

MILESTONE COMPLETION REPORT
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Date : April 22, 2032

Task Number : 1

Task Description : *Contraceptive Technologies and Services Expanded and More Widely Available*

Milestone No.: 1.1

Milestone Description: Expansion plan for new methods (PP and PA IUD TL, progestin-only pill, and LAM) developed.

Source of Verification: Expansion plan document

Planned End Date: October 31, 1999

Status : completed

Comments:

EXPANSION PLAN FOR NEW METHODS DEVELOPED (PP and PA IUD, Tubal Ligation, Progestin-Only Pill, and LAM)

I. INTRODUCTION

Task 1 has seven strategic goals, of which one is measured in part by Milestone 1.1: Expansion plan for new methods developed.

This task supports elements of two Intermediate Results: Enhanced Supply and Increased Demand. Specifically, it directly contributes to Enhanced Supply through expanded use of new contraceptive technologies, increased contraceptive use in specific groups, and expanded availability of products in the private sector. In terms of Increased Demand, the task directly supports increased knowledge about postpartum contraception and improves knowledge about specific methods.

This submission focuses on the progestin-only pill and the one-month injectable. The one-month injectable is the latest new product introduced in Egypt and is added to the list of new products available at the time of the POP IV design. The additional PP and PA IUD programs are described in Milestone 1.5 previously submitted and approved by USAID. LAM will be described in Milestone 2.6 (40th Day Program Described and Introduced). Tubal ligation is introduced to Ob/Gyn students in their medical school training and is not addressed in the context of this milestone.

The effort to expand contraceptive choices across the three sectors: public, NGO and private, requires: 1) a standardized approach to introduction and expansion of methods, 2) parallel processes for quality improvement and management, and 3) a mechanism for cross-sectoral coordination.

The initial expansion strategy recognized and depended upon the continued leadership of the MOHP in developing clinical standards for all contraceptive methods and selected reproductive health (RH) services. The strategy followed these basic steps:

- Review, update, and disseminate standards for all methods and services—first throughout the MOHP and then to the private and NGO sectors;
- Revise curricula to support new methods (covering client education, counseling, clinical procedures, and management of side effects), and RH services;
- Train master trainers in revised curricula to conduct training in new methods to the district level;
- Plan training and orientation for all provider types: doctors, nurses, counselors, IEC officers, and outreach workers.

A parallel strategy has been followed to expand choice of new methods in the private commercial sector. Product availability has been increased through new method information and supportive promotion campaigns. The centerpiece of this program, a strong “direct to consumer” television ad campaign supporting hormonal contraception (progestin-only pills, a one month injectable, and three month injectables), has been utilized to increase consumer demand. A planned promotion of

combined oral contraceptives in the first quarter of 2002 will also include information on emergency contraception. In addition to the four basic steps outlined above, this report/plan includes a:

- Description of the private sector's enhanced supply and increased demand initiatives, and
- Proposed public sector expansion plan for new methods that capitalizes on private sector promotions.

II. BACKGROUND

New products in the contraceptive market invariably expand overall usage of contraception, not just in the specific class of the newly introduced product. In Egypt, new products tend to be introduced by the private sector and later, in the public sector. During POP III and POP IV programs, these new product introductions include the progestin-only pill (POP), the one-month injectable, emergency contraception, new OC formulations, and new IUD presentations. The one exception to this trend of private sector introduction is the implant (Norplant and Implanon) program through the public sector. Norplant introduction was facilitated by the public sector's training capacity and remains solely a public sector program. Implanon, a one-rod technology introduced by Organon, will capitalize on the Norplant training program within the MOHP.

An important step in support of a new method's expansion is to ensure that providers understand the new products at the time of introduction. One step in this process is to issue standards of practice. This helps providers understand the product, prescription guidelines, and how to manage any side effects that may occur. Revised curricula, which include information concerning new products within the MOHP and the private sector, are another important element of new method introduction.

This paper describes the plan by which new contraceptives are introduced, how demand is created, and how public and private sectors work together to ensure maximum coverage.

Objective

The primary objective of the expansion plan for new methods is to increase contraceptive use through additional choices of methods.

Strategy

The primary strategy of Pathfinder/POP IV's plan for Introduction and Expansion of Methods and Services is to utilize:

- public sector resources to ensure standard approaches to the use of new contraceptive methods through training and regulation,
- private commercial sector motivations to expand existing and new methods, and
- NGO sector resources to extend coverage to segments of the population difficult to reach.

An additional strategy calls for the public sector to capitalize on private sector promotion where product is available in the MOHP system.

Comment

Many elements of this milestone have been implemented or have been described in other milestone plans. As a consequence, this milestone summarizes activities accomplished to date as well as plans for the final year. Where a plan is described in other milestones submitted to USAID, the plan or milestone will be referenced. In addition to the newly introduced contraceptive methods, expansion plans for the three-month progesterone only injectable have been carried out in both the public and private sector. Support for the expansion of these methods is outlined in the following sections A-F.

III. APPROACH

A. Review, update, and disseminate standards for all methods and RH services disseminated throughout the MOHP and the private and NGO sectors

Public Sector

Standards of practice tend to be updated on an ad hoc basis, whenever there are major changes in health policy, or when one or more new methods become available. SOPs for the **progestin-only pill (POP)** have been approved within the MOHP (Attachment 1). SOPs for **emergency contraception** and the **one-month injectable** have not been approved within the MOHP, though a seminar was held to discuss new prescription guidelines for both methods. This seminar on emergency contraception and the one-month injectable was held at Pathfinder International in the fourth quarter of 2000 and was chaired by Pathfinder's Training Advisor. The meeting was attended by MOHP/SDP training professionals, selected university medical school faculty members, representatives from the Regional Center for Training (RCT), a representative from the distributor of emergency contraception (Postinor), AlphaChem, Pathfinder's Quality Assurance Advisor, and Pathfinder's Private Commercial Sector Advisor (See Attachment 2 for presentations). Approval for **emergency contraception** and the **one-month injectable** SOPs will be a high priority for the "follow-on" program of POP IV.

