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NORPLANT® INTRODUCTORY PROGRAM IN EGYPT

Implementation Plan

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NORPLANT® INTRODUCTORY PROGRAM IN EGYPT THE IMPLEMENTATION PLAN

1.0 BACKGROUND

NORPLANT®, a subdermal contraceptive implant containing the synthetic progestin levonorgestrel, will be introduced in Egypt over 5 years starting April 1994. The introduction of NORPLANT® follows successful clinical trials conducted in Egypt.

There have been two sets of pre-introductory, or clinical trials of NORPLANT® implants in Egypt. The first was supported by the Rockefeller Foundation and the Population Council in the early 1980s. The second clinical trial began in 1988 under the coordination of the Egyptian Fertility Care Society (EFCS), with support by the United States Agency for International Development and technical assistance from Family Health International. Physicians from five University Hospitals in Egypt (Alexandria, Assuit, Ain Shams, Mansoura, and Al Azhar) have provided NORPLANT® implants to 1,537 women during 1988 - 1990. There have not been any new insertions since the closing of the clinical trials enrollment in 1990. Follow-up of NORPLANT® clients and removal of the implants upon the request of the client or their expiration is on-going in each of the five clinical trial sites.

The Egyptian Clinical Trials have gone very well by all accounts. An acceptability study (Hassan, et.al, 1992) indicated that 93 percent of the NORPLANT® clients surveyed were satisfied with the method. "The major advantages were NORPLANT®'s long duration, its ease of use, that it produced less side-effects than the pill or IUD, that insertion was in the arm rather than in the genital area, and its effectiveness in preventing pregnancy." (Hassan, et.al., 1992). Continuation rates of the 1988 Clinical Trial are comparable to other, international trials: after three years approximately 66 percent of the NORPLANT®'s clients were still using the method.

The clinical trials demonstrated the acceptability and safety of NORPLANT® to the satisfaction of the Government of Egypt (GOE). NORPLANT® was registered with the GOE and given regulatory approval in February 1993.

Preliminary results of the 1992 Demographic and Health Survey for Egypt show the contraceptive prevalence rate to be 47.1%, of which oral contraceptives and IUDs contribute over 80%. Introduction of NORPLANT®, which will expand the method mix and increase contraceptive choice will help the Government of Egypt achieve its CPR objective of 53% in 1997. [3] At the level of service projected by this strategy and implementation plan, NORPLANT® may account for approximately 2.6% of total CPR by 1999.

Based on the positive experience gained through the clinical trials and DHS indicators, the Ministry Of Health in Egypt developed the Strategy and Regulations for the Use of Subcutaneous Implanted Capsules (NORPLANT®). Furthermore, a NORPLANT® Task Force was formed to develop the Implementation Plan based on MOH strategy paper.

This document, NORPLANT® INTRODUCTORY PROGRAM IN EGYPT: The Implementation Plan, is the result of the NORPLANT® Task Force work and it provides the broad guidelines for expanding the use of NORPLANT® beyond the University Hospital environment of the 1988 Clinical Trials.

The health system in Egypt has over 250 hospitals and many health care centers managed by the public sector and parastatal organizations. PVOs and private practitioners also own and operate numerous clinics. Introduction of NORPLANT® will be primarily hospital-based and will spread vertically to three categories of health facilities as training and service delivery systems are strengthened.

Category 1 facilities are university hospitals, teaching hospitals and the Curative Health Organization (CHO) hospitals in Cairo and Alexandria. There are approximately 32 hospitals in this category which are concentrated in Cairo and Alexandria. The five university hospitals from the clinical trials are included in this category of service delivery points.

Category 2 facilities are Health Insurance Organization (HIO) hospitals, additional CHO sites and general hospitals and the major centers of the Clinical Services Improvement (CSI) program. This category is comprised mainly of networks of facilities and includes over 170 sites nationally that have a wide variation in the quality of the infrastructure as well as the range of services offered.

Category 3 facilities are District hospitals, Urban Health Centers, MCH Centers and some of the polyclinics of HIO. There are over 350 of these facilities located throughout the country.

Criteria will be established for selection of sites from the pool of available service delivery points of each category.

This Implementation Plan describes the parameters of the NORPLANT® Introductory Program's overall design and principle activities as determined by the NORPLANT® Task Force. Working Groups will be formed during the pre-implementation phase of the Introductory Program to work on the principle activities described herein.

2.0 PROGRAM GOAL AND OBJECTIVES

2.1 Program Goal

To increase contraceptive prevalence by expanding the choice of available contraceptive methods through the provision of NORPLANT® implants as part of the Egyptian family planning program

2.2 Program Objectives

At the end of the five year Introductory Program the following objectives will have been met:

- a) To provide substantial programmatic experience with the provision of NORPLANT® implants in a variety of service delivery systems within two governorates;
- b) To examine the effect on contraceptive use dynamics by adding NORPLANT® to the already existing method mix of the Egyptian family planning program;
- c) To ensure availability of NORPLANT® implants in an adequate number of sites in each governorate in Egypt.

3.0 PROGRAM DESIGN

The Egyptian NORPLANT® Introductory Program is not a method specific introductory program. The program's design reflects a concern of identifying the most appropriate manner of adding this new contraceptive technology into the existing service delivery system so that the Egyptian family planning client may have her choice of available methods expanded.

The NORPLANT® Introductory Program is a transition between the Clinical Trials and the integration of NORPLANT® within the standard method mix of the Egyptian Family Planning Program. The five year period is an opportunity to develop the management capacity for ensuring the smooth operations of the clinical and programmatic sub-systems that support the provision of this new contraceptive, and to study the effect of adding NORPLANT® to the family planning program.

