

FAMILY PLANNING

# Injection Of Hope

**F**AMILY planning in India has always been dogged by a debilitating combination of moral, sociological, superstitious and even political complexes. Post-1977, however, while the nation's population control effort has acquired the coy appellation of 'family welfare', encouraging work has been done towards adopting newer and safer techniques of birth control.

Last fortnight Dr Badri Nath Saxena, deputy director-general of the Indian Council for Medical Research (ICMR) announced that clinical trials of a new injectible contraceptive for women, effective for three months, had been successfully tested on a sample group of 2,600 women in 14 centres around the country.

**Encouraging Results:** The women selected for the programme were between the ages of 20 and 35, healthy, had at least one child, and were non-lactating. The final success rate worked out to 62 women per 100, with 11 women in every 100 a year discontinuing because of amenorrhoea (stoppage of menstrual periods), and 18 women out of every 100 discontinuing because of irregular bleeding.

The drug, called norethisterone oenanthate, and commercially marketed, had been tested earlier in 1977, but a dissatisfactory failure began in early 1980, and 'recruitment' of the women involved took 14 months. As many as 8,500 women-month cycles have been intensively studied.

Saxena, 45, heads the ICMR's National Programme for Research in Human Reproduction, begun in early 1980. The 1977 experiment consisted of three-monthly injections of 200 milligrams of norethisterone oenanthate; this time around, all the women were initially administered the injections once every two months for six months. Half of them then switched to a three-month regimen.

**Anticipated Success:** By June this year the researchers hope to conclusively prove that if a woman is 'primed' for an initial

six-month period and then switches to a more cost-beneficial three-month regimen, the results do not differ from the two-month regimen. The 1977 experiment showed that most pregnancies occurring in the sample group were in the first six months.

Tests with norethisterone oenanthate are also being conducted simultaneously in



Norethisterone oenanthate ampoules: safe technique



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—DR BADRI NATH SAXENA

80 other countries under the auspices of the World Health Organisation (WHO). The drug is marketed mainly by the multinational Schering, and costs between Rs 27 and Rs 45 per injection. Its action results in inhibition of ovulation in the user woman over a two- or three-month period. The ICMR has, however, been told

by the Government of India that prices can be reduced substantially once the drug is mass-marketed.

The injectible contraceptive compares well with oral contraceptives and intra-uterine devices (IUD's), which have a success rate of only 30 or 40 per 100. Currently, the ICMR is also researching the efficacy of monthly injections of 50 milligrams of norethisterone oenanthate combined with between 2.5 and 5 milligrams of either of two natural oestrogens—the oestradiols valerate and cypionate—since natural oestrogens do not carry the danger of thrombo-embolic, or clotting, side-effects. By the end of this year, the researchers hope to have a good idea of the efficacy of this mixture.

**Varied Research:** Aside from an advisory group on contraceptives, the ICMR is aided by task forces engaged in time-bound programmes on hormonal contraceptives, male contraception, female sterilisation, medical termination of pregnancy (MTP), IUD's, standardisation of laboratory methods and national quality control programmes, and psychosocial and health services research. The work ranges from basic clinical research to field and epidemiological research, and members consist of scientists and technocrats around the country. In addition, a Human Ethical Research Committee has to approve every human clinical trial, and a Toxicology Review Panel examines every new drug before it goes up to the Drugs Controller of India for final approval.

The ICMR's family planning research effort is helped by three regional centres for chemical research in human reproduction at Calcutta, Madras and Gauhati, three basic research centres at Bangalore, Ahmedabad and Ludhiana, and 22 human reproduction research centres in medical colleges' obstetrics and gynaecology departments around the country. The Institute for Research in Reproduction (IRR) in Bombay, an affi-

liate of the ICMR, has also done considerable work in the field of basic research.

"Increasingly," says Saxena, "the Government realises the tremendous value of basic research in population control and the search for better methods than the time-tested spacing method, condoms, IUD's, or pills. For instance, we have tested

the Copper-T200 device and recommended that it is better than the plastic Lippe's Loop IUD introduced in the early 1960s. The Government IUD factory at Kanpur has begun marketing Copper-T 220s."

**Determined Safeguards:** After researching possible side-effects of oral contraceptives, the ICMR found that malnourished women were in no greater danger of suffering adverse side-effects than well-nourished women. Nevertheless, it has given the Union Ministry of Health and Family Welfare a comprehensive check-list of signs and symptoms that even a paramedical worker can tick off with women in rural areas, with the proviso that the user women must be seen by a medical practitioner once every three months.

"As regards female sterilisation," says Saxena, "we studied 32,000 women and obtained data that indicates that minilaparotomy using the modified Pomeroy's technique is the best method for our needs, and has the least complications if done in the post-partum period immediately after delivery of a child. We have also recommended that laparoscopic sterilisation should be confined only to those centres where trained manpower is available. Elsewhere, we have proven that

the fears of vasectomies on men resulting in cardio-vascular or atherosclerotic side-effects is not substantiated."

In the case of MTP's, legalised since 1972, the ICMR found that abortion in the first trimester (less than 12 weeks after conception) is safest, but that vacuum suction should be preceded by slow cervical dilation. Here again, the Central Drug Research Institute at Lucknow has developed an isabgol-based cervical dilator that is as effective and less expensive than the presently imported seaweed-based dilator from Japan called 'laminaria tent'. For second-trimester MTPs, the ICMR is working on the prostaglandin 'E' series drug in collaboration with the Karolinska Institute in Stockholm and the WHO; Karolinska is also negotiating with the Government of India for marketing of vaginal suppositories that can enable women to perform early abortions at home.

**Substantial Advantages:** Pregnancies are usually confirmable only if two consecutive periods are missed, says Saxena, and most women used to rush for MTPs only when one period had been missed, leading to a 30 per cent false alarm rate. Now, the IRR in Bombay has developed the 'Nancy Kit', marketed by Hindustan

Antibiotics Limited, which uses simple-to-use enzyme-linked amino-acids to indicate whether conception has occurred or not.

During the next few years, says Saxena, family planning research ought to result in substantial new advantages for the country. Already the ICMR had conducted tests using the Norplant-I six-wing sylvatic sub-cutaneous implant for women, but the fan-shaped contraceptive worked out expensive—so 100 women in Delhi and Calcutta are currently undergoing tests with the cheaper two-wing Norplant-II.

The IRR and the Indian Institute of Science in Bangalore have also isolated a substance called inhibin, which suppresses the Follicle Stimulating Hormone (FSH) in both males and females. Research is also going on into the side-effects of hormonal male contraceptives, which usually aim at azoospermia (total suppression of sperm).

"Everywhere we look," says Saxena, "there is hope that these efforts will help us achieve our population targets. Only when we bring down the birth rate from 33 per thousand to 21, and more and more couples in the country realise that contraception is a safe and easy method of preventing babies, will this national campaign bear fruit." —CHAITANYA KALBAG

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