Ravindra, T.K.; Berer, Marge.: Contraceptive Safety and Effectiveness: Re-Evaluating Women's Needs and Professional Criteria. Reproductive Health Matters. May 1994. No.3.p.6-11.

Contraceptive Safety and Effectiveness: Re-Evaluating Women's Needs and Professional Criteria

T. K. Sundari Ravindra and Merge Berer

Never before in History have so many People used contraceptive technology to regulate and control their fertility. Contraceptive prevalence in developing countries has increased from 9 per-cent of couples in 1965-70 to over 50 percent in 1985-90. [1] There were an estimated 500 million married contraceptive users in the world in 1989. [2] This is reason enough for contraceptive safety and effectiveness to be important reproductive health concerns.

On what basis, then, should the safety and efficacy of contraceptive methods be defined and assessed? The priorities and perceptions of scientists and researchers, family planning service providers, women's health activists, and users of contraception in response to this question can be astonishingly different, as this issue of the journal shows.

Contraceptive Safety

Everyone agrees that contraceptives should be safe, but how safe is safe, and safe from what and for what?

From one point of view, a contraceptive can be considered safe if there are no life threatening or serious negative health consequences from using it. This does not mean that any method will be absolutely safe or safe for everyone; contraindications and precautions are essential for defining these limits. However' given the potential for widespread use of these methods, they must certainly be safe for the vast majority of people for whom they are intended.

Yet for a whole range of reasons, some modern contraceptive methods considered to be safe by most scientists are sometimes believed to be unsafe by other people. Differences in under standings of what constitutes safety an unsolved problem.

In September 1993 some members of the Women's Global Network for Reproductive Rights, the Women's Health Action Foundation and the Feminist International Network of Resistance against Reproductive and Genetic Engineering began a campaign to ban further research on contraceptive vaccines - which they believe to be potentially dangerous. The scientists involved in this research, on the other hand, believe on the basis of the available evidence that contraceptive vaccines could be safer and less interfering in the body than any existing hormonal method, but that it is too early in the research process to make definitive statements.

Because there has been little non-specialist information available in support of the development or this new method, we invited some of the scientists who are working on one of the vaccines to submit a paper. David Griftin et al describe the current state of knowledge Gelid research on potential vaccines and address concerns that have been expressed regarding their safety.

We would not be surprised if one or two of the vaccines being researched turned out to be safer or more effective than the others, given past experience with other types of methods. However, we were discouraged to discover that neither scientists nor feminists have publicly addressed the question of whether the research process is being carried out for each of the different vaccines with equal thoroughness and concern for ethical standards.

Nor are dithering perceptions of safety confined to the research phase. Mirjana Rasevic shows that many women in. Belgrade who had abortions believed that all modern contraceptives were dangerous for health. Some had experienced adverse effects themselves, but it also seems that based on what little information they had about reproductive processes and contraception, the women developed their own theories and fears about how contraceptives worked and whether they were safe.

Scientists understand how the body works, as well as the way in which contraceptives affect the body. For many people, however, this knowledge is sketchy or non-existent. Uncertainty about the consequences of interfering with fertility is probably ages old and not easily dispelled.

Nor does a contraceptive method's safety exist in a vacuum. It is clearly associated with the provision and use of that method. As such, it cannot be assessed independently from the conditions in which, it is provided, the conditions in which it is used or the personal circumstances and health of the user.

IUDs and surgical procedures are a good example. The more sophisticated research methods of recent years have found that IUDs themselves do not increase the risk of pelvic inflammatory disease. Were all those past studies simply wrong? Can we now assert without qualification that IUDs are safe?

Some professionals seem to be doing so. A thorough review of research on IUDs, summarised in the Round-Up section, finds that pelvic infection related to IUD use occurs most often in the 20 days following insertion and is related to the background risk of sexually transmitted infection among users. So, if there is a risk of sexually transmitted infection or pre-existing reproductive tract infection of any kind, then IUD use is not safe. Similarly, we cannot ignore the risk of infection introduced during IUD or implant insertion, surgical abortion, sterilisation or any invasive procedure in less than hygienic conditions.

