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Introduction

Over the past decade concerted national efforts to solve population problems have come into being.^{1,2,3} The major thrust of these programs has been to make means of fertility control freely available to men and women in the reproductive age ranges.

As experience with these voluntary family planning programs has increased, it has become clear that the nature of the available fertility control technology is highly important to the success of these programs.^{4,5} Programs offering a limited range of fertility control means are less successful than those offering a variety of techniques. Particularly important are the availability of post conceptive means (i.e., pregnancy termination^{6,7}) sterilization^{8,9} and contraceptives which can be self-administered independent of the existence of an elaborate medical service infrastructure.⁵

This paper will examine the importance of the availability of oral contraceptives in less developed countries, the practicality of using traditional medical channels for their provision in these countries, and the magnitude of any hazards associated with a family planning strategy based on non-clinical provision of oral contraceptives.

The Acceptability and Importance of Using Oral Contraceptives in Less

Developed Countries

Acceptability

In developed countries, where the cost of oral contraceptives is not high relative to income and where there are adequately accessible supply outlets and medical care services, the pill is the most commonly employed reversible means of contraception.

After their introduction in the U.S. in 1960, new users averaged over one million per year up to 1968 at which time use was estimated at 8.5 million.^{4,10} Prevalence of use in 1971 was estimated at 9.7 million¹¹ at which time new prescriptions for oral contraceptives numbered 15.6 million.¹²

Although available data allows only very rough approximations, current estimated usage of various means of fertility control in developed and less developed countries is presented in Table 1. Reports from Mainland China do not give exact data but they confirm that there are millions of users of the pill which is the most widely used contraceptive.¹³

It is now clear that oral contraceptives are a highly acceptable and effective means of fertility control in developed countries. Evidence of their acceptability in less developed countries is substantial, though less conclusive because this means of fertility control has not usually been made freely available. When oral contraceptives have been offered and made fully available to women in less developed countries, they appear to be as popular as in the developed countries.

Ravenholt, Piotrow and Speidel have recently reviewed the status of the pill in family planning programs which have been in operation long enough to allow evaluation. In Singapore, Hong Kong, Thailand, The Philippines, Mainland China, Indonesia, Taiwan and Korea the pill is playing an increasingly important role, and success in terms of reduction of birth rates has been greater than in countries not using the pill such as India and Pakistan (Pakistan has recently made the pill increasingly available).⁴ The rapid growth in use of oral contraceptives in population programs assisted by the Agency for International Development is shown in Figure 1.

Demographic Impact

In addition to acceptability, the demographic impact of oral contraceptives as a means of fertility control must be considered. Although many have considered oral contraceptives less suitable than IUDs for use in developing countries, the evidence is increasingly clear that wherever women have free choice of methods, orals are the preferred means of contraception. It is not always recognized that prevalence of use (the number of users at a point in time among sexually active women in the reproductive age range) is the crucial measure of impact of the method.

Furthermore, many studies of continuation rates do not use life table techniques and almost none standardize by the age and parity of the user.¹⁴ Typically, younger women accepting the pill are compared to older higher parity women using other methods such as IUDs (see Figure 2). Comparisons standardized by age and parity considerably narrow the continuance gap between these two methods.^{15,16}

Since oral contraceptives appeal to more users and to women of younger age and parity than other good methods such as sterilization or IUDs, they have a particularly important demographic role.^{14,16}

Practicality of Medically Based Provision of Oral Contraceptives in Less Developed Countries

In deciding upon the extent of professional supervision needed for distribution and use of oral contraceptives, consideration must be given to both possible risk of non-medical distribution and the practicality of requiring professional medical supervision for such distribution.

In developed countries, where the ratio of physicians to population is high and where women ordinarily obtain expert medical care for pregnancy and childbirth, it may be appropriate to limit the availability of orals to prescription by physicians. In developing countries, however, the ratio of physicians (or even paramedical personnel) to population is as low as one tenth or one hundredth found in developed countries. To restrict orals to prescription by physicians is the equivalent of denying them altogether to most of the populations, especially the poor and those living in rural areas which may be totally devoid of physicians.