As part of the process, a Steering Committee from university medical schools reviewed the MOHP Standards of Practice for POPs. The university team's Head of the Steering Committee communicated a review of its findings to the POP IV Training Advisor for Curriculum Development. At the same time, the medical schools updated their own Standards of Practice (SOP) for **emergency contraception** and the **one-month injectable**. These are included in the Guidelines for Family Planning Services in Egyptian University Hospitals. (For SOPs, see Attachment 3). LAM has been introduced through the integrated programs of MCH services and Healthy Mother/Healthy Child.

Private Sector

The Standards of Practice for the **one-month injectable and emergency contraception** will be disseminated to private sector physicians and NGOs during the first quarter of 2002 as a secondary message of the PSP oral contraceptive promotion campaign. Standards for the **progestin-only pill (POP)** are scheduled for dissemination in the second quarter of 2002 as part of the 40th Day Postpartum Contraception campaign.

Private Sector/CSI

As part of the dissemination program of the MOHP, standards of practice for each of the new methods will be provided to the CSI clinical system.

The table below summarizes the overall plan of development and distribution of the SOPs.

SOP Status	MOHP	University Medical Schools	CSI*	Private Physicians*	Pharmacists*
Developed	POP-only	- POP - One-month injectable - Emergency contraception	N/A	N/A	N/A
Disseminated	POP-only	- POP - One-month injectable - Emergency contraception			

* SOPs to be distributed as part of the Private Sector promotion programs in the first and second quarters of 2002.

B. Revise curricula to support new methods (covering clinical procedure, management of side effects, counseling, and client education), and RH services

Public Sector

The description of the revised curricula is provided in the approved Milestone 1.2. The cover page for this milestone and letter of approval are shown in Attachment 4. No new methods were included in the revised curriculum for the MOHP, though the SOP for the progestin-only pills was added.

University Medical Schools

The Medical School curriculum has been revised and standardized for all 14 medical schools. New methods were included in this revision and standardization. The Table of Contents is shown in Attachment 5.

Private Sector

In the first year of the project, the POP III Continuing Medical Education (CME) materials for physicians were revised to include new methods (See Attachments 6A and 6B). As of November 1, 2001, 2,647 physicians have attended a one-day CME course on "Hormonal Updates on Contraception." This course includes new information on the progestin-only pills, emergency contraception, and the one-month injectable hormonal contraception. The number of courses provided as of June 30, 2001 is 52.

During the same period, POP III Continuing Medical Education (CME) materials for pharmacists were revised to include new methods (See Attachments 7A and 7B). As of November 1, 2001, 3,018 pharmacists have attended at least one of 50 courses on "Oral Contraceptive Pills." This course includes information on the progestin-only pill and emergency contraception. The corresponding numbers for the CME course on "Contraceptive Injectables" are 2,462 and 45, respectively. This course includes information on the new one-month injectable.

Private Sector/CSI

In the latter part of 1999, all CSI physicians attended a regional course on general family planning methods using POP III materials. These materials included information on the progestin only pill and the three-month injectable.

Private Sector/Final Year Plan

In the third quarter of 2001, the overall program was again revised to incorporate some of the approaches of Evidence Based Medicine (See Attachment 8). Information concerning new methods has been incorporated into these materials. As of November 1, 2000, 159 physicians have attended 3 EBM/family planning speakers programs.

The table below summarizes the overall curricula revisions to include new methods.

Method	MOHP	Medical Schools	CME for Private Physician	CME for Pharmacists
POP	Included as SOP attachment only [Note: POPs were not available within the MOHP at the time of revision]	Included in revised curriculum	Included in revised curriculum	Included in revised curriculum
One-month injectable	Not included [Note: product not available within the MOHP]	Included in revised curriculum	Included in revised curriculum	Included in revised curriculum
Emergency Contraception Pill	Guidelines for use distributed with emergency contraception pills.	Included in revised curriculum	Included in revised curriculum	Included in revised curriculum

C. Train master trainers in revised curricula to conduct training in new methods to the district level

Public Sector/Post Partum IUD

The Postpartum/Post Abortion training program is described in Milestone 1.5 . This milestone has been approved by USAID (See Attachment 9 for cover and approval letter).

Public Sector/New Methods

Three contraceptive update programs have been conducted for those responsible for training in new methods at the governate level. The first was held in the July 1999, the second in April 2000, and the third in March 2001 (See Attachment 10 for agendas). These courses were attended by MOHP medical personnel including master trainers from each of the governates.

Public Sector/Final Year

No contraceptive update meetings for master trainers are planned for the final year of the project.

Private Sector

CME/Physicians

Senior OB/Gyn specialists have been utilized to conduct the CME program during the first two years of the project. MEDTEC, the firm contracted to conduct the CME course for physicians, provides a general orientation for each of the specialists.

CME/Pharmacists

OB/Gyn specialists with university appointments undergo a training of the trainers (TOT) for the new curriculum. The schedule of these training programs held in Cairo is shown below.

Oral Contraceptive Pill Update Injectable Contraceptive Update	Modified Hormonal Contraceptive Curriculum Based on EBM
June 17-18, 1999	September 7, 2001
January 27-28, 2000	

Additionally, in March 2001, a one-day reproductive health update for private sector trainers was conducted by FHI consultant, Dr. David Grimes. As a result of this seminar, an additional reproductive health update was held at the request of CSI (See Attachment 11 for agenda).

Private Sector/Final Year Plan

As part of the CME program for pharmacists, a TOT program for hormonals was conducted in late September 2001.

D. Plan training and orientation for all provider types: doctors, nurses, counselors, outreach workers

Public Sector/Postpartum

Introduction of training for inpatient Postpartum/Postabortion services is described in the approved Milestone 1.5.