The Introductory Program will take into account the expansion of the injectable contraceptive into the public sector. Although this is not specifically highlighted in this Implementation Plan it is an important underlying consideration to the development of the NORPLANT® Introductory Program's activities (which are described in the following sections of this document).

The expansion of NORPLANT® services into the private sector will be made after the mid-program evaluation in phase III.

The following three principles guided the development of the NORPLANT® Introductory Program Implementation Plan.

1. Ensuring high quality NORPLANT® services while broadly introducing the new contraceptive method through Horizontal Introduction.
2. Examining the impact of introducing NORPLANT® on the service delivery systems through Vertical Introduction into a specific geographic area.
3. Understanding use dynamics of NORPLANT® through systematic monitoring and evaluation.

3.1 Ensuring High Quality (Horizontal Introduction)

The NORPLANT® Horizontal Introduction is a design strategy to ensure high quality NORPLANT® services in a broadly based introduction program.

The NORPLANT® Introductory Program will begin with an expansion into the Category 1 facilities¹ that meet the selection criteria. The horizontal introduction of NORPLANT® provides a broad geographic coverage in approximately 12 governorates in category 1 facilities then it will expand, based on the experience gained, into other governorates in category 2 facilities and so on. This approach will provide highly qualified OB/GYN specialists in leading institutions throughout Egypt with an experience in providing the new contraceptive. The vertical expansion from one category of health services to another will provide the Technical Steering Committee the opportunity to monitor and ensure the quality of NORPLANT® services.

On the other hand, the horizontal introduction will provide a relatively restricted environment for developing and fine tuning the function of the clinical sub-systems involved with NORPLANT®, (e.g., training, logistics, information systems, IEC and follow-up). The broad geographic introduction into a few Category 1 facilities in each governorate will not sufficiently penetrate the family planning service delivery system to provide an adequate programmatic experience with managing NORPLANT® implants in a wide variety of service delivery contexts, however, nor will it provide a large enough case load to adequately evaluate its contribution to the national family planning program. The Egyptian NORPLANT® Introductory Program will therefore complement the broad geographic expansion into a few sites with a restricted vertical expansion into many different sites within a limited geographic area.

¹ The list of facilities that correspond to Category 1, 2 and 3 is presented in the Background section of the Implementation Plan.

3.2 Examining the Impact (Vertical Introduction)

The NORPLANT® Vertical Introduction is a design strategy to examine the impact of introducing NORPLANT® on the service delivery systems.

Two governorates, Kalioubia and Fayoum, are selected for vertical introduction of NORPLANT®. In these two governorates, NORPLANT® will be introduced into a variety of service delivery points, including Category 1, 2 and 3 facilities. Each of the facilities will be carefully selected for participation in the NORPLANT® Introductory Program.

The vertical introduction within a governorate will give the NORPLANT® Introductory Program an in-depth experience in a variety of Category 1, 2 and 3 service delivery points. The focus on a confined geographic area will enhance control of the Introductory program, (including selection and follow-up of clients, aseptic procedures, and removal of the NORPLANT® implants).

3.3 Understanding Use Dynamics

Program monitoring and evaluation is an important element to develop a sound understanding of the NORPLANT® use dynamics.

The Introductory Program is intended to be a transition period between the Clinical Trials and the widespread use of NORPLANT®. Fundamental questions regarding the method's contribution to the overall contraceptive prevalence and changes in the method mix of the Egyptian family planning program will be examined by the Introductory Program. The programmatic implications of different levels of NORPLANT® prevalence in Egypt are profound, (an illustration of the commodity requirements based on a one percent national prevalence rate is included in the Appendices as an example of the critical nature of this issue). The long term sustainability of providing NORPLANT® will be significantly enhanced by devoting adequate resources to the study of these issues during the next few years.

The use dynamics of adding NORPLANT® to the existing method mix will be studied in a comprehensive evaluation plan, described in the Monitoring and Evaluation section of this Implementation Plan. A capsule summary is presented here to orient the reader to the baseline studies that will be used in formulating the content of the Introductory Program's activities.

A Situation Analysis of the service delivery points in the two vertical introduction governorates will provide baseline information on the quality of care provided in the NORPLANT® Introductory Sites, and will assist in developing the clinical sub-systems to an acceptable level of quality. A baseline contraceptive prevalence study will also

be conducted in the same governorates prior to the NORPLANT® Introduction. A baseline Situation Analysis study will also be conducted in one district in each of the two governorates targeted for the Quality Improvement Project. This district will serve as a comparison group for assessing changes in the quality of care that are attributable to the NORPLANT® Introductory Program.

The results from the baseline Situation Analysis (in the vertical introduction governorate and the Quality Improvement Project's district) and contraceptive prevalence study will be compared to a post test study. The analysis of these pre-test / post-test studies will provide reliable data on changes in the quality of care and use dynamics. This information will help policy makers and program managers in Egypt design family planning services to deliver NORPLANT® effectively well beyond the catchment areas of the vertical introduction governorate.

A mid-project evaluation will be conducted. The composition of the mid-project evaluation team, and the evaluation indicators, will be developed by the Technical Steering Committee, described below, that focus on the management capacity and the quality of care provided by the NORPLANT® services. Based upon the results of the mid-project evaluation the Ministry of Health may decide to accelerate the introduction of the NORPLANT® Introductory Program to include a limited vertical introduction into other governorate(s).

