Relative Risk of Pregnancy vs. Risk of Contraception.

In the note I shall first discuss the possible adverse effects of childrearing on maternal health (and on the health of the child), and then exemine contraception method-specific problems or risks. I draw on available studies and research on these two themes. In the final section, various issues which emerge are outlined for discussion.

I. Effects of Child bearing on Maternal Health:

It has been a common wisdom that childbearing, the aspect of human reproduction which is unique to female sex, requires optimal age, say between the ages 20 and 30, good health and good medical care to minimize maternal risks. The factors which increase these risks are : i) pregnancy at the two extremes of childbearing span, i.e. before age 20 or teenage pregnancy and after age 30, but really speaking, after age 35; (ii) high parity, i.e. large number of children; and (iii) short inter-pregnancy inervals.

It has been shown that these pregnancies are more likely to cause hemorrhage or high blood pressure, which lead to maternal death. Also, closely spaced pregnancies may lead to anemia and malnutrition among women.

Many surveys are replete with findings that support this list of risk factors. "Risk" is measured in terms of maternal mortality, and there are many studies both in developed and less-developed countries which indicate that maternal mortality or complications arising due to pregnancy are higher among teenagers, among older women, at the time of deliveries fourth and subsequent children and when the birthinterval or inter-pregnancy interval is very short. However, in developed countries, thanks to good or excellent medical or obstetric care, maternal mortality even in these "high risk" categories has been brought down considerably, although compared to the risk

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of maternal mortality in the ideal age group 20-30, deaths in the presence of these factors are still several times higher.

Maternal mortality rates for select countries or areas shown in Table 1, suggest that the overall problem is quite massive in Asia compared to any other region of the world. However, one must concede that the estimates based on vital statistics may underestimate the levels of maternal mortality compared to the survey results.

In developed countries, the low level of maternal mortality is believed to be achieved by reduttion in the number of high-risk pregnancies; i.e. only a small fraction of births occur in the presence of the four high risk factors. In the developed countries, maternal deaths account for less than 2 percent of all deaths among women in the age group 15-44. In Mexico, this proportion is 10 percent and according to Matlab data, maternal deaths accounted for 27 percent of deaths among women in the repreductive ages.

Further, in addition to those who die, many women probably suffer from serious illnesses related to pregnancy, abortion or childbirth. A survey in Alwa region in Rajasthan state conducted between 1974 and 1979 found that, for each maternal death, there were 16.5 illnesses related to pregnancy, childbirth and the puerperium.

Wherever relatively good quality data are avilable, maternal mortolity rates form a J-shape when plotted against age and when plotted against parity. However, the scales for developing countries are two to four times higher than those for developed countries at every age, although the shapes are similar.

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Table - 1

Maternal Deaths per 100,000 Live Births,
Selected Areas, 1951 - 1982.

Country or Area	Year	Rate
Vital Statistics		
Kenya	1970	204
Mauritius	1979	99
Hong Kong	1980	5
Philippines	1976	142
Costa Rica	1980	24
Ecudar	1977	199
Mexico	1978	103
Egypt	1978	83
Australia	1980	10
Japan	1980	21
Sweden	1979	1
U.S.	1978	10
Area Surveys		
Matlab, Thana, Bangladesh		
132 villages.	1967-68	770
Total Matlab	1976-85	570
Villages of Bakripalnagar Alwar, Rajasthan, India	1974-79	592
Bali, Indonesia	1980-82	508

Note: Maternal death rate is the annual number of deaths among women per 100,000 live births, caused by deliveries and complications of pregnancy and childbirth and the puerperium. Deaths resulting from complications of induced abortion are also included in these statistics.

Source: Rinehart, Ward and Kols, Adrienne, "Healthier Mothers and Children Through Family Planning " Population Reports, Series J., Number 27, May - June 1984. P. J-661.

