

Introduction

Since the inception of this grant, 18 sub-projects have been developed and implemented. Seven sub-projects have been completed. Eleven sub-projects were active during fiscal year 1975, and detailed progress reports on these projects are attached to this report.

Because of financial restrictions in A.I.D. as well as uncertainties regarding the continuation of this granting mechanism by A.I.D., no new sub-projects were funded under this grant during fiscal year 1975. These financial constraints and policy uncertainties, however, did not deter the faculty from moving ahead with project development activities. In fact, as will be outlined below, more than one dozen projects moved through various stages of development during fiscal year 1975; five have been funded through other A.I.D. funding mechanisms or through other agencies. Four are currently being implemented; one in Lebanon has been postponed because of political conditions. Four proposals are still in the development stage or have been formally submitted to funding agencies for consideration.

Two proposals that were developed over a period of one year for consideration for funding under this grant, one for a project in Indonesia, a second for continuation of advisory services in Turkey, have died because of lack of project funds under this grant and other administrative difficulties and policy considerations.

Summary of Active Sub-projects

Detailed descriptions of the eleven currently active sub-projects under this grant are appended to this report. A brief description of the sub-projects, classified within the framework of the grant objectives, is given below.

Techniques of Fertility Regulation

There are four sub-projects directly related to developing new techniques for fertility regulation. These are:

1. Investigation of Danazol as a Contraceptive Agent by Anne C. Wentz and Georgeanna Seegar Jones.
2. Investigation of Androgen Implants in Suppressing Spermatogenesis, by Larry Ewing.
3. Clinical Trials of the Falope-Ring Laparoscopic sterilization Techniques, by InBae Yoon and Theodore M. King.
4. Clinical Studies of Thyrotrophin Releasing Hormones in Prolonging Postpartum Infertility, by John Tyson.

Among the above projects, progress in developing the Falope-Ring Laparoscopic sterilization procedure for wider general use is moving ahead very well. Over the past two years, more than 600 sterilizations have been carried out by Hopkins utilizing this procedure. The rates of complications and failure are quite low. With the possible added advantage of being more easily reversible, this technique appears to have considerable promise for female sterilization. A proposal for a wider study of this technique by collaborating investigators throughout the world has been developed and submitted for consideration by A.I.D.

The investigations by Dr. Tyson, utilizing thyrotrophin releasing hormones taken orally in lactating women to enhance milk production and prolong postpartum amenorrhoea, are moving ahead very well. The investigations in Chile indicate that TRH given orally twice a day not only augmented lactation and resulted in greater weight gain for the breastfeeding children, but also apparently prolonged the period of natural infertility. Based on these studies, a proposal to extend this investigation in rural Bangladesh is currently being developed. This line of investigation appears to be particularly promising since there is a possibility of TRH being used as a first stage in contraception among breastfeeding women to both improve infant nutrition and assure birth spacing.

Improvement of Family Planning Services Delivery Systems

There are three projects under this category, two in Bangladesh and one in Taiwan. These are:

1. Clinical and Epidemiological Studies of ^{Post-partum} Fertility Control Techniques by W. H. Mosley and Atiqur Rahman Khan.
2. Field Studies of Contraceptive Techniques in Rural Bangladesh, by W. H. Mosley and Atiqur Rahman Khan.
3. Distributing Contraceptive Supplies to Encourage Family Planning Practice in Taiwan, by L. P. Chow.

These studies in Bangladesh are designed to determine the effectiveness and acceptability of various modern contraceptive techniques in the Bangladesh population. Of particular concern is the effects of the estrogen containing pills on lactational patterns in breastfeeding women. In addition, the project is undertaking detailed field investigations of new contraceptive innovations as they are introduced, including the use of the long-acting injectible progesterones and the use of paramedics to do tubectomies in the rural areas. Data from this research will form the basis for recommendations for use of various contraceptives in the national program in Bangladesh.