Menstrual irregularities, anaemia, weakness, dizziness, and loss of libido are common adverse effects of certain contraceptives, but are usually not considered serious health risks. However, such problems can disrupt a woman's ability to earn a living and her normal social and sexual functioning significantly and thereby transform relatively minor health effects into potential catastrophes.

There can be no doubt that the pill has been a safe and welcome method of contraception for millions of women in the past thirty years. It is currently considered a matter or debate whether the pill would continue to be as safe if it were available over the counter, that is, without any screening or counselling. Helen Rees argues that the manner in which contraceptives are delivered does affect their safety and is concerned that over-the-counter provision of the pill will not only compromise method safety but also have detrimental effects on quality of care.

Although the diaphragm may have almost no adverse effects in itself, it may become a potential source of infection if used without access to clean water and the possibility of hygienic storage. We can see this potential from a study in Bangladesh, summarised in the Round-Up section, on how re-used menstrual cloths can become a source of reproductive tract infection in similar circumstances.

Because of STDS, HIV and AIDS, no discussion of safety can ignore the fact that protection from unwanted pregnancy and protection against sexually transmitted infection are interrelated. When contraceptive methods are ranked according to their ability to protect against infection, their safety ranking is altered drastically. Condoms - treated for some decades now with scant respect by those concerned with family planning - emerge as the best choice. If only they were less subject to failure ... Still, as Juliet Richters says, condoms fail mainly because people don't put them on.

Further, condoms are all we are currently able to recommend for dual protection. It is disturbing that with all the contraceptive choices open to us, there is not one

method that is safe, highly acceptable and very effective for protection against both pregnancy and infection.

As a result, we are being forced to re-assess the safety and efficacy of dual purpose methods like spermicides and withdrawal, methods that are considered by most family planning professionals to be poor excuses for contraception altogether - even as millions of people continue to use them. Juliet Richters shows that although almost nothing is known about withdrawal as an HIV risk reduction technique, it is being used for that purpose in at least three countries. Anecdotal evidence, reported in the Round-Up section, shows that some gay

men are using 'female' condoms for anal intercourse even though they were not designed for this. Safety from this perspective approaches the bottom line - that something is better than nothing. Indeed, many people probably use and view contraceptives- in this bottom-line way anyway.

Contraceptive Effectiveness

An integral component of a contraceptive method's safety is its effectiveness in preventing pregnancy, measured as the number of pregnancies per 100 woman years of use. In the past 30 years, contraceptive effectiveness has greatly increased and has also become a priority in new contraceptive development. This has arisen for a multitude of reasons, e.g. increased knowledge of reproductive processes and the ability to control them, mortality and morbidity arising from unwanted pregnancy, global population growth rates, and because women want contraceptive methods to be effective.

High rates of contraceptive failure in countries where the risk of maternal, morbidity and mortality are high can contribute substantially to that risk. In these circumstances, effective contraception can be particularly important, even life-saving, for women who want to avoid pregnancy. However, the risks of pregnancy and unsafe, illegal abortions deserve attention in their own right and ought not to be used as the main justification for why effective contraceptive methods are needed. Investing in contraception to save women's lives at the cost of investing in antenatal care and abortion will not solve the problems of maternal morbidity and mortality.

Because of demographically driven politics, the effectiveness of contraception in preventing unwanted pregnancy sometimes appears to have become important only for the purpose of reducing high population growth rates. This is probably the single most important cause of feminist suspicion of methods like contraceptive vaccines, implants, and injectables. Thus, something intrinsic to the purpose of contraception and that women very much need from contraception

can come to be identified - by those who support women's right to contraception - as a negative quality.