In Table 2, the ratio of physicians to population is shown in typical developed countries and in 20 largest less developed countries which will (excluding Mainland China) contribute 80% of the growth in less developed countries in the next decade.^{17,18}

Risk Associated with Non-Clinical Distribution of Oral Contraceptives

Thromboembolism

Thromboembolic disease is the only well established serious hazard related to use of oral contraceptives.^{4,19,20} If it is true that the higher dosage oral contraceptives are associated with greater risk,²¹ in view of the recent growing use of lower dose preparations, one might anticipate that the risk has or will become even less.²² Preliminary data from recent studies in the U.S. suggest that relative risk of thromboembolism may only be two times as great among users vs non-users whereas previous studies with higher dosage compounds found an increased relative risk of 4.4 times.^{20,23}

In assessing non-clinical distribution of oral contraceptives, it is important to compare the risk of thromboembolism among women receiving oral

contraceptives from professional medical sources with the risk among women receiving oral contraceptives with no supervision. While among healthy users there is no way to detect who is likely to have a thromboembolic problem, consideration must be given to the importance of detecting disease conditions such as varicosities, history of phlebitis, etc. which might be expected to predispose to thromboembolic problems. Unfortunately very little information exists on relative risk of thromboembolism to users and non-users with conditions thought to be predisposing.

The retrospective case-control studies of Inman and Vessey show no statistically significant difference in risk of thromboembolism to those with predisposing conditions when users were compared to non-users of oral contraceptives in Great Britain.²⁴ Perhaps when predisposing conditions are present the diathesis toward thromboembolism outweighs the importance of the presence or absence of the pill. Although most medical authorities advocate careful medical screening and elimination of those with predisposition to thromboembolic problems from the ranks of pill users, what little evidence we have suggests this may not be highly important in preventing thromboembolic disease. Since there is no medical way to predict who will have this problem, there is so far no established reason based on thromboembolism for restricting the non-clinical availability of oral contraceptives.

In fact, there is a strong argument relating to risk to life for making oral contraceptives freely available. In assessing overall hazards of oral contraceptives, risks must be compared to use of alternative techniques and to non-use of contraception. Use effectiveness of the contraceptive method (effectiveness in actual use conditions) must be considered in this

comparison. Relative risks of the contraceptive methods can best be evaluated in a model population of 100,000 women, by comparing mortality rates from contraceptive usage and maternal mortality rate from pregnancy and childbirth and taking into account the actual use effectiveness of the alternative contraceptives.

Table 3 has been calculated using a method presented by Tietze.^{4,25} It shows the risk to life for those not using contraception and for those using each method of contraception. These figures, particularly as they relate to the less developed countries, must be viewed only as approximations, chiefly because the mortality related to use of the method may differ greatly in the less developed countries, which do not have good medical treatment facilities to care for complications associated with pill and IUD use. There is inadequate experience to give a good estimate of risk of abortion in the hospital or outpatient setting found in the less developed countries.^{4,25}

Bearing in mind these cautions, it can be seen from Table 3 that, even in the U.S., women of reproductive age are less likely to die if they use oral contraceptives than from complications of the reproductive process when attempting its control by other methods. The user of other contraceptive methods also runs a much greater risk of an unwanted pregnancy than does the oral contraceptive user.