Dr. Chow's project in Taiwan is the first indepth investigation of the hypothesis that simply making contraceptive supplies available by delivering them house-to-house will result in many women beginning to practice family planning with relatively limited motivational effort. This study is being carried out in two groups of women; in six townships, women

are being contacted in the first three months postpartum; in six other townships, all women are being contacted. This study has found, in both areas, that this house-to-house approach has received favorable initial response and relatively high acceptance rates. The results are encouraging in indicating that this approach can have a significant impact. Further study is required to determine what the continuation rates will be and whether or not more visits are required to reinforce and encourage continuation of use.

Strengthening of Institutional Capabilities in Less Developed Countries

There was one project under this category which was completed this year. This is:

1. Development of a Project Development Bureau for the General Directorate of Population Planning, Turkey, by W. H. Mosley.

This project had a dual role of assisting the General Directorate of Population Planning in developing a variety of programs and projects to strengthen their family planning services. At the same time, a major component of the project was staff development so that the General Directorate of Population Planning would have its own leadership capability for program operations in the future. The sub-project under this grant terminated in June 1975, and a request for extension of Hopkins advisory services was not approved for funding by A.I.D. Fortunately, Hopkins has been able to continue its program of both project development and staff development through grants obtained through other funding agencies. One of these is a grant from the UNFPA which is providing a training program for five members of the General Directorate. This program is being coordinated by Johns Hopkins. A second is a grant from the Pathfinder Fund to initiate a pilot project which will provide the basis for a major contraceptive distribution program in Turkey. Thus, although the attached report regarding the Project Development Bureau represents the termination of this sub-project under this grant, it does not represent the termination of this effort by Johns Hopkins.

Analysis of the Interrelationships of Economic, Social and Demographic Variables

There is one project under this category. This is:

1. Pilot Studies on Population Dynamics and Maternal and Child Health in Rural Ethiopia, by L. P. Chow.

The purpose of this project is to develop a population laboratory in rural Ethiopia for health and population planning services. One element of this has been training the faculty and students in Haile Sellassie I University regarding their needs for health and family planning services in rural Ethiopia. Family planning remains a rather sensitive topic in Ethiopia, and the purpose of this project is to promote awareness among the leaders to these problems and to indicate to them the felt need for these services by the people in the rural areas. As Dr. Chow notes in his report, the results of this project are coming out at a time when Ethiopia

is moving towards a more positive view regarding family planning. Thus, the data being generated will be valuable to Haile Sellassie University in providing a scientific foundation for a proposed policy shift.

Evaluation Methodology and Its Application

There are two projects involving data analyses by investigators in Baltimore. These projects, involving data from Taiwan, Pakistan, and Bangladesh, have direct relevance to program development in these countries. These projects are:

1. Analysis of Data from the Study on the Epidemiology of Outcome of Pregnancy In Taiwan, by Rowland Rider and L. P. Chow.

2. Survey Methods in Family Planning Research and Evaluation in Pakistan and Bangladesh, by Ismail Sirageldin.

Dr. Chow's studies have been particularly valuable in defining more clearly the prevalence and trends of abortion in Taiwan. A multiplicity of approaches have been used to obtain this sensitive data. For example, five different approaches were studied to get information on abortions from obstetricians and gynecologists. The best methods suggested that the abortions to livebirths ratio for 1973 was somewhere between 59 per 100 to 74 per 100. These results were much higher than previous estimates done in 1967 which give a ratio of 18 per 100. The methodological studies conducted in Taiwan will have wide application for other countries seeking to define the magnitude of induced abortions. Another significant aspect of this study was the observation that women who had not been contracepting prior to an abortion tend to remain non-contraceptors after the abortion. From this finding, a proposal for a special post-abortion contraceptive program has been developed. All of the data from these studies have been made available to the Government of Taiwan for their consideration in reforming the existing abortion laws.

Project Development Activities in Fiscal Year 1975

In reviewing project development activities under this grant in Fiscal Year 1975, it should be recognized that these efforts were undertaken in spite of the fact that the prospects for this granting mechanism being continued were in doubt throughout much of the year. Specifically, because of these fiscal uncertainties, although project development efforts were extensive, as will be noted below, no sub-projects were funded under this grant mechanism. The obvious reason for this was insufficient funds from A.I.D. to allocate to this grant. Clearly, it did not reflect insufficient funds from A.I.D. for project funding, since, in fact, three projects developed under this grant have, indeed, been funded by A.I.D. through other granting mechanisms.

