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THE SORDID STORY
OF CHEMICAL STERILISATIONS
OF WOMEN

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We would also like to thank all the women's groups, other organisations and individuals who have played an important role in helping us put this report together.

We hope that it will prove to be a useful document in the campaign against Quinacrine sterilisations, hazardous contraceptives and aggressive population control.

In solidarity,

The Saheli collective

Saheli

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INTRODUCTION

Quinacrine. Today the very mention of this means of chemical sterilisation of women brings to mind the controversy that surrounds it. Contrary claims confound the picture. Is it an old, tried and tested method? Does the fact that the basic compound has been used for decades as an anti-malarial drug make it safe for insertion into the uterus for sterilisation? Is it a magically precise method of sterilisation, or a barbaric attack on women's bodies? Are the trials and use of Quinacrine as a method of sterilisation legal in India? How are the interests of the population control lobby being served by promoting Quinacrine sterilisation all over the Third World? What are the reasons for the worldwide protests against Quinacrine sterilisation? And, in the midst of all this debate, what is happening to the thousands of women who have been subject to Quinacrine sterilisation?

From its sordid beginnings in Nazi concentration camps where it was forcibly used on Jews, Gypsies, Communists and other 'undesirable' sections, Quinacrine has come a long way to its contemporary 'status' as a method of sterilisation being discussed in 'respectable' scientific journals and conferences. This report attempts to trace the history of this hazardous and illegal method of sterilisation; expose the effort to promote it as a saviour for womankind; describe the way it works in a woman's body; analyse the scientific data available, and more importantly, the lack of information on this so called 'old and reliable' method; and highlight the legal and ethical issues concerning its misuse by private practitioners, medical colleges and non-governmental organisations (NGOs) involved in the widespread use of the Quinacrine method of sterilisation. We have tried to address these issues as well as the implications of mass use of Quinacrine sterilisation in India in the context of the experiences of women who have been subjected to the procedure. The role of governmental regulatory and licensing authorities has also been analysed in the current context of increasing de-regulation and withdrawal of the government from the arena of public health and family welfare and the entry of NGOs into this sphere.

This report is based on published and unpublished documents, papers, articles, press clippings, documentary films and interviews conducted by members of Saheli. We have interviewed the Drug Controller of India, Additional Director of the Indian Council of Medical Research, doctors associated with clinical trials in Lady Hardinge Medical College, New Delhi, and the CHIP Trust in Bangalore. We also met the owner of Dr Jain Clinic Private Limited, one of the largest distributors of Quinacrine for sterilisation and several other doctors in Delhi.

Our attempt has been to put together research data as well as relevant critiques from a variety of sources in order to make available a comprehensive document on the current status of Quinacrine sterilisations.

WHAT IS QUINACRINE? A HISTORICAL BACKGROUND

Quinacrine was discovered in the 1920s and has been used as a drug for more than 60 years. It is a derivative of acridine orange, a yellow coloured dye (6-chloro--9-(1-methyl-4-diethylamino) butylamino-2-methoxy-acridine). Quinacrine was the product of a search by the pharmaceutical industry for a drug to treat malaria. Ever since the 1930s until after World War II, it was used extensively for the treatment of malaria. It was also found to be useful for the treatment of various parasitic infections like tapeworm infestation, amoebiasis and giardiasis. Today, it is still the mainstay of treatment for giardial infection.

In addition to its use in infectious diseases, systemic lupus erythematosus is a disease of auto-immune nature where the drug has been successfully tried.

For most of these conditions, Quinacrine was used in the form of oral tablets and occasionally as injection. Quinacrine is known to produce corrosion and irritation of the membranous substances it stays in contact with. The corrosive action results in the two adjoining surfaces sticking together permanently - a process called *sclerosis*. In some patients with cancer, proteinaceous fluids tend to accumulate repeatedly in various sites in the body - e.g the cavity in the abdomen (peritoneal cavity) and the chest (pleural cavity) are commonly affected sites. Instillation of Quinacrine in these cavities, resulting in sclerosis, can prevent subsequent accumulation of fluid in these spaces.

However, the major use of Quinacrine has been for the treatment of malaria. Over a period of time, the importance of Quinacrine as the drug of choice for the treatment of malaria decreased for two reasons: Firstly, malarial parasites developed resistance to Quinacrine in many parts of the world; and secondly, more effective drugs like chloroquine became available following further research by the pharmaceutical industry.

Side effects of oral use of Quinacrine: Quinacrine is commercially available in a hydrochloride form and is not easily soluble in water. When given by the mouth, it is absorbed efficiently through the gut lining and quickly reaches the blood stream. The oral administration (i.e. by mouth) of the drug is associated with several relatively short-term and potentially reversible side-effects such as - yellow pigmentation of the skin, nausea, vomiting, abdominal cramps, diarrhoea, fever and headache.

Somewhat uncommon side-effects include dermatitis (inflammation of the skin), lowering of blood pressure, and various manifestations of excitation of the central nervous system (CNS) such as mental disturbances, excitability, insomnia and hyperactivity. [Goodman & Gilman, The Pharmacological Basis of Therapeutics].

Quinacrine accumulates in the body if given repeatedly and hence long-term use of the drug, as was recommended for soldiers during World War II for prevention of malaria, can be associated with many more side-effects. The major problems associated with chronic use of Quinacrine taken by the mouth were yellow discolouration of the skin in 33% cases. Skin rashes were common and quite severe in a small number, even resulting in fatalities. In a small percentage, it resulted in skin cancer. Aplastic anaemia occurred in about 1 to 3 per 1,00,000 soldiers. There were also reports of hepatitis associated with long term use of Quinacrine.

Quinacrine. One of the Many Experiments Towards Chemical Sterilisation

Jaime Zipper, a Chilean scientist, first published reports in the late 1960s and early '70s about the potential use of Quinacrine for tubal blockage by inserting it into the uterus. The information about the use of Quinacrine as a sclerosing agent gave Zipper the idea to try its effects on the fallopian tubes. The fallopian tubes get blocked when any sclerosing agent is instilled in the uterus through the vagina, thus resulting in female sterilisation.

However, Quinacrine is not the first drug which has been tried for its use as a tubal blocking agent. RM Richart (Research Frontiers in Fertility Regulation, 1981) and the World Health Organisation (Progress, No.36, 1995), quote formalin with or without alcohol, tetracycline, phenol mucilage, silver nitrate, and methylcyanoacrylate as some of the agents used for female sterilisation. Most of these agents are known to cause burning and corrosion, resulting in irritation of the surface they come in contact with - whether it be the skin or the mucous linings like inside the mouth or internal bodily surfaces like the lining of the fallopian tube. The irritant action causing eventual scar tissue formation can result in closure of the patency of the tube.

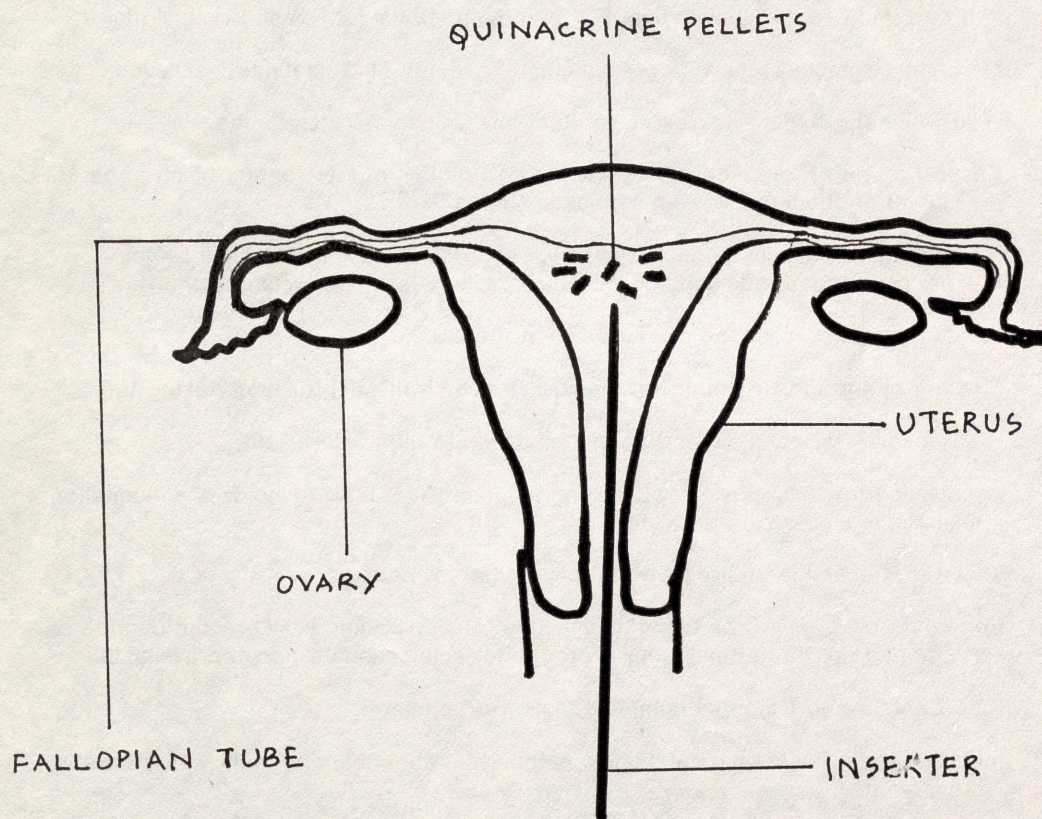
From Quinacrine Slurry to Pellets : One Step Closer To Mass Use

Initially, Zipper tried to use 1500 mg of Quinacrine in the form of a slurry for female sterilisation. This was inserted in a woman's uterus through her cervix (transcervical use). There was every possibility of the slurry leaking out of the uterus in both directions : inside via the tubes to the abdominal cavity causing irritation of the membrane, or to the outside through the cervix to the vagina. The leakage outside could even cause

possible closure of the cervical opening (cervical stenosis). The skill of the inserter and the co-operation of the woman were of extreme importance. There were many failures reported with this method. Early experiments reported by Zipper and his colleagues in 1976 (Int. J. Gynecol. Obstet. 14, 499) showed haphazard results with low efficacy and major side effects.