In developing countries, where maternal mortality may exceed 1,000 deaths/100,000 live births, the hazard to life for young women may be hundreds of times greater from unwanted pregnancy than from use of oral contraceptives--even if one assumes the incidence of thromboembolism to be the same as in the U.S. and Britain. Furthermore, there is some data to suggest

that among women of reproductive age with different ethnic composition and diet living in the developing countries near the equator, who are leaner, more active, and do not smoke cigarettes, the incidence of thromboembolic phenomena is probably much lower and perhaps negligible.^{4,26,27,28}

Malignant Neoplasia

Oral contraceptives have not been demonstrated to have an unfavorable effect on incidence or mortality patterns from cancer of the uterus and breast.⁴ Long term primate studies currently in progress in the U.S. have shown no increase in malignancies. Epidemiologic studies in progress sponsored by the U.S. National Institutes of Health give no evidence of increased risk of neoplasia among pill users.²³ In the U.S. since 1960 there has been a steady decline in uterine cancer mortality and little change in breast cancer death rates. Recent case control studies have shown a decline in benign breast lesions and no change in breast carcinoma.^{29,30} The cytology testing carried out concomitantly with prescription of oral contraceptives has probably had a beneficial effect on carcinoma of the cervix rates, although there is some evidence that endometrial cancer rates may be little affected by screening programs.³¹

Since early carcinoma of the breast and endometrium are difficult to detect even in the best clinical screening programs, steroidal contraceptives may occasionally be used in the presence of pre-existing neoplasia. Lack of evidence of unfavorable effects provides some reassurance with regard to the use of steroidal contraceptives in settings where screening and curative services are not available.

In summary, despite use of oral contraceptives by probably more than 100 million women during the last decade no evidence has been adduced that such use has either provoked or aggravated malignant neoplasia. While maintaining surveillance for yet possible untoward affects in the future, the likelihood thereof becomes less with each passing year.

Metabolic Changes

Many metabolic and biologic effects of oral contraceptives have been identified. Changes in liver function tests, increased plasma lipids, and decreased glucose tolerance are common, and high blood pressure sometimes occurs. The metabolic changes appear to be reversible and at present there is no clear measure of their effects upon health. (Similar metabolic changes occur during normal pregnancy.)^{4,20,32}

Several of these effects might be expected to be of less significance in less developed countries where obesity contributes less to hypertension and abnormal tolerance to glucose. However, other effects are of greater theoretical concern because of prevalent health problems including anemia, (secondary to frequent childbearing, nutritional deficiencies and parasites such as malaria, hookworm, schistosomiasis), other liver diseases, and a generally more precarious nutritional status.

Recent studies have suggested that oral contraceptives influence the metabolism of vitamin B₆, Folic acid and to a lesser extent other vitamins and minerals.³³⁻³⁷

Although megaloblastic anemia has been reported, the net effect of oral contraceptives on the blood status of the average user in a less developed country is unknown but could be beneficial. The most commonly occurring anemias doubtlessly relate to parasitically caused blood loss and depletion of iron stores from childbirth. The decreased menstrual blood loss³⁸ and the provision of iron in the seven "space" pills of the 28 day regimen commonly used in less developed countries may result in increased hemoglobin levels. The avoidance of childbirth also allows some restitution of iron stores. Alternate means of fertility control, notably abortion or use of IUD's, is associated with increased blood loss.^{38,39,40}

The most serious nutritional problem related to use of oral contraceptives is decreased volume and protein content of breast milk from nursing mothers. In parts of the world where adequate nutritional supplements for infants are not available, it would appear that oral contraceptives should be used with caution until the infant is also receiving adequate food from another source.^{32,41-45}

Another problem associated with use of oral contraceptives is an increased likelihood of contracting gonorrhoea following exposure to an infected male.⁴⁶

Conclusion

At present there are many unanswered questions relating to use of oral contraceptives in less developed countries. However, risk of this means of fertility control seems minimal compared to the benefits. Present evidence suggests that over an extended period of use only the nonreversible methods

of female sterilization and vasectomy are safer.⁸ Experience from many less developed countries which have made oral contraceptives available suggests that they are remarkably trouble free. In the pilot pill study in India more than 30,000 women used the pill with no reported serious side effects.⁴⁷

In Malaysia, about 90% of all family planning acceptors use the pill, and the majority of prescriptions are given by nurses or sometimes lay personnel following a brief history.^{48,49}

