

V. Annex

PD-3 (September 1982) (Formerly PD-70 June 14, 1977)

USAID Policy Guidelines on Voluntary Sterilization

I. Overview

The World Population Plan of Action of the World Population Conference of 1974 observed that; "All couples and individuals have the basic right to decide freely and responsibly the number and spacing of their children, and to have the information, education and means to do so..."

The Foreign Assistance Act (FAA) of 1961 (as amended) reflects additional considerations:

(1) the process of economic and social development which is in turn affected by the pace, magnitude and direction of population growth; and,

(2) in many LDCs high rates of population growth limit attainment of broader development goals, contribute to economic hardship and hazardous health conditions, and deny opportunities for improved quality of life for many parents and their children.

In carrying out a comprehensive population assistance program *authorized by the FAA*, USAID has responded to the growing number of LDC requests for assistance and has helped to make the various methods of family planning permitted by our legislation available on a broader scale to the rural and urban population for use on a strictly voluntary basis.

More recently, LDC governments and nongovernment organizations have requested assistance to extend the availability of voluntary sterilization (VS) services.⁴ Such requests are partially in response to the preparatory work conducted by various

⁴ VS service programs include those activities which are primarily intended to provide voluntary male and female sterilizations to persons requesting this type of contraceptive procedure. For purposes of this discussion, however, VS training programs are included,

organizations which have received USAID support, including the Association for Voluntary Sterilization (AVS), the Pathfinder Fund, the International Fertility Research Program (IFRP), and the Johns Hopkins University Program for International Education in Gynecology and Obstetrics (PIEGO) as part of its broad program of advanced training in obstetrics and gynecology. These organizations have contributed to significant advances in the development of new surgical techniques which make sterilization safer, simpler and less expensive as an outpatient procedure. They have developed specialized equipment and given LDC medical personnel specialized training in the practice of obstetrics and gynecology, including endocrinology, identification of cancerous conditions, maternal care, and the management of infertility and fertility, including sterilization procedures.

In providing support for sterilization services, USAID must reaffirm its long-standing and complete commitment to the basic principle of voluntary acceptance of family planning methods and determine basic conditions and safeguards within which USAID support for sterilization activities can be provided. These conditions and safe- guards are needed because of the special nature of sterilization as a highly personal, permanent surgical procedure and to ensure that the needs and rights of individuals are scrupulously protected.

The official positions of national governments are mixed. While voluntary sterilization has become a basic part of comprehensive family planning services in many countries, in some there is only unofficial approval for action by non-government agencies while in other countries there is opposition to the method. A.I.D staff and USAID-funded grantees and contractors must be fully aware of national sensitivities and must receive USAID/W and mission approval before making any commitments on commencing support for sterilization activities in any context.

II. General Guidelines

USAID acknowledges that each host country is free to determine its own policies and practices concerning the provision of sterilization services. However, USAID support for VS program activities can be provided only if they comply with these guidelines in every respect.

A. Informed Consent: USAID assistance to VS service programs shall be contingent on satisfactory determination by the USAID (bilateral programs) and/or USAID-funded grantees or contractors that surgical sterilization procedures, supported in whole or in part by USAID funds, are performed only after the individual has voluntarily Presented himself or herself at the treatment facility and given his or her informed consent to the sterilization procedure.

Informed consent means the voluntary, knowing assent from the individual after he or she has been advised of the surgical procedures to be followed, the attendant discomforts and possible risks, the benefits to be expected, the availability of alternative methods of family planning, the purpose of the operation and its irreversibility, and his or her option to withdraw consent anytime prior to the operation. An individual's consent is considered voluntary if it is based upon the exercise of free choice and is not obtained by any special inducements or any element of force, fraud, deceit, duress or other forms of coercion or misrepresentation.