4.0 PROGRAM COORDINATION

As the major source of financial and technical assistance for population and family planning activities in Egypt, the Ministry of Health (MOH) plans to support most of the activities related to NORPLANT® introduction through subprojects of the USAID/Cairo bilateral project, Population/Family Planning III (POP/FP III). Management of NORPLANT® introduction is the responsibility of the Executive Director of the Systems Development Project (SDP), a subproject of POP/FP III under supervision of the Undersecretary for Family Planning. The Executive Director will work with the Technical Steering Committee, the NORPLANT® Coordinator and other POP/FP III subproject directors to coordinate activities and resources needed for NORPLANT® introduction.

4.1 NORPLANT® Technical Steering Committee

A NORPLANT® Technical Steering Committee will be responsible for supervising the implementation of the Implementation plan of NORPLANT® Introductory Strategy and for providing technical guidance to critical aspects of the NORPLANT® Introductory Program. The Undersecretary for Family Planning will chair this committee.

The NORPLANT® Technical Steering Committee will provide an opportunity for bringing together key decision makers from each of the principle agencies involved in the NORPLANT® Introductory Program. The coordination role of this committee is therefore critical to smooth operations of the Egyptian NORPLANT® Introductory Program.

The composition of the NORPLANT® Technical Steering Committee should reflect the diversity of the agencies involved with the implementation of the NORPLANT® Introductory Program. In addition to the Ministry of Health technical and managerial staff, the NORPLANT® Technical Steering Committee could also include the following members:

- ✓ Undersecretary for Family Planning, Chairperson
- ✓ Ministry of Population and Family Welfare Representative
- ✓ Dr. Ezz El-Din Osman
- ✓ Mrs. Sawsan El-Bakly, State Information Services (IEC Activities)
- ✓ Egyptian Pharmaceutical Trading Company, CIIS (Commodities)
- ✓ Dr. Roushdi Amar, Director, Regional Center for Training
- ✓ USAID Representative
- ✓ Population Council

The NORPLANT® Technical Steering Committee will oversee the Working Groups (e.g., Training, IEC, Standards of Practice, Standards of Health Facilities, Monitoring and Evaluation). Once the Introductory Program begins, the Technical Steering Committee will meet periodically to review progress made with the Introductory Program. The Technical Steering Committee will oversee the mid-project evaluation.

An important function of the Technical Steering Committee is the coordination of the technical assistance agencies that will provide support to the NORPLANT® program.

4.2 NORPLANT® Coordinator

The Ministry of Health will assign a staff member to be the NORPLANT® Coordinator, (seated within the Family Planning System's Development Project Office). The NORPLANT® Coordinator will manage the day to day activities of the NORPLANT® Introductory Program, including the following key personnel decisions:

- ✓ Selection and supervision of the NORPLANT® Introductory Program Working Groups within SDP units
- ✓ Designation of staff to provide local supervision and coordination for the program at the central and governorate levels
- ✓ Creation of a registry of trained physicians in each governorate
- ✓ Development of criteria for the selection of NORPLANT® providers, and selection of candidates for training

5.0 INSTITUTIONAL FRAMEWORK

The Ministry Of Health will be the body responsible for the NORPLANT® Introductory Program. There will be other organizations involved in the implementation such as the Teaching Hospital Organization (THO), the Health Insurance Organization (HIO) hospitals and polyclinics, the Clinical Services Improvement (CSI) clinics, the Regional Center for Training (RCT) in Family Planning and cooperating Universities, the State Information Service (SIS), the U.S. Agency for International Development, the Population Council, and other institutions.

The Egyptian NORPLANT® Introductory Program will be conducted under the auspices of the Ministry of Health through its Systems Development Project (SDP) which is a subproject of the Population/Family Planning III project supported by USAID. Most of the service delivery points of NORPLANT® will be in the MOH hospitals and health facilities.

The THO hospitals will be service delivery points and three of their training sites will provide training on NORPLANT® to THO and MOH service providers. These activities will be mainly funded through the THO/FP subproject under POP/FP III supported by USAID.

The Health Insurance Organization (HIO) hospitals and polyclinics and the Clinical Services Improvement (CSI) clinics will participate as service delivery points of NORPLANT®.

The Regional Center for Training (RCT) in Family Planning at Ain Shams University will be the main training institution. The training curricula will be approved by the Technical Steering Committee. For its limited capacity to train all service providers in the country, RCT will have subagreements with the five Universities that conducted the clinical trial to conduct training as well. All NORPLANT® training activities in RCT and cooperating Universities will be funded through RCT subproject under POP/FP III supported by USAID.

The State Information Service (SIS) will be responsible for developing IE&C materials to promote the use of NORPLANT® based on the approval of the Technical Steering Committee. IE&C activities conducted by SIS will be funded through SIS subproject under POP/FP III supported by USAID.

USAID will support major activities in the NORPLANT® Introductory Program through its POP/FP III project and provide long and short term T.A., as appropriate, through I/G&S contract.

The Population Council will contribute in the situation analysis study, the contraceptive prevalence studies, and other operations research studies.

6.0 PROGRAM ACTIVITIES

There are five general categories of activities associated with the NORPLANT® Introductory program. The parameters of each activity are identified in this section. A Working Group will be composed for each category during the pre-implementation phase of the Introductory Program. The Working Groups will be charged with developing detailed implementation plans and substantive guidelines for each activity. Each Working Group will make clear distinctions between clinical service activities and program management issues in their implementation plans.