Zipper then modified the formulation to prepare pellets which could be inserted into the uterus with the help of a modified version of the inserter used to insert IUDs (intrauterine devices) like the Copper-T. Quinacrine pellets when introduced in the uterus are expected to stay near the roof of the uterus (the fundus), in the vicinity of the fallopian tubes. Once inside the uterus, the pellets of Quinacrine dissolve within about 30 minutes. Usually, women undergoing insertion experience pain in the lower abdomen for a few hours following the procedure. It has been proposed that Quinacrine acts as a sclerosing agent specifically on the inner lining of the fallopian tubes and not of the uterus. The zinc content of the uterine lining is shown to be higher than that found in the tubes and that somehow seems to confer specificity to the action of Quinacrine. (E.Patek, Acta Obstet. Gynaecol. Scand. 58, 561, 1979).

The tubal lining shows signs of irritation within the first 24 hours of exposure. Within the next few days, the inflammation destroys the lining of the tube, with further progression of inflammation resulting in fibrosis that caused blockage of the tube due to scar formation. These changes have been documented by Dr Merchant from Bombay in her trial of Quinacrine with the help of X-rays and histopathological examination in women who were to undergo hysterectomy operation within a few weeks of Quinacrine instillation.



THE QUINACRINE STERILISATION PROCEDURE

CALENDAR OF EVENTS : QUINACRINE OVER THE YEARS

- 1920IG Fabenindustrie laboratories discovered Quinacrine.
- 1930 Quinacrine introduced as an antimalarial drug
- 1945 onwards ... Quinacrine phased out as the drug of choice for the treatment of malaria. Chloroquine starts replacing Quinacrine.
- 1960s Jaime Zipper [Chile] starts animals experiments in use of Quinacrine and other chemicals for sterilisation.
- 1970 Zipper reports use of Quinacrine slurry for chemical sterilisation of women.
- 1973 Davidson & Wilkins [USA] report use of Quinacrine sterilisation of women.
- 1976 Zipper and others start using Quinacrine pellets for chemical sterilisation.
- 1976 onwards ... Kessel and Mumford appear on the scene for funding research on Quinacrine sterilisation.
- 1979 Biral Mullick [Calcutta] begins Quinacrine sterilisations.
- 1980 Bhatt [Baroda] completed early studies on women on Quinacrine instillation.
- 1981 Toxicological studies completed by Johns Hopkins University. Based on which Family Health International [FHI] obtained investigational exemption for a new drug from US Food and Drug Administration. FHI granted approval for Phase I clinical trial.
- 1986 Merchant [Bombay] reports a pre hysterectomy study of Quinacrine instillation.
- 1989 Hieu [Vietnam] begins a large scale study on Quinacrine sterilisation.
- 1990 Second round of toxicological studies initiated by FHI due to reports of an apparent cluster of cancers following studies in Chile.
- 1991 Review of toxicological data on Quinacrine by WHO toxicological panel. Panel recommended additional toxicological tests before conducting further trials.
- 1992 Manufacture of Quinacrine closed down in the US.
- 1992, June Meeting by the Indian Council of Medical Research [ICMR] for undertaking trials.
- 1993-1994 ICMR begins clinical trials and abandons it due to high failure rate.
- 1993 Dec Association for Voluntary Surgical Contraception [AVSC, USA] holds a consultation on Quinacrine sterilisation procedure.
- 1993 Dec Trials of Quinacrine sterilisation abruptly halted in Vietnam.
- 1994 July Formal review by WHO on use of Quinacrine for sterilisation. WHO recommended stoppage of further trials until thorough toxicological data become available.
- 1994 - 1996 Kini, Bhateja and Rajgopal complete trials in Bangalore.
- 1995 January Indian experts visit Vietnam and show enthusiasm about starting multicentric trials in India.
- 1995 February ... Vietnamese government decides to re-evaluate the results of the trials.
- 1995 April Indian Express reports on trials by private practitioners in Karnataka and West Bengal.
- 1996 August Ganatantrik Mahila Samiti protests outside Mullick's clinic in Calcutta.
- 1997 Kini and Bhateja aim to complete 25,000 Quinacrine sterilisations in 2 years.
- 1997 May Demonstration by women's groups in Delhi to protest against a big role of Jain in Quinacrine sterilisation campaign.
- 1997 July All India Democratic Women's Association and Mohan Rao ready to file a public interest litigation to stop unethical use of Quinacrine.

QUINACRINE STERILISATION : NEW FORMULATION, NEW ROUTE

It is widely accepted that this new formulation (pellets) and new route of application (into the uterus) needs further trials to overcome concerns about the potential of the drug to cause changes in tissue (mutagenicity), its potential to cause cancer (carcinogenicity) and possible effects on the foetus (teratogenicity). Toxicity studies conducted at the Johns Hopkins University to test route of administration and to establish safety criteria, found that acute toxic effects were related to the dose and route of administration. Central nervous system (CNS) stimulation, sleeplessness, nightmares and abnormal EEG (Electroencephalogram) were noted in high doses. Intraperitoneal administration led to severe abdominal pain with fever and sometimes CNS toxicity.

A group of scientists from the Johns Hopkins University reported some data on teratologic and mutagenic studies (Female Transcervical Sterilisation, 1983). The results are far from satisfactory. Some crucial experiments have been carried out on too few animals in a group; some experiments have been carried out on different strains of rats, thus making comparisons between groups difficult. The available reports, however, do indicate that Quinacrine can cause mutations, and that this needs further testing.

The Procedure of Instilling Quinacrine Pellets

The instillation of Quinacrine is recommended to be carried out between the 6th - 12th days of the menstrual cycle (the proliferative phase), or 6 weeks post-partum when the uterus has returned to its normal size. No anaesthesia or hospitalisation is required, and the procedure can be performed in an outpatient facility. According to the video titled, Quinacrine Sterilization Clinical Procedure (1995), produced by the Empowerment Project Media Centre, and made by the Institute for Developmental Training (IDT), International Federation for Family Health (IFFH) and Centre for Research on Population and Security (CRPS), "all that it takes is a vaginal speculum, a cervical tenaculum, sterile gloves, betadine or alcohol, gauze, a 4 mm Karman cannula, Quinacrine pellets, Ibuprofen, an insertor, and 5 minutes of the provider's time".

The Issue of Dosage

Most of the recent studies introduce 7 pellets of 36mg each, i.e. a total of 252 mg. of Quinacrine at a time into the uterus. The scientific basis for this dosage is unclear. Also, no specific dosage studies seem to have been carried out prior to its use in different countries. Additionally, there is still no consensus about the number of instillations to be used for optimal results. However, two or three monthly instillations have been commonly recommended due to high failure rates associated with a single instillation.

Additional Contraceptive Cover

Since the occlusion/blockage/sclerosis is meant to take 6-12 weeks to occur, an additional contraceptive cover is provided for a period of 3 months from the first instillation. While the earlier practice was to prescribe contraceptive pills, in many of the trials conducted all over the world in the last few years, Depo Provera or medroxyprogesterone, a long acting hormonal injectable contraceptive is commonly being given.

Higher failure rates were reported with use of contraceptive pills as an adjunct to Quinacrine pellets in comparison to the use of Depo Provera. The inclusion of a drug like Depo Provera in a large number of trials being conducted, and even in the IFFH protocol is indeed surprising. Addition of one hazardous contraceptive to the protocol for the evaluation of another potentially hazardous agent is only likely to compound the undesired effects!

The Question of Efficacy

Published reports quote varying efficacy rates of 90 to 95% for the Quinacrine method of sterilisation. But there are no proper controlled studies carried out to determine the optimal dose and the regimen to be used. Yet the promoters of Quinacrine sterilisation have repeatedly claimed that "those who have two insertions are half as likely to experience a method failure as those who have only one insertion". [Training Package for Health Workers, IDT].

Also, most reports show a steady increase in the failure rate over a 10 year period after sterilisation. Marge Berer (Reproductive Health Matters, 1994) quotes David Sokal's (Family Health International) data from Chile showing a cumulative pregnancy rate for two insertions of about 8.7% after five years and 11.6% at ten years after insertion in women under 35 years of age. However, long-term follow-up data on comparative failure rate (with women undergoing surgical sterilisation used as controls) are not available.

Additionally, the data on efficacy in many of the research findings have also been distorted to present a higher efficacy than was actually found. (See details in Section on 'International Research : Incredibly Unscientific'). On the other hand, the Phase II clinical trials by the Indian Council for Medical Research (ICMR) conducted between July 1993 - Sept. 1994 on 8 women reported a failure rate of 50%.

Even the methods used to ascertain the success of Quinacrine sterilisation are not foolproof. Tubal blockage is checked by hysterosalpingogram (HSG), a technique which uses a dye to visualise the uterus and fallopian tubes using X-ray. Dr. Puneet Bedi, a practising gynaecologist from Delhi, pointed out the potential fallacies in the interpretations of results of HSG. He said, "Aberrations, both false negative as well as false positive, are a distinct possibility when the HSG is conducted. This is because the dye is introduced into the uterus under some pressure and it is known that tubes which might have been blocked open up under such pressure. Alternately, the chemical in the dye may cause sudden spasm of the tubes and may prevent passage of the dye, inspite of their opening being intact otherwise. This understanding is crucial for an accurate assessment of the success of the Quinacrine method of sterilisation".

Contra-Indications

In the absence of systematic studies, there is insufficient knowledge of all the conditions in which Quinacrine sterilisation is clearly contraindicated. What is known is that pregnancy, genital tract cancers and uterine distortions - fibroids, congenital malformations, etc., are absolute contraindications for Quinacrine sterilisation.

Also, women with active uterine bleeding, pelvic inflammatory disease, cervicitis or vaginitis should be cured before being sterilised by the procedure. And, with its known side effects on the central nervous system, Quinacrine sterilisation is also contraindicated for women with a history of seizures and fits.

