

A BRIEF NOTE ON QUINACRINE TRIALS

Quinacrine is a drug belonging to a group of drugs known as 8-Aminoquinolines. It is cheap and widely available, listed in pharmacopoeia as an anti-malarial.

Current interest in the drug stems from the novel use that has in the past decade been found for this drug: as a method of non-surgical female sterilisation and the issues of safety, efficacy and ethics that have been raised during the controversial course of its trials.

The method was developed in Chile by Jaime Zipper in the 1970s and tried out over the next decade and a half in three public hospitals involving 1500 women. For non-surgical sterilisation, the method involves the trans-cervical application of pellets of quinacrine in the proliferative phase of the menstrual cycle using a modified copper-t IUD inserter into the fundus of the uterus. While various schedules have been tried, the most common involves seven pellets of 36 mg of quinacrine performed either once or twice.

The insertion of quinacrine into the fundus of the uterus is followed by a local inflammation. The scar tissue that follows the inflammation, leads to tubal occlusion, and hence, irreversible sterilisation.

The insertions do not require anaesthesia or trained personnel and can be performed in areas with no access to health facilities. While these are listed as some of its operational

advantages, given the nature of family planning programmes in many developing countries and the poor development of public health infrastructure, it is precisely these factors which endow this method with a high potential for abuse.

In Vietnam more than 31,000 women had quinacrine sterilisation between 1989 and 1993 before the trial was called off. A retrospective study of more than 1600 of the women was carried out in 1994 but the report of this study has not yet been published.

In June 1994, the WHO Consultation on Female Sterilisation Methods called for the conduct of four pre-clinical toxicology studies on quinacrine before approval of the drug for clinical testing.

Family Health International, an NGO in the US, previously involved with Norplant trials in Bangladesh that raised ethical and scientific questions, decided to carry out these studies with funding from USAID. The rationale was that a safe and effective non-surgical method of sterilisation would be cheaper than surgical methods of sterilisation.

In September 1995, the FHI's publication indicated that three of four tests with Quinacrine were positive, i.e., that quinacrine was mutagenic. More tests would be required to assess if the drug was carcinogenic. Problems have however developed with this next step involving trials on rodents: problems with route of insertion, dosage, number of insertions, and the high mortality among rodents which have to be subject to repeated

anaesthesia during the course of the trials.

In Chile, meanwhile, there was an outcry in 1994 led by a broad based coalition called Open Forum for Reproductive Health and Rights on the question of quinacrine trials. The group voiced four main concerns:

- 1) Unresolved issues of safety;
- 2) The WHO recommendation that clinical trials not be carried out till toxicology trials are satisfactorily completed;
- 3) The need for informed consent procedures that were lacking in the Chilean trials;
- 4) Scrutiny of the trial documents by an ethics committee to assess both ethical and safety standards.

The Chilean Ministry of Health withdrew its support to the trial in December 1994; the public hospitals were asked to review their internal ethical procedures. However Dr. Zipper and his team are reportedly continuing the trials in private hospitals with the financial support of the US based NGO, Centre for Research on Population and Security.

The Centre for Research on Population and Security is a two-man NGO run by two doctors, Dr. E. Kessel and Dr. S. D. Mumford. They receive funding from right-wing anti-immigration groups. Dr. Kessel is on record that as a patriotic American he is proud to receive funding from the anti-immigration groups as he believes that should the US allow free immigration, it would soon be turned into a third world country. The Centre for Research on Population and Security is funding quinacrine research in India.

Bangladesh and Chile. In India it funds the quinacrine "trials" being carried out by a Calcutta based NGO, Humanity Association, 34 A Shashi Bhushan De Street, Calcutta. Reports indicate that trials may also be in the offing in other cities in India.

There is an urgent need to halt these trials and to do both short-term and long-term follow-up studies on women who have been sterilised by quinacrine. Further, the Ministry of Health and ICMR should be answerable to the public regarding the regulation of such "trials" by institutions not competent or authorised to carry them out.

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