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AN EVALUATION OF THE
PROGRAM FOR APPLIED RESEARCH
ON FERTILITY REGULATION
AT NORTHWESTERN UNIVERSITY

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ABBREVIATIONS

AID	Agency for International Development
DHHS	Department of Health and Human Services
FR	Fertility Regulation
IFRP	International Fertility Research Program
IRB	Institutional Review Board
LDC	Less Developed Country
NICHD	National Institute of Child Health Development
NIH	National Institutes of Health
NU	Northwestern University
Ob/Gyn	Obstetrics/Gynecology
PARFR	Program for Applied Research on Fertility Regulation
RAC	Research Advisory Committee
RFFR	Frontiers in Fertility Regulation
SAC	Scientific Advisory Committee
WHO	World Health Organization

1. INTRODUCTION AND BACKGROUND

Purpose of the Evaluation

The purpose of the site visit was to evaluate the accomplishments, future directions, and functions of the Program for Applied Research on Fertility Regulation (PARFR), Northwestern University (NU), a component of AID's population research program.

Composition of the Team

The members of the evaluation team were:

- Samuel M. Mishik, M.D., Chairperson, Research Advisory Committee (RAC), AID
- D. J. Patanelli, Ph.D., Contraceptive Development Branch, National Institute of Child Health Development (NICHD), National Institutes of Health (NIH)
- Daniel R. Mishell, Jr., M.D., Chairperson, Obstetrics and Gynecology, University of Southern California

Approach and Methodology

The visit was made on December 2-4, 1980, and took place in the PARFR offices in Chicago, Illinois.

Participants from PARFR were:

- John J. Sciarra, M.D., Ph.D., Program Director
- Gerald I. Zatuchni, M.D., M.Sc., Director of Technical Assistance
- Alfredo Goldsmith, M.D., M.P.H., Head, Research Project Development
- Diane Krier Morrow, M.B.A., Director of Administration

The team met with two officials of the university to discuss PARFR's relationships within the framework of the university. The two officials were:

- David Mintzer, Ph.D., Vice President for Research; Dean of Science, Northwestern University
- Robin D. Powell, M.D., Associate Dean, Northwestern University Medical School

The team visited the laboratories of two universities, where four PARFR-supported projects are underway. The principal investigators who were visited were:

- Robert T. Chatterton, Ph.D., Northwestern University
- Lourens J. D. Zaneveld, D.V.M., Ph.D., University of Illinois

During their discussions with the team these investigators presented brief progress reports on their PARFR-funded research.

Project Background

The PARFR was established in 1972 at the University of Minnesota. It was moved to its current location at Northwestern University in 1975. Its cumulative funding totals \$9.6 million (to June 30, 1981). The PARFR was founded to pursue promising leads of goal-directed research to develop new or improved means of fertility control suitable for use in less developed countries (LDCs). One of its functions is to provide a flexible mechanism for modest support of researchers with promising new ideas.

Emphasis is to be given to methods that:

- do not require physician services;
- do not require frequent administration;
- do not require high levels of motivation;
- can be self-administered;
- can be effective for post-coital use or in hindsight; and
- can minimize supply and distribution problems.

The following research areas are given the highest priority for development by the PARFR:

- self-administered methods;
- long-acting female methods;
- male methods (non-surgical);
- female sterilization techniques;
- male sterilization techniques;
- intrauterine delivery systems; and
- contragestational methods.

The program has requested support for an additional five years. Its total budget request for that period is \$17,792,833.

II. SUMMARY OF THE EVALUATION

It is clear that the PARFR employs a staff with considerable expertise, dedication, enthusiasm, and commitment to the objectives of the program.

To date, 137 projects have been funded. Nearly all are preliminary studies designed to probe or explore topics of interest. (These research projects are grouped in the seven categories listed at the end of Chapter I.) For 34 of the projects which have sufficient promise, final preclinical or early clinical trials are planned. The majority of these more promising projects--approximately 80 percent--are unique to the PARFR. They are not being supported by any other grant agency. If after further development the fertility regulation methods prove to be effective, their use in developing countries should be considered.

The projects for which clinical tests are scheduled to begin fulfill the stated priorities of the PARFR. It has not been possible to develop projects on contraceptive methods that emphasize specific methods of delivery or use.

The range of approaches is broad, and there is a reasonable balance of contraceptive methods. There is no unnecessary duplication of projects supported by other funding agencies. Certain areas of fertility research have not been covered by the PARFR because they have been funded by other grant agencies (e.g., IFRP, WHO, and NIH).

The principal investigators for the two subcontracted projects in Chicago are competent. Staffing and laboratory facilities are adequate. The research designs and plans reflect consideration of the projects' objectives.

Clinical and Laboratory Research

The PARFR is attempting to conduct as much as possible clinical and laboratory research in LDCs. Twenty-one projects have been initiated in 10 countries. Because most projects are about to begin clinical trials, investigators in LDCs are planning to do more investigative work.

PARFR staff have visited many sites for proposed clinical tests in LDCs. AID's restrictions, political problems, and investigators' commitments to other agencies such as the WHO have created difficulties in certain countries.

Subcontracts

Initially, a widespread request for proposals for subcontracts was issued. One-year subcontracts are being awarded now for existing projects for which actual trials in the field may begin in the near future. The projects vary in size. Funding for one year appears to be appropriate although the investigators are constrained, more so because clinical trials are being planned.