Participant Type	Course Topic	Number Trained	Number of Courses	Course Duration	Course Location
Ob/Gyn Specialist MOHP	PP IUD Insertion	140	24	5 days	Central Level

Public Sector/New Methods

Training and medical education for new methods such as POPs, the one-month injectable, and emergency contraception were included in the MOHP's Basic Training of Service Providers. For PY2, the number of trainees and courses for physicians and nurses is shown below. Course descriptions for basic family planning and reproductive health service provision are shown in Attachments 12A and 12B.

Participant Type	Course Topic	Number Trained	Number of Courses	Course Duration	Course Location
Physician service providers	Basic FP and RH Service Provision	1000	10	14 days	Governorate
Nurse service providers	Basic FP and RH Service Provision	975	15	10 days	Governorate
Nurse service providers	FP and RH Client Counseling	450	15	4 days	Governorate

Note: This table excerpted from the System Development Project Implementation Plan of October 2000.

Public Sector/Final Year

During the final year of POP IV, a training program to expand use of new methods will be developed similar to that for the period 2000/2001. The scheduled courses are shown below.

Participant Type	Course Topic	Number Trained	Number of Courses	Course Duration	Course Location
Physician service providers	Basic FP and RH Service Provision	1400	10	12 days	Governorate
Nurse service providers	Basic FP and RH Service Provision	900	60	10 days	Governorate

Note: This table excerpted from the System Development Project Implementation Plan of November 2001.

Private Sector/Final Year

An extensive speakers program, a series of roundtables, and continuing education programs are designed to acquaint physicians with the key issues surrounding hormonal contraception. Similarly, for pharmacists, speakers programs and continuing education programs to acquaint them with the key issues are planned. A complete program plan for physicians and pharmacists is shown in Attachment 13.

D. Identify and incorporate quality indicators for each method into the QIP monitoring system (Task 2)

Updates to the QIP checklist occur when a new method or service is made available in the MOHP. For the postpartum IUD, a checklist was designed, and will be implemented as part of the expanded postpartum program outlined in Milestone 1.5. No method specific indicators have been incorporated into the checklists though there are general indicators that are available.

F. Enhanced Supply

POP IV's Private Sector Project (PSP) has supported the expansion of new hormonal methods in Egypt by encouraging the pharmacy sector to stock and provide information concerning these products. PSP support has been given primarily to progestin-only pills and the one-month injectable. During the pharmacy promotion campaigns for each of these products,

- non-binding orders are taken from the pharmacists visited by PSP and turned over to the companies responsible for their promotion for follow-up
- information brochures giving detailed information about the safety (including possible side effects) and effectiveness of the product are distributed (See Attachments 14A and 14B).

For private physicians (including CSI physicians), detailed information about the safety (including possible side effects) and effectiveness of the product is distributed.

In addition, market segmentation studies conducted by the PSP have aided the commercial market to make better estimates of potential market size for each of the new hormonal methods (i.e., progestin-only pills and the one-month injectable). Some of the problems related to product outages are traceable to poor predictive market growth models of contraceptives in Egypt. A new market segmentation study is underway and will provide additional market size information. This will be presented in the first quarter of 2002.

1. Progestin-Only Pills (POP)

Public Sector

The public sector has purchased a limited supply (270,000 cycles) of progestin-only pills from Organon. POPs are now available in the public sector, but on a limited basis. POP IV is currently working with the MOHP to develop potential market expectations for the POP.

Private Sector

Progestin-only pills were introduced in Egypt during the last quarter of 1997 with approximately 70% of all pharmacies carrying the product by the start of POP IV. Distribution has been slowed primarily by underestimation of product potential in the commercial sector and subsequent outages. POP IV's Private Sector Project (PSP) has promoted POPs primarily to pharmacists using the MEDTEC pharmacy sales force. Using co-promotion strategies with the pharmaceutical sector, the PSP utilized the sales forces of Organon and Schering to make visits to physicians. Given the strong promotion capability of these two companies, it appeared unnecessary to utilize PSP resources to make additional contacts with physicians.

The results of the pharmacy promotion are that:

- as of April, 2001, approximately 80% of all pharmacies carry at least one of the two POPs available in the market.
- as of January, 2001, 84% of all pharmacists had heard of the POP as compared to 46% in January, 2000.
- as of January 2001, 73% of all pharmacists knew that it was good for breastfeeding women as compared to 15% in January, 2000.

In addition to the pharmacy promotion program, a POP IV market segmentation study based on the 1995 DHS data suggested that the market is still growing, a finding contrary to the understanding of the commercial sector. As a result of this study, Schering decided to continue to promote this product to physicians and distribute PSP materials through their pharmacy distributor. Organon continues to maintain strong support for its POP through promotion to physicians and pharmacists.

2. One-Month Injectable

Public Sector

The MOHP does not offer the one-month injectable, though plans for a tender in early 2002 are under consideration.

Private Sector

The one-month injectable was introduced in Egypt during the first quarter of 1999. Because of poor promotional support for this product on introduction at both the pharmacy and physician levels, sales have been less than 90,000 units per year. The PSP developed a campaign to promote this product to both pharmacists and private physicians (including CSI). Distribution has been slowed, primarily by an underestimation of the impact of the PSP promotion program. Product was not available for almost three months during the first and second quarters of 2001. Currently, approximately 45% of all pharmacies carry the product, though by the end of POP IV, it is projected that this percentage will approach 80% based on current sales trends. In early 2002, market potential for the one-month injectable will be estimated for the private sector market.

G. Increased Demand

1. Progestin-Only Pills (POP)

Public Sector

Oral contraceptive consumer leaflets have been developed and include information concerning the POP.