The specific project development efforts in Fiscal Year 1975 will be described according to the developing country that is involved.

Indonesia

The major project development activity in Indonesia was a continuation in FY 1975 of efforts to establish institutional development project with

the University of Medan in North Sumatra. Negotiations for this project began in 1972 and were most extensive during FY 1974 when three faculty members spent five man-months in Indonesia developing a detailed proposal.

Negotiations continued during FY 1975 with additional trips by Dr. Stanley Reedy who was a proposed resident advisor. In spite of rather heroic efforts, including multiple budget revisions, the proposal finally collapsed because of what became referred to an exchange of correspondence as a "catch 22" situation whereby the Mission could not extend full support to the project without support from Washington, and Washington could not give support without a clear indication of priority from the Mission. Johns Hopkins was unable to keep Dr. Reedy, the proposed advisor with long experience in Indonesia and language capability, waiting indefinitely for this situation to clarify. When Dr. Reedy finally accepted a position elsewhere after waiting two years for the project to materialize, Johns Hopkins withdrew the proposal because of the inability to assure that a highly qualified faculty advisor could participate in the project.

Turkey

Four major project development efforts were undertaken in Turkey during FY 1975. First, there was a proposal to continue and expand the Hopkins advisory services as the Turkish program moved from project development to project implementation by establishing an office of program management. This proposal was discussed at length with A.I.D., but because of uncertainties of funding under the USA grant, as well as administrative difficulties with the proposal and political problems related to Turkey, the project was never moved forward.

A second project related to continuation of staff development for the Directorate of Population Planning by providing foreign training for five of the personnel. This project was developed and submitted to the UNFPA which provided the funding. In January 1975, three members of the General Directorate of Population Planning, -the Acting General Director, the Director of Training, and the Director of Administration, -came to the United States for six months of language training and then 12 months of academic and technical training relating to program organization and management. This training program is being coordinated by Johns Hopkins.

A third major project that Johns Hopkins was involved in, through the resident advisor, was assistance to the General Directorate of Population Planning in developing a proposal for a national contraceptive distribution program through the village midwives. This was a five year national program requiring a total funding of over 14 million dollars. The proposal was formally submitted to A.I.D. for commodity assistance; however, political factors have deferred further action on this proposal. Currently it is under re-consideration by the General Directorate for submission to the UNFPA.

In conjunction with the national contraceptive distribution project, Dr. Jeanne Newman from the faculty went to Turkey and assisted Mr. Robert Bertera, a UOPI intern, and the resident advisor in developing a data

system for a pilot project to train village midwives in the delivery of family planning services. Because of lack of funds under University Services Agreement, this pilot project was submitted directly to the Pathfinder Fund and has been funded and is being implemented. In this project, the training materials, training methods, supervisory program, and data systems will be worked out for the national contraceptive program.

Taiwan

The initial contraceptive distribution project in Taiwan is proving to be quite successful; however, it is becoming apparent that the duration of the project is quite limited in terms of answering questions about the continuation of contraceptive use or the demographic impact. On this basis, a new project proposal has been developed to extend the studies of the contraceptive distribution project to particularly answer questions relating to the demographic impact, as well as the need for various levels of followup and motivation to get the maximum recruitment and continuation of contraceptive use.

Because the analyses of the data from the Taiwan Outcome of Pregnancy Study reveal that most women who had not been contracepting prior to an abortion tended to remain non-contraceptors after abortion, a specific project proposal has been developed to tackle this problem. This proposal, titled "Post-abortion Contraceptive Innundation Program," will prescribe a strategy of offering contraceptive services to women immediately after an abortion. Because of the high abortion ratio in Taiwan, it would appear that such a post-abortion strategy could have at least as much effect as the postpartum strategy commonly used in family planning programs. The experience in Taiwan with such an approach would be very relevant in other countries where there are high abortion ratios, including Turkey, Egypt, as well as many of the Latin American countries.

Bangladesh

Four proposals have been developed for Bangladesh, two of which are funded and in operation, one which is before a funding agency, and one which is still in the preparatory stage.