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However, in recent years, there are certain studies, which do question this model of "too many, too early or too late, too quickly" leading to high maternal mortality, Increasingly, it has been found that atleast in developed world, teenage pregnancy per se is not risky or is any more or less risky than childbearing in the early twenties. The factors causing higher mortality are not the age but socio-economic and environmental factors. The methodological problems related to measuring effects of childbearing on maternal health are discussed in the last section.

The life-threatening complications affecting the mothers are hemorrhage, pregnancy-induced hyper-tension and sepsis. Hemorrhage is much more common among older women with many children. Pregnancy-induced hypertension or pre-eclampsia affects mainly women with no children and older women with several children. Sepsis or infection, on the other hand, is not directly linked to maternal age or parity and can accompany any delivery.

In developing countries, the major problem among mothers is believed to be malnutrition and anemia, or often referred to as maternal depletion syndrome, by Jellife. Given the estimated extra untritional demands due to pregnancy and breast -feeding, it is assumed that closely spaced pregnancies, when work, are a cumulative drain on nutritional status of women. If a woman cannot recover fully from the effects of her last pregnancyand period of breast-feeding before becoming pregnant again, her nutritional status might be expected to deteriorate with each successive pregnancy.

The evidence on this syndrome of maternal depletion is, however, is inconsistent and weak. Studies conducted in El Salvador, Bangladesh, Sudan, Thailand support this hypothesis. On the other hand, the WHO studies on Family Formation Patterns and Health (using a height for weight as a measure of malnutrition, and hemoglobin level as a measure of iron -deficiency anemia) found no link between malnutrition or anemia and age ornumber of children.

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Childbearing Patterns and Infant Mortality:

The patterns of childbearing which are statistically found to be risky for mothers, are also found to be risky for the infants. When pregnancies occur before age 18, after age 35 or in women with four or more children or within two years of another pregnancy, there is a greater risk of stillbirth or death during infancy.

Most research that has examined the affects of the birth interval has done so in the context of the interval before the birth of the child under study. Such studies undertaken in most developing countries (thanks to the World Fertility Surveys) point to the conclusion that a short preceding birth interval is dangerous to the infant and that shorter the birth interval, the higher the infant death rate.

When this is examined in the context of the mother's age and birth order, it was shown that birth spacing had more impact on infant mortality than either birth order or mother's age.

However, it has been shown that early antenatal care, a nutritious diet, safe delivery conditions, etc. do compensate for some of the risk factors, Also, socio-economic status of the families is believed to be an inportant confounding variable, and yet, due to problems of small numbers, the socio-economic differences are not taken into account in most studies.

II. Risk of contraception:

It has often been stated in literature that relative to the risk of childbearing, the risk of contraception as an alternative to maternity - is minimal. Not only that, some methods are even considered to be prophlactic and thus help in reducing the risk of mortality.

However, it has been recognized that the contraceptive methods are equally safe; they very in their risks and side effects. Before we examinemethod-specific risks or dangers as well as advantages, ~~sew~~ two methodological points should be made.

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One, the relative safety of contraception compared to pregnancy and childbearing has been established statistically so far for developed western countries. Further, it has been assumed that in the developing countries, the safety of contraception is even greater because the dangers associated with childbearing are high. This set of premises are being increasingly questioned now as more and more research is done on the effects of some of the contraceptives on women's health.

Two, there are disparities in the safety of various contraceptives and therefore, the relative risks of each method should be assessed in different ways. Often people simply add up the relative risks of each method, but this procedure is clearly faulty. Adding up deaths directly caused by each method is to an extent, warranted. However, since the various methods do very in their reliability, a realistic assessment should take into account deaths associated with pregnancy and childbirth when contraceptives fail.

Table 2 presents the relative risk of each contraceptive method. This exercise was undertaken in the early 70s and since then medical research has brought to light certain risks which were unknown then. The long term effects of certain methods have become known only recently. Also the data are for developed countries, where the health status of women is relatively good. The same method may, in the presence of certain physiological conditions, increase the risk factor. For example, IUD was considered a fairly safe method even through it is associated with increased blood loss and infection. In a developing country, where anemia or iron deficiency among women is highly prevalent, excess blood loss can be dangerous for the already anemic women.