6.1 Standards of Practice

The *National Standards of Practice for Family Planning Clinical Services Delivery* (March 1993) produced by the Ministry of Health, (including the *Family Planning Clinical Procedures Manual for Physicians* and the *Family Planning Clinical Procedure Manual for Nurses*, and the *Standards of Service for Quality Improvement Program Monitoring System*) will be supplemented by a full and complete reference to NORPLANT® implants.

The following are the sections and some of the issues that need to be addressed in the revised Standards of Practice:

6.1.1 Counseling and IE&C

Informed choice is an essential part of quality services. Counseling must provide information about all family planning methods to prospective clients and help them make an informed choice of a method based on their medical histories, reproductive objectives and individual preferences. A client's ability to return regularly to the clinic for check-ups and for methods which require resupply, i.e., vaginal tablets, pills, condoms and injections, must also be taken into account during counseling. All of these considerations reinforce a family planning services orientation rather than a method-specific approach.

Because NORPLANT® is provider-dependent, client satisfaction depends to a large extent on counseling. Clients who select NORPLANT® will receive thorough pre-insertion counseling to inform them about the potential side-effects, especially menstrual irregularities. Insertion and removal procedures, physical exams and laboratory analyses which may be required will be explained to the client. The counselor will also explain the follow-up schedule and necessity of removal after five years.

Post-insertion counseling includes instructions for caring for the insertion site and warning signs of complications which require prompt return to the clinic. Post-insertion counseling also reinforces information about follow-up visits and eventual removal. The client will be assured that she can return to the clinic at any time if she has questions or concerns. Procedures and conditions for ensuring follow-up and removal of NORPLANT® implants, clarifying that "removal upon demand" is a priority of the Introductory Program, need to be developed.

Materials about NORPLANT® were found to be helpful by the clients in the clinical trials. Additional prints of the client booklet which was developed during the clinical trials will be done and other materials will be adapted or developed to provide clients with the information they need.

6.1.2 Clinical Services

Only physicians who have been trained will be allowed to insert/remove NORPLANT®. Insertions must be done carefully and according to proper procedures to prevent infection and expulsion. Guidelines for accrediting physicians for NORPLANT® insertion and removal need to be established. Selection criteria for NORPLANT® clients will be developed as part of the development of service standards and guidelines.

Although clients will be encouraged to keep the NORPLANT® implant for at least three years, access to removal upon request at any time will be assured. Women requesting early removal will be seen by a counselor to determine whether the client has questions and concerns about side-effects which can be addressed by counseling, whether she is generally dissatisfied with the method or whether she has decided to remove the implant because she wants to become pregnant. Whatever the reason, if after counseling the client still wants to have the implant removed, arrangements will be made for the procedure. Prior to leaving the clinic, clients who remove NORPLANT® because of concern or dissatisfaction will be counseled about other available contraceptives and encouraged to choose another method. Guidelines relating to method switching and the appropriateness of a "transitional period" between contraceptive methods, particularly between two hormonal contraceptive methods such as an injectable contraceptive and NORPLANT® implants need to be documented.

6.1.3 Technical support and supervision

Dynamic and supportive supervision is a demanding responsibility since staff and material resources in family planning clinics are often limited. Because NORPLANT® is a provider-dependent method and requires particular attention to asepsis and counseling, good supervision is critical to integration of NORPLANT® and quality service.

6.1.4 Record Keeping

Client records and clinic registries will include information about NORPLANT® users. A suggested list of information which will be required includes:

- ✓ Name and location of clinic where NORPLANT® insertion occurred
- ✓ Date of the insertion
- ✓ Clear and complete client name and address / residence identifiers
- ✓ Expected date of removal
- ✓ Actual date of removal, including reference to the principle reason
- ✓ Complications, expulsions, etc..
- ✓ Information on FP use e.g. reinsertions, previous methods, etc..
- ✓ Name and address of a reference person not residing with the client.

6.1.5 Follow-up

A schedule of routine follow-up visits for NORPLANT® clients will be included in the service standards and guidelines.

Follow-up of clients five years after insertion is necessary to insure proper removal of NORPLANT®. Effective mechanisms for follow-up will be developed and tested during the course of the introduction period.

6.2 Standards of Health Facilities

A Working Group will be formed from existing SDP staff during the pre-implementation phase to develop the guidelines and establish the selection criteria of sites for the NORPLANT® Introductory Program. These guidelines for the accreditation of a clinic to provide NORPLANT® may include the minimum number of trained staff, equipment and facilities, aseptic procedures, information system capabilities. This Working Group will conduct site visits and assist in reviewing the pool of available service delivery points for each of the Introductory Program's phases. The Technical Steering Committee, or a sub-group of this committee, will be charged with the final selection of the sites. The results from the baseline Situation Analysis in the 'fast track' governorates, Kalioubia and Fayoum, can be applied to the determination of the final selection of sites.

6.3 Training

A training management plan will be produced by a Training Working Group from existing SDP staff that emphasizes the introduction of NORPLANT® into the existing family planning services. This orientation will hence provide for refresher training (where appropriate) in the technical management of other contraceptive methods,

particularly hormonal methods, and improving providers's counseling skills for all types of clients.

The training management plan will elaborate upon several key issues, including:

- The number and category of providers to be trained in each site, including training of replacement providers due to transfers of certified staff;
- The minimum number of insertions and removals for each provider required prior to certification;
- Technical support and follow-up of providers during the post-training phase, with special reference given to removal procedures, counseling and ensuring aseptic procedures;
- Increasing awareness of and referrals for NORPLANT® Implants among service providers in family planning service delivery points that currently do not offer NORPLANT® Implants.