SIDE EFFECTS & COMPLICATIONS : UNACCEPTABLE BY ANY STANDARDS

The procedure of instilling Quinacrine pellets into the uterus for the purpose of sterilisation is a blind one. In effect, it serves to burn the walls of the tubes and possibly damage the lining of the uterine wall. In the absence of sufficient studies on its side effects, it is impossible to know all the short and long terms effects it could have. However, some of the known complications and side effects it is associated with are:

Recorded Complications

Perforation of the uterus may be caused by forceful insertion of either the sounding device used to measure the length of the uterus, or the Quinacrine insertor itself. Subsequent intra-peritoneal deposit of the pellets and the possible toxic effects of the dissolved Quinacrine in the peritoneal cavity is a matter of concern to many experts.

Cervical stenosis (closure of the aperture of the cervix) resulting in accumulation of blood in the uterus is also one of the major adverse effects observed in women undergoing transcervical Quinacrine sterilisation.

Uterine synechia, a serious condition of adhesions between the anterior and posterior uterine walls has also been reported following multiple instillations of Quinacrine.

Short Term Side-Effects

A short term change in the menstrual pattern, a side-effect due to its local action in the uterus, is commonly observed. The disturbances could manifest as anything from absence of bleeding, to scanty bleeding and heavy bleeding, and can last upto a few months.

Itching of the vagina and vaginal discharge are also observed in a large proportion of cases within the first few days of insertion.

Pain in the lower abdomen is another common short-term side-effect.

Headaches, dizziness and backaches are also commonly reported soon after the procedure.

Infection of the pelvic cavity due to insufficient care during the procedure is also a known complication.

Effects on the Central Nervous System: Quinacrine is known to bring about excitation of the central nervous system documented as psychic stimulation, motor acceleration (rapid, uncontrollable movements of arms, legs, etc), restlessness, insomnia and changes in the EEG, (Goodman and Gilman). Quinacrine also inhibits many enzymes like cholinesterase, phospholipase-A2 and some enzymes involved in maintenance of oxygen balance in the tissues. Some of the side-effects of the drug, especially the effects on the nervous system, can be due to its effect on cholinesterase.

Effects during Pregnancy: Quinacrine is absorbed very rapidly from a pregnant uterus, as shown by some studies on monkeys. Higher blood levels reached due to such rapid absorption of the drug can result in mental disturbances and toxic psychosis. It is thus imperative that pregnancy is strictly ruled out before using Quinacrine for sterilisation.

Effects on the Foetus: Given the mutagenic potential of Quinacrine sterilisation, there are serious concerns surrounding the possible effects on the foetus following failure of the procedure. But despite the high failure rate, no indepth studies have been done even on this issue.

Risk of Ectopic Pregnancy: Ectopic pregnancy (pregnancy occurring outside the uterus) is a serious side-effect reported subsequent to Quinacrine sterilisation. Since Quinacrine acts on the tubes, and blocks the tubes by inducing corrosion and sclerosis, theoretically the chances of development of ectopic pregnancy increase manifold. The first reason is that the corrosion leading to scar formation can easily bring about a not-so-clean block in the tube. Chances of incomplete closure of the tube also increase and this may result in the passage of a few sperms into the tubes resulting in fertilisation of the egg. If closure is not complete, the fertilised egg is more likely to start developing in the tube itself. Secondly, the rough surfaces resulting from scar formation will hamper the movement of the egg, thus adding to the first problem. This form of ectopic pregnancy, tubal pregnancy -- when the foetus begins to develop within the tube -- must be treated as a medical emergency, since the rupture of the tube can lead to death if not diagnosed early and treated urgently. In fact, the risk of maternal death associated with ectopic pregnancies is 10 times higher than the risk associated with childbirth [J. American Med. Assoc., 1984].

Estimated figures of ectopic pregnancy rate consequent to Quinacrine sterilisation vary from one study to the other. The incidence ranges from 0.14 per 100 woman years [Kessel et al] to as high as 0.89 per 100 woman years [Hieu et al]. Proponents of Quinacrine method brush off this important fact by comparing it with the

incidence of ectopic pregnancies associated with IUD use. However, one important difference is that women who have undergone Quinacrine sterilisation have to live with this increased risk of ectopic pregnancies for the rest of their reproductive lives. Naturally, this makes Quinacrine sterilisation sufficient cause for concern.

While repeatedly acknowledging that "Quinacrine sterilization unfortunately does not prevent ectopic pregnancy", it is interesting that the June 1996 issue of the Quinacrine Sterilization Newsletter, in response to concerns about incomplete closures and the risk of ectopic pregnancy, should state, "A few cases of QS were collected but not reported since their number was very small. For these cases, one tube appeared completely normal with the other tube closed. It would seem from this limited experience that QS (Quinacrine sterilization) is an all or none response. If Quinacrine reaches the tube it nearly always results in closure and most failures occur because quinacrine did not reach the tube". By their own admission, the promoters of Quinacrine sterilisation have not taken the issue of ectopic pregnancies seriously enough.

In an interview with Saheli on 2.5.97, Dr Badri Saxena, Addl. Director General, ICMR, revealed that in addition to high failure rate, one of the reasons that ICMR decided to abandon the clinical trials in 1993-94 was the incidence of ectopic pregnancy in the first few cases enrolled for the trial.

Says Woman #2, a 34-year old woman who was part of the trials conducted by the Lady Hardinge Medical College, New Delhi in 1996, "About 1 year after I was given Quinacrine, my periods stopped, but I didn't suspect anything. Then, suddenly, about 2 months later, I started bleeding heavily, so I was rushed to the hospital. You can imagine my shock when they told me I was pregnant, and that the pregnancy was in my tubes". (The Yellow Haze, documentary film, Mass Communications Research Centre, Jamia Millia Islamia University, 1997)

Unresolved Issues Concerning Long Term Side-Effects

Despite decades of use of Quinacrine as a sterilising agent, several issues remain unresolved regarding its long term effects. These are serious concerns, because without adequate knowledge of the possible effects of Quinacrine sterilisation in the long term the drug cannot be considered fit for use and medical practitioner should be not be recommending or conducting Quinacrine sterilisations, nor can any authority approve its use.

Safety Not Established:

A major area of controversy is about the safety of the drug when used as a sterilising agent, because adequate data are not available about its mutagenic potential (potential to cause changes in tissue), teratogenicity (effect on the foetus), carcinogenicity (potential to cause cancer) and persistence of the compound in the tissues.

Indications of Mutagenicity and Carcinogenicity : What do these terms mean and why should one worry about the effects when Quinacrine has been used as an anti-malarial drug for the past 60 years? Mutagenic potential means the ability of the drug to induce changes in the DNA sequences. Carcinogenicity signifies that the drug can induce tumours (cancers). If the drug persists in the body for a long time after attaching itself to the DNA of the host, it can potentially cause any of these effects. Hence, before proclaiming any drug associated with human pregnancy and its manipulation to be safe, it is necessary that extensive toxicological studies be done. Follow-up of (572) recipients of Quinacrine in Chile has revealed a small cluster of cancer, including one case of leiomyosarcoma. (AVSC Working Paper, No.6, 1994).

Survey of the other available literature shows that the incidence of cancers associated with Quinacrine use is not significantly different from the normal population. However, many of these reports show a small statistically insignificant increase, but nevertheless an increase in the incidence of cancers. These findings only serve to reiterate the fact that the toxicity studies for Quinacrine sterilisations are necessary.

The WHO Toxicology Panel Report 1991 stated, "Quinacrine is a positive mutagenic agent in bacterial systems and there is inconclusive evidence in mammalian systems. There is lack of carcinogenicity assessment in animal systems, but limited evidence that there may be carcinogenesis in humans". The Report further states, "The rationale for using additional 'potentiating' agents (e.g ampicillin, ergotamine, ibuprofen) in combination with Quinacrine is unclear and not supported by any experimental or clinical evidence. The combined effect of these agents has not been assessed. It is possible that the proposed combination could raise additional toxicological issues having in mind the existing literature data on ibuprofen and ergotamine leading to embryo-toxicity in two animal species."

In 1994, based on data from various reports on official and unofficial use of Quinacrine as an agent of female sterilisation, WHO stated that the information available on toxic effects of topical application of Quinacrine is inadequate. Dr Benagiano, WHO states, "Further use of Quinacrine requires that the necessary toxicology

testing, including the full range of genotoxicity studies be completed, and if needed, long-term animal carcinogenicity testing. Other animal tests, including tests for teratogenicity, should be done if these initial results are satisfactory. If initial toxicology tests are satisfactory, Phase I and Phase II clinical studies of intra-uterine Quinacrine following properly designed and peer-reviewed protocols should be initiated." (Lancet, 344, 689, 1994).

Fears Concerning Teratogenicity : Quinacrine binds to the genetic material, DNA, very efficiently. This is one of the reasons why it is necessary to examine whether this DNA intercalating property (possibility of inserting itself into and interrupting the sequence of genetic information) will bring about mutations (changes) in the DNA of the developing foetus in cases where Quinacrine has failed as a method of sterilisation, as well as in cases of insertion when pregnancy has not been detected before insertion. This could cause genetic disorders in such infants.

The high failure rate is a concern for the well being of children born to mothers sterilised with Quinacrine. Dr Ralph Heywood, a consultant toxicologist states, "...Quinacrine is less than 100% effective as a sterilising agent, therefore concerns exist with respect to teratogenic risk." (Marge Berer, Reproductive Health Matters, No 4 Sept. 1994). He further says, "There is evidence that Quinacrine is a DNA intercalator, a mutagen and possibly is an inhibitor of DNA excision repair. Until appropriate tests have been conducted, it is not possible to comment on the compound's genetic toxic potential."

Reversibility not Proven

In the case of Quinacrine sterilisation, whether the destruction brought about in the epithelial lining of the tube is a permanent feature or whether it can be reversed is unresolved. Animal studies show that estrogen and progesterone, two hormones necessary for normal functioning of the female reproductive tract, can bring about some reversal in the pathology of tubal blockage. However, this has not been found to be true in women undergoing sterilisation with Quinacrine. Some reference to using a cannula for opening the blocked tube has been made, but as yet there is no clearly documented method to bring back fertility, despite assertions to the contrary by Quinacrine proponents like Dr JK Jain. This, despite the fact that the training film titled Quinacrine Sterilization Clinical Procedure, made by the Empowerment Project clearly states, as one of the disadvantages of the procedure, the fact that "it is non-reversible".

Obviously, in places where the healthcare system is poor, infant and child mortality rates are high, and where women get sterilised at an early age, the option to regain fertility is mandatory.