Given that some newer contraceptive methods are near 100 percent effective, we must now ask whether all methods in future must attain this goal and whether older existing methods must be rejected if they are less effective. In other words, should everyone wanting contraception automatically go for the most effective method available? Although many professionals would not hesitate to answer yes, the fact is that women's health advocates and contraceptive users do not agree.

Celia Pyper and Maureen Freely's paper, extracted from a book they published last year, explores people's concerns, priorities and feelings about fertility within their relationships, with a rare (for this subject) sense of humour. As they so forcefully point out, most people are full of ambiguous and changing feelings about pregnancy and having children. While it would be lovely to think that the existence of effective contraception has made everyone rational and perfectly organised about planning and having children, it just doesn't work that way.

Near 100 percent efficacy in a contraceptive is essential for some women but not equally important to everyone. Some unintended pregnancies become earlier-than-intended babies. They are a decision made by default and not problematic at all. Even when a pregnancy is not wanted, high efficacy may not be enough to make other aspects of a method acceptable and it may be rejected in favour of a less efficacious method that has other desired aspects. Mirjana Rasevic found that some women who had been relying on withdrawal changed to a more effective method after having had an abortion, while for, others withdrawal and abortion remained preferable to methods they considered unnatural and undesirable.

As with safety, the parameters of what affects contraceptive efficacy need to be explored beyond the two measures that are most commonly delineated - how often a method fails to work when used correctly and consistently and, how often it fails to work in whatever way it is actually used.

Amy Allina and Francine Coeytaux discuss this issue in relation to oral contraceptives. Evidence is emerging of sometimes high failure rates and mistakes in taking the pill. This again raises questions about the wisdom of providing the pill - or any other method - over the counter if information, counselling and support are then missing. As with safety, the effectiveness of contraceptive use depends partly on the quality of information and other aspects of service delivery. Are consistent suppliers readily available, are they accessible

when needed, are users taught how to use the method well and given ongoing support for doing so?

Snehalata Vishwanath's experiences in a community-based distribution programme for oral contraceptives in north India, illustrate the importance of these well-known programme attributes and a few unexpected ones besides. She found, for example, that one of the most exciting aspects of teaching fertility awareness is that it can be used both to get pregnant, which she helped a whole group of women from one Indian village to do, or to prevent pregnancy.

In addition to hopes and fears about having babies, fertility and health, contraceptive use effectiveness may have far more to do with sexual matters and sexual behaviour than with any other single factor. Use or non-use, consistent or inconsistent use, continuation or discontinuation of methods are often linked to feelings, hopes and fears about sexual potential, sexual desires, and the demands and expectations of partners.

Included in this issue are a number of papers which focus on sexuality in relation to contraction, pregnancy and STD/HIV infection. Magaly Marques reviews an IPPF-produced training pack that includes four videos on counselling and sexuality, valuable for family planning service providers who want to address sexuality within the context of contraceptive counselling.

Stephen Schensul et al., found in Mauritius that most young women are not 'going all the way' but are involved in many forms of sexual expression besides intercourse. However, the young women were not equipped with anything like the information and services they needed if and when they did go further. In Malawi, Deborah Helitzer-Allen and co-authors found in one-to-one interviews that young women's knowledge and experience of reproductive and sexual matters were much greater than they revealed in more public focus group discussions. Their paper raises questions about how to provide sensitive information to young women when social norms restrict what, when and from whom young women are permitted to learn about sex, contraception and related issues.

Juliet Richters' paper on researching condoms is a refreshing change from the usually distanced and clinical analyses that abound on the subject of contraception. She tries to get to the heart of what happens in sexual relationships to explain the problems surrounding effective condom use - e.g. the social and symbolic meanings of sexual performance for men and the consequences of being in a state of high sexual excitement for both partners. Her paper points up with great humour how difficult it can be to get past a laboratory mentality when investigating the bedroom.