Initially NORPLANT® training will be conducted at the five University Hospitals that participated in the clinical trials. Priority will be given to establishing a governorate level training facility/program for the two vertical introduction governorates. The training management plan will work towards the creation of a cadre of master trainers in NORPLANT® that will branch out from the University Hospitals to form NORPLANT® training centers in other existing facilities such as THO Training Centers. More details regarding a number of issues related to training, including cost and capacity estimates, are found in the Appendix to the Implementation Plan.

6.4 Information, Education and Communication

An IEC strategy and work plan will be developed by a Working Group on IEC in collaboration with the State Information Service (SIS). The strategy will identify target audiences and define the communication media for reaching each of them. The following are the objectives of the IEC program:

- Increase awareness of the new method among women matching the selection criteria
- Dispel rumors about NORPLANT® in the general public
- Expanding upon teaching materials for service providers developed during the Clinical Trials

Since the NORPLANT® Introductory Program will not be national in scale (except in a few limited services) and will focus largely on two governorates, the communication strategy aimed to increasing awareness among potential users will have to rely on developing local communication events for increasing awareness and motivating new clients. Activities aimed at dispelling rumors, however, should be national in scale and target specific audiences (cited below).

Among the target audiences and communication channels that will be exploited are the following:

- Information dissemination to Non-Governmental Organizations, women's health advocates and the media to dispel myths and misconceptions about NORPLANT® (see Population Council, 1993 for a reference on the type of information available that targets these groups);
- Women that match the NORPLANT® selection criteria to increase their awareness of the new contraceptive method, including graphic arts, mass media and clinic pamphlets;
- Clinic based teaching aides to be used by service providers when explaining the mechanisms of NORPLANT®.

6.5 Logistics

A fifth Working Group will be composed to address issues related to the logistics required for the NORPLANT® Introductory program. This Working Group will mainly look into the work on forecasting demand, estimating needs, developing plans for receiving, storing, and distributing NORPLANT® sets.

6.5.1 NORPLANT® Procurement

The estimate for the initial quantity of implants requested is based on the consumer demand and client satisfaction expressed during the NORPLANT® clinical trials and on the volume of services expected during the first year of the introduction. Many of the sites to be targeted for NORPLANT® introduction during the first year of implementation are Category 1 facilities, which includes the five clinical trial sites. Service delivery capacity of these sites and the volume of consumer demand are expected to be similar to that of the clinical trials. Assuming that 20 sites (of the 32 in that category) begin NORPLANT® services within the first year and that supply is deliberately restricted to approximately 40 clients per month:

$$20 \text{ sites} \times 40 \text{ insertions/month} \times 12 \text{ months} = 9,600 \text{ insertions}$$

The request for 10,000 implants will cover new acceptors and some of the clients from the clinical trials who will be due for 5-year removal but who may wish to continue with the method.

USAID/Cairo will start procuring NORPLANT® sets during the pre-implementation phase of the Introductory Program. The MOH will submit commodities forecasts and procurement requests to USAID in June of each year of the introduction period, starting in 1995. An initial request of 10,000 NORPLANT® sets was submitted to USAID to cover the first year of service delivery and it will be activated pending submission of required documentation to USAID.

The volume of services and the projected commodity requirements for the two vertical introduction governorates will be determined. The results from the baseline Situation Analysis study of vertical introduction governorate's sites will be useful in developing precise equipment and supplies lists for support of the NORPLANT® Introductory Program.

The volume of services will be carefully monitored to provide accurate estimates of commodity requirements for subsequent years of the introduction to prevent under- or over-supply.

In addition to the NORPLANT® implants, USAID is requested to procure the trocars required for insertion. The trocars and commodities are usually packaged at a ratio of 1 trocar per to 50 sets. Trocars in the ratio of 1 to 20 will be requested.

Adequate quantities of sterilized linens and instruments for NORPLANT® insertions and removals must always be available. Site visits conducted prior to start-up of activities at new introduction sites will determine the need for redistribution or procurement of autoclaves for the family planning clinics to improve infection prevention practice. Procurement of this equipment will be discussed with USAID, UNFPA and other donor agencies.

6.5.2 NORPLANT® Storage and Distribution

Storage and distribution of NORPLANT® will be handled in the same manner as other contraceptives for public sector activities. This had been carried out by the Egyptian Pharmaceutical Trading Company (EPTC). Whether EPTC or another company will be responsible for distribution of USAID-donated commodities under POP/FP III will be determined by the MOH and USAID.

In addition to the NORPLANT® implants, insertion and removal requires expendable, medical supplies. Systems of distribution of the regular supplies to the family planning clinics will be provided through the same distributive systems of MOH and public sector, additional supplies specific to NORPLANT® will be verified by the MOH prior to the initiation of services.

6.6 Management Information Systems (MIS)

The scope of NORPLANT® related information to be recorded on the client medical record, and the most appropriate mechanism for ensuring its recording will be established by the Working Group on MIS. The purpose of the MIS is to upgrade the existing system to incorporate adequate information to enable the tracking of the NORPLANT® clients.

Guidelines for creating and maintaining governorate and central level registries of NORPLANT® clients will be specified prior to beginning the NORPLANT® Introductory Program.

Routine surveillance of the NORPLANT® information will be conducted and included into the existing the service statistics of the MOH. This information will prepared quarterly to track client characteristics, the volume of new clients per site, removal rate and categories of reasons for removal. These data will facilitate program monitoring and operations research.