Private Sector

Consumer brochures have been produced for distribution to the pharmacies as well as television and radio advertisements. The combined promotions to pharmacists, physicians, and the media campaign have resulted in a near doubling of POP sales from 413,000 cycles at the end of the year 1999 to 732,000 by the end of the year 2000. Projections for sales are predicted by the pharmaceutical sector to achieve 2,000,000 by the end of 2002. The PSP will continue to support this product via television and radio through the end of POP IV.

2. One-Month Injectable

Public Sector

Informational consumer leaflets have been developed on the one-month injectable.

Private Sector

The combined promotions to pharmacists and the media campaign have resulted in nearly a five-fold increase of sales during 2001, compared to total sales of less than 90,000 in 2000. Projections of sales are predicted by the pharmaceutical sector to achieve at least 460,000 by the end of 2001 and exceeding 1,000,000 by the end of 2002. The PSP will continue to support this product via television, radio, public relations events, consumer and pharmacy sales promotions through the end of the POP IV program in mid-2002.

ATTACHMENT 1
Progestin-Only Pill SOP Developed by MOHP

**STANDARDS OF PRACTICE
Progestin-Only Contraceptive Pills (POPs)**

A. Clinical and Technical Procedures

1. Using the approved medical record, take the client's history. The general contraceptive history will give attention to:
 - a. History of cancer in the breast
 - b. History of liver disease or jaundice (yellow eyes), or gall bladder disease
 - c. Breastfeeding
 - d. Irregular unexplained vaginal bleeding
 - e. Long-term medication with drugs that reduce effectiveness
 - f. Symptoms of pregnancy
 - g. Date of last menstrual period
 - h. History of diabetes
2. Perform a physical exam to identify **factors that would affect contraceptive medical eligibility, and to provide preventive health care (including RTI screening, diagnosis and treatment, cervical cancer screening, and breast self-exam.**

The physical exam will include, but not be limited to:

- a. Breast examination
 - b. Abdominal palpation
 - c. Blood pressure
 - d. Weight
 - e. Pelvic examination
3. Laboratory procedures will be ordered according to the needs/direction of clinician.

4. **When to start:**

After childbirth:

If breastfeeding:

- As early as 6 weeks after childbirth
- Fully or nearly fully breastfeeding and amenorrheic women: 6 months after childbirth or immediately when she has her first menstrual period, whichever comes first.
- Partially breastfeeding: 6 weeks after childbirth
- If menstrual period has returned, start at any time it is reasonably certain she is not pregnant.

Not-breastfeeding

- Immediately or at any time in the first 4 weeks after childbirth. No need to wait for her menstrual period to return.
- After 4 weeks, any time it is reasonably certain that she is not pregnant.

After miscarriage or abortion:

- Immediately or in the first 7 days after either first or second-trimester
- Later, any time it is reasonably certain she is not pregnant

Menstruating:

- In the first 5 days of menstrual bleeding. The first day of menstrual bleeding is best
- Any time it is reasonably certain that she is not pregnant.
- If not starting in the first five days of her menstrual period, she should use condom or spermicide or avoid sex for the next 48 hours

After stopping another method:

- Immediately. No need to wait for a first period after using injectables.

THE PROGESTIN-ONLY ORAL CONTRACEPTIVE PILLS SHOULD BE TAKEN CONTINUOUSLY AT THE SAME TIME WITHOUT PERIODS OF REST

All clients who desire to use Progestin-Only Oral Contraceptive Pills must be screened for the following conditions:

1. Known or suspected pregnancy
2. Known or suspected breast cancer
3. Impaired liver function, active liver disease or history of liver tumor
4. Unexplained vaginal bleeding during the past three months

According to the WHO medical eligibility criteria, progestin-only contraceptive pills should NOT be used in the following condition (WHO category 4)

- Pregnancy

According to the WHO medical eligibility criteria, progestin-only contraceptive pills can be used after careful medical evaluation in the following conditions (WHO category 3)

- Unexplained abnormal vaginal bleeding
- Current or past history of breast cancer with no evidence of disease in the last 5 years
- Active viral hepatitis
- Severe (decompensated) liver cirrhosis
- Liver tumors (benign or malignant)
- Current treatment with antibiotics (rifampin or griseofulvin) or anti-convulsants for epilepsy except valproic acid
- Less than 6 weeks after childbirth
- Schistosomiasis with severe liver fibrosis

B. Follow-up Procedure

1. Unless client has complaint, there is no need for routine visits except for re-supply of pills.
2. Annual medical checkup may be advised.
3. Encourage client to report to the clinic if she wants any help, advise, or to change her method
4. Instruct the client to come back immediately if she experiences one of the following conditions:
 - Unexplained abnormal vaginal bleeding
 - Heart diseases due to blocked arteries
 - Very bad headaches

- Breast changes
- Active liver disease
- Taking antibiotics (rifampin or griseofuvin) or anti-convulsants for epilepsy except valproic acid

ATTACHMENT 2
Discussion Seminar About
Emergency Contraception and Combined Injectables

*Discussion Seminar about
“Emergency Contraception and Combined Injectables”*

10:00 – 10:15	Orientation and discussion of seminar objectives
10:15 – 11:00	Presentation on <i>“Emergency Contraceptive Pills and Combined Injectables”</i>
11:00 – 12:00	Discussion

Objectives:

- Discuss technical contents of training materials that will be used in training of service providers.
- Discuss issues related to correct use and dissemination of appropriate technical information related to the products (postinor & mesigyna).
- Respond to questions that will arise during the presentation.

Emergency Contraception

EC

EC is used to prevent pregnancy after unprotected intercourse, including method failure or incorrect use.

Emergency contraception is a safe and effective approach to the prevention of unintended pregnancy and can reduce the number of abortions and maternal deaths.