Interestingly, supporters of national family planning methods appear to pay more attention to relationships than many other professionals in this field. Following a paper in support of NFP methods in the British Medical Journal recently, there was a flood of correspondence, a selection of which we reprint here. A few of these letters reveal that it is possible to be pro-choice and pro-NFP at the same time, an uncommon position on both sides of the NFP debate. Supporters of natural methods stress other values in addition to efficacy, including the value of communication, co-operation and mutual respect between partners, self-discipline in refraining from intercourse when required, and shared responsibility between partners.

Are men really driven by uncontrollable sexual urges, some of the letters ask. Is uninterrupted availability of sexual intercourse necessarily empowering for women - or men? With natural methods, effective use depends on mutual responsibility in a relationships. It is telling that this fact is bemoaned by some of the correspondents and praised by others. Responsibility or no, the bottom line is that no contraceptive is 100 per cent elective and no contraceptive user is always a perfect user, which means that there is always a risk of an unintended pregnancy down the rocky road of heterosexual intercourse.

Although abortion is the preferred or only easily available method of family planning for some women, for most women it is a necessary back up. Indeed, abortion is the most effective family planning method of all. Odd, then, that those in the field who stress the importance of efficacy are sometimes so ambivalent about abortion.

What About Quality of Care?

With so many people using contraception, the quality of the methods themselves, of service provision and of contraceptive use have become major issues.

Juan Guillermo Figueroa Perea points out that quality of care is usually high when a new contraceptive method is being developed, tested and introduced, but he shows that in Mexico this level of care is not sustained once methods are routinely available throughout the national programme. He raises many questions about the implications of allowing the level of care to deteriorate and draws a powerful comparison between the need for quality of care when introducing a new method into a national programme and when introducing a woman to a method she has never used before.

Ninuk Widyantoro finds similar problems when she looks at the history of implant introduction and use in Indonesia, problems that have emerged only

with hindsight and experience, such as the failure to prioritise training in removal early on. On one level, such problems can be classed as abuses. The potential for abuse, especially in programmes driven by demographic goals, is a legitimate concern, for abuses are not uncommon in such settings. On the other hand, it is worthwhile examining whether the most appropriate way of dealing with these problems is to ban the methods themselves. Why are we not talking more about suitable monitoring and accountability mechanisms? Why are demands for improvement in the quality of services not as loud as those for banning and excluding this or that method?

In the UK, training in implant insertion is not being done fast enough to meet the higher than anticipated demand for this method. As Joan Walsh and Toni Belfield point out, implants have proven that the more complicated it is to provide a method well and the more skills and training that are needed to provide it, the more likely such errors are to occur.

Methods that require considerable skills and surveillance cannot be safely introduced in settings with inadequate health infrastructures, unless programmes and infrastructure are upgraded to accommodate them. Widyantoro finds that mistakes have served as lessons in how to improve the way the national programme is organised in Indonesia and hopes that this will have positive effects on the entire programme.

Clearly, providing a range of methods is more difficult than providing only one or two. New methods like implants, once-a-month injectables, no-scalpel vasectomy (see Round-Up), IUDs that require a different insertion technique - all make increasing demands on the skills and resources of national programmes and planning providers. However, as Griffin et al and Walsh and Belfield say, limiting women's already limited choices is also not in women's interest.

Improvements in the safety and effective of existing methods are to be much welcomes. New kinds of barrier methods for both women and men are absolutely required. In fact, a whole range of new methods are worth pursuing, both because existing methods are not as good as we would like them to be and because a dozen or so methods for millions of users is not an excessive number. On the contrary, it is pathetically few.

Further, if we are really concerned about both choice and effective use, then it is not just hormonal methods, IUDs and sterilisation that are at issue. How many other existing methods are most service providers trained to teach people how to use? How many women or men can say that they have ever been taught the skills of fertility awareness, condom or spermicide use, or discussed the practice

of withdrawal anyone, as compared with how many actually used those methods?