6.7 Monitoring and Evaluation

This element is critical to the successful introduction of NORPLANT®. As specified under *Program Design* section (above) the NORPLANT® Introductory Program is organized to collect information relative to the use dynamics of expanding the contraceptive choice. In addition to the baseline and post - test data collection activities there will be a number of other, related operations research studies and routinely collected data for monitoring the implementation of the NORPLANT® program. This section of the Implementation Plan briefly describes the parameters of the types of operations research and monitoring activities that will be conducted during the Introductory Program. A Monitoring and Evaluation Working Committee will develop these topics into full research proposals.

6.7.1 Situation Analysis Study

The Situation Analysis methodology focuses on the 'supply side' characteristics of the family planning program, i.e., those factors which are more or less under the control of a program manager. The Situation Analysis methodology was originally developed as a rapid and cost effective approach for diagnosing the quality of family planning services that a program provides its clients, (Miller, et.al., 1991).

The Situation Analysis study is usually (although not necessarily) conducted in a representative sample of service delivery points within a geographical area. Data is collected by teams of interviewers that utilize the following three research methods:

- Direct interview techniques with service providers and clients
- Structured observation of family planning consultations
- Inventory of the facilities' equipment and materials (including service statistics)

*Clinic Sub - Systems Analyzed by
a Situation Analysis Study*

- ✓ Logistics / Supplies
 - ✓ Facilities
 - ✓ Staffing
 - ✓ Training
 - ✓ Supervision
 - ✓ IEC
 - ✓ Record Keeping
-

Indicators from each of these sub-systems are measured that will assist program managers and administrators to answer to the following basic questions:

1. Is each sub-system in place, (i.e., is it potentially ready to provide services)?
2. If in place, is each sub-system functioning, (i.e., is it providing some level of services to clients)?
3. If functioning, is each sub-system providing quality services in terms of the following elements (Bruce, 1990):
 - Choice of Contraceptive Methods
 - Provider - Client Information Exchange
 - Understanding Clients
 - Information to Clients
 - Provider Competence
 - Qualifications
 - Technical Skills and Knowledge
 - Client - Provider Relations
 - Mechanisms to Encourage Continuity
 - Appropriate Constellation of Services

A baseline and post-test Situation Analysis study will be conducted of the service delivery points of the governorate selected for the vertical introduction of NORPLANT®, and a comparison district where NORPLANT® will not be introduced but the Quality Improvement Program will enhance the quality of services provided. The baseline Situation Analysis study will provide useful baseline information for developing the Training, IEC and Resource Management elements of the NORPLANT® Introductory program. The comparison of the baseline and post test measures will be useful in understanding changes that the NORPLANT® Introductory Program made in the quality of the family planning service delivery system.

6.7.2 Contraceptive Prevalence Study

A study will be conducted to assess changes in method mix and contraceptive prevalence that are attributable to the NORPLANT® Introductory Program. The long term implications of the relative contribution of NORPLANT® to Egypt's contraceptive prevalence rate is a fundamental issue that the Introductory Program will address.

In addition to examining the impact of the NORPLANT® Introductory program on contraceptive prevalence, the use dynamics of adding a new method to the Egyptian family planning program are equally important for the national program to understand. For example, the extent to which the new method will make it possible for non users (never users and past users) to start practicing contraception, as opposed to simply having users of other contraceptives switch to NORPLANT®, is a critical dimension of the Introductory Program's objective of expanding contraceptive choice. The pre-test / post-test contraceptive prevalence studies will provide information on how well the Introductory Program met this objective.

6.7.3 Operations Research Studies

The NORPLANT® Introductory Program will conduct a number of highly focused operations research studies. These studies will be useful for fine tuning the implementation of key activities as well as building upon past client acceptability studies conducted during the Clinical Trials. Although the exact number and content of the NORPLANT® Introductory Program's operations research activities will be determined by the Monitoring and Evaluation Working Group, the following topics are indicated as a starting point for the deliberations:

- Client Acceptability Study
- Testing of Different Strategies for Ensuring NORPLANT® Removal
- Impact of Counseling Training on Providers and Clients' Behaviors
- Cost Elasticity Study and the Effect of Cost on Sustained Use
- Client Follow - Up Study (NORPLANT® users compared to users of other contraceptive methods)

7.0 PROGRAM WORK PLAN

7.1 Pre-implementation Phase: 9 months (4/1/94 - 12/31/94)

The duration of this phase extends for 9 months from April 1 through December 31, 1994. The major activities during this phase will include the following:

- Establish the NORPLANT® Technical Steering Committee
- Appoint the NORPLANT® Coordinator
- Compose the different Working Groups and develop plans
- Complete standards of practice of NORPLANT® services
- Procure, receive and distribute NORPLANT® devices
- Select health facilities for NORPLANT® service delivery based on standardized selection criteria
- Develop the MIS records/registry
- Conduct the baseline research in 2 vertical introduction governorates

7.2 Phase I: 15 months (10/1/94 - 12/31/95)

The duration of this phase extends for 15 months from October 1, 1994 through December 31, 1995. In this phase, both the horizontal and vertical introduction programs will be launched:

- Provide NORPLANT® services in Category 1 health facilities
- Train service providers in Category 1, Category 2 and in the health facilities selected for vertical introduction

7.3 Phase II: 24 months (7/1/95 - 6/30/97)

The duration of this phase extends for 24 months from July 1, 1995 through June 30, 1997. In this phase, the following activities are planned:

- Expand NORPLANT® services provision in Category 1 and 2 health facilities to ensure geographic coverage
- Train service providers in Category 2 and 3 health facilities
- Complete installation of services in all appropriate Category 2 and 3 facilities in the two governorates
- Conclude operations research studies