The Importance of Skill of Insertion

Quinacrine insertion is a blind procedure. There is always some possibility of pellets not being deposited at the desired site near the fundus, thus possibly resulting in a failure to initiate tubal blockage. The Vietnam trial showed variation in efficacy of sterilisation in different provinces of Vietnam, putatively because of the skills of the personnel involved. (Lancet, 1993, 342: 213-7). In this report, the authors, Hieu et al show have reported that "the failure rate varied between the operators (from 0-17.2%) when some 4000 women out of the 31,781 undergoing Quinacrine sterilisation were followed for upto 2 years".

Also, it is essential to determine the uterine position accurately by a bi-manual pelvic examination in order to ensure that the pellets are placed near the fundus and that no perforation occurs which could deposit the pellets in the peritoneal cavity, leading to serious problems.

Not surprisingly, the training film, Quinacrine Sterilization Clinical Procedure, states that, "the quality of the training affects the success of the procedure. Training is of crucial importance, as is experience. The provider should have performed at least 100 bi-manual pelvic examinations and 50 IUD insertions". In fact, it goes on to say that "if the provider does not have this experience, training in Quinacrine sterilisations should be postponed till the provider gains this experience".

When Quinacrine sterilisation is being visualised as a procedure that can be provided by para-medics and auxiliary health workers on a large scale, the question of their experience, training and skill, and its effect on the effectiveness of the procedure and the prevalence of side effects for the women gains importance.

Concerns of Insufficient Follow Up

Whether the reported incidence of ectopic pregnancies and other side-effects and complications in all the studies, is a genuine finding or a result of under-reporting due to poor follow-up of the women, is a major worry. Dr Biral Mullick, a proponent of Quinacrine from Calcutta is quoted as saying, "What do you mean by monitoring the women patients? If they have problems, they will come to me. I have not received a single complaint in the last ten years. Moreover, I do not have the money to do any follow-up" (Sunday Telegraph, 19.1.97). When Dr Shree Mulay (Prof. Dept. of Medicine, McGill University, US), met Dr Syeda Noorjehan Bhuyian of the Chittagong Medical College in February 1997, Bhuyian echoed the same reasoning as Mullick - she has no money for follow up. A similar story is that of Dr Altaf Bashir's trial in Pakistan. Dr Maya Sood,

Head of Department, Gynaecology and Obstetrics, Lady Hardinge Medical College, New Delhi also told Saheli at an interview on 18.6.97 that she also had no funds for following up women who were part of the trials of Quinacrine sterilisation. These instances, as well as the Vietnam study, are important tools to highlight limitations of the mass scale operation carried out in developing countries.

Thus it appears that the proponents of Quinacrine have enough money to insert Quinacrine, but suddenly become devoid of resources when it comes to follow-up of the women. Apart from the unscientific nature of such trials, this is a clear violation of the rights of these women to proper follow-up and care.

Arguments Against Need for Further Testing

* The major excuse given by the proponents of the Quinacrine sterilisation for not carrying out systematic studies on the procedure is that it is an old drug that does not need any new research. But standard medical practice has it that when the formulation and route of administration of any drug changes, it needs to be studied for the effects of its new course of action. Also, in the case of Quinacrine, there is sufficient scientific data that indicates serious short and long term effects. This only reaffirms the necessity of further research.

* Another major reason they put forth for not carrying out the recommended tests is lack of funds. They claim that "approximately US \$8 million and 8 years will need to be spent before Quinacrine sterilisations can be approved by a drug authority like the US Food and Drug Authority (USFDA), and that no pharmaceutical company or funding agency has come forth with the money" (Kessel in the video documentary, The Yellow Haze). Instead of seeing that as a sign to stop all work on Quinacrine, its proponents are merely using it as an excuse to bypass all scientific and ethical norms.

* The promoters of Quinacrine also argue that the 'population bomb' is ticking all the time and needs to be tackled on a 'war footing', so there is no time to be spent researching Quinacrine sterilisations. Obviously, in their hurry to control population, concern for women's health doesn't seem to be a concern.

* Some voices also claim that certain mutagenic agents have been licensed for human use. These people conveniently hide the information that these mutagenic drugs like methotrexate are used for treatment of cancer or some life threatening conditions. Use of Quinacrine for female sterilisation does not come anywhere near a life threatening condition.

In the light of prior experiences like the DES tragedy, in which drugs given to women with a history of premature births, miscarriage, diabetes, hypertension or bleeding in early pregnancy between 1945-70, revealed a higher incidence of vaginal and uterine abnormalities, higher risk of vaginal cancer and higher incidence of infertility in 'DES Daughters'; and a higher incidence of testicular abnormalities, low sperm count and lowered fertility of 'DES Sons' who were exposed to the drug *in utero*. While the adverse effects became apparent only when DES Daughters and Sons attained puberty, what is really distressing is that there were grounds for serious concern right from the beginning, when animal studies had indicated carcinogenicity. Some of the concerns surrounding the use of Quinacrine as a sterilising are not very different.

Such experiences make it clear that in the matter of women's health, it is safer to err on the side of caution.

INTERNATIONAL RESEARCH ON QUINACRINE STERILISATION : INCREDIBLY UNSCIENTIFIC

For more than two decades now, Quinacrine sterilisations have been conducted in 16 countries, and quoted at seminars and conferences all over the world. But the fact is that the research into the use of Quinacrine for female sterilisation smacks of researchers proving what is convenient to them, and reaching conclusions they set out to establish. A few examples are given below.

VIETNAM : The largest study poses the largest problems

The study by Hieu et al from Vietnam involving 31,781 women was published with much fanfare in *Lancet*, a prestigious medical journal, in 1993, as a major success story for Quinacrine sterilisation. Critical analyses of this study however, reveal several lacunae in collection, maintenance and interpretation of data, highlighting the fact that the failure rates and the incidence of side-effects reported for Quinacrine sterilisation are far from reliable.

Ectopic Pregnancy: For instance, the ectopic pregnancy rate reported was 0.89 per 1,000 woman years. However, as researchers at the Association for Voluntary Surgical Contraception (AVSC) point out (AVSC Working Paper No. 6 1994), this rate is based on a two-insertion protocol with data from only one province. Ectopic pregnancy rates were found to vary between provinces, but the data from one province were extrapolated to the whole group of 31,781 women.

Several panellists at the AVSC have raised concerns regarding the difficulty of assessing ectopic pregnancy rates in rural areas of developing countries where the cause of death for women who die as a result of ectopic pregnancy may not be identified or recorded.

Efficacy: Dr Shree Mulay, in the *Economic and Political Weekly*, April 26, 1997 points out that the statistical analysis of data by Hieu et al is faulty. For instance, the authors reported 818 pregnancies and calculated the life-table pregnancy rate at 2.63 at one year and 4.65 at two years for 9,461 women and 5.15 at one year for 2,225 women receiving one insertion. Thus, pregnancy data were analysed for only 11,686 women and not the entire sample of 31,781 women, as would appear at first glance.

It thus becomes necessary to reinterpret data accurately to arrive at more realistic conclusions, rather than believe statistics used for propaganda.

BANGLADESH : Further evidence of scientific inaccuracy

In Bangladesh, Mulay recalculated the data on trials conducted on 513 women by Dr Syeda Noorjehan Bhuyian, Principal of the Chittagong Medical College. It was found that follow-up was done on not more than 30% of the patients over a two-year period. Accordingly, at most, only 150 women out of the 513 were actually followed up. Thus, while the reported failure rate was 4%, the recalculated failure rate was found to be as high as 14%. Similarly, while lower abdominal pain was reported in 2%, the recalculated percentage was 8%.

Further, four different protocols were tried with combinations of other drugs like ibuprofen and ampicillin, but all the data were pasted together. It is significant that both Kessel and Mumford already had information on ibuprofen and ampicillin from other studies that suggest that ibuprofen, an anti-prostaglandin, interferes with the inflammatory action of Quinacrine. Yet, the IFFH memorandum, dt. 4.4.1994 to organisations interested in Reproductive Health states, "The addition of ibuprofen 55.5 mg as 3 pellets improves efficacy and helps relieve mild side-effects.

Mulay also questions why Bhuyian was asked to test the lower doses and single insertions of Quinacrine when the information was already available.

IRAN : Taking liberties with research protocols

In a trial on 160 women in Tehran, Sheitaneh Soroodi-Moghaddam inserted 3 doses of 7 pellets, each of 36 mg Quinacrine at one month intervals. However, after 62 cases, the researcher began to insert 2 doses at one month intervals. The change in protocol however, is not reported in the data showing results.

INDIA : More evidence of arbitrariness

In his trials on 58 women (1992-93) and 229 women (1993-94) (*Advances in Contraception* 1995, 11: 239-244), Dr Biral Mullick reports nine separate protocols, including data for tetracycline as a sclerosing agent. These protocols were conducted simultaneously with no regard as to what may be the most effective protocol, and to the validity of results obtained with very small numbers.

Even with these few examples, it is apparent that Quinacrine trials in most countries are shoddy and cannot withstand scientific scrutiny or rigorous statistical analysis, much less, form the basis for the advocacy of Quinacrine as a large scale method of female sterilisation.

PROMOTERS OF QUINACRINE STERILISATION : GLOBAL AMBITIONS, LOCAL REACH

Given the widespread promotion of Quinacrine all over the world, critical questions that come to mind are : Who are the people involved, and what do they stand to gain? It is important to understand the linkages between the funders and promoters from the First World, and practitioners from all over the Third World.

Dr Elton Kessel of the International Federation of Family Health (IFFH) and Dr Stephen Mumford of the Center for Research on Population and Security (CRPS), both based in the US, have been actively involved in promoting Quinacrine in several countries.

For decades now, Kessel and Mumford, through their respective organisations, IFFH and CRPS, and through personal contact, have been actively networking with medical practitioners and NGOs all over the Third World, for instance, Jaime Zipper in Chile, Hieu in Vietnam, Altaf Bashir in Pakistan, Bhuyian in Bangladesh and Biral Mullick, Kini, Bhateja, Jain and many others in India. They have been providing funding, supplies and technical assistance for trials of Quinacrine for more than 30 years. Both these organisations are funded by right-wing anti-immigration groups like the Leland Fikes Foundation, William Buffet Foundation and The Ted Turner Foundation; Federation for American Immigration Reform (FAIR) and the Americans for Immigration Control. Mumford has gone on record saying, "If the borders of the US are not closed, the US would become a Third World country" (The Human Laboratory, Horizon, BBC, 1994).

