptives for women who are chronic carriers of the hepatitis B virus; the safety of different contraceptives for nursing mothers; the long-term safety and efficacy of the widely used copper-containing intrauterine devices; improving the safety of sterilization procedures; the safety of the NORPLANT contraceptive implant, and the complex problems posed by contraception and HIV infection.

15. New and Improved Methods. Research into new methods of fertility regulation has concentrated on the development of methods critically needed in the developing world--long-acting systemic methods, vaccines, male methods and post-ovulatory methods. Great progress has been made with two female methods which have been brought to the stage of large-scale introduction. These methods are a once-a-month injectable, and a steroid-producing vaginal ring. In fact, two once-a-month injectable preparations have been produced, and both offer an alternative to the three-monthly injectables which, while proven to carry no major health risk, disrupt menstrual patterns in a way that makes them unacceptable to many women. A great deal of work has gone into the development of a birth-control vaccine, and early trials have proven so encouraging that a prototype vaccine is nearing the stage of trials with women volunteers. HRP has continued to assess the efficacy and safety of the new non-surgical approach to early pregnancy termination, involving the use of a combination regimen of an anti-progestin, mifepristone (often known as RU-486[2]), and a prostaglandin. Regulatory approval has been granted in France and Great Britain. Success with male methods is further away but some progress is being made. Promising results from the first clinical trial of male hormonal contraception have recently been published. A non-surgical and potentially reversible method of male sterilization is being pursued.

16. Infertility. HRP has been one of the foremost agencies investigating the causes and incidence of infertility. It has already established that infertility is a condition that affects some 35 to 70 million married couples around the world, and that a principal cause, particularly in women, is infection as a result of a sexually transmitted disease. Other causes are miscarriage and delivery in conditions of inadequate health care, and illegal abortion.

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[2] HRP's own research on RU-486, a substance which has attracted some controversy, accounts for 1.8% of the total HRP budget.

The causes in men are less well understood. HRP has recently started a multinational project to study the prevalence of past chlamydial and gonococcal diseases as a cause of male and female infertility. It is also promoting the development of a simple diagnostic kit for chlamydial infection, testing new and established barrier methods for the prevention of reinfection with STDs, and testing drugs effective in preventing transmission. In addition, it is supporting preliminary studies on the development of a vaccine against chlamydial infection.

17. Behavioral and Social Factors. HRP was one of the first, and remains one of the few, organizations to conduct research into the behavioral and social determinants of fertility regulation, exploring the attributes of methods that make them acceptable to users, and the processes by which users select, adopt and continue contraceptive use over time. Its studies have demonstrated the importance of providing a range of methods among which clients can choose, of counselling, and of continued contact between provider and client--all aspects of what have come to be called the "user-perspective". As the programme becomes increasingly involved with the introduction of new methods into family planning programs, such research becomes even more important.

18. Contraceptive Introduction. The introduction of the new contraceptive implant, NORPLANT, is a good example of HRP's involvement in the field. Once the contraceptive was developed by the Population Council, HRP coordinated with the Council and with Family Health International on its limited introduction in many countries and in post-marketing surveillance. A 20-center cohort study in 10 countries has been initiated to determine the medium- and long-term benefits or problems of NORPLANT use. No contraceptive compound has ever before been introduced with such care.

Resources for Research

19. HRP helps national authorities and institutions in developing countries to establish research infrastructure in the area of reproductive health, giving priority to developing epidemiological and social science capability. The

program concentrates its activities on a selected number of countries in which it can make a significant contribution. As institutions become more self-reliant, core support is gradually withdrawn and transferred to other countries, but many of the "graduate" organizations compete successfully not only for funding from the Task Forces, but from other agencies engaged in reproductive research. The original focus of the program was on individual institutions, but has recently shifted to building national capacity with the objective of identifying, and finding solutions to, locally prevalent problems in the broad field of reproductive health.

20. The Committee on Resources for Research makes recommendations on how to improve the developing countries' research resources. The main instrument for research-capability strengthening is the Long-Term Institutional Development Grant. This type of grant covers several dimensions of institutional development: technical assistance in the drawing up of a nationally relevant research program, strengthening of material resources, and developing human resources through Research Training Grants to individual scientists. Since 1986, 38 institutions in 29 developing countries have received long-term institutional development grants. Other grants are available to support scientists after their training abroad, to purchase equipment and supplies, to hold training courses and workshops, establish postgraduate degree programs and provide visits for exchange of experience.

21. Recently HRP carried out a survey of scientists and supporting staff who had received Research Training and Visiting Scientist Grants between the start of the program in 1972 and the year 1987. There were 954 such grantees, of whom 855 came from developing countries. The encouraging finding was that two-thirds of those for whom information was obtained (84%) were still engaged in research.

## FINANCIAL SUPPORT FOR HRP

22. Over the years HRP has attracted funds of well over $250 million. Table 1 shows the level of funding since its inception. (HRP became a Special Programme in 1972, but there was a pre-existing WHO program.) In the first two years of Bank financial support for the program, 23 governments and agencies (including WHO)