A check-list xxxx comparable to Table 2 for developing countries is in order. However, good quality method-specific large data set is needed to generate such probabilities or simulation methods. Also recent evidence on the side effects or complications which do not manifest themselves

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in the short run, but which become evident in the long run has to be built in such a model. This is, however, not the place or time to undertake such an exercise, although its need is very great. I shall at this juncture draw on redent evidence to examine contraceptive method-specific risks.

Table 2

Safety of Family Planning Aleternati es for Women Beginning Birth Control at Age 30 (Developed Countries)

Method of Fertility Control.	Cumulative Repreduction Related Deaths from Age 30 to End of Reproductive years 1/ (Deaths per 100,000 women)
1. No. contraception	245
2. Legal abortion (first trimester)2/	92
3. Oral contraception to end of reproductive years3 /	188
4. Oral Contraception to age 40, followed by diaphram or condom use.	80
5. Intrauterine devise (IUD)	22
6. Diaphram or condom	55
7. Diaphram or condom with leval abortion as back up	14
8. Tubal sterilization.	10 -20
9. Vasectomy (male risk)	0

1/ Includes contraceptive-associated deaths, abortion-associated deaths and birth-associated deaths in case of contraceptive failure or nonuse.

2/ Assumes abortion is the only fertility control used, resulting in an average of 13 abortions per women.

3/ Oral contraceptives are not recommended for women over 40 in developed countries, where safer alternatives are available.

SOURCE: Based on data from the United States and Great Britain and adapted from : Tietze, C., Bongaarts, J. and Scheater, B., "Mortality Associated with the Control of Fertility", Family Planning Perspectives, Vol. 8 No.1 January - February 1976, pp. 6-14.

Intra-Uterine Device or IUD:

In the mid-1970's after more than a decade of experience, IUD, was considered to be the ideal contraceptive for world wide use. It was not quite lived upto its promise, although a lot of research has focussed on improving its performance. Three areas where research has been concentrated are: (1) improvements in technique and training for insertion (to reduce perforation and infection), (2) optimal size and configuration of the device itself and (3) addition of bioactive substances to reinforce the contraceptive effect or reduce beeding and pain.

After a lull period, IUD appears to be coming back again world wide as sone of the safest, and effective forms of birth control. The basic problems of IUD - increased menstrual bleeding, expulsion soon after insertion, pain and increased frequency of pelvic infection - remain unresolved.

In addition, problems that are rarer but mora serious than pain, bleeding and expulsion have emerged now when long term and widaspread use has made it possible to detect these events. The serious complications are a higher risk of ectopic pregnancy, a septic second trimester abortion (in cases where pregnancies occur with the device in situ), and a higher risk of subsequent infertility caused by pelvic infection than among women not using IUDs.

Survey data on pregnancy and expulsion of various types of IUDs world wide are available and indicate that pregnancy rate per 100 women is relatively low; it falls in the range of 0.4 to 3.0. Expulsion rate for certain types of IUDs is relatively high. Lippes loop is the worst among various IUDs on this score. The expulsion rate per 100 women has ranged from 2.2 to 19.3.

However, due to bleeding and pain, women opt for removal and it is estimated that 8 to 18 percent of the women have the device removed within one year. It has also been estimated that these problems are more serious or that

both expulsion and removal rates are higher in developing countries like India and Bangladesh than in European countries or in the US.

As far as the newer problems which have come to light, the available data base is scant and there is need to closely monitor the performance of the device in a given population. The need for better health service support and follow-up is very very essential if the method has to become acceptable as a safe reversible spacing method. In the last three years, the number of yearly acceptors of IUD - mainly Copper T - have increased from 751,000 in 1981-82 to 2,562,000 in 1984-85, indicating nearly three and a half fold increase in just three years. Continuation rates remain very low, but if the device has to gain popularity, better follow-up and health service support must receive priority.