The major project development effort in FY 1975 was a proposal to study the effectiveness of a house-to-house contraceptive distribution program in the Matlab research area operated by the Cholera Research Laboratory. This proposal was initiated by Dr. Mosley in a project development trip in November 1974. As enthusiasm for this project was being generated at the Cholera Research Laboratory and negotiations began to move ahead, it became clear that this project would not be funded under the University Services Agreement for a variety of reasons. A primary factor was that the cost of the project was beyond the funds available under the USA grant. Additionally, the prospects of any project being funded under the grant during FY 1975 appeared quite remote. On this basis, a proposal was prepared which was submitted directly by the Cholera Laboratory to A.I.D. This proposal was funded in June 1975, and the project is under way.

Johns Hopkins is participating in supporting this project, particularly through assisting the Cholera Laboratory in setting up a system for managing the demographic data, as well as other data analyses required for the contraceptive distribution project. In February 1975, Dr. Jack Eblen, a Research Associate from Johns Hopkins, went to Bangladesh to provide direct assistance in analyses of the demographic data. Subsequently, in May 1975, Ms. Helen Hiltabidle, a programmer, spent six weeks in developing a system to assist the Cholera Laboratory in handling the demographic data, as well as the data requirements for the contraceptive distribution project.

Because of the extensive cost of analyzing the data as well as of setting up a data management system which could not be covered under the limited budget of the contraceptive distribution project, a collaborative project proposal was developed by Hopkins and the Cholera Lab to cover the cost of data analysis and data management. Because of the prospect that funds would not be available under the University Services Agreement for this activity, this proposal has been submitted to the NIH for funding.

A third project proposal in Bangladesh has evolved out of the interest of the Cholera Laboratory in conducting more basic research into the factors affecting reproductive performance in Bangali women, particularly the relationship of nutrition and breastfeeding to birth spacing. To pursue this important research question, the Cholera Lab's research program was augmented with a research proposal by Ms. Sandra Huffman, a graduate student in the Department of Population Dynamics, who was sent to Dacca as a UOPI intern. This combined project proposal to study the biological determinants of fertility has been funded for the first year by the Cholera Research Laboratory and is currently being implemented. The plan for long term funding is that it may be expanded into a collaborative project involving the Cholera Laboratory and investigators in several institutions in the United States, with a search for funding probably with the National Institutes of Health.

The fourth project proposal in Bangladesh involved a larger scale field trial of the use of thyrotropin releasing hormone as an agent to enhance lactation and prolong lactational amenorrhea. Dr. John Tyson, in the Department of Obstetrics and Gynecology, has developed a collaborative proposal with Dr. Mosley and Dr. George Curlin at the Cholera Research Laboratory which would involve the field testing of this drug on approximately 400 lactating women. A preliminary draft proposal has been submitted to A.I.D. The final proposal will most likely not be funded under the University Services Agreement because the cost would exceed the funding limitations under this grant. It should be noted that this proposal will be a logical extension of the basic research on determinants of nutrition in fertility that is currently underway by Ms. Huffman and other members of the research team at the Cholera Research Laboratory.

Lebanon

In the Spring of 1975, Ms. Juliette Sayegh, a faculty member at the American University of Beirut, completed her doctorate degree in the Department of Population Dynamics. Her thesis involved the implementation

of a postpartum education program in Lebanon. Out of this thesis, a broad based project proposal was developed to survey the maternity services in Lebanon, provide training services for the staff, and commodities to initiate a national postpartum contraceptive program. Because of lack of funds under the University Services Agreement, this proposal was submitted to the Pathfinder Fund where it was received with enthusiasm and an award for a three year project was made.

Ultimately, because of the political situation in Lebanon, this proposal has had to be withdrawn. Dr. Sayegh will be staying on the faculty at Johns Hopkins to explore the possibility of implementing a project of this nature in Syria, Jordan or one of the other Mid-Eastern countries. Funds for her exploratory trips for extended project development have been provided, both by the International Development Research Corporation in Canada and by the Pathfinder Fund.