How we can vastly improve every aspect of service delivery is a question that remains to be answered. The emphasis on cost-effectiveness seems to be increasing as the number of contraceptive users grows. Neil Price looks at social marketing of contraceptive methods in this light and finds both pros and cons. He questions the overall effect of social marketing on quality of care and calls for evaluation of existing programmes. Finally, Neil Price, Helen Rees and several papers on the costs of services summarised in the Round-Up caution that efforts to increase access to contraceptive methods may not succeed and can result in loss of quality of care.

Re-Evaluating Women's Needs and Professional Criteria

People who use contraception, especially women, make jokes about it, cry about it, get frustrated and enraged by it, find it terrific or a pain in the neck, love it and hate in turns. For most people, contraception is a 'good thing' and fear of unwanted pregnancy is a powerful motivator. But that doesn't mean people like contraception or always deal with it rationally - often it is merely tolerated and barely so, at other times it is just too much to cope with, and sometimes it is the last thing on people's minds.

Give that in today's world gender power relations are grossly unequal, methods that rely on male co-operation and responsibility are not the most obvious choices for women. A male injectable, described in the Round-Up section, may be on its way, but will women trust the men in their lives to use it? According to surveys, says Jon O Brien, the answer is no. Male responsibility for sperm management, as Celia Pyper and Maureen Freely call it, is not yet as developed as it might be. On the other hand, can men always trust women to use a contraceptive? Pyper and Freely also remind us that in the inevitable power imbalances between partners, women are not always the ones with less power when it comes to making or not making babies.

We have yet to work our way through the contradictions in simultaneous demands for both male responsibility and for women's autonomy and control. Women need to talk more about this. Do men also need to get together and talk? Jon O'Brien and a number of his male colleagues in the IPPF Europe Region thought so, but some of the women they work with said they didn't trust men to meet without women present. His paper, a defence of men's ability to take responsibility for not making babies they don't want, is a hopeful sign that the dream of gender equality may not be impossible. Men still have a near monopoly at the top of all the powerful institutions in family planning policy, research and

services, but if some men in the field have started feeling hard done by, maybe the women they work with are getting somewhere. The question is, where have we got to and where do we want to go?

Professionals and feminists, not to mention anti-abortionists, are so earnest about contraception. For some it has become a sort of religious symbol, a saviour for the world, the environment, even the very future of humanity. And Perhaps in reaction, for others it has become the devil. What a pity that so many of us do not incorporate our own and others' personal experiences with contraception into our professional and/or feminist perspective. Perhaps we would pontificate less. Service providers and policymakers are prone to make choices on behalf of women. They have tended to place undue emphasis on efficacy and dismiss 'user-controlled' methods or give only one-sided information as a result. But feminists are equally guilty of labelling methods as good or bad, and making value judgements on the basis of their own beliefs about what women want - or ought to want. 'Provider-controlled' and 'longacting' methods, they say, are not good/safe for women. These have almost become litanies, and it is time they were challenged. Overemphasis on efficacy on one hand and paranoia about safety on the other are equally unhelpful.

Do women want a contraceptive they can control in order to control their fertility or do they want the contraceptive to be in control so that they need not worry about it? The evidence is that some women prefer one or other type of method, and some aren't satisfied with any.

Research and debate about, contraception need to take a giant step forward. Figueroa Perea raises crucial questions that we would do well to answer. The depth of user perspectives has yet to be plumbed. If discussions about priorities for the future are to have any value, they need to be based on what people themselves consider important. Now that people are finally seen as contraceptive users rather than as contraceptive acceptors (or are they?), surely their views count most.

References

- 1. Contraceptive boom points to breakthrough reproductive health. Progress 21, 1992.
- 2. United Nations, 1989. This usually quoted figure includes only those who are married because data on contraceptive prevalence among single people are not sufficient for inclusion in international estimates.