- ◆ **Emergency contraceptive options include emergency contraceptive pills (ECPs) and insertion of copper IUDs within 5 days after unprotected intercourse. We are considering ECPs in this presentation.**

- ◆ **Combined oral contraceptive pills and progestin-only pills (POP) can be used for emergency contraception.**
- ◆ **Researches has shown that the progestin-only pills are more effective and have fewer side effects.**

Possible Side Effects:

- ◆ **Nausea and vomiting**
- ◆ **Headaches, dizziness, fatigue**
- ◆ **Breast tenderness**

Generally, do not last more than 24 hours after second dose, although in a few cases they may last up to two days.

Possible Mechanisms of Action:

- ◆ **Depending on when used during the cycle, may inhibit or delay ovulation.**
- ◆ **May affect the endometrium, which could theoretically prevent implantation.**

N.B.

Once implantation has occurred, emergency contraceptive pills are no longer effective thus, ECP do not interrupt an established pregnancy.

How to use ECPs:

It is used immediately after unprotected intercourse (within 72 hours) to prevent pregnancy. It should not be used instead of other continuous methods for contraception.

Indications:

- ◆ **Unprotected intercourse.**
- ◆ **Method failure such as torn condom**

Progestin-Only Pills (POP):

The best studied progestin-only regimen consists of a pill containing 0.75 mg of Levonorgestrel available in the market as Postinor. One pill of postinor should be taken immediately after unprotected intercourse and within 72 hours, followed by another pill 12 hours later.

COPs:

If Postinor is not available, low dose Ocs can be used by taking 4 pills immediately after unprotected intercourse and within 72 hours. A second similar dose should be taken 12 hours after the first dose. The POP regimen is better than using the COPs because it causes nausea and vomiting.

N.B.

Timing:

Most effective when taken early.

Source: WHO task force, lancet, 1998

WHO study found that the sooner emergency contraceptive pills are started, the more effective they are:

- ▶ POPs prevented 95% of the expected pregnancies when initiated within 24 hours after unprotected intercourse.**
- ▶ COPs Prevented 77% when initiated within 24 hours.**

Key Counseling Messages:

- ◆ **More effective the sooner they are begun**
- ◆ **Side effects (nausea and vomiting) may occur, especially with the COs regimen**
- ◆ **Next menses may come a week earlier or late.**
- ◆ **Do not provide protection for future intercourse**
- ◆ **After using, regular method should be considered**

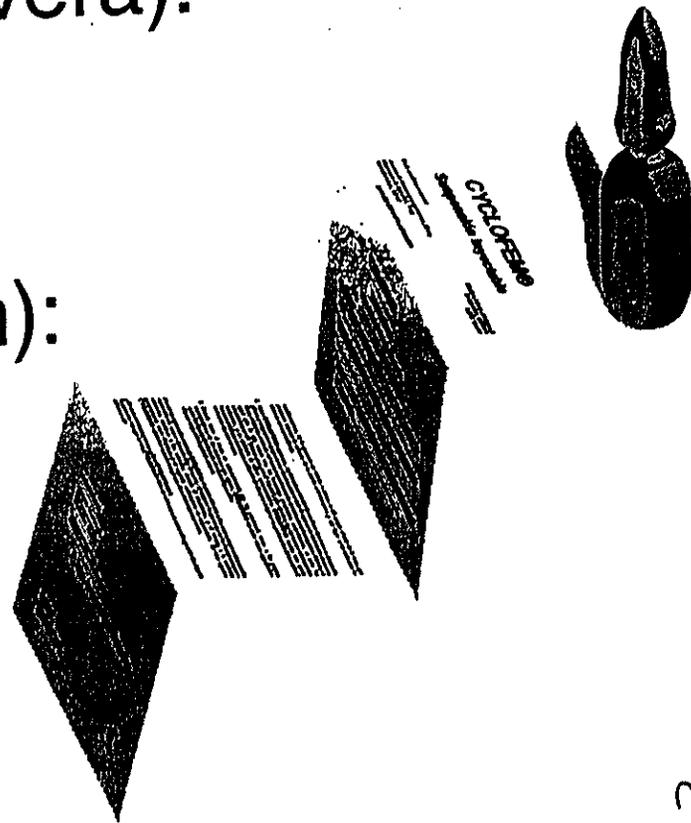
Combined Injectable Contraceptives

Contain progestin and estrogen

- Used by 1 million women worldwide
- Administered monthly
- Provide more regular bleeding cycles
- May result in estrogen-related side effects

Combined Injectables: *Newer Products*

- Cyclofem (or Cyclo-Provera):
25 mg DMPA
5 mg estradiol cypionate
- Mesigyna (or Norigynon):
50 mg NET-EN
5 mg estradiol valerate



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Combined Injectables:

Disadvantages

- Cause side effects, including bleeding irregularities
- Provide no protection against STDs, including HIV
- Action cannot be stopped immediately
- Require more frequent injections than progestin-only injectables

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Combined Injectables: *Less Common Side Effects*

Weight gain

Headaches

Dizziness

Breast
tenderness

***Can result in
discontinuation***

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Combined Injectables:

