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Male Involvement and Contraceptive Methods for Men : Present and Future

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In recent decades, the most common means by which couples regulate fertility have changed from methods requiring control or cooperation by men, e.g., condoms, withdrawal and periodic abstinence, to those for which women bear primary responsibility e.g., virtually all-reversible modern methods. This paper briefly describes present use of male methods, and proposes that one cannot assess the potential acceptability of modern methods for men without fully engaging the male partner in Family Planning. Presumed obstacles to acceptability, such as incompatibility with culture, have elsewhere been overcome through attention to training, accessibility and IEC. Nevertheless, current male methods are not comparable to existing methods for women, and inherent drawbacks can be expected to limit acceptability of the condom and vasectomy to some extent. A synopsis of efficacy clinical trial of a prototype hormonal method for men. Quotes from interviews with participants in the trial are used to illustrate key points in the argument made for the development of new reversible methods for men that will offer comparability to methods available to women.

Introduction

Historically, the predominant methods of preventing births in most parts of the world were methods used by or requiring the cooperation of men. The oldest of these, coitus interrupts or withdrawal, was known to at least three ancient religious traditions (Cummings & Bremner, 1994) and historical demography reveals that it was the principal method responsible for the demographic transition in Europe in the last century (Wrigley, 1969). It is still used by an estimated 35 million couples worldwide, and is the method most widely used in Turkey, a country with substantial access to modem methods. Nearly as many couples are thought to rely on periodic abstinence or the rhythm method (Herndon, 1992).

The condom has prevented births for more than 250 years, but only recently has the spread of AIDS prompted studies on acceptability and prevalence of use. Most of these studies have confirmed dissatisfaction with some aspects of the condom (Kirumira, 1991; Lamptey *et al.*, 1978; Mbizvo & Adamchak, 1989; SekaddeKigondu *et al.*, 1991). The condom is used by 75 percent of contracepting Japanese couples perhaps largely, because of the lack of alternative methods of contraception such as the oral pill. In no other country does condom use exceed

40 percent. While the condom is the most effective of the three in preventing pregnancy, the principal reason that men discontinue use of the condom, withdrawal or periodic abstinence is method failure.

Vasectomy has been known for a century and is the method used by about 5 percent of couples of reproductive age worldwide. The prevalence of vasectomy exceeds 10 percent in Australia, China, Korea, the Netherlands. North America and the United Kingdom but it is a method that is still largely unknown in Africa (Sekadde-Kigondu *et al,.* 1991, Ezeh, 1996).

Factors affecting use of methods for men

In contrast to historical prominence, these four commonly identified `male methods', - coitus interruptus, periodic abstinence, vasectomy and the condom, now account for only 30 percent of contraceptive method use worldwide. [1] Although this figure is still indicative of extensive male involvement in fertility regulation, reliance on methods for men has fallen off dramatically since the advent of the pill and as global contraceptive prevalence has steadily climbed. While use of the condom has increased among those at risk of sexually transmitted disease, vasectomy has lost ground in Latin America, India and elsewhere with the advent of female sterilization (Vernon *et al,.* 1989: Vernon, 1991; Alderman & Gee, 1990; Atkins & Jezowski, 1983; De Silva *et al.,* 1988: Huber, 1985; Kwon *et al.,* 1979; Ross &, Buber 1983 Nigam, *et al,.* 1994). The ratio of female to male sterilization is now 3 to 1 in China, 4 to 1 in Latin America, and 9 to 1 in India (United Nations, 1994). The United Kingdom and the Netherlands are the only countries in the world where the percentage of vasectomised men equals or exceeds the percentage of sterilized women.

If the development of reversible male methods been considered a high research priority (Diller and Hembree, 1977, Matlin, 1994), if men had been considered essential to the success of Family Planning programmes, and if had women been in policy and programmatic positions to demand that men share the burden for contraception with them, the history of contraception might have been written differently.

Gearing Family Planning programmes towards women (Freedman, 1987; Hammouda, 1987; Meredith, 1989) may have seemed pragmatic and cost effective at the time, but it failed to take into account that men frequently hold the contraceptive decision-making power (Joesoef *et al.,* 1988; WHO, 1982). Ignoring the role that men play in this area may have contributed to the halt in the rise of contraceptive prevalence in some parts of the world, and has certainly led to a growing dissatisfaction among women about the disproportionate burden they have to bear for contraception.

In its Plan of Action, the 1994 International Conference on Population and Development (ICPD) acknowledged that men had been bypassed by Family Planning programmes and needed to be reintegrated into sharing jointly the responsibility for contraception:

"Recognise that appropriate methods for couples and individuals vary ... and ensure that women and men have information and access to the widest possible range of safe and effective Family Planning methods in order to enable them to exercise free and informed choice" (ICPD. 1994).