Further, the recipient of USAID funds used all or in part for performance of all procedures must be compared to document the patient's informed consent by (a) a written consent document in a language the patient understands and speaks, which explains the basic elements of informed consent, as set out above, and which is signed by the individual and by the attending physician or by the authorized assistant of the attending physician or (b) when a patient is unable to read adequately a written certification by the attending physician or by the authorized assistant of the attending physician that the basic elements of informed consent were orally presented to the patient, and that the patient thereafter consented to the performance of the operation. The receipt of the oral explanation shall be acknowledged by the patient's mark on the certification and by the signature or mark of a witness who shall be of the same sex and speak the same language as the patient.

since training generally requires that trainees conduct supervised procedures on patients who have voluntarily presented themselves at a service/training facility for sterilization.

Copies of these informed consent forms and certification documents for each VS procedure must be retained by the operating medical facility, or by the host government, for a period of three years after performance of the sterilization procedure.

USAID Missions should note their responsibility to monitor USAID-assisted VS programs-whether such programs are funded bilaterally or by USAID-funded grantees or contractors- to ensure continuing adherence to the principle of informed consent. In order to carry out this monitoring function effectively, all proposed programs-either bilaterally funded or funded by USAID-supported intermediaries-shall be approved by the mission and USAID/W prior to any commitment of funds or promise to commit funds for VS activities. In carrying out this responsibility, USAID staff should be thoroughly familiar with local circumstances and government administrative patterns and be able to communicate effectively with host country representatives.

B. Ready Access to Other Methods: Where VS services are made available, other means of family planning should also be readily available at a common location, thus enabling a choice on the part of the acceptor.

C. Incentive Payments: No USAID funds can be used to pay potential acceptors of sterilization to induce their acceptance of VS. Further, the fee or patient cost structure applied to VS and other contraceptive services shall be established in such a way that no financial incentive is created for sterilization over another method.

D. Quality of VS Services: Medical personnel who operate on sterilization patients must be well-trained and qualified in accordance with local medical standards. Equipment provided will be the best available and suitable to the field situations in which it will be used.

E. Sterilization and Health Services: To the fullest possible extent, VS programs-whether bilaterally funded or conducted by USAID funded private organizations- shall be conducted as an integral part of the total health care services of the recipient country and shall be performed with respect to the overall health and well-being of prospective acceptors. In addition, opportunities for extending health care to participants in VS programs should be exploited to the fullest. Consideration must also be given to the impact that expanded VS services might have on existing general health services of the recipient country with regard to the employment of physicians and related medical personnel and the use of buildings or facilities.

F. Country Policies: In the absence of a stated affirmative policy or explicit acceptance of USAID support for VS activities, USAIDs should take appropriate precautions through consultation with host country officials in order to minimize the prospect of misunderstandings concerning potential VS activities. In monitoring the consistency of USAID-supported VS programs with local policy and practices, USAIDs and USAID-funded donor agencies shall also take particular note of program activities among cultural, ethnic, religious or political minorities to ensure that the principles of informed consent discussed under "A" above are being observed and that undue emphasis is not given to such minority groups.

Addendum to PD-3 (*formerly Addendum to PD-70, 2/9/81*)

Additional A.I.D Program Guidance for Voluntary Sterilization (VS) Activities

1. INTRODUCTION: The previously provided Policy Determination No. 3 (PD-3), remains in effect. However, in light of several years experience, additional clarification of a number of points relating to the application of PD-3 and specific interpretation of its provisions appears to be needed.

2. APPLICABILITY OF PD-3: PD-3 states "USAID support for VS program activities can be provided only if they comply with these guidelines in every respect". This means that the provisions of PD-3 must be applied if USAID funds are used for whole or partial direct support of the performance of VS activities. However, as also noted in PD-3, "USAID acknowledges that each host country is free to determine its own policies and practices concerning the provision of sterilization services". The provisions of PD-3 do not apply if USAID provides support for population and family planning programs within a country and

provision of VS services is not called for in the support agreement, i.e., VS activities may be a part of the host country's program, but USAID funds are not used to support such services. For example, if USAID support for VS program activities is geographically confined to particular parts of a country, PD-3 applies only to those areas with VS program activities supported by USAID PD-3 does not apply if activities and projects are only peripherally related to provision of VS services, for example, USAID support for construction of multipurpose buildings or broad-based training in reproductive health which includes VS techniques. Finally, in USAID supported population and family planning programs in host countries which use USAID funds for activities other than VS and support VS activities; with their own or other non-USAID funds, PD-3 does not apply.