7.4 Phase III: 24 months (1/1/97 - 12/31/98)

The duration of this phase extends for 24 months from January 1, 1997 through December 31, 1998. In this phase, a number of activities are planned including:

- Review Program Performance to fine tune program operations
- Expand number of sites in the horizontal introduction governorates if indicated by mid-program evaluation
- Conduct post-test research (situation analysis and contraceptive prevalence survey)
- Establish the regulations that govern the provision of NORPLANT® services in the private sector

7.5 Phase IV: 12 months (7/1/98 - 6/30/99)

This phase extends for 12 months from July 1, 1998 through June 30, 1999. There will be 2 major activities:

- Conclude post-test research
- Evaluate the NORPLANT® Introductory Program
- Develop post-introductory plan for NORPLANT® services

NORPLANT INTRODUCTORY PROGRAM IN EGYPT
FIVE YEAR WORK PLAN

April 1, 1994 - June 30, 1999

Calendar Year	94				95				96				97				98				99	
	Q2	Q3	Q4	Q1	Q2																	
POP/FP III Project Year	YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5					
1.0 Preimplementation Phase	X	X	X																			
2.0 Phase I			X	X	X																	
3.0 Phase II					X	X	X	X	X													
4.0 Phase III								X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5.0 Phase IV																						

8.0 PROGRAM SUSTAINABILITY

The long term sustainability of the NORPLANT® depends upon the extent to which the program is able to make a significant contribution to the Egypt's contraceptive use rate, the diversification of funding sources for the public sector program, and the expansion into the private sector.

Achievement of the GOE's demographic objectives and CPR of 53% requires increased use of effective contraceptive methods and decreased discontinuation rates. Introduction of NORPLANT® in the National Family Planning Program can significantly contribute to these objectives.

Despite the high up-front cost of NORPLANT®, the MOH considers it to be an important method for provision through the public sector. In addition to improved method effectiveness and continuation, NORPLANT® introduction will expand the method mix and improve choice.

IUDs and oral contraceptives currently account for over 80% of contraceptive use in Egypt. Subsidized prices for these commodities, available through both the public and private sectors, has been kept very low which may have contributed to their popularity. The cost of an IUD which can be used for 8 years is currently less than \$1.00. A 5-year supply of pills at current prices would average \$17.00. Pressure from international donors and commercial distributors to allow sales and distribution of contraceptive commodities at more realistic prices is likely to result in price increases for IUDs, pills, condoms, etc. The 5-year cost of injectables is approximately \$21, almost equivalent to the cost of NORPLANT®.

The price of NORPLANT® device has been set at LE 50 (\$15). This price is intended to contribute to partial cost recovery, to encourage long-term use and discourage early removals and to moderate demand which could otherwise overwhelm the capacity of the service delivery system.

The price of LE 50 was based on the responses of clients surveyed during the clinical trials about their willingness to pay for NORPLANT® and other anecdotal evidence. The current price of injectables was also taken into consideration. Market surveys and cost studies to be conducted during the introduction period will provide data to better understand the elasticity of demand for NORPLANT® and other contraceptive services and will provide the basis for establishing realistic a fee structure in the future. As the NORPLANT®, initially, will be donated by USAID, the revenues from the provision of NORPLANT® services will be governed by an agreement among the MOH, EPTC and USAID.

Introduction of this method through the vast network of public sector hospitals and clinics using donated product will create a service delivery base from which training and systems support can expand to the private sector.

Currently the private/commercial sector plays the major role in the provision of family planning commodities and services. The private sector is expected to provide an increasingly greater share of NORPLANT® services within 5-7 years. This method, once available from private practitioners, will probably have wide appeal to middle and upper class clients who can better afford to pay market rates for products and services.

To make more methods available to all potential acceptors of contraceptives in Egypt, NORPLANT® must be available through the public sector at subsidized prices. Financial sustainability, however, is likely only in the private sector.

During the 5-year introduction period, the MOH will discuss NORPLANT® commodities procurement and cost-sharing with other donors such as UNFPA and the World Bank.

APPENDICES

APPENDIX 1.

Illustrative Example: Projected Commodity Requirements and Cost Estimates for One Percent Prevalence of NORPLANT® Users in Egypt within Ten Years

Egypt Annual Acceptors, Users, and Cost Required to Have One Percent of MWRA Using Norplant Within 10 Years (and to Maintain One Percent Use Thereafter)					
Year	MWRA	Prevalence End of Year	Acceptors During Year	# Users End of Year	Cost
1994	9,195,000	0.01	750	623	\$23,760
1995	9,420,000	0.03	2,766	2,834	87,634
1996	9,655,500	0.05	3,270	5,155	103,594
1997	9,891,000	0.08	3,791	7,586	120,114
1998	10,126,500	0.10	4,331	10,127	137,217
1999	10,362,000	0.28	24,793	29,014	785,454
2000	10,608,000	0.46	29,992	48,797	950,150
2001	10,843,500	0.64	34,533	69,398	1,094,020
2002	11,079,000	0.82	39,256	90,848	1,243,618
2003	11,314,500	1.00	44,129	113,145	1,398,008
2004	11,550,000	1.00	33,523	115,500	1,062,004
2005	11,826,000	1.00	36,861	118,260	1,167,766
2006	11,944,260	1.00	37,570	119,443	1,190,218
2007	12,063,703	1.00	40,013	120,637	1,267,621
2008	12,184,340	1.00	42,530	121,843	1,347,343
2009	12,306,183	1.00	37,737	123,062	1,195,501
Total			415,847		\$13,174,024

Note: Assumes continuation rate of ar-rt; with a=.9 and r=.15

(Source: P. Mauldin, Population Council 1993)

APPENDIX 2.