Elton Kessel and Mumford first collaborated on Quinacrine trials through the International Fertility Research Program (IFRP), Research Triangle Park, North Carolina, USA, an institution of which Kessel was the founder member. The IFRP has subsequently been renamed the Family Health International (FHI), which describes itself as a non-profit US based organisation dedicated to contraceptive development, family planning and reproductive health and AIDS prevention around the world. Through the FHI, Kessel and his colleagues made two attempts to get the approval of the USFDA on Quinacrine sterilisations, but failed. Currently, Kessel is Secretary General of IFFH, while Dr JK Jain, New Delhi, is its President.

Kessel, Mumford and their colleagues literally traverse the globe with Quinacrine pellets in their suitcases, urging gynaecologists at meetings and conferences to try Quinacrine sterilisation. For instance, Kessel turned up at a meeting of the Patiala Obstetrics and Gynaecological Society in January 1997 and delivered an oration entitled, '100,000 Quinacrine Sterilisations'. "Probably the most important need", he claimed, "is to encourage expansion of Quinacrine sterilisation in the private sector as an 'off-label drug' as it is approved almost everywhere for treatment of malaria. Dr Maya Sood, HOD, Gyn. & Obs., Lady Hardinge Medical College, New Delhi, revealed in the documentary film, *The Yellow Haze*, that she was going to meet Kessel shortly in Agra. Similarly, Dr Sneh Vishwanathan, Consultant, Parivar Seva Sansthan (Marie Stopes, India) also reported having met Kessel in a conference in Karachi in 1994, and becoming convinced about the Quinacrine sterilisation method.

The ubiquitous CRPS was also present at the Global Forum at the Fourth World Conference on Women, Beijing (September 1995) where they promoted Quinacrine as a way to improve women's health and reduce maternal mortality. In a classic example of doublespeak, their training video was produced by the "Empowerment Project". Fortunately, a number of women's health activists were at hand to challenge them.

Sarah G Epstein, another vehement advocate of Quinacrine, along with her husband Donald A Collins, also a population consultant, attended the Beijing Conference to carry out pro-Quinacrine propaganda. For two weeks prior to the Conference, they toured Chinese villages and cities with a group from the Population Institute, Washington DC. They met local health service officials to promote Quinacrine as an effective, safe and inexpensive sterilisation method. Epstein and Collins, not incidentally, are also on the Board of the Federation for American Immigration Reform (FAIR).

In February 1996, through an oversight of the Conference organisers, Kessel and Mumford participated in the Women's Expo '96 and personally staffed a booth in the exhibit area and took out an advertisement in the program book that made unsupportable claims about the Quinacrine method of sterilisation.

But these are not the workings of a few isolated groups and individuals determined to promote this hazardous method of sterilisation that they believe is most suited to developing countries. They are part of the population control lobby that seeks to control the population of developing countries at any cost to the health and well-being of their peoples, especially women.

QUESTIONABLE JUSTIFICATIONS FOR THE PROMOTION OF QUINACRINE STERILISATION

Despite the fact that Quinacrine sterilisation is not scientifically proven to be either safe or effective, its proponents argue that it has a vital social impact, wherein the benefits far outweigh the risks. It is claimed that although Quinacrine sterilisation is not a proven method, it presents an easy and economical alternative to the prevalent practice of surgical sterilisation. Further it is also claimed that it can serve to significantly lower maternal mortality rates, fulfil the unmet need for contraception and thereby play a crucial role in reducing population growth in developing countries. However, all these arguments and their underlying motives are equally problematic.

Kessel's plea that the gap between developing and developed nations is so wide in terms of health and contraceptive prevalence, that it is inappropriate to apply a single standard for clinical trials to both. In its place they propose the WHO "risk/benefit criterion for tropical diseases", i.e. that the risk of the disease is high enough to justify the use of inadequately tested drugs. This criterion is seriously problematic on two counts: In the first place, allowing the use of inadequately tested drugs even for treating diseases is itself unethical and medically unsound. Secondly, viewing reproduction as a disease to be 'treated' with untested drugs reveals an anti-woman bias which runs through such research. Women's fertility is regarded here as uncontrolled and untamed, to be reined in by any means and at any cost -- cost to the woman, of course.

The Non-Surgical Option

The promoters of Quinacrine sterilisation never fail to start the argument in favour of the procedure by highlighting the prevalence of sterilisation *per se* as a contraceptive method in the world today. On the basis of this, they argue that the only way to 'control' world population is through sterilisation, and that surgical sterilisation cannot meet the projected demand. Additionally, they claim that the Quinacrine method provides the safer, simpler, cheaper and lower risk option.

In an article titled 'Potential demand for voluntary female sterilization in the 1980s', Kessel and Mumford make their position clear when they state, "Not to be ignored are the disastrous implications of world overpopulation, best summarized in the recent United States Government's heavily documented *Global 2000 Report*. If the dire projections set forth in this report are to be avoided and any nation is to enter the 21st century peacefully and secure, sterilization is certain to play an important role".

According to Tim Black of Marie Stopes International, London, "Sterilisation is the most widely used method with 45 percent of all contraceptors relying on this procedure". (The Quinacrine Imperative). There are several projections of the estimated 'demand' for sterilisation in the 1990s that vary from 170 million - 200 million. Hence, Black goes on to say, "Unless funds are made available to socially market vasectomies, most of the sterilisations will be female procedures - at the very least 85 percent".

Such tokenism towards the need to encourage vasectomies is not uncommon. While the promoters of Quinacrine sterilisation acknowledge that "increases in the number of procedures have been largely due to improvement of surgical techniques, with concomitant effective training programs over the last two decades". (Quinacrine pellet method of non-surgical female sterilization, Kessel et al) they maintain that "Reliance on surgical sterilization to meet world demand for sterilization services in this decade is certain to result in a serious shortfall. The quinacrine pellet method offers hope that this shortfall can be remedied. [Sterilization needs in the 1990s: The case for quinacrine nonsurgical female sterilisation, Mumford and Kessel].

Kessel et al argue that Quinacrine sterilisation offers a simpler, cheaper, safer, lower risk option to surgical sterilisation. The indisputable facts that Quinacrine sterilisation is a simpler procedure does not necessarily make it a better one. In fact, in the context of the mass use that it is advocated for, the ease of use of Quinacrine sterilisation offers greater potential for abuse. A paper by Mullick et al states, "The most desirable protocol for a nonsurgical female sterilisation method should be one that is safe, effective, inexpensive, acceptable and can be provided by paramedical personnel during a single visit". (Advances in Contraception, 1995). In fact, it is this quick-fix approach to Quinacrine sterilisation that lies at the root of its potential for abuse. In the light of the contraindications and possible complications, the wisdom of promoting it in this manner presents a great threat to women's health, especially in developing countries where the health infrastructure leaves so much to be desired.

One of the other 'powerful arguments' in favour of Quinacrine sterilisation is that it is one of the cheapest forms of contraception - costing just a few rupees per insertion. This low cost of the pellets is one of the primary grounds on which the promoters of Quinacrine sterilisation are aggressively promoting the method in the Third World. But what they fail to take into account is the cost that women have to pay, in terms of illhealth and potential health hazards posed to them as well as their progeny.

The claim that Quinacrine sterilisation is a lower-risk option is based on their assertion that unlike laparotomy and minilaparotomy, the two most commonly used forms of surgical sterilisation, the Quinacrine procedure does not present any risk of surgery-related complications. Two problems arise out of this argument. Firstly,

any new method should provide a qualitative improvement upon existing methods. Replacing the shortcomings of surgical sterilisation - namely, surgery-related infections, dysmenorrhoea, cancer, menorrhagia, and death (Lyn Turney, School of Social Enquiry, Deakin University, Australia) with a higher failure rate and unacceptable side-effects of Quinacrine sterilisation (like higher risk of ectopic pregnancy, mutagenicity, carcinogenicity, effects on the foetus, etc.) hardly qualifies as an any kind of improvement.

Secondly, both laparotomy and minilaparotomy have been seen to have a higher rate of complications, failure and death in semi-urban, rural and camp settings that fail to meet the requisite standards of hygiene, carry out the necessary checks for contraindications or provide prompt support for any side-effects or adverse reactions that may occur. This is precisely the setting and manner in which Quinacrine sterilisation is being advocated and carried out. Consequently, worries about lack of quality care for women undergoing the procedure remain as serious for Quinacrine sterilisation.

Further, although no fatalities have been recorded as a direct result of Quinacrine sterilisation, we have already seen that the grossly inadequate nature of follow-ups (in most places, non-existent) can hardly substantiate such a claim.

Impact on Maternal Mortality

It is claimed that in developing countries with high maternal mortality rates (MMR), each sterilisation performed for accounts for 2 births averted. According to this claim, since the MMR for India is 5.5 per 1,000 births (Bhat, PN Mari et al 'Maternal Mortality : Estimates from an Econometric Model', Monica Dasgupta et al (ed) Women's Health in India : Risk and Vulnerability, 1995), each 1000 additional sterilisations performed with the Quinacrine method will prevent 11 maternal deaths. Kessel claims that 'No one has suggested that the Quinacrine method could kill that number of women.'

The basic premise in this argument is that the pregnancies which lead to maternal mortality are all unwanted pregnancies, which a contraceptive method would avert. However, this assumption fails to recognise that most of these are wanted pregnancies, and that women will continue to bear children until the desired family size is reached.

A closer look at deaths in the "reproductive years" shows that while 'cause of death' may be maternity related, underlying conditions include fever, tuberculosis, malnutrition and a range of undefined illness syndromes. Causes of death due to pregnancy/childbirth include sepsis and toxemia of pregnancy, as well as underlying conditions like anemia and malnutrition. These are eminently preventable with timely and accessible ante-natal care.