In Thailand, a 1969 study of use of auxiliary midwives to prescribe oral contraceptives in four rural provinces resulted in a 400% increase in acceptance of the pill. In mid 1970 the Ministry of Public Health ruled that after being trained all auxiliary midwives could prescribe the pill using the simple questionnaire reproduced in Table 4. In 1971, there were over 400,000 new acceptors of family planning services or about 10% of the eligible couples. 73% of these acceptors chose the pill.^{48,50} Similar schemes using a checklist are now being put into effect in Pakistan and Ghana. In Pakistan lactating mothers are excluded for the first five months.⁵¹

In Brazil, it is estimated that 3.25 million women (22% of those married) use the pill. About 2.5 million of these users (17% of married women) buy the pill from physicians' offices, drugstores and other commercial outlets.^{52,53} Annual outlays of \$80 million in India (fiscal 1970-71) have been required to achieve program coverage of 12.7% of eligible couples--the pill is not available in this program.^{54,55}

In addition to restrictive professional requirements, use of oral contraceptives in developing countries has long been greatly impeded by the inability of many women to afford this relatively expensive method. Until recently, the cost per monthly supply of pills in many countries often exceeded one dollar. In many programs where IUD's have been made available free of charge, a substantial fee has been charged for orals.

However, cost need no longer be a barrier to full availability of oral contraceptives. Both the U.S. and Swedish governments and UNICEF are assisting in providing oral contraceptives, either on a bilateral basis or through the International Planned Parenthood Federation and other non-government organizations. Through fiscal 1971, the Agency for International Development purchased 30 million monthly cycles of orals; in fiscal 1971 alone, purchases jumped to more than 35 million monthly cycles. A.I.D. is now able to meet virtually all requests for orals but the demand is going up rapidly and supplies may become a problem several years hence.

Provision of these oral contraceptives in a standardized attractive package (see Figure 3) will facilitate informational campaigns to promote their use.

In April 1970 a meeting of the Central Medical Committee of the International Planned Parenthood Federation and a distinguished group of advisors met to discuss the known and postulated side effects of steroidal contraception. The conclusions are excerpted below:

"It is agreed that in women with (a) a previous history of thrombosis, (b) severe heart disease, or (c) certain blood dyscrasias, it is prudent to deny the use of steroidal contraceptives if alternative effective methods of family planning are acceptable to potential users.

It is thought wise to substitute an alternative method of contraception six weeks before major elective surgery and during the immediate post-operative period. If any of the following symptoms appear, the advisability of the continued use of steroidal contraception should be carefully assessed: (a) cramps, pain or oedema in the legs, (b) sudden severe migraine or unusual headache, (c) sudden onset of severe chest pain, or (d) visual disturbances.

The incidence of thrombotic disease in the absence of steroidal contraception shows marked geographical variation. It is not known if this is due to ethnic or environmental differences. It is the impression of the Committee that in those areas where thrombotic disease is especially rare, women are also less prone to the thromboembolic complications of steroidal contraception.

The use of cervical cytology and routine breast palpation when distributing steroidal contraceptives is sound preventive medicine. It is desirable, but not imperative, to carry out such examinations at regular intervals on steroidal contraceptive users. The availability of such examinations is not a precondition for the distribution of steroidal contraceptives.

The Committee notes that rare cases of hypertension which appear to be causally related to the use of steroidal contraceptives have been reported. This phenomenon is reversible in most instances. A blood pressure measurement as a precondition for the distribution of steroidal contraceptives, and subsequent checks during use, should be judged in the context of the health facilities of the community.