Training Load and Cost Estimates

2.1 Costs of the Training Course

The Regional Center for Training on Family Planning has developed a training course on NORPLANT for Ob/Gyn specialist. The course length is 6 days. The average number of participants will be 10, 3 from Cairo and 7 from outside Cairo. The direct costs of the course are:

Meals and M&I:

7 part. x 6 days x L.E. 100 = L.E. 4,200

Transportation:

7 part. x L.E. 40 = L.E. 280

Training Materials:

10 part. x L.E. 50 = L.E. 500

TOTAL = L.E. 5,980

L.E. 6,000 will be used to simplify the computation of the cost.

NOTES:

1. Since the training will start at 5 training sites almost at the same time, it is fair to assume that those who come from outside Cairo (or the vicinity of the training center) will be less than 7 participants. Therefore an estimate of 5 participants from Cairo or the vicinity of the training center may be reasonable which will lower the costs of the course.
2. The above per diem (lodging, meals, miscellaneous and incidental costs) and transportation rates are those used by RCT under USAID funding, these rates differ from the MOH rates. However, NORPLANT training in the introduction strategy will be mostly conducted by USAID funded training centers. It is therefore safe to use the above rates provided that all USAID funded projects use the same per diem rates for participants.
3. These are the direct costs, however, there are the indirect costs which include costs of developing, printing, and binding the materials; photocopying; clinical training supplies; trainers; and administrative support. These costs will be born by RCT and the other USAID funded training centers during the introduction strategy.

4. *A course for nurses and/or social workers may take as well 7 days, therefore the same figure of L.E. 6,000 will be used for training courses on infection control and counseling on NORPLANT.*

2.2 *Training Capacity*

1. Training is limited by the number of training centers available, the number of service delivery sites, and the number of providers that need to be trained.
2. In phase I there will be 5 training centers, in phase II there are an additional 13 centers (4 THO and 9 University Hospitals) while in phase III there are 5 more centers in HIO hospitals based on selection criteria established by the Technical Steering Committee.
3. Given the nature of "rotation on duty" in the hospitals, the reasonable number of service providers that need to be trained to ensure adequate coverage and quality of service would be 4 Ob/Gyn specialists, 2 nurses and 2 social workers/counselors. A 25% turnover per year needs to be considered.
4. In the first phase, there will be 38 hospitals involved, 5 University hospitals will be available as training centers and 33 hospitals will be visited for selection of potential sites for NORPLANT service delivery. It is estimated that at least 2 and a maximum of 4 Ob/Gyn specialists will be trained in each site. The maximum number of participants is therefore 132 specialists (33 sites by 4 specialists) since the specialists in the 5 Universities were already trained during the clinical trial. These 132 specialists may be trained in 13 courses, each course will cost around L.E.6,000. The subtotal costs of training Ob/Gyn specialists in the first phase will be then L.E.78,000. The training of nurses will require 6 courses (2 nurses per site, total 66 nurses divided on 6 courses) and the same of number of courses for social workers (2 per site). The subtotal cost of training nurses and social workers will then be L.E.72,000. The total training costs will then be L.E.150,000.
5. In the second phase, there will be an additional 170 sites introduced. If only 132 sites are selected in this phase for service delivery, this will constitute 4 times the capacity in the first phase. That means we need to conduct 52 courses for Ob/Gyn specialists and 48 courses for nurses and social workers in 18 training centers (4 THO and 14 University Hospitals). Therefore the estimated budget for training service providers on NORPLANT in phase II will be L.E.600,000
6. In phase III, it is projected that the estimated number of selected sites will be 396 sites, therefore the estimated budget for training will be L.E.1,800,000.

7. A major constraint in accomplishing this training plan is the client flow in the training centers which will permit the participants to be adequately trained. Even with adequate clients coming for implanting the capsules, it seems that removals will be problematic. An entire training course may be conducted without a single case coming for removal. Therefore, flexibility may be allowed to conduct training courses with less than ten participants particularly in the first year.
8. It is important to note that a minimum number of clients should be served and flowing in any particular site before certifying this site for training. If the potential trainers did not serve an adequate number of clients and became skillful they will not be able to provide training on this skill. The implication is that the potential number of training sites may become less than what was assumed.

APPENDIX 3.

**Estimated NORPLANT® Insertions during
the Introductory Period**

- 1) 20 sites x 40 clients/mo x 48 months of service = 38,400
- 2) 15 sites x 30 clients/mo x 36 months of service = 16,200
- 3) 35 sites x 30 clients/mo x 30 months of service = 31,500
- 4) 35 sites x 20 clients/mo x 24 months of service = 16,800
- 5) 85 sites x 15 clients/mo x 24 months of service = 30,600
- 6) 85 sites x 10 clients/mo x 12 months of service = 10,200

TOTAL = 143,700

Lines 1 and 2 represent the category 1 facilities targeted for NORPLANT® introduction and the number of years that services might be available.

Lines 3 and 4 represent approximately 50% of the category 2 facilities and reflect the number of years that services are expected to be available.

Lines 5 and 6 represent approximately 50% of category 3 facilities and reflect the number of years that services are expected to be available.

Assuming this level of service, NORPLANT® could account for approximately 2.6% of total contraceptive prevalence in 1999 through the public sector alone.

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