The other major reason for death due to pregnancy/childbirth is the absence of basic and emergency obstetric care facilities. Only 33% births are attended by trained personnel in India, as compared with 94% in China and 100% in the industrialised nations (World Resources (1994-95) A Guide to the Global Environment - A Report by the World Resources Institute with UN Environment Programme and UNDP). Access to medical facilities is restricted not only by distance, but also by mode of transportation (walk, bullock carts, bus), which may take hours, or even days. Hospitals, where present, are poorly equipped with life-saving drugs, facilities for blood transfusions and emergency surgery. Unless these issues are addressed, merely pushing methods like Quinacrine sterilisations will not significantly lower maternal mortality rates.

Even within the framework that contraceptive use would lower the MMR, the promotion of non-invasive, safe and effective barrier methods like the condom and diaphragm would be a first choice from the point of view of safety. Moreover, vasectomy - a safe and simple procedure, which also furthers male responsibility for contraception, needs to be promoted.

The supposed 'benefits' of Quinacrine sterilisation are nullified when considered alongside the potential hazards. Thus, while there may be no 'reported' deaths due to the method (the reasons for under-reporting could be several - from lack of adequate follow-up to lack of proper data maintenance), the side-effects and long-term risks (detailed earlier) would contribute to morbidity which is not measurable or predictable, since they have not been sufficiently studied.

Reducing maternal mortality in these pregnancies would have to be tackled by strengthening the health care system, and not by the Quinacrine method of sterilisation.

Fulfilling an Unmet Need for Contraception

The promoters of the Quinacrine method claim that they are fulfilling the huge unmet need for contraception in developing countries, and thus reducing both population growth and lowering MMR rates. However, populations that do not have access to contraception are only a small proportion of the total of the developing countries.

In Africa it was 0.58 (Congo, Equatorial Guinea and Gabon). In Latin America it was 9.55 percent and in Asia the percentage was 2.42. In India, while the percentage of couples using contraceptives is only 43%, the population which does not have access to contraceptives is very small - only 2.42% (UN World Population Monitoring, 1991). Thus, the factors contributing to high birth rates cannot be attributed to an unmet need for contraceptives. If at all there is a need, it is for safe methods of contraception and sterilisation, not hazardous ones like Quinacrine.

Politics of Population Control

Kessel and Mumford have repeatedly declared, both in writing and in interviews, that the Quinacrine method of female sterilisation is ideal for Third World countries. In the video documentary, *The Yellow Haze*, Kessel says that quinacrine sterilisation will "have very little health impact in a country like the United States, but a huge health impact in a country like India". In the *Quinacrine Sterilisation Newsletter*, he goes on say, "In conducting a risk/benefit assessment of any contraceptive clinical trial with the potential for raising contraceptive prevalence, it becomes apparent that the benefits for a developing country far outweigh those for an industrialised nation". This assertion only serves to reiterate a clear population control agenda, skewed against the women of developing countries.

The philosophy of population control rests on the fundamental fallacy that "over" population is one of the main causes of hunger, poverty and environmental degradation, and that these problems can be overcome by population control - i.e. restricting the numbers of people. All population control programmes, even if garbed in euphemisms like "family welfare" and "reproductive health", aim at reducing the numbers of certain groups of people - poor, marginalised and powerless.

Fallacy : Socio-Economic 'Benefits' Will Be Reaped By Reducing Population Growth Rate

The philosophy of population control is that 'over' population is one of the main causes of hunger, poverty and environmental degradation.

However, the reason for hunger, poverty and environmental degradation is the unequal distribution and consumption of resources. Unsustainable consumption patterns of the industrialised nations contribute in greater measure to depletion of resources at the global level :

~ The US, with 1/3 the population of India consumes nearly 3 times as much iron ore as India; 4.6 times as much steel, 3.6 times as much coal, 12 times as much petroleum, 3 times as many heads of cattle and sheep.

~ US consumption of all sources of fossil energy is so large that per capital emissions of carbon dioxide, a principal greenhouse gas, are 19 times those of India. In fact, US is the world's leading producer of greenhouse gas emissions, which may result in global warming, and it plays a significant role in degrading the global commons.

~ In India consumption by the highest income group [1.44% of the population], of electricity, petroleum products, and machine-based household appliances - products that have global environmental impact - is about 75% of the total consumption for these commodities in India.

~ In the US, residential home owners spend about \$7.5 billion a year to care for their lawns, despite the fact that run off from lawn chemicals contributes to municipal water pollution, grass clippings to solid waste disposal problems and exhaust from lawnmowers to urban pollution.

~ Northern families spend about \$9 billion a year on video games for their children. In 1989-91, by comparison, US foreign development aid of all kinds totalled \$10.1 billion, and that of Japan \$9.7 billion.

The other fallacy of the philosophy of population control rests on the fundamental fallacy that the fastest and most cost effective way to reduce birth rates is to provide women with modern contraception, and that family planning should be a higher priority than the basic health care.

However, many social and economic forces interact to cause rapid population growth - poverty, lack of social security, low status of women, high infant and child mortality. Hence, merely providing contraceptives, or even coercing people to use them will not ensure lower birth rates. What is urgently needed is a stronger emphasis on the health care infrastructure.

For elites, both in the First World and Third World, this analysis is compelling because it obscures the inequitable social and economic relations at the root of poverty and environmental degradation and indeed at the root of population growth itself. Additionally, for many government leaders, population control is a much more attractive development option than genuine challenges to the status quo such as land reform, expansion of social services, or democratisation. In targeting women, population control also absolves men of responsibility for contraception and ignores issues of male control of women's sexuality.

As Betsy Hartmann, Director, Population and Development Program, Hampshire College, points out, "Population control is enjoying a resurgence in the 1990s as the Cold War obsession with military expenditures gives way to new definitions of security and other means of social control. For example, in a recent study of US foreign policy in a 'New World', the Carnegie Endowment for International Peace claims that population growth threatens 'international stability'. While acknowledging that economic growth and empowerment of women are necessary to reduce birth rates, it nevertheless asserts that family planning is the 'least costly' and 'most pragmatic' means for defusing the population explosion. "The American interest is clear", it states. 'We need to commit our leadership and resources to a multi-lateral effort to drastically expand family planning services in the developing world.' (Old Maps and New Terrain : The Politics of Women, Population and the Environment in the 1990s, 1993).

International financial institutions also view rapid population growth as a threat to economic recovery. In the 1990s, World Bank ideology on poverty and population underwent a major shift away from the more liberal view that poverty alleviation through social and economic development was the main key to fertility decline. Now, according to analyst Peter Gibbon, the Bank believes that population problems cannot wait "for their solution on socio-economic development; their urgency has been increased by the threat of ecological imbalance and by the necessity to succeed with the structural adjustment effort." On the other hand, Kessel says, "The benefits of contraception in terms of morbidity and mortality prevented, as well as the socio-economic concerns of rapid population growth, are greater for a developing country such as Vietnam. In applying a North standard for contraceptive research to a developing country, HRP-WHO (Human Reproduction Program of the World Health Organisation) has made a value judgement that is not based on science or logic."

In terms of direct impact on policy, one of the most widely used systems today, is RAPID (Resources for the Awareness of Population Impacts on Development) a micro-computer software developed by the Futures Group, a firm under contract to US Agency for International Development (USAID). RAPID country models dramatise the supposed 'perils of over-population' with simple graphs, highly selective statistics and elementary Malthusian reasoning, and prejudice public opinion.

As far back as 1974, the US-based IFFH and CRPS which are spearheading the promotion of Quinacrine sterilisation in the Third World, and are also closely linked with the Republican far right, were instrumental in getting a study commissioned on "Implications of World Population Growth for US Security and Overseas Interests" under President Nixon. The document targets 13 countries, including India, Bangladesh, Pakistan, Brazil and Egypt, and supports population control to stem radical dissent and protect US access to strategic minerals. It advocates using food aid as leverage and recommends "mandatory programmes" and coercion as possible tactics.

But the population control lobby is not restricted to the First World. In India, Dr JK Jain who is interestingly, the President of the IFFH, is another vociferous proponent of the population control argument in favour of Quinacrine sterilisation. In a written statement given to women's groups on 2nd May, 1997, he states, "Population is a major problem for this country and neither the Government of India nor WHO have come up with workable solutions. It has, like so many other developmental exigencies, been left to others to tackle".

QUINACRINE STERILISATIONS ALL OVER THE THIRD WORLD : SIMILAR PATTERNS

The questionable practice of large scale use of the Quinacrine method of female sterilisation is not unique to India. Over the past 20 years or so, the method has been used on women in 16 countries including India, Chile, China, Indonesia, Philippines, Vietnam, Bangladesh, Iran, China, Bangladesh, Venezuela, Romania, Malaysia, Pakistan, Costa Rica, Croatia and Egypt. What these countries share is that they are all Third World countries, and the Quinacrine method has been experimented mostly upon illiterate women from a lower socio-economic stratum. Most of these women live in rural areas where access to medical facilities, especially emergency services, is poor or completely lacking. These women were not told that the Quinacrine method is an experimental one, and is not approved by any national or international regulatory body.

The 'trials' in most of these countries follow a similar pattern - there is no evidence of informed consent, the research protocols are shoddy and unscientific, and there is a glaring lack of adequate follow up. Another common thread running through the 'trials' is that more often than not, they are carried out through private practitioners and/or NGOs, rather than governmental bodies which can be held accountable. An important link between these countries is the involvement of persons like Sarah G. Epstein, Kessel and Mumford, and organisations like IFFH, CRPS in the US and Mother and Child International in Switzerland who offer 'technical assistance' and supplies of Quinacrine pellets and inserters.

While the proponents of Quinacrine attempt to buttress their argument that the Quinacrine method is a safe and effective method by quoting its use in many countries, actual facts reveal that the use of the Quinacrine method has been dogged by controversy and protests in almost all the countries where it has been tried. Following are a few examples of countries where Quinacrine has been used, and the protests by women's organisations in these countries which have forced a review of this method. Importantly, protests against the unethical trials of this hazardous drug have also come from women's groups and health organisations in the First World.