3. **INFORMED CONSENT:** The recipient of A.1 -D support used fully or in part for performance of VS procedures must obtain and document voluntary informed consent as part of the conduct of any VS procedure. USAID does not require any specific format for this procedure. However, the elements of the procedure described in PD-3 (i.e., an explanation of the nature of the procedure, the attendant risks and benefits, availability of alternative methods of family planning, that the procedure is irreversible, and that the patient may withdraw consent) all must be part of the process of obtaining informed consent.

4. **METHODS OF PAYMENT:** All acceptor and/or provider payments in cash or kind beyond VS service costs as well as fees charged for VS and other contraceptive services shall be established in such a way that no financial incentive is created for sterilization over another contraceptive method.

(A) Payment of Acceptors: It should be noted that guidance differs for payments which may be made to acceptors of VS as contrasted to payment to providers of VS (guidance applicable to providers of VS services is described in para 4.B. below). As stated in PD-3, para C, "no USAID funds can be used to pay potential acceptors of sterilization to induce their acceptance of VS". Further, USAID support generally cannot be provided to VS services which include incentive payments paid to potential acceptors. For example, a VS program supported by USAID cannot be supplemented with acceptor incentives to induce acceptance of sterilization services. Determination of what constitutes an incentive must be made locally based on thorough knowledge of social and economic circumstances of potential acceptors. In general, recompense to acceptors for legitimate, extra expenses related to VS program services such as transportation, food during confinement, medicines, surgically related garments and dressings and the value of lost work are not considered incentive payments and are eligible for USAID support. It should be emphasized that these payments must be of a reasonable nature and aimed at making VS services equally available at the same cost as other contraceptive services. For example, payment for lost work must correspond to a reasonable estimate of the value of lost labor over a reasonable duration of convalescence.

(B) Payment of Providers of Services: In light of experience, it seems desirable to modify the previous USAID program guidance relating to reimbursement for VS services as defined in USAIDTO Circular 393 (10/27/77), page 6, section 3, "operating service costs", para. 4. The suggested prohibition of reimbursement to providers of VS services on a per-case basis has not proven practical in that payment per case or procedure is the time honored method of paying for surgical procedures both in developed and less developed countries. Reimbursement of physicians, paramedical and other service personnel on a per-case basis can be an acceptable procedure. Compensation to providers for items such as anesthesia, personnel costs, pre and postoperative care, transportation, surgical and administrative supplies, etc., on a per-case basis is also generally acceptable. These payments to providers must be reasonable relative to other medical and contraceptive services provided so that no financial incentive is created for the providers to carry out VS procedures compared to provision in other methods of family planning. As in the of payments to acceptors, this is a judgment which will have to be made on a country and

program specific basis. However, in both cases, USAID in Washington will provide assistance and guidance in making such determinations, and decisions relating to application of PD-3 should be submitted to USAID/Washington for review. Even though payment on a per-case basis is often customary, USAID Missions are advised to encourage patterns of service delivery and methods of payment which do not unduly emphasize VS procedures compared to other methods of fertility control. For example, if physicians who carry out the surgery are paid on a per-case basis and they have no role in the selection or counseling of patients, these service providers cannot induce additional patients to accept sterilizations over other contraceptive methods. Payments of physicians on a per-session rather than a per-case basis may also serve the same function. Since payments on a per-case basis do raise questions, often of a complex nature, beyond those raised by other types of compensation, where a mission can persuade a government to use such other frameworks for payment, whether immediately or phased-in, it should do so.

(C) Payment of Referral Agents: In some countries fieldworkers are employed to inform and refer potential acceptors of contraceptive methods including VS. When extra expenses are incurred in informing and referring VS acceptors, a per-case payment of these costs is acceptable. Again, as is the case with payments to providers and/or acceptors, a country or program specific determination that the payment is for legitimate extra expenses or activities associated with VS referral must be made. The aim is to make all available contraceptive methods available at the same cost to the acceptor.