The Committee recognizes that the availability of medical personnel differs widely in different parts of the world. In areas where there is a shortage of doctors, the distribution of steroidal contraceptives by paramedical personnel under medical supervision may free the physician's services for more demanding and urgent tasks."³²

A WHO Scientific Group suggested the following guidelines for the use of steroidal contraceptives:

"In many areas it is usual for physicians to take full medical histories and carry out complete physical examinations before they prescribe oral contraceptives. As a result, opportunities for the detection of cancer (e.g., by examination of the breasts and study of exfoliated cervical cells) have reached a larger proportion of women than might otherwise have been possible. In the same areas, it is accepted practice for women using oral contraceptives to undergo medical review at regular intervals of 6 or 12 months, affording an opportunity for repeated examination of breasts and study of cervical cytology. Such examinations are considered necessary not because the women are taking oral contraceptives, but because they are a health measure that is applicable to all women.

Even in areas that have the standards of medical care noted above, the use of oral contraceptives is undertaken with an awareness of the substantial limitations in our knowledge of their immediate and ultimate effects. The guidelines outlined above may have to be modified to permit the use of hormonal steroids for contraception in given countries, regions, or localities where cultural and other factors may differ. When such modifications are necessary, an assessment should be made of the risks of steroid contraception in comparison with those of other methods and with

those of not using contraception at all. Consideration should also be given to the possibility of using paramedical personnel; when such personnel are employed they should be properly instructed and supervised."⁵⁵

The standards and conditions for provision of a health service or a preventive medical service must take into account local resources. It would appear that in some countries a more absolute standard for use of oral contraceptives has prevailed thereby denying access to this method.

Numerous countries are now moving to make the pill available through paramedical personnel, trained to carry out the necessary screening histories and physical examinations and to educate the recipient to the untoward signs noted in the IPPF statement above. Even when pills are freely available without a screening procedure, those few women who experience difficulty will in all likelihood discontinue use upon the occurrence of severe side effects. Therefore in settings where neither medical nor paramedical provision of oral contraceptives is possible, their availability through other outlets is justified, particularly when one considers that the risk of the complications of pregnancy will be greatest in these settings.

It should be recognized that however natural and appropriate it may be for a clinician or public health administrator to consider clinics and hospitals as ideal centers for dissemination of family planning services, the public would prefer to obtain birth control by simple means available at low cost from a handy and impersonal drugstore or similar commercial outlet.

Certainly, family planning services should be fully available through all appropriate health programs and facilities, but such programs and facilities should not monopolize the means.

One observer commented, "Over the long run, to promote family planning by dispensing fertility control means only from clinics or hospitals makes about as much sense as promotion of dental hygiene by dispensing toothpaste only through dental clinics."⁴

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Table 1

ESTIMATED WORLD USAGE OF MEANS OF FERTILITY CONTROL
PREVALENCE (IN MILLIONS) IN 1971*

<u>Method</u>	<u>Users in Developed Countries</u>	<u>Users in Less Developed Countries</u>	<u>Total Users</u>
Surgical Sterilization	10	15	25
Oral Contraceptives	20	10	30
Intra-uterine Devices	5	7	12
Condoms	12	13	25
Vaginal Diaphragm, Chemical, Other Methods (rhythm, etc.)	18	34	52
Surgical Termination of Pregnancy**	10	22	32

*Excludes People's Republic of China

**Annual Incidence

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TABLE 2

PHYSICIANS PER CAPITA AND
PERCENT CONTRIBUTION TO TOTAL GROWTH AMONG
LESS DEVELOPED COUNTRIES 1970 - 1980 BY COUNTRY
(20 OF 97 TOTAL COUNTRIES ARE LISTED, MAINLAND CHINA
IS EXCLUDED BECAUSE OF LACK OF DATA)

	<u>% Contribution to*</u> <u>LDC Growth</u>	<u>Physicians per 100,000*</u> <u>Population</u>
India	31.68	21
Pakistan	7.47	16
Brazil	6.30	42
Indonesia	6.24	3.2
Mexico	3.78	50
Nigeria	3.10	2.3
Philippines	2.97	75
Thailand	2.71	14
Turkey	1.95	35
Iran	1.94	26
U.A.R.	1.67	44
Korea	1.61	37
Colombia	1.47	40
Burma	1.26	8.4
Morocco	1.14	8.2
Sudan	1.10	3.9
Ethiopia	1.89	1.6
Vietnam	1.01	3 (south)
Algeria	.96	12
Congo	.93	3.7
	<hr/>	
<u>Total</u>	80.38%	
Soviet Union		210
United States		148
Japan		109
United Kingdom		115

*International Demographic Statistics Center, U.S. Bureau of the Census estimate 1971.