Table 1: Income for 1988-1989 and for the period 1970 to 1989 (in US$ thousands)

| Source of funds | 1988 | 1989 | 1970-1989 |
|---|---|---|---|
| Australia | 160.3 | 185.1 | 1,513.1 |
| Bangladesh | 5.0 | . | 5.0 |
| Canada | . | . | 3,401.9 |
| China | 50.0 | 50.0 | 400.0 |
| Cuba | . | 4.0 | 22.6 |
| Denmark | 2,268.3 | 2,083.4 | 19,211.0 |
| Family Health International (USA) | . | 205.0 | 205.0 |
| Finland | 230.5 | 251.3 | 1,797.8 |
| Ford Foundation (USA) | . | . | 1,000.0 |
| France | . | . | 6.5 |
| Germany, Fed. Rep. of | 1,339.4 | 719.4 | 6,288.1 |
| IDRC (Canada) | 233.9 | 302.2 | 516.5 |
| India | . | 79.3 | 456.0 |
| Italy | . | . | 259.8 |
| Kenya | . | . | 0.5 |
| Malaysia | . | . | 1.1 |
| Mexico | 3.0 | 3.0 | 66.0 |
| Netherlands | 392.7 | 343.6 | 2,407.7 |
| Nigeria | . | . | 51.2 |
| Norway | 1,923.1 | 1,965.1 | 32,736.6 |
| Pakistan | . | . | 5.0 |
| Rockefeller Foundation (USA) | . | 350.0 | 1,050.0 |
| Sweden | 2,548.2 | 2,280.7 | 80,692.5 |
| Switzerland | 283.3 | . | 577.5 |
| Thailand | 7.5 | 15.0 | 71.6 |
| United Kingdom | 5,966.5 | 3,573.7 | 34,838.1 |
| United States of America | . | . | 3,220.6 |
| USSR (in kind) | 46.3 | . | 46.3 |
| UNDP | . | 56.5 | 56.5 |
| UNFPA | 3,250.0 | 3,500.0 | 27,040.0 |
| WHO | . | . | 75.0 |
| World Bank | 3,000.0 | 2,000.0 | 5,008.3 |
| Miscellaneous | 33.3 | 1.0 | 36.0 |
| Interest | 449.0 | 661.3 | 9,412.4 |
| Handling change for reagents | 128.4 | 157.1 | 719.0 |
| Patents | . | . | 68.9 |
| Sub-total | 22,318.7 | 18,687.7 | 238,269.1 |
| WHO Regular Budget and Special Account | 649.1 | 649.1 | 8,825.0 |
| UNFPA funds for country and inter-country projects | 1,526.1 | 1,397.8 | 17,063.6 |
| Total income | 24,493.9* | 20,734.6 | 264,157.7 |

* Of which $21,434.0 relates to 1988 and $3,059.9 to 1987. The latter amount consists of two 1987 pledged contributions ($2,059,925 from the United Kingdom and $1.0 million from the World Bank) which arrived at the beginning of 1988 and therefore had to be taken up as 1988 income in WHO's Financial Report.

Source: See Fig. 1.

contributed, of which 6 were developing-country governments. The major bilateral donors are the U.K., Sweden, Denmark, Norway and Germany. The Bank's contribution provides general support to the program, whose outlays 1986-1989 are shown in Table 2. In FY89 and in FY90 the Bank contributed a further $1 million to WHO to support activities for AIDS research. Of this, $665,000 was used to finance activities agreed between the Global Program on AIDS (GPA) and HRP, and $335,000 went to activities agreed between GPA and TDR. The Bank's financial support of HRP, part of the Special Grants Program, is administered by the Population and Human Resources Department of PRE.

Table 2: Obligations during the biennia 1988-1989 and 1986-1987 by Programme Area (in US$ thousands)

| Programme Area | 1986-1987 | | 1988-1989 | |
|---|---|---|---|---|
| | Obligations | % | Obligations | % |
| Advisory Bodies | 272 | 0.7 | 471 | 1.1 |
| Research and Development | 18,169 | 50.2 | 22,104 | 51.0 |
| Resources for Research | 9,332 | 25.8 | 10,836 | 25.0 |
| Statistics and Data Processing | 2,143 | 5.9 | 2,348 | 5.4 |
| Programme Management | 2,997 | 8.3 | 3,922 | 9.1 |
| Collaborative Projects | 183 | 0.5 | 745 | 1.7 |
| UNFPA Country projects | 3,119 | 8.6 | 2,924 | 6.7 |
| Total | 36,215* | 100.0 | 43,350 | 100.0 |

* A sum of US$1,882,000 relating to Research and Development and Resources for Research was obligated only in early January 1988 due to the late arrival of two contributions pledged for 1987 (see footnote* on Table 1). This amount has been included under 1986-1987 in this table and in Table 3 to avoid distorting the trend of obligations.

## EXTERNAL EVALUATIONS

23. Three major external evaluations of HRP have been undertaken. The most recent took place in 1986 - 1988, and focused on HRP's impact, especially in developing countries. The Report concludes: "The Evaluation Team

is very positive towards the work of HRP and recognizes that the Programme has had a major impact. Indeed it has been the principal, if not the lone impact in many areas, e.g. the developent of new fertility regulation methods and its unique role of coordination of research efforts on a global scale." The Evaluation Report firmly recommends that HRP continue as a Special Programme within the U.N. system. Recent reports from two highly regarded bodies--the Commission on Health Research for Development, and a Committee of the U.S. National Research Council and the Institute of Medicine--gave the HRP strong endorsement.

## ROLE OF THE BANK

24. The Bank's co-sponsorship of HRP has strengthened the program's links with governments and facilitated its access to ministries outside the health field. The Bank's role is considered important in assisting policy coordination, and in helping to sustain donor commitment to the program. The Bank's contribution of $2 million a year represents 10% of HRP's total funding. Bank staff have played an active part on the Policy and Coordination Committee, the Standing Committee, and in the Behavioral and Social Determinants Task Force. Its policy, management, and technical advice and expertise have been important in providing program direction. The work of the program in developing new technology, establishing the safety and effectiveness of existing technology, studying broad areas of reproductive health concern--infertility, maternal health, and AIDS--and supporting the development of national research capacity complements the population and health work of the Bank in many ways. HRP has gained international respect, and by its solid record of achievement has justified the expectations placed on it when it became a co-sponsored program two years ago. It merits continued and expanded Bank support.

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