Management of Menstrual Changes

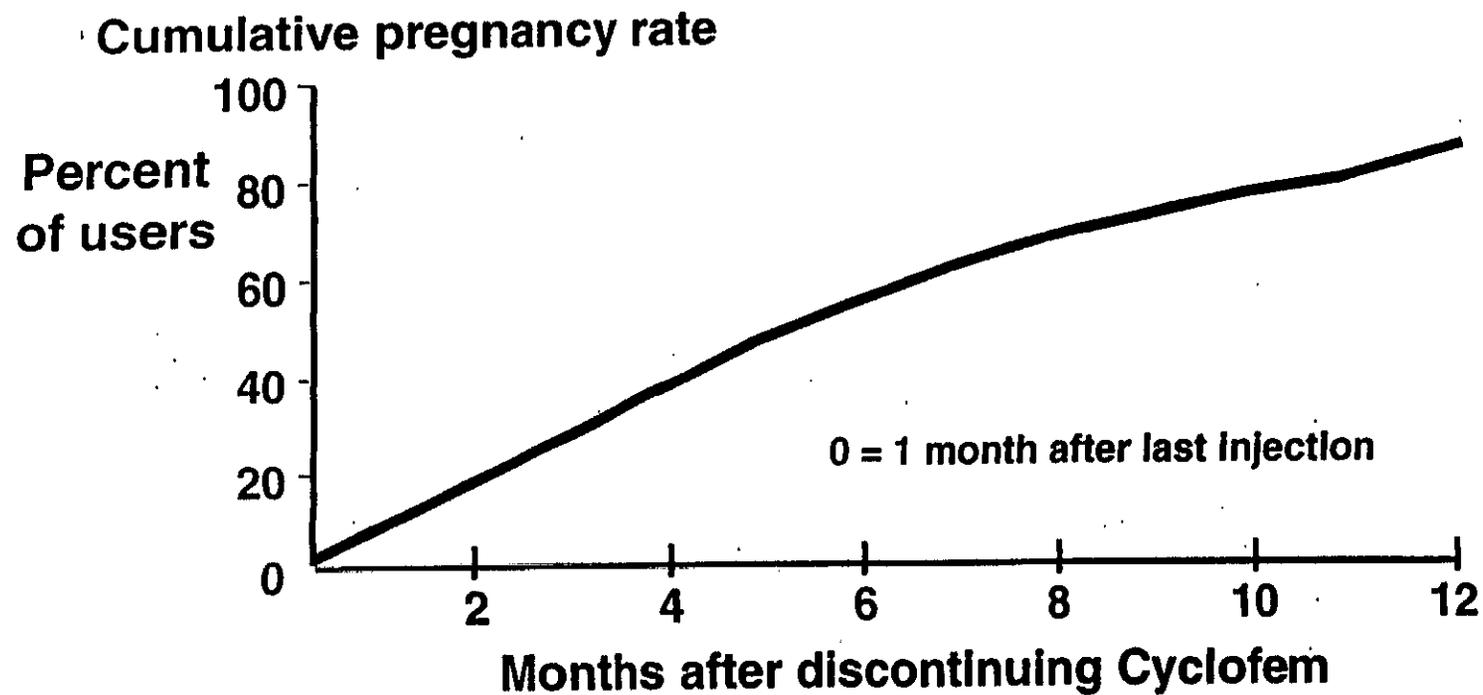
Bleeding

- Usually can be managed through counseling
- Ibuprofen or short course of COCs can be administered, if necessary

Amenorrhea

- Counsel and reassure, as needed

Combined Injectables: *Return to Fertility*



Source: Bahamondes, 1997.

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Combined Injectables: *Safety*

- Safety of progestins is well established
- Daily dose of estrogen is small
- Long-term safety information not yet available
- Contraindications based on those for COCs

Combined Injectables:

WHO Eligibility Criteria

Category 4: Unacceptable health risk

- Breast cancer
- Blood pressure over 180/110
- Deep venous thrombosis

Category 3: Risks outweigh benefits

- Moderate hypertension
- Heavy smokers over 35 years of age

Combined Injectables:

WHO Eligibility Criteria (cont.)

Category 2: Benefits outweigh risks

- Nonvascular diabetes
- Biliary tract disease
- Women over 40 years of age

Category 1: No restriction

- Varicose veins
- Thyroid disorders
- STDs

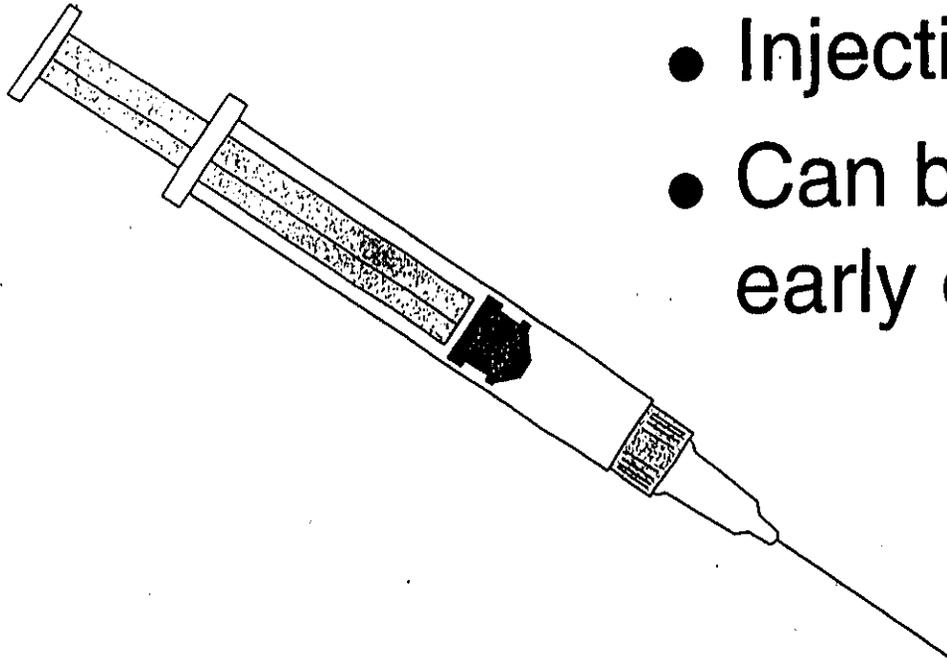
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Combined Injectables: *When to Begin*

- Any time during menstrual cycle
 - backup recommended if given after day 7
- Postpartum:
 - not breastfeeding: delay 3 weeks
 - breastfeeding: delay of 6 months recommended
- Postabortion: immediately

Combined Injectables: *Injection Schedule*



- Injection every month
- Can be up to 3 days early or late

Counseling About Injectables

Factors for client to consider

- Other available contraceptive options
- Advantages and disadvantages
- Side effects including menstrual changes
- Timing of return to fertility
- Need for regular, timely injections

Counseling About Injectables (*cont.*)

Messages for clients who choose injectables

- Do not massage injection site
- Expect bleeding 12-15 days after injection
- Return if problems arise
- No protection from STDs, including HIV

Programmatic Issues: *Training*

- Characteristics of injectables
- Key counseling points
- Sterile injection technique
- Management of side effects
- Recognition of problems
- Referral procedures
- Record keeping

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ATTACHMENT 3
Standards of Practice*

*Excerpted from Guidelines for Family
Planning Services in Egyptian
University Hospitals

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STANDARDS OF PRACTICE

Emergency Contraception

Emergency contraception is the use of certain methods immediately after unprotected intercourse to prevent pregnancy. However, it should NOT be used instead of other continuous methods for contraception.