Sterilization :

i) Vasectomy

As indicated in Table 2, the male risk in vasectomy a surgical sterilization, is zero or nil. Vasectomy is acclaimed as the safest, simplest and most effective method of contraception. Yet, it is a neglected method in much of the world, including India. After becoming quite popular, through camps in India in the early 1970's, the number of vasectomies has been declining, as the emphasis has shifted to female sterilization.

The number of vasectomies performed per year in India ranged between 879 thousand and 2613 thousand during 1967-73. Since then barring the emergency period of 1976-77, this number has steadily declined and in the 1980's around 500 thousand vasectomies are performed every year. There are several possible reasons for the recent declines in the annual number of vasectomies. The increasing availability of other methods, new procedures making female sterilization safer and simpler than before (although still more complex compared to vasectomy) are some of the possible reasons for the popularity that vasectomy has lost.

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Equally, if not more important are the male attitudes or fear that vasectomy will adversly affect their sex lives or virility. Even though such fears are totally unfounded, nothing much has been done to counter these attitudes. Quite the contrary. By officially promoting female sterilization, on a mass scale, an indirect support is being given to the prevailing attitude on vasectomy, even when the procedure is extremely simple and the medical problems are non-existent or minimal at best.

It is possible that vasectomy would become popular and more acceptable if it were a reversible method. Theore - tically, surgical rejoining of the vas is possible but as of today, its reversibility cannot be guaranteed on a large scale.

Female Sterilization:

In recent years, female sterilization - tubectomy, laparo-scopy or minilaparotmy - is the most widely used method all over the world. In India, out of 32.3 percent of effe-ctively protected couples (in 1984-85), 25.0 percent (or 77 percent of all protected couples) were protected by sterilization procedures. Of these 85 percent depended upon female sterilizationto control their fertility. This rapid spread of female sterilization in the last decade or so has been made possible partly by improve-ments in the technique of sterilization. The new techniques are believed to be highly effective and safe.

It is stated that female sterilization does not cause any long-term complications. Some discomfort or pain is likely after surgery. The risk of complications depends not only on the type of procedure but also on the experience of the doctor and the characteristics of the women. Female steri-lization should cause very few deaths, if performed by trained, skilled doctors in acceptic situation and if the clients are carefully screened before hand. Large surveys have reported 3 to 19 deaths per 100,000 procedures n in developing countries. In India, an ICMR survey of 13 teaching hospitals, however, reported higher mortality rates of over 70 per 100,000 procedures. It is possible

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that many of these deaths could have been prevented by following certain guidelines ~~of~~for proper selection and insisting on asceptic conditions during surgery, since infection and hemorrhage are the major causes of death.

Among the procedures of female sterilization, laparoscopy is being promoted in the national family planning programme because it can be performed very quickly and requires a small indision and no hospitalization. However, it has been increasingly brought to ~~xiht~~ light that the failure rate of laparoscopy is quite high - may be as high as 20 percent.

It appears that some of the assential preconditions are overlooked in a mass drive to promote family planning. Laproscopy is suited to a specilized setting with the ~~x~~ availability of certain back-up facilities. Doctors performing it should have experience in abdominal surgery or be specialists in obstetrics and gynacology. Some of us, on the other hand, are aware of or have personal experience of situations where laparoscopy has been conducted in camps with minimal facilities by doctors whose skill is also less than optimal. While the sufferer is the poor women who has opted for sterilization, the long term effect of such instances of the programme would be very adverse.

In sum, Table 3 attempts to present rather succinctly the comparative advantages of vasectomy and female sterilization. It is time, in my opinion, to propogate and popularize vasectomy as a permanent method of family planning mainly because of its very low score ofassociated risks, if for no other reason.

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Table - 3.

Comparison of Vasectomy and Female Sterilization.