Lack of male involvement and lack of widely acceptable reversible male methods are separate but interlinked issues. The first issue can be addressed immediately by a change in programme focus, in taking men into account, in gaining their support for their partner's decision to use a method, and in encouraging them to use a male method. The lack of acceptable reversible methods for men can only be addressed through a commitment to research.

The failure to involve men in Family Planning programmes implies a failure to assess the potential acceptability of existing male methods. Having never explored the possibilities of fully engaging the male partner, the true acceptability of methods for men remains unknown. The history of vasectomy in India over the past nearly 20 years, is a case in point. Fear of further backlash from the vasectomy campaigns that took place during the "Emergency" period of the early 1970s has, in all likelihood, gone on far longer than memory of the events dictates. A lack of providers trained in the newer non-scalpel technique and a persistent belief that Indian men will never again choose vasectomy, inevitably leads to a failure of the method to thrive. However, there is evidence from India that where providers have been trained in the no-scalpel technique, vasectomy has been shown to once again be "acceptable" (Nigam et al., 1994). Much more could be done to test the presumed lack of acceptability of existing male methods in India and elsewhere (Sarkar, 1993, Pariani & Soebadi, 1995).

Acceptability appears to be highly sensitive to cultural factors, but without having explored the effects of education, counseling, and peer support, the impediment that culture may present is likely to be overestimated. Physicians may assume that their clients would find a contraceptive such as vasectomy unacceptable (Bailey *et al.,* 1991; Covington *et al.,* 1986) or believe that a certain family size should be achieved by clients before sterilization (Bertrand *et al.,* 1990; Miller, R.A. *et al.,* 1991). They are likely to recommend those procedures that they themselves perform. When a provider of Family Planning services in Mexico learned that the proportion of sterilized women among its contraceptive users was about 25 times that of vasectomized men, researchers found that the lack of

training in vasectomy surgery was limiting access to this method. An increase in trained providers has facilitated an increase in the number of vasectomy acceptors in Mexico, as well as in Brazil and Colombia (Martinez-Manautou et al., 1991). In Turkey, training providers to counsel men about vasectomy, following abortion, has been successful in increasing the number of acceptors of this method (Gural *et al.,* 1993). In addition to physicians, policy makers exert control over access to new contraceptive technologies. The 'gatekeepers' of new technologies include village leaders, headmen, and politicians. Religious leaders, particularly in the Muslim world, are key figures influencing whether male methods are used (Ahmed, 1976), suggesting that their support be solicited.

`Machismo' was presumed to be the limiting factor in the acceptance of vasectomy in Latin America, but research points instead to inadequate information, education and accessibility (Bailey *et al.* 1991. Vernon, 1991; Foreit, *et al.,* 1989), as well as a lack of a critical mass of previous vasectomy acceptors. A study of new vasectomy acceptors in Latin America revealed that the great majority knew a previous acceptor. The knowledge that someone he knew had undergone the procedure was important in an acceptor's decision (Martin *et al.,* 1990).

Although clients typically learn about a method through communication with a spouse, friend or relative, a substantial minority of clients also attribute initial information to clinic personnel (Vernon, 1991). For a surgical method such as vasectomy, the role of the provider in explaining the procedure is clearly important, even if peers or the spouse influenced the decision to become sterilized. Qualitative research in Indonesia indicates a positive correlation between extent of information provided and satisfaction after the procedure (Pariani & Soebadi, 1995).

Regardless of the fact that much more could be done with existing methods for men, acceptability of existing methods is limited by their inherent characteristics, such as decrease in tactile sensation with the condom (Population Reports, 1990; Kisekka, 1991; Caldwell *et al.,* 1987). Although reasonably effective when used correctly, existing male methods are often perceived as inconvenient and difficult to use. Men and women in stable monogamous unions do not expect to rely on condoms. While many do not reject vasectomy as a possibility for the future, both the difficulty of reversal and the surgical nature of the procedure put many men off using this method (Finger, 1995).

Side effects of methods for women

Contraception, in addition to being a right and a privilege, can also be a burden. Since there are few side effects with existing male methods, and the majority of

method use by men does not-require interaction with the Family Planning service delivery system or a provider women primarily bear the time, opportunity and social costs, as well as the side effects of contraception. The significance of contraceptive side effects for women and for couples has not been given sufficient attention. Demographic and Health Surveys consistently show that side effects and health concerns are the leading cause of contraceptive discontinuation for women (see, for example, the Philippines National DHS. 1993). Problems with contraception can be a source of friction and frustration, especially where motivation to limit family size is very high. The need to contracept is a constant fact of life for most women, requiring punctuality. Diligence time and effort, and responsible behaviour for upto 30 years. It is not surprising that women are becoming more vocal in their demand for more contraceptive options for men.