A. When to Use Emergency Contraception

In cases of unprotected intercourse and:

- No contraception was used (including coercive sex rape)
- Method did not function properly (e.g., torn condom)
- Method was used incorrectly (e.g., missed pills)

B. Options for Emergency Contraception

Special regimens of contraceptive pills that can be taken immediately or within 72 hours after unprotected intercourse:

1. Progestin-only pills

The best studied progestin-only regimen consists of a pill containing 0.75 mg of levonorgestrel. One pill should be taken immediately and certainly within 72 hours of unprotected intercourse, followed by another pill 12 hours later. This regimen causes less nausea and vomiting than combined oral contraceptives.

2. Combined oral contraceptive pills

Combined oral contraceptive pills containing ethinyl estradiol and levonorgestrel can be used as emergency contraception. The so-called Yuzpe regimen is to take 4 tablets of a low dose combined oral contraceptive immediately and certainly within 72 hours after unprotected intercourse. A second similar dose should be taken 12 hours after the first dose.

3. Copper IUD

- Inserted within 5 days after unprotected intercourse
- Highly effective (0.1% pregnancy rate)
- Side effects include cramping, heavy menstrual bleeding, and spotting
- After insertion, can be used for ongoing contraception

STANDARDS OF PRACTICE
Combined Injectables (Once-A-Month Injectable Contraceptive)

A. Clinical and Technical Procedures

1. Using the approved medical record, take the client's history, including, but not limited to:
 - Age
 - Smoking
 - Breastfeeding
 - Menstrual history, last menstruation, possibility of pregnancy
 - Breast cancer
 - Migraine
 - Liver or gall bladder diseases
2. Perform a physical examination including:
 - Measuring blood pressure
 - Weight
 - Breast examination
 - Abdominal examination
 - Pelvic examination
3. Other elements can be carried out as part of health screening but are not critical to use once-a-month injectables.
4. Starting Once-A-Month Injectables
 - Start during the first five days of the menstrual cycle. However the first injection can be given anytime you can be reasonably sure that the woman is not pregnant.
 - If the woman presents later than the first 5 days of the menstrual cycle and you can be reasonably sure that she is not pregnant, and she is unable to protect herself by using a condom or spermicide until the next menstruation, then give the injection. However, the woman should be counseled to use a backup method or avoid sex for the next 48 hours.
 - After childbirth:
 - a. If not breastfeeding: 3-6 weeks after childbirth. No need to wait for the menstrual period to return.
 - b. If breastfeeding, after she stops lactation.
 - In the first 7 days after first trimester abortion
5. Subsequent injection: every 30 days \pm 3 days.

All clients who desire to use Once-A-Month injectable must be screened for the following conditions:

1. Known or suspected pregnancy
2. Impaired liver function, active liver disease or history of liver tumor
3. Known or suspected cancer of breast
4. Coronary artery disease (or history thereof)
5. Blood clots in the leg, pelvis, lungs, brain (or history thereof)
6. Breastfeeding
7. Severe headaches
8. Hypertension (diastolic blood pressure more than 90)

9. Diabetes mellitus (insulin dependent)
10. Age 40 and heavy smoking (more than one pack per day)
11. Unexplained vaginal bleeding during the past three months
12. Immobilization of the legs or pelvis (i.e., leg cast or surgery)

Once-A-Month injectable should NOT be used in the following condition

- Proven pregnancy
- Heavy smokers aged 35 or more
- Severe hypertension
- Past or current thromboembolic disorders or ischaemic heart disease
- Valvular heart disease with complications
- Major surgery with prolonged immobilization
- Migraine with local neurological symptoms
- Breast cancer
- Active viral; hepatitis, cirrhosis of the liver with impaired liver function and hepatic tumors
- Less than 6 months after childbirth in breastfeeding mothers
- Schistosomiasis with severe liver fibrosis

Once-A-Month injectable can be used after careful medical evaluation in the following conditions

- Age 35 and over and a light smoker (20 or fewer cigarettes per day)
- Past hypertension when blood pressure cannot be evaluated
- Diabetes with vascular diseases or diabetes for more than 20 years
- Unexplained vaginal bleeding
- Past history of breast cancer with no evidence of disease in the last 5 years
- Current gall bladder diseases or gall bladder treatment with medication
- Past history of jaundice related to COCs
- Mild (compensated) liver cirrhosis
- Current treatment with antibiotics (rifampin or griseofulvin) or anti-convulsants for epilepsy except valproic acid
- 6 weeks to 6 months after childbirth
- Less than 21 days postpartum in non-breastfeeding women

B. Follow-up Procedure

1. Follow-up visits are indicated for repeat injections every 30 days. The window for repeat injections is \pm days. Thus regular attention to the date of the next visit should be emphasized.
2. Client should be encouraged to come to the clinic if they need any help, if they have any questions or they want to change the method.
3. Clients should be instructed to come immediately if they develop one of the following symptoms:
 - Severe, constant pain in the chest, legs, or belly
 - Very bad headaches
 - See flashes of light or zigzag lines
 - Jaundice

4. At each visit women should be:
 - Asked if they have any problem
 - Given the injection
 - Instructed of the date for the next visit
 - Document visit and findings in the medical record

5. Annual examination is encouraged along with other routine preventative

STANDARDS OF PRACTICE
Lactation Amenorrhea Method (LAM)

A. Clinical and Technical Procedures

There are no clinical or technical elements to note when recommending breastfeeding as the contraceptive method. This method presents a counseling challenge to the provider.