CHILE : Trouble in the Birthplace of Quinacrine Sterilisation

Chile can be said to be the 'cradle' of the use of Quinacrine for female sterilisation. This method was developed by Jaime Zipper of Copper T fame. In his garage home in Chile, Zipper had experimented with a number of agents like formaldehyde and sulphuric acid to block the fallopian tubes of rabbits and rats. Soon, with the support of Elton Kessel and later Stephen Mumford, he began to conduct experiments on women. Between 1970-79 he instilled slurries of Quinacrine into 1,109 women in doses ranging from 250-3,000 mg per insertion. While Zipper claimed that there were no deaths in these initial trials, the manufacturer of the drug, Winthrop Pharmaceuticals reported 3 deaths following the use of Quinacrine slurries. Despite these deaths, experiments on humans continued, and the US-based FHI assisted Zipper in formulating less toxic methods of delivery, and testing them on poor Chilean women.

The trials in Chile were part of the national contraceptive research landscape since the early 70s, supervised by Zipper in 3 public hospitals. In 1994, a public controversy erupted over the Health Ministry plans to participate in expanded trials. Women's health activists received copies of a September 1994 memorandum from the US-based CRPS, which stated (erroneously, as it later turned out), that the Chilean Health Ministry was replacing surgical sterilisation with Quinacrine in the nation's two most populous regions. However, on further probing, it was found that the Chilean Health Ministry was, in fact, studying plans to join Zipper in providing Quinacrine sterilisation to upto 1000 women in central and southern Chile.

Lezak Shallat provides a context to understand the use of the Quinacrine method in Chile (*Reproductive Health Matters*, No.6 Nov.1995, 144-46) : "Female sterilisation is highly restricted in Chile under a 1975 decree by the pro-natalist Pinochet regime, which mollified the Catholic Church in the reproductive rights arena at a time of rampant human rights abuse. Sterilisation is available only to women over age 30 for medical reasons, and a woman must have 4 living children and spousal authorisation. In practice, these restrictions apply primarily to public health services, since women with private physicians generally have no problem getting sterilised. Vasectomy, though technically legal, is viewed by the Catholic Church as a form of mutilation, and is virtually impossible to get in the public health services. Abortion for whatever reason (including to save the woman's life) is strictly illegal.

"While governed by the same restrictions as surgical sterilisation, the out-patient Quinacrine sterilisation procedure provides Chilean women who cannot afford private medical care, with a fast track to sterilisation that eliminates the long wait for a public hospital bed. While women are informed that it is irreversible and has a 3% failure rate and that alternate methods exist, nowhere is it stated that the procedure is classified as 'investigational'."

The Santiago based coalition of activist groups, the Open Forum for Reproductive Health and Rights voiced 3 main concerns regarding the 'trials' :

1. Unresolved issues of safety including the internationally agreed (WHO, USFDA) recommendations to delay clinical use until toxicological trials are satisfactorily completed.

2. Need for improved informed consent procedures.

3. Need for greater transparency of information and improved access to hospital Ethics Committees. (In Chile's decentralised public health system, ethical decisions about research are made by the Ethics Committee of each hospital).

Subsequently, the Chilean Health Ministry withdrew its support for Quinacrine research, and in December 1994 called for a suspension of its use. More than a ban, this proved to be a short hiatus in which the three public hospitals providing the method were asked to review their internal ethical procedures. However, Zipper and his team have reportedly continued with the financial support of the CRPS. As for the Ministry's decision to hold off reclassification of the method from investigational to procedural status, Zipper proposed a compromise so as to increase the number of patients enrolled, as if it were a routine hospital procedure, while maintaining the level of follow-up required for investigational treatments.

Interestingly, in a meeting with the Open Forum, Zipper's team acknowledged the weakness of existing informed consent protocols, and suggested holding additional meetings with the Forum to discuss the issue. The Forum has discussed the possibility of enlisting the support of the Pan American Health Organisation's Latin American and Caribbean Regional Program on Bioethics, created in 1994, with its headquarters in Santiago. The program's head, Dr Julio Montt, a former Chilean Health Minister, has already expressed reservations about the unresolved issues of Quinacrine safety and informed consent to the national health authorities. While the Forum succeeded in building public opinion to ensure accountability in research and safeguard the interests of women, it now faces the challenge of how to sustain the pressure and address larger questions of ethics and the direction of reproductive research.

PAKISTAN : Widespread Use Of Quinacrine By An NGO

Dr Altaf Bashir of the Mother and Child Welfare Association, was also Chairman, Department of Obstetrics and Gynaecology, and Dean Punjab Medical College in Faisalabad. She reported sterilising 2,100 women residing in nearby rural and urban areas from 1990-91. The women were 'motivated' by her traditional birth attendants, lady health visitors and doctors, through street camps in rural and urban areas. According to Dr Bashir, "In our joint family system, most women do not like their relatives and friends to know that they are using family planning methods. There is crying need for the government to approve a non-surgical sterilisation method and to offer family planning to the masses at a very low cost, with minimum complications and at their doorsteps". It appears that Dr Bashir took matters into her own hands and proceeded to provide this 'service' even in the absence of government approval for the method.

An independent nurse-practitioner who went to Faisalabad in 1993 was able to observe Dr Bashir's clinical work and have discussions with the staff responsible for Quinacrine insertions. While she preferred to remain anonymous, she agreed to publication of her report (Reproductive Health Matters, No 4. Nov 1994) :

"Some patients are recruited at 'street camps' and given little information or time to fully understand and think about the implications of this type of procedure. Patients receiving treatment at regular clinic facilities receive a bit more information, but are not informed that this method has not been formally sanctioned for use in Pakistan. Insertions are primarily conducted by paramedical workers with limited skills necessary to rule out any underlying pathology.

Essentially, no established follow-up of these patients is conducted. The patient is told to "return if she has any problems". Dr Bashir claimed that the women don't return to the clinic because they have no problems. But in this part of the world it is much more likely that a woman who has experienced problems would simply not be permitted by her family to return to the same clinic, precisely because she had problems, but would be taken elsewhere for help."

Another observer reported (Reproductive Health Matters, No 4. Nov 1994) : "Dr Bashir was not strict enough about finding out the women's gynaecologic history. She did not exclude problems like pelvic inflammatory disease, and there was no screening for reproductive tract infections of any kind. When asked about this, she claimed that reproductive tract infections were not a problem in Pakistani women. Nor did she check whether the woman had any children over the age of 5 years or how many, to exclude those women who might regret the procedure if one or more of their children died. When asked if there had ever been an independent evaluation of her work, Dr Bashir said no."

Since the murder of Dr Bashir, it is not clear whether Quinacrine sterilisations are still being done in Pakistan, but Dr S Vishwanathan, Consultant, Parivar Seva Sansthan (Marie Stopes, India), in an interview with Saheli on 9.5.97, stated that Marie Stopes, Pakistan, was carrying out sterilisations with the Quinacrine method.

The Pakistan example reflects the similarity of abuse of women's health in the sub-continent, and the potential for mobilising against such violations.

IRAN : Private Practitioners Promote Quinacrine

Between 1990 and 1994, Dr Sheitaneh Soroodi-Moghaddam, a private practitioner in Tehran, performed sterilisations with the Quinacrine method on 168 women. She applied the study protocol of the International Federation for Family Health based on the work of Zipper and his colleagues. The protocol however, was not consistent, since 70 women were administered 3 doses at one month intervals, and 98 were administered 2 doses at one month intervals. Therefore, the results of the study have to be viewed in the light of this fact. All prospective acceptors and their husbands were counselled by a family planning specialist about side-effects, irreversibility and possible complications. However, they were not informed that they were subjects of a trial, and that Quinacrine sterilisation is not a tested and licensed procedure.

Although approximately half of the women experienced complications or side-effects within the first two months of the procedure, the study concludes that the complications were minor, and that "In several respects, sterilisation with Quinacrine appears to be superior to other contraceptive methods available in Iran." (International Family Planning Perspectives, 22:122-123, 1996.)

BANGLADESH : Medical College Conducts Illegal Trials

In an interview with Dr Shree Mulay on February 15 1997, Dr Syeda Noorjehan Bhuyian, Principal of the Chittagong Medical College and the Head of the Obstetrics and Gynaecology Dept. revealed, "We are doing the Quinacrine method secretly. It has not been advertised. We get our clients through others who have had the procedure."

A total of 513 sterilisations were performed between 1990-96. However, follow-up was done for one to two years on only about 30% patients. Bhuyian cited lack of funds as the reason for not doing extensive follow-up studies. According to Bhuyian, there was a 4% failure rate. This is high enough, but Mulay has recalculated the data and come up with a figure of 14%, which is completely unacceptable for a sterilisation method. Four different protocols were followed with combinations of other drugs like ibuprofen and ampicillin, but all data were pasted together. Needless to say, women in the Bangladesh Quinacrine trial were not informed that the method was purely experimental, and not approved by any national or international regulatory body.

Dr Syeda Firoza Begum, a prominent gynaecologist in Dhaka conducted many sterilisations 20-25 years ago, using both slurries and pellets of Quinacrine. However, she is now convinced that Quinacrine is not a good method because the failure rate is too high and side-effects are significant. As the Chair of the Regional Medical Review Committee of the International Planned Parenthood Federation, she has turned down the Quinacrine sterilisation method four times since 1994. According to Mulay, Syeda Begum is reluctant to condemn the use of Quinacrine by Bhuyian, stating that Bangladesh does not have a regulatory body that can enforce ethical conduct of trials.

The Shammilit Nari Samaj, a coalition of women's organisations, UBINIG, and alternative policy research group have undertaken to campaign against Quinacrine sterilisation and violation of women's rights in Bangladesh.

VIETNAM : Mass Use By The Ministry Of Health

In 1993, publication of the results of a retrospective clinical trial on 31,781 women in Vietnam in the prestigious medical journal Lancet, gave the Quinacrine method a great deal of legitimacy. This study was conducted by the Vietnamese Ministry of Health between January 1989 and October 1992 with technical assistance from Elton Kessel and Stephen Mumford, and pellets supplied by Mother and Child International, Switzerland.

The publication of this paper in Lancet was followed by much questioning regarding the safety and efficacy of the method, as well as ethical issues related to its use. The Association for Voluntary Surgical Contraception (AVSC) based in the US, and the WHO, convened their technical committees following this controversy. The main concerns raised were that the proponents of the Quinacrine method had failed to provide credible scientific data on pharmacokinetics using the intra-uterine route, mutagenicity and carcinogenicity, as well as embryotoxicity of Quinacrine. Another concern was regarding ectopic pregnancy and the difficulty of assessing ectopic pregnancy rates in rural areas of developing countries.