The fact that about 70% of contracepting couples rely on a female method (United Nations, 1994) may be due in part to the limited contraceptive choices that men have (Ringheim, 1993). A number of surveys have shown that the majority of men believe they should be jointly responsible for birth control with their wives, and have expressed willingness to use methods that are as yet hypothetical, such as a pill for men (Davidson *et al.,* 1985; McGinn *et al.,* 1989; Keith *et al.,* 1974; Posner & Mbodji, 1989). Male partners of women experiencing side effects may, especially, want to share responsibility for contraception.

Research on new reversible methods for men

The second impediment to male involvement requires continuing research to develop methods for men that are more comparable to what we can now offer women. Recently, the Institute of Medicine's Committee on Contraceptive Research and Development issued its recommendations for priority research in a 'women centered' agenda. `Methods for males that would expand their contraceptive choices and responsibility' was one of the three research priorities (Institute of Medicine, 1996).

Given the growing demand for shared responsibility, what is the status of research on methods for men that would be more comparable to existing methods for women? The Institute of Medicine concluded that hormonal methods for men, such as combined androgens and progestogens given as injections or implants, were the most promising for the short term. These hormones suppress spermatogenesis by inhibiting LH and FSH secretion. Progestogens act synergistically with androgens to shorten the time to achieve azoospermia (Bebb *et al.,* 1996 (absence of sperm) or oligozoospermia, (sufficiently low sperm count as to be functionally infertile, eg., less than 3 million sperm/ml).

The USAID Office of Population, the National Institute of Health and The World Health Organization are principal players in the development of new contraception for the male. Research supported by USAID includes, in addition to hormonal methods, development of devices or agents to occlude the male reproductive tract, preventing the release of sperm. Some of these as occlusion techniques have the potential to be more easily reversed than vasectomy. A drop of silicone injected into the vas deferens quickly forms a plug that may be removed by a relatively skilled surgeon. This technique has already been used with over 100,000 men in China with successful reversals having been achieved in a few hundred men (Shengcai, 1990).

For those who are at risk of HIV/AIDs and STDs, nothing on the horizon can soon supplant the male or female condom. Efforts to improve the acceptability of condoms hare produced two new types of novel non-latex condoms for men. Slippage and breakage studies of these are underway, and use-effectiveness studies are planned.

Potential agents that inhibit sperm function are being tested in animal models, and these include plant extracts, including gossypol, tripterygium wilfordii and neem oil.

For long term development, the Institute of Medicine's Committee on Contraceptive Research and Development ranked a number of approaches as holding the greatest promise for male contraception. In addition to those that inhibit sperm production, these include methods that disrupt sperm maturation or function, interrupt sperm transport, prevent sperm deposition, or prevent sperm-egg interactions. They include genetic and immunologic (vaccine) approaches. While holding great promise for the future, research on these approaches is still at the basic science level.

Contraceptive research is a long, tedious process involving many years of research. Ten to twelve years of basic science may precede Phase I clinical trials, during which toxicity and minimal effective dose are established. Phase II clinical trials, during which the contraceptive efficacy of a product is assessed, may require 5-10 years. If successful, Phase III clinical trials introduce the regimen to a larger cohort of subjects. Phase II clinical trials have been completed for an injected androgen for men. Meanwhile, pharmaceutical companies must also be convinced that new methods for men will be marketable.

The World Health Organization conducted Phase II trials of an injected androgen as a contraceptive agent in 15 centres in 9 countries between 1987 and 1994. Nearly 700 men in stable unions participated. They received weekly injections of testosterone enanthate to achieve and maintain infertility. These trials

demonstrated that the androgen had a high contraceptive efficacy and were completely reversible (WHO, 1990; 1996).

Motivation and acceptability of a reversible method for men

Acceptability studies are often initiated during Phase II clinical trials to determine if men and women find the method to be satisfactory, and to gather information on how the method could be improved and what audiences it is likely to appeal to. During the multicentre trial, focus group discussions with clinical trial participants were held in five countries, and in one centre, interviews and focus groups were held with both men and their female partners (Ringheim, 1996).

Although this self-selected, nonrandom sample is not representative, the participation of these individuals in the first Phase II clinical trial of a hormonal method for men places them in a unique position to comment on the present and future of contraceptive options. A few of their verbatim comments are included here.