1. Using the approved medical record, take the client's medical history with specific emphasis on the following:
 - a. Are you fully breastfeeding your baby?
 - b. Is your baby less than 6 months old?
 - c. Has your menstrual bleeding not returned since you stopped postpartum bleeding? (If so, please describe.)

If the answer to all 3 questions is yes, breastfeeding is an appropriate method of contraception. When any of these change or if the answer changes to no, the client needs to use a backup method.

2. Perform a physical examination to:
 - a. Conduct routine health screening
 - b. Identify nipple pathology
 - c. Give breast self-examination instructions.
3. The client can assume she is protected against pregnancy as long as all of the following are true:
 - a. She is not menstruating
 - b. The baby is fully (or nearly fully) breastfeeding
 - c. The baby is less than 6 months old.

When any of the previously mentioned conditions are changed or if the client desires, another method of contraception should be used.

B. Follow-up Procedure

1. Clients need to be seen for the routine six-week postpartum visit to assure that contraceptive information is clear and that childbirth issues are resolved.
2. Unless one of the items under clinical and technical procedures occurs, the client need not be seen until six months following childbirth.
3. It is possible to become pregnant while breastfeeding. If symptoms of pregnancy occur, the client should return for evaluation.
4. The client must have a backup method available if one of the items under the clinical and technical procedures occurs.
5. The client should return to the clinic if one of the items under the clinical and technical procedures occurs.

ATTACHMENT 4
Milestone 1.2: Standards and Curricula
for New Methods Updated

MILESTONE COMPLETION REPORT
CONTRACT NUMBER : 263-C-00-99-00017-00

To : Chris McDermott
COTR

CC : Donella Russell
Contract Officer

From : *Waleed Alkhateeb*
Waleed Alkhateeb
Chief of Party

Date : January 30, 2000

Task Number : 1

Task Description : Contraceptive Technologies and Services Expanded and More Widely Available

Milestone No.: 1.2

Milestone Description: Standards and Curricula for New Methods updated

Source of Verification: Updated standards and curricula documents

Planned End Date: October 31, 1999

Status : Re-submitted

Comments: Attached are the Arabic Versions of the revised SOP , the Family Planning and Reproductive Health Procedure Manual for Physicians , and the Family Planning and Reproductive Health Manual for Nurses . The MOHP has accepted the revisions . The Arabic version of the SOP has been sent for printing by the MOHP . The MOHP standing orders requires that all printing has to be made in-house. This causes some delays .
MOHP dates for finalization of printing and distribution cannot be anticipated.

The English version of the revised SOP were submitted earlier to USAID

USAID



CAIRO, EGYPT

UNITED STATES AGENCY for INTERNATIONAL DEVELOPMENT

Dr. Waleed

March 6, 2000

Dr. Waleed Al Khateeb
Chief of Party, Pathfinder
28L El Safa St., Off El Gazayer St.,
New Maadi, Cairo, Egypt

REF: Contract # 263-C-00-99-00017-00
Task Number 1
Milestone No. 1.2 "Standards and
Curricula for New Methods updated"
Planned end date: October 31, 2000

Dear Dr. Waleed:

This is to acknowledge receipt of documents related to milestone performance under the referenced contract and to provide Pathfinder with USAID's official response to Pathfinder's reporting of this milestone as "completed". The Ref. documents were received on February 1, 2000.

USAID Comments: The document presented by Pathfinder, "Standards and Curricula for New Methods updated", represents satisfactory supporting documentation on the achievement of the milestone.

Action(s) Requested: As this milestone has been met, no further action is needed.

Yours truly,

Chris McDermott
Cognizant Technical Officer

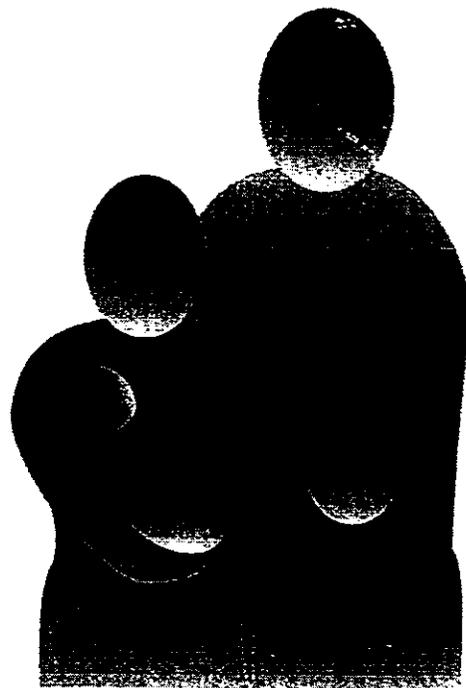
Celeste Fulgham
Contract Officer

cc. Jayne Cody, Pathfinder, Boston

USAID/Egypt
Zahraa El Maadi, Maadi
Cairo, Egypt

ATTACHMENT 5
Medical School Curriculum Outline

**Egyptian Medical Schools
Reproductive Health
Curriculum:
Family Planning Methods
Module & Student Handbook**



Family Planning

2

Oral Contraceptives

3

Injectable Contraceptives

4

Other Hormonal Methods

5

Intrauterine Devices

6

Female & Male
Sterilization

7

Barrier Methods

8

Lactational Amenorrhea
Method (LAM)

9

Other Non-Hormonal
Methods

Emergency
Contraception

ATTACHMENT 6A
Private Sector Continuing Education for Physicians
Hormonal Updates on Contraception: Part 1
Oral Contraceptives