Vasectomy.	Female Sterilization
Effectiveness.	
Very effective, but slightly higher rate of spontaneous recanalization and pregnancy.	Very effective; slightly lower failure rate
Effective 6 to 10 weeks after surgery.	Effective immediately
Complications	
Procedure involves almost no risk of internal injury or other life -threatening complications.	Procedure involves slight risk of serious internal injuries and other life-threatening complications
Very slight possibility of serious infection	Slight possibility of serious infection.
No anesthesia-related deaths	Few anesthesia-related deaths.
Acceptability.	
Minute scar.	Scar can be small but still visible.
Slightly more reversible	Slightly less reversible.
Less expensive	More acceptable in many cultures.
Personnel.	
Can be performed by one trained person with or without an assistant	Team needed including one doctor, one trained anesthetist, and at least two assistants with more training than needed for vasectomy assistant.
Safely performed by trained paramedics	More difficult for paramedics to learn and to perform
Can usually be performed in half the time of most female sterilizations	Usually only physicians with training in gynecology can perform laparoscopy and laparotomy. Minilaparotomy is simpler.
Equipment	
Requires no specialized equipment. Equipment readily available	Laparoscopy requires expensive, complex equipment, which needs to be carefully maintained. Manilaparotomy requires only simple standard surgical instru-

Can usually be performed under local anesthesia	Systemic sedation necessary as well as local anesthesia.

Back-Up Facilities.

No. back-up facilities needed for immediate complications.	Back-up facilities needed in case of damage to abdominal organs and blood vessels or othercomplications that require laparotomy.

Possible Long-term Side Effects.

None demonstrated. Uncertainty about effect of increase in sperm antibodies.	Slight risk of ectopic pregnancy

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Source: Liskin, Laurie, "Vasectomy - Safe and Simple", Population Reports, Series D, Number 4, November - December 1983, p. D-69.

Oral Contraceptives:

In India until recently, oral contraceptives or OCs were essentially available from private sources only; they were not part of the national programme until 1974. Although oral pills were included in the programme on a small pilot project basis in 196[illegible], the project was extended to urban centres and to those PHCs which had "adequate monitoring facilities" in 19[illegible]4 only. Since then, pills have been promoted as a form of birth control initially rather cautionsly and in the last two to three years quite vigorously. Compared to the distribution performance in 1982-83 of 2.[illegible] million cycles of oral pills, the number increased to 9.5 and 16.8 million during 1983-84 and 1984-85, respectively. This several fold increase has been possible because the pills are now distributed by all the health personnel associated with the PHCs and their subcentres. The only condition is that the acceptor of the oral pills must be examined by a doctor within three months of acceptance.

Knowledge of the benefits and risks of the pill has grown considerably in recent years. Pills are acclaimed as the most effective reversible means of preventing pregnancy (effectiveness depends upon regular use). It has also been noted that oral pills protect women against pelvic inflammatory disease and also against ectopic pregnancy (IUD fares badly on both these counts), against uterine and ovarian cancer. In addition, pill provide relief from a wide range of common menstrual disorders.

As far as risks are concerned, it has been found that among the women who smoke and who are over 35 years of age, there is a siggificant increased risk of problems of circulatory system. More specifically, pill users who smoke and are over 35 years of age, non-smokers who are above 40 years of age reported significantly higher incidence of venous thrombo-embolism, heabt attack, stroke and hypertension. A large study undertaken in Britain reported that these high risk women (i.e. older smokers) were four times more likely to die of any of the circulatory system cilment than nonusers of oral pills, Pills are therefore not recommedned as a method of birth control for older women.

However, most of the research on oral pills has been done in the US and the UK and the large surveys have been conducted in these countries. It is difficult to know the extent to which these findings hold true for women in developing countries like India. It is often hypothesised that women in developing countries do not smoke as much as they do in developed countries or that they do not suffer from heart diseases to the same extent, and therefore, they are likely to be less adversely affected by the problems of oral pills. All the same, one ought to be very coutious before prescribing pills to all and sundry. A lot more medical research is still needed with the specific health conditions of Indian women in mind before promoting them for wider use.