The Scientific Advisory Committee

The composition of the Scientific Advisory Committee (SAC), the tenure of SAC members, and the mechanism for decisionmaking have been cause for serious concern. Each member of the SAC has a good scientific background; however, considered as a whole, the committee has a disproportionate number of ob/gyn clinicians. Considering the current range of topics, there is a lack of expertise in certain areas and a consequent lack of competent advice on all proposals. For example, there is no pharmacologist, polymer chemist, or toxicologist on the SAC. Few of the members have experience performing clinical trials of drugs. No statistician or epidemiologist is on the committee. However, consultants in different fields have been used for ad hoc projects.

In view of the composition of the committee, there may be a conflict of interest. The director of the program is also the chairperson and a voting member of the SAC. Several members of the SAC have received or are now receiving funds from the PARFR--a cause for concern, even though these members excuse themselves from the room when their projects are being discussed and abstain from voting.

The frequency of meetings (three times per year) appears to be appropriate, although the one-day agenda is crowded and there may not always be sufficient time for adequate review. The projects appear to be monitored quite well by PARFR staff who visit each project at least once a year. The entire SAC formally reviews each project at least once a year. The principal investigator submits progress reports semi-annually or more frequently.

The ethical aspects of all proposals are fully covered and the subjects' rights appear to be well protected. Informed consents are included in all proposals involving human subjects. These consent forms conform to the guidelines of the Department of Health and Human Services (DHHS). Each project must be approved by its own institutional review board (IRB), and by the IRB of Northwestern University--an apparently redundant and therefore unnecessary requirement for U.S. institutions that have the general assurance of the DHHS.

PARFR's Relationships with Other Agencies

The relationship between the AID project officer and PARFR appears to be good at this time. The evaluation team was unable to fully explore the method AID used to monitor the program. It seems that the one program officer has most of the responsibility and makes most of the decisions. Staff of the PARFR seem to have good relationships with other funding agencies, such as the IFRP, NICHD (CPR), WHO, and the Population Council (ICCR). In the past, these organizations held annual meetings. Meetings now are scheduled biennially. Contacts during the year are frequent, and administrators of the programs meet informally at scientific meetings. There appears to be little overlap in the projects funded by the PARFR and other agencies. The PARFR and the IFRP have established an excellent, co-operative relationship that is of particular interest and importance. The PARFR institutes Phase I and Phase II clinical tests. If these are successful, Phase III testing is taken over by the IFRP. This division of responsibility allows the two agencies to use their respective expertise and funds without duplicating each other's effort.

Publications

Despite its small staff, the PARFR has undertaken a monumental effort to publish information on the development and status of methods of fertility regulation. Particular emphasis is given to methods in PARFR projects. In addition, the PARFR sponsors international workshops at frequent intervals and publishes the proceedings of those workshops rapidly in excellent format. However, distribution to workers in the field in the U.S. and abroad is limited.

PARFR's newest publication, Research Frontiers in Fertility Regulation (RFFR) is particularly valuable; it contains current reviews of various fertility regulation methods that are written by authorities in the field. These reports supplement existing publications and provide new, and previously unavailable, information.

Staffing and Location

PARFR staff are highly motivated and well organized. The size of the staff is small. Some positions are vacant and additional staff are urgently needed.

The space available to staff is small, given the size of the operation, but the location is good; it allows the director of the project, the chair-

person of Ob/Gyn at Northwestern, to spend sufficient time with the administrative staff. Furthermore, affiliation with the university lends prestige to the entire project. University officials have expressed their full support to the project. The hospital now rents space to the PARFR for a modest fee. This has resulted in considerable savings to the PARFR, for indirect costs to the university are calculated at the lower off-campus rate.

Funding

In the opinion of the evaluation team, the PARFR has the capacity to use effectively the funds it has requested for the next five years. If funding were to be curtailed, some promising and worthwhile projects would have to be terminated. The team believes that all the projects that have been proposed are worthy of further study and could result in the development of useful methods of fertility regulation that could supplant or augment existing methods. If full support to develop these new methods is awarded, more administrative staff could be hired and additional office space could be acquired.

III. RECOMMENDATIONS

The team highly recommends that this program be continued. In addition, it recommends the following action:

1. Funding should be provided in the full amount requested in the proposal and support should be ensured for five years. With this funding, the PARFR and the subcontractors will be able to continue their work and improve their planning.
2. The term of SAC members should be limited to three years. No member should serve consecutive terms. There should be an interval of at least two years.
3. New SAC members should not receive funds from the PARFR at the time of appointment.
4. Incumbent SAC members should not be eligible for new contracts while serving on the committee.
5. To broaden areas of expertise, statisticians, epidemiologists, toxicologists, pharmacologists, and individuals who have performed clinical trials of contraceptive agents should be appointed to the SAC.
6. The chairperson of the SAC should not be an administrative member of the PARFR.
7. The number of PARFR staff should be increased. The recruitment of persons with expertise in clinical trials should be emphasized.
8. Additional space should be added to the present quarters. Additional secretarial help should be hired.
9. Significant information on ongoing research should be published more frequently in peer review journals. The proceedings of workshops should be published in Index Medicus and other reference organs.
10. Reviews and reports on developments in contraceptive technology should be published periodically in recognized journals to improve the dissemination of information to workers in the field.
11. If funding at the requested level cannot be provided, the most advanced projects and projects about to begin clinical trials should be continued. Less advanced projects should not be renewed.
12. The PARFR should continue to encourage private industry to support certain promising leads.

13. A site visit and review should be made two years from now to evaluate the progress of initial clinical trials. Subsequent site visits and reviews should be considered every three years.