In December 1993, the Quinacrine programme in Vietnam was abruptly halted. The stoppage followed a letter from the WHO to Linda Demers, Country Director of the UNFPA in Vietnam raising questions about the possible carcinogenicity of Quinacrine. The WHO stand and subsequent suspension of the programme prompted vehement reactions from Kessel and Mumford who put forth their risk-benefit argument in favour of continuing trials in third world countries with high maternal mortality rates. Proponents of Quinacrine contended that the caution recommended for use of the method was politically motivated rather than based on scientific data. For instance, Mumford (Lancet Vol. 344 Nov 1994) held that the Association for Voluntary Surgical Contraception, "face[ly] the prospect of sitting on the sidelines" while a non-surgical method of

sterilisation was popularised, was raising objections. He further alleged a "hidden agenda" of AVSC. According to a policy inspired by the Reagan administration, NGOs supported by the USAID (of which AVSC is one) cannot use money for family planning methods not approved by the USFDA. Similarly, Dr Elizabeth Conant (Speak Out magazine, Summer 1995), alleges that the "well-known Catholic influence within WHO has made the organisation historically resistant to family planning initiatives."

The huge Vietnamese programme has been at the core of much of the international controversy surrounding Quinacrine. The firm stand of the Vietnamese government to suspend Quinacrine use in the face of intense pressure from foreign NGOs and Quinacrine lobbyists, is appreciable in an age where international NGOs are able to indulge in arm-twisting as well as cajoling of third world governments to gain their ends.

QUINACRINE STERILISATION IN INDIA : NOTHING OFFICIAL ABOUT IT

Fourteen years before the first official trials of Quinacrine by ICMR, at least one doctor in Calcutta was already conducting clinical trials on 414 women, without the requisite permissions or licences. In 1991, doctors from Baroda presented the findings of their Quinacrine trials in the First International Symposium on the Quinacrine Pellet Method of Nonsurgical Female Sterilisation in Bandung, Indonesia. Unfortunately, this trend has actually gained momentum over the years. Today, despite the fact that the ICMR had prematurely terminated its trials due to a high failure rate, and that the Drugs Controller of India has refused to approve the use of Quinacrine for chemical sterilisation of women in India on the grounds that "the long term toxicity search reveals that the possible risk perhaps outweighs the intended use" (Letter No.12-19/92-DC dt. 8th May 1997 to Saheli), widespread trials are being blatantly held in different parts of the country, by private practitioners, NGOs and even established public hospitals. The following are brief reports on the activities of some of the practitioners of Quinacrine sterilisation : Dr Biral Mullick in Calcutta, Drs. Praveen Kini and Sita Bhateja of Bangalore alongwith Dr Rajgopal of Mangalore, Dr JK Jain, and the Principal and Staff of Lady Hardinge Medical College of New Delhi, based on press reports, published papers and interviews by members of Saheli.

Dr BIRAL C. MULLICK, CALCUTTA : Twenty Years Of Malpractice

Dr Biral Mullick of Calcutta has been one of the 'pioneers' of Quinacrine use for sterilisation in India. As far back as August 1979 to June 1984, a study was undertaken on 414 women under the auspices of the Indian Rural Medical Association in Calcutta, an off-shoot of the "Humanity Association". Mullick is the General Secretary of this Calcutta-based NGO which receives funds and Quinacrine pellets from the US-based CRPS (Frontline Dec.27, 1996). In a promotional video made for the IFFH, Mullick claims to have used the Q-method on more than 10,000 women over the past twenty years or so. Not only does Mullick provide Quinacrine sterilisation in his own clinic, he has also been introducing Quinacrine to homeopathic and ayurvedic doctors for the last 10 years through the Indian Rural Medical Association. This is done mainly through what he describes as a comprehensive family planning training course that includes a 2-day practicum in one of three rural training centres on how to insert Quinacrine, and a further one day's extra training and instruction in his own clinic. Supplies of Quinacrine have been obtained from Kessel, and the modified IUD insertors are purchased from a local manufacturer.

In an interview with Saheli on 7.5.97, the Drugs Controller of India (DCI) stated that following press reports of the use of Quinacrine in West Bengal, his office had been conducting an investigation into the activities of Dr Mullick. The DCI claimed that Mullick had stopped Quinacrine use since 1994 due to lack of supplies of the drug. The DCI's team, attempting to probe into the supplier source received a written denial from the pharmaceutical firm named by Mullick. Yet, instead of probing the matter further, the DCI merely said, "He is an old man, he must have forgotten". Since the DCI's "investigation" seems to rely only on an old man's alleged gaps in memory, not much more information was available from the DCI's office except the routine "He has also given us some names in Chile, we have written to them and our High Commissions there, but received no response".

The current status appears to be that Mullick has indeed, stopped Quinacrine use, but there is no concrete evidence of this. While Mullick claimed (Frontline, May 2, 1997) that he had stopped when WHO sounded a warning in June 1994 that all Quinacrine trials be stopped immediately, activists of the Ganatantrik Mahila Samity (GMS) say that he only abandoned Quinacrine sterilisations after they staged a demonstration in front of his clinic at Sashi Bhushan Dey Street in Calcutta in August 1996. Shortly after the demonstration, the West Bengal State Health Department initiated an enquiry into Mullick's practice. Mullick is said to have submitted his findings on Quinacrine to the Department, alongwith relevant documents. However, he continues to assert that he will help train other physicians in Quinacrine sterilisations.

The nature of Quinacrine use by Mullick defies definition. While the mass use of the method without adequate trials still falls in the realm of an "experiment", the lack of scientificity and legal sanction precludes it from being called a "clinical trial". In his 1987 paper authored along with Mumford and Kessel in the *Advances in Contraception Journal* (1995 11:239-244), he reported nine separate protocols, including data for tetracycline as a sclerosing agent. Many protocols were conducted simultaneously with no regard to what may be the most effective protocol, and to the validity of the results obtained for each in small numbers.

In an interview reported in the *Sunday Telegraph* (Jan. 19, 1997), Mullick, overturning standard guidelines for monitoring and follow-up of subjects of clinical trials said, "What do you mean by monitoring women patients? If they have problems they will come to me. I have not had received a single complaint in the last 10 years. Moreover, I don't have the money to do follow-up". In the same paper he co-authored with Kessel and Mumford, Mullick admits, "The lack of systematic follow-up (which stems from our lack of resources) makes it impossible to completely rule out under-reporting of significant events. However, we have good reason to believe that all or most significant events are reported to us". Nevertheless, he fails to reveal the 'good reasons' that support his assertions.

Despite the unscientific basis for the data generated by Mullick, the ICMR, the premier research body in the country legitimised his 'research' by quoting it in the ICMR protocol of Phase II clinical Trials on Quinacrine (1993). Further, Mullick was invited to a meeting convened in June 1992 by ICMR on "The use of Quinacrine for Tubal Sterilisation". Lending such credibility to the unauthorised and illegal "trials" by Mullick brings into sharp focus the loopholes in the set-up for drug licensing, research standards and official sanction to conduct trials and mass use of hazardous contraceptive drugs in the country. At the same time, Dr Badri Saxena, Addl. Director General of ICMR, in an interview with Saheli on 2.5.97, stated that he had no information about the activities of Mullick or any of these NGOs.

CHIP TRUST, BANGALORE : Illegal Trials Galore.

In September 1994, an article appeared in 'Sunday' magazine about Drs Pravin Kini and Sita Bhateja of the Contraceptive and Health innovations Project (CHIP Trust) in Bangalore who were actively sterilising women all over Karnataka with Quinacrine.

CHIP has recruited 300-400 doctors from different parts of Karnataka. Pravin Kini, in an interview with Frontline (May 2 1997) revealed, "We compiled a mailing list of all doctors who are involved with family health in Karnataka, and sent them literature on the Q-method. We send, to those who respond positively, the medicines and equipment to do 10 sterilisations". The doctors are asked to maintain two registers - one to document the health of the woman and her immediate reaction to Quinacrine, and the other as a follow-up register to be submitted after a year, which will report failure or medical complications". Two administrations of Quinacrine are recommended with a one month gap, in conjunction with 200 mg ibuprofen to prevent adverse inflammatory reaction. But in an interview with a Saheli member in Bangalore on 4.7.97, Bhateja said that she "also adds an antibiotic in order to prevent infection".

The Frontline (May 2 1997) reported that the CHIP Trust is currently involved in a two year project to sterilise 25,000 women by the Quinacrine method. But in an interview with a Saheli member in Bangalore on 3.7.97, Kini denied that they were working towards such a large target. He said that he does not carry out Quinacrine sterilisations himself, but that Bhateja has completed 300 instillations, and Dr Rajgopal of Kasturba Medical College, Mangalore had completed another 300 between July 1994 and July 1996. He also said that they will be presenting the combined results of both these studies at a meeting of Gynaecologist & Obstetricians to be held in Copenhagen in August 1997.

Kini also said that Quinacrine pellets and inserters are sent free to CHIP Trust by Dr JK Jain (Dr Jain Clinic Private Limited and President, IFFH). Although CHIP Trust supplies the equipment free of cost to the doctors, they charge the women anywhere between Rs. 50 - Rs. 200 for an instillation. Bhateja, in an interview with a Saheli member in Bangalore on 4.7.97 said that while she offers Quinacrine sterilisation free for her poor patients, she charges 'women who can afford it', Rs. 300 per instillation.

The CHIP Trust promotional folder on Quinacrine sterilisation circulated to doctors, voluntary organisations and governmental agencies contains more hysteria and hype than scientific facts. In bold type it claims, "Every 100 sterilisations prevents one young mother from dying and 3 young children from being orphaned." Justifying the use of the method without official sanction, the folder states, "In case of the Q-method of sterilisation the government has started trials and will, in its standard bureaucratic slowness, take time to promote the programme. Do we need to wait till then and allow some more young mothers to die needlessly?"

Clearly, the use of Quinacrine method of sterilisation by Dr Kini et al is violative of the law, since the Drugs Controller of India, Dr P