+Corsa, L., Oakley, D., "Consequences of Population Growth for Health Services in Less Developed Countries - An Initial Appraisal", Chapter X, Vol. II, in Rapid Population Growth, National Academy of Sciences, Johns Hopkins Press, Baltimore, 1971, 696 pp.

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Table 3

Annual Rates of Pregnancy and Death Associated with Contraception, Pregnancy, and Induced Abortion per 100,000 Fertile Women of Reproductive Age

Method of fertility regulation*	No. of pregnancies	No. of deaths from method in U.S.	Total No. of deaths with maternal mortality 25/100,000 births (Approx. U.S. or developed country rate)	Total No. of deaths with maternal mortality 500/100,000 births (typical rate in less developed countries)**
No contraception	40,000-60,000	0	10-15	200-300
Oral contraception Use effectiveness = 0.7	695	3	3	6
Condom or diaphragm Use effectiveness = 20	19,900	0	5	100
I.U.D. Use effectiveness = 2.0	2,721	2	3	15
Legal abortion in hospital	100,000	3	3	3+ ?

* Effectiveness figures are pregnancy rates per 100 women per year.

** The figures for I.U.D.'s and oral contraceptives are only approximate since they assume the death rate from the method to be the same as in the U.S.

Source: Modified from,
Ravenholt, R.T., Piotrow, P.T., Speldel, J.J., "Use of Oral Contraceptives: A Decade of Controversy". International Journal of Gynaecology and Obstetrics, 8:6, November 1970, Part 2 of 2 Parts, pp 941-956

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TABLE 4

QUESTIONNAIRE FOR MIDWIVES PRESCRIBING ORAL CONTRACEPTIVES

	Yes	No
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History: ask if the patient has had a history of any of the following

- Yellow skin or yellow eyes
- Mass in the breast
- Discharge from the nipple
- Excessive menstrual periods
- Increased frequency of menstrual periods
- Bleeding after sexual intercourse
- Swelling or severe pains in the legs
- Severe chest pains
- Unusual shortness of breath after exertion
- Severe headaches

Examination: check the following

- Yellow skin and yellow eye color
- Mass in the breast
- Nipple discharge
- Varicose veins
- Blood pressure (yes = above 160)
- Pulse (yes = above 120)
- Sugar in urine
- Protein in urine

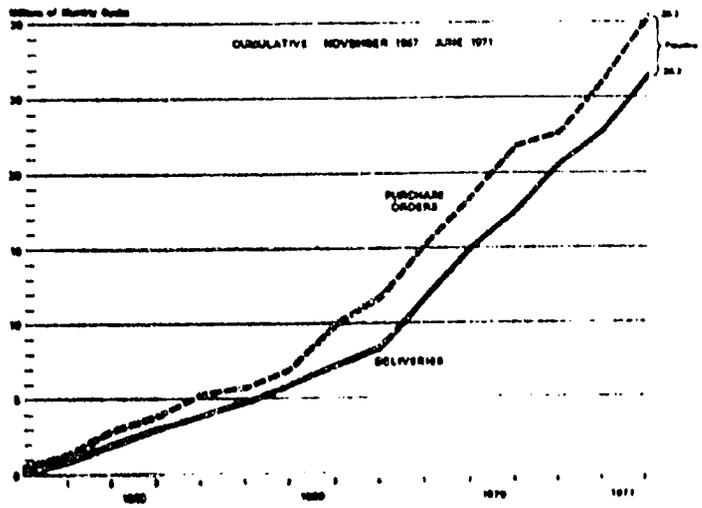
Instructions: If all the above are answered in the negative, the patient may receive oral contraceptives. If any of the above are answered in the positive, the patient must be seen by a physician before oral contraceptives may be prescribed.