Philippines

In January 1975, Dr. Eblen went to the Philippines to initiate exploratory discussions for collaborative projects with the Development Academy of the Philippines. This is a semiautonomous organization specifically devoted to national development. Following the discussions, Dr. Mosley went to the Philippines in the summer of 1975 and drew up a formal agreement to develop joint project proposals. These proposals will directly relate to the delivery of family planning services, particularly by paraprofessionals in the rural areas. It is anticipated that a staff member of the DAP will be visiting Johns Hopkins this Fall to draft tentative proposals for submission to A.I.D.

A second project proposal in the Philippines was developed in collaboration with Dr. Trinidad Osteria of the Institute of Public Health. Dr. Osteria has undertaken a prospective study of a large group of postpartum women in Manila some of whom began oral contraceptives and accepted intra-uterine devices. Preliminary analysis of her data suggested that the oral contraceptives had a marked effect in suppressing lactation. Further, there is evidence that women accepting oral contraceptives discontinued use rather quickly and subsequently had pregnancies at about the same pace as non-contracepting women.

Because the observations of Dr. Osteria have tremendous relevance to the Philippines national program, a small project proposal was prepared to analyze this data in more detail. This proposal was initially submitted to the IDRC in Canada but was rejected. It has been revised and submitted to A.I.D. for funding under the University Services Agreement.

Budget Summary

The budget summary for FY 1975 is shown on Table 1. It will be noted that although the estimated expenditures were \$138,019, the actual expenditures for the fiscal year were \$113,672.

Also noted on Table 1 is a brief summary of funds available for the life of the project and expenditures through fiscal year 1975. Of note is the fact that by the end of fiscal year 1975 a balance of \$61,785 remains.

November 30, 1975. A detailed budget proposal regarding this obligation of the funds has been submitted separately to A.I.D.

Effective November 30, all funds on the original grant will have been expended. A detailed proposal for a new grant to be funded effective December 1, 1975, to continue core support has been submitted separately to A.I.D.

Future Programs

As this annual report has indicated, the faculty of Johns Hopkins University has continued to pursue a vigorous program of project development in spite of the funding restrictions and uncertainties of the University Services Agreement. Such efforts will continue with funding mechanisms sought wherever possible in order to get the job done.

It has become apparent in the past year that, while core funds for travel and project development support are exceedingly important, the restrictions on sub-project funds may make it more appropriate to seek actual support for project implementation from other A.I.D. funding mechanisms or from other agencies. We anticipate continuing to seek and utilize these other mechanisms for project support whenever appropriate and feasible.

With regard to the general thrust of project development efforts in fiscal year 1976, several directions seem quite clear. First, the faculty are gaining increasing experience with projects relating to the house-to-house distribution of contraceptives. The project in Taiwan has now been going on for more than two years, and a similar project has been initiated in Bangladesh. Currently, the implementation of a house-to-house contraceptive distribution project in Thailand is being actively explored by Dr. Rowland Rider.

We feel that, with the experience and expertise that Johns Hopkins is gaining in this innovative approach to contraceptive delivery, and particularly with the clear definition of programmatic issues that are evolving out of this experience, Hopkins could serve as a center for coordinating international research efforts in this area. Currently, this concept is being explored with A.I.D.

A second thrust of project development will be to explore the possibility of initiating family planning efforts in the Middle Eastern countries. As noted above, one project proposal for introducing family planning in the maternity hospitals in Lebanon was actually approved and funded by Pathfinder but subsequently was withdrawn because of political considerations. Dr. Juliette Sayegh has joined the faculty and will be undertaking an extensive project development tour in Lebanon, Egypt, Jordan, Syria, and Iraq under the auspices of the IDRC and the Pathfinder Fund. Her trip to Syria will be coordinated with recent exploratory investigations by the Health Division of A.I.D. It is anticipated that out of this effort collaborative projects, most likely integrating family planning into the health or MCH system, will be developed for some of these Middle Eastern countries.

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A third major programmatic interest relevant to this grant is the further study of human reproduction in the developing world with a particular focus on the interactions of lactation and nutrition and the development of contraceptives that are appropriate to traditional populations. In this context, as noted above, the project undertaking contraceptive field studies in rural Bangladesh is specifically examining the interactions of oral contraceptives and their effect on lactation. Further, Ms. Sandra Huffman, a graduate student, is initiating basic studies on the interrelationships of maternal malnutrition, lactation, and lactational amenorrhea.