Injectables and Implants:

The place of injectables in family planning has remained quite incertain. While the manufacturers consider them to be quite effective and convenient, controversy surrounds their safety. Depo Provera was until recently used as the most popular injectable and was pushed in countries like Thailand. However the controversy over the injectables in the US, ranged for more than a decade, and finally the Public Board of Inquiry on Depo Provera recommended in its report to the Food and Drug Administration that it not be approved for use as a contraceptive in the US. However, this has international implications and the injectable has come under attack in many other areas.

The risks associated with the injectables are breast and endormerial cancer, although most of the studies are animal studies. Studies on women suing Depo Provera are not of long duration or of adequate number to positively assets that its use leads to malignancies. Other problems associated with the use of injectable are excessive bleeding, depression, headache, weightgain, etc. These side effects, important in themselves, are not considered to be ofserious medical consequences.

In India, another injectable known by the name of NETEN is being tried out. Several phases of clinical trials have been underway, and a decision to include NETEN in the official family planning programme has been taken. The results of the earlier trials are not in the public domain. What is known is that the ICMR conducted as a part of the WHO project, a two year study (1981-83). This study pointed to a high pregnancy rate among the users & a high dropout rate because of menstrual problesm.

In addition to these, of course, are the conventional contraceptives such as condom, diaphragms, foam tablets etc. which are, if used correctly, quite effective and at the same time safe. They, however, require a fairly high level of motivation and mutual understanding. Since the risks associated with them are minimal, I have not touched upon them in this note.

Issues:

What the brief foregoing discussion points to is that the risk of mortality due to different methods of fertility control varies, that the risk varies also between various age groups, i.e. a given method may be quite safe during a certain phase of the reproductive span, but not towards the beginning or the end of the period.

Further, any method which tampers with the normal hormonal balance carries greater risk than the mechnical methods. This is quite evident in Table 4.

What is noteworthy is also that the risk of childbearing is higher at most ages than the risk of mortality due to contraception use except for pills used by smokers. It is tempting to conclude that the safest (in terms of risk factor) approach is to use the condom and to back it up

Table 4

Cumulative Risk* of Mortality per 100,000 Nonsterile Women, by Fertility Control Method, According to Age - Group.

Regimen	15-44	15-34	15-19	20-24	25-29	30-34	35.39	40-44
No control	462	192	35	37	46	74	129	141
Abortion	41	26	3	6	7	10	9	6
Pill/nonsmoker	251	21	3	3	5	10	70	160
Pill/smoker	977	132	12	18	~~68~~34	~~257~~ 68	257	288
IUD	45	25	6	6	6	7	10	10
Condom	23	19	6	8	4	1	2	2
Diaphragm/ spermicide	53	28	10	66	6	6	11	14
Condom and Abortion	1	1	@	@	@	@	@	@
Phythm	68	36	12	8	8	8	14	18

* Calculated by multiplying the age-specific annual death rares by five.

@ Less than 1.0

Source: Howard W.Ory,"Mortality Associated with Fertility and fertility Control : 1983", in Family Planning perspectives, Vol. 15, No.2, March/April 1983, P. 60.

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with abortion in the event of method failure. However, women or individual couples do not make choices soley on the basis of perceived risk of mortality. Similarly, the decision to have children or to postpone childbearing is generally make independently of the mortality risks associated with such choices.

What seems the most humane approach is to make available various methods to the couples without zealously promoting one over the other in order to fulfill certain tergets, along with knowledge about the associated risks, failures etc. Equally important can be a sound education on childbearing under certain risk conditions.

Methodologically, one must not add up the relative risks of each method to arrive at a figures of contraceptive risks because a given couple uses only one method at a time. We must not ~~xxx~~ cloud the issues unnecessarily.

/Chavan/
Npn.