Men were questioned about their reasons for joining the clinical trial. These were found to be predominantly related to problems that the couple had with female methods. It is likely that these participants and their partners had more severe contraceptive difficulties than occur in the population at large. Indeed, several felt they had exhausted their options for reversible methods.

> "Its got to do with the fact that my wife gets depressed when she takes the pill, and I saw this on the telly and I just rang up. That's the main reason I came on [the trial]."

In all, 61% of men who joined the trial were motivated to do so by their partners' problems with female methods. Thirty-five percent of couples had also experienced a contraceptive failure.

Nearly 40% of participants were not motivated to join the study because of problems with female methods, but rather wanted to trade off responsibility for contraception:

> "I just thought it was a good idea. It's about time fellas started taking responsibility for this kind of thing. I hadn't been wandering around with the burning desire to take part in male contraceptive trials."
>
> "I always told the wife, if something came along for men, I'd take it."

> "I think men have been allowed to be lazy about this. I mean, I don't know who decided it, but it always seemed to be pushed on the woman to be responsible."

While most simply felt that contraception should be a joint responsibility, a few men indicated that they were interested in taking control of their own fertility.

The WHO clinical trials have shown that androgens can successfully induce infertility. However, the length of time required to achieve this averaged 120 days, and the percentage of men who became infertile was less than 100 percent. Furthermore, the need to inject supraphysiologic doses of androgen on a weekly basis was not viewed as feasible from either a service delivery or an acceptability standpoint:

> "At the end of the trial, I thought GREAT! No more bloody injections! On the other hand, what are we going to do now for contraception?"

Researchers are confident that with combined androgens and progestins, frequency of injection can be reduced to 1-3 month intervals (Waites, 1992).

Conclusion

Aside from innovations in technique - for example, no-scalped vasectomy, improved methods of calculating the fertile period and plastic condoms - little has been added in the past century to the contraceptive repertoire available to men. Low prevalence of use of any method for men does not necessarily mean that men have unfavourable attitudes toward Family Planning (Posner & Mbodji, 1989; Hall, 1971; Mbizvo & Adamchak, 1992; Ellertson, 1992). Male methods that are both long acting and reversible could relieve women of responsibility for contraception during at least part of their reproductive lives. A reversible, non coitus-dependent method may substantially alter the willingness of men to take responsibility for fertility regulation. Among the clinical trial participants described above, 81 percent of men and 78 percent of women would have continued using the hormonal method for men if given the option. Over all centres, more than 80 percent of men who completed a follow-up questionnaire said they would use the method if it were offered as a 3 month injectable (Ringheim, 1996). Expanding reversible options for men could substantially relieve the contraceptive burden now borne by women, and lead to greater equity in responsibility for fertility regulation:

> "To some older guys, women are second-class citizens. They go to the pubs and leave the women at home. I think it will probably take 20 years before this dies away, but a male contraceptive would appeal to

> my circle of friends. They are like me and think men should be responsible."

Male participation in fertility regulation is needed to balance reproductive health care more evenly between men and women, and to increase the numbers of active users of contraception (Martinez-Manautou *et al.,* 1991) at a time when the rapid rise in reproductive-age couples will demand dramatic increases in numbers of users just to maintain current prevalence (United Nations, 1991). An 'ideal' contraceptive, free of all side effects and 100% effective is a far-off goal and one that neither men nor women expect for the short term:

> "If she goes on the pill again there is always a risk, isn't there? And my way of thinking is once she's taken the risk for a few years, I'll take the risk. Then you halve it."

Although clinical trial participants are not representative of the population as a whole, problems with female methods and other motivations for using a reversible method for men are sufficiently common that a safe, reversible method for men should find a niche, and would offer couples another option that would certainly favour satisfaction and continuation of contraceptive use by one partner or the other. As the female partner of one participant noted:

> "It was perfect. If it were available tomorrow, we'd jump at the chance. We really liked it. Friends were mainly asking 'Are you sure it works' We'd like to know when its going to be on general release. We'll be waiting."

Unfortunately, such a method will remain 7-10 years away from introduction without a strong financial commitment to research and with collaboration of the private sector.

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[1] In developed countries, 40% of couples of reproductive age, or 56% of all contracepting couples, use a male method. Nineteen percent of users rely on condoms, 6% on vasectomy, and a surprising 31% rely on "nonsupply" methods, principally withdrawal and periodic abstinence. Use of these last two methods reaches very high levels in parts of Europe, although it is quite likely that they are used alternatively or sequentially with other methods such as the condom, diaphragm or other coitus-dependent methods.