Source:

Rosenfield, A.G., "Family Planning: An Expanded Role for Paramedical Personnel", American Journal of Obstetrics and Gynecology, Vol. 110, No. 7, August 1, 1971, pp 1030-1039.

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A.I.D. FINANCED ORAL CONTRACEPTIVES¹

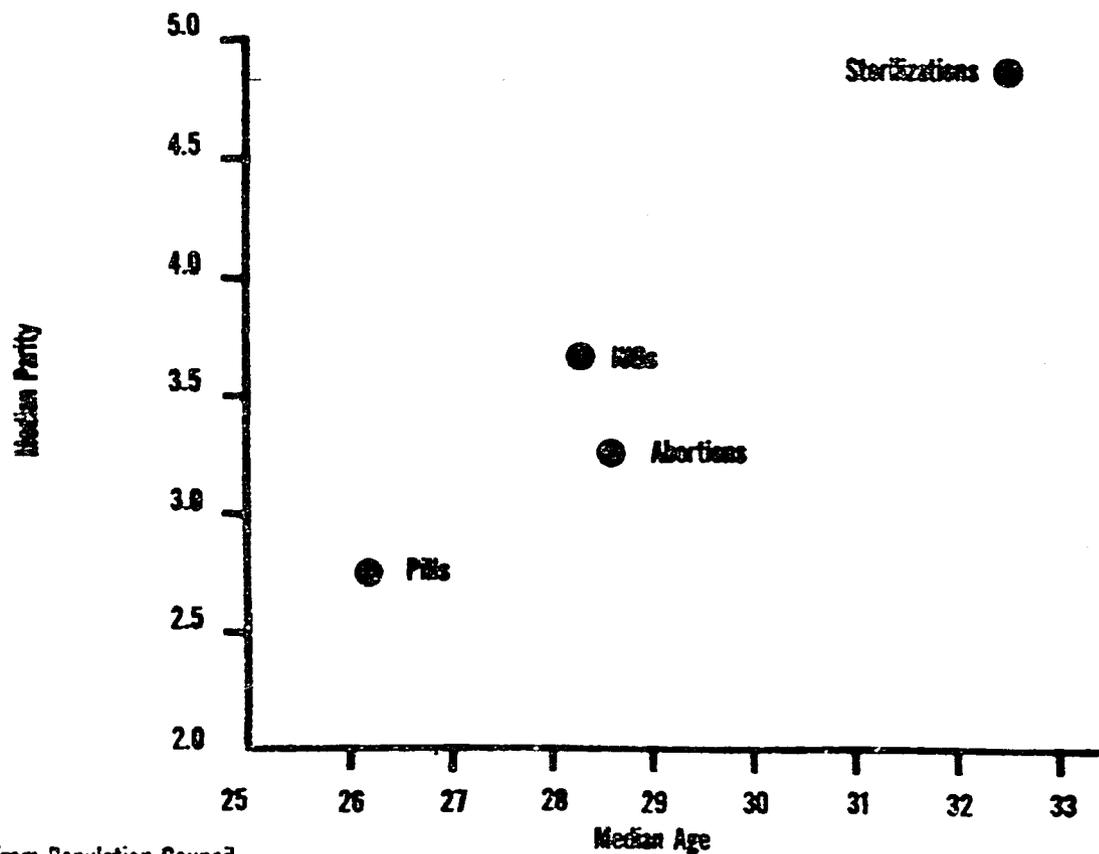


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Fertility Control Acceptors by Median Age and Median Parity

Postpartum Family Planning Program

All Hospitals and Countries, 1970



Data from Population Council

NB/TA/Pop 7115