A major new project that is in the final stages of development related to these issues is the field testing of thyrotropin releasing hormones in a group of women in rural Bangladesh. This project, which is a collaborative effort of the Department of Gynecology and Obstetrics and the Department of Population Dynamics and the Cholera Research Laboratory in Bangladesh, has the promise of leading to a contraceptive that would be most appropriate in rural traditional populations where long breast-feeding is a universal practice. It should be noted that, because of the funding restrictions under the University Services Agreement, this project proposal will probably not be submitted directly under this grant.

Table 1

Core Expenditures
 University Services Agreement
 Fiscal Year 1975

	<u>Estimated</u>	<u>Actual</u>
Personnel:		
Professional	\$53,500	\$46,348
Administrative	15,455	22,500
Fringe	<u>10,343</u>	<u>10,117</u>
Sub-total	79,298	78,965
Travel:	9,500	10,387
Other:		
Supplies)		
Program Sup.)	<u>11,216</u>	<u>1,462</u>
Total Direct	100,014	90,814
Indirect	<u>38,005</u>	<u>22,858</u>
	138,019	113,672
Funds obligated for life of project (core)		443,461
6/30/75 - Expended to date		<u>381,676</u>
Balance available to 11/30/75		\$ 61,785

JOHNS HOPKINS UNIVERSITY POPULATION CENTER
 FINANCIAL REPORTS SUB-PROJECTS
 UNIVERSITY SERVICES AGREEMENT AID/cod - 2956

As of June 30, 1975

JHU Budget no.	Title	Principal Investigator	Amount	Date Approved	Expended	Expended	Expended	Expended	Cumulative Expended	Balance Unexpended	Remarks
					7/1/74 9/30/74	10/1/74 12/31/74	1/1/75 3/31/75	4/1/75 6/30/75			
H.55.5003 CORE	CORE Support	W. H. Mosley	443,461.	6/30/71	30673.57	27259.03	25197.89	30621.26	381676.00	61785.00	
H.14.5009 72/3	Trisil Silastic Band.	I. B. Yoon	123,451.	5/31/72	19019.84	18590.52	15461.93	8175.03	123451.00	---	Complete
H.32.5031 73/2	Pop. Dynamics, MCH in Ethiopia.	L. P. Chow	149,978.	1/1/73	19561.67	7483.00	5179.76	15251.91	99535.15	50442.85	
H.32.5033 73/4	Androgen Implants	L. Ewing	48,925.	4/27/73	4063.36	8594.59	4232.53	4142.27	53067.27	(4142.27)	Complete
H.32.5032 73/5	Proj. Dev. Bureau Turkey.	W. H. Mosley	301,626.	3/29/73	35961.56	27780.99	30970.83	45714.45	266863.55	34762.45	Complete
H.32.5034 73/6	Add'l Anal's Taiwan Data on abortion.	R. V. Ridor L. P. Chow	79,166.	5/15/73	9689.82	10120.20	9703.99	10394.98	79166.00	---	Complete
H.32.5035 73/7	Dist. Contra. Taiwan	L. P. Chow	149,710.	6/25/73	7455.68	5858.03	6408.01	9669.10	55386.50	94323.50	
H.32.5036 73/8	Survey Meth. in F.P. Res. Evaluation.	I. Sirageldin	98,373.	6/30/73	11177.24	12517.32	17890.84	20103.38	96012.44	2360.56	Complete
H.14.5016 74/1	Danazol as contraceptive agent.	A. C. Wentz	49,974.	6/20/74	6585.26	8426.99	6337.44	22332.97	43682.66	6291.34	Complete
H.14.5016 74/2	Prolongation Post-partum Infertility.	J. E. Tyson	100,000.	6/30/74	2898.00	8503.00	21305.00	25504.44	58410.44	41789.56	
H.32.5037 74/3	Clin.-Epid. Study Dacca.	W. H. Mosley	148,864.	6/28/74	6076.34	10192.56	9651.08	8214.71	34134.69	114729.31	
H.32.5039 74/4	Field Studies Contraceptives Bangladesh	W. H. Mosley	148,393.	6/29/74	5721.55	8259.02	12252.40	8964.54	35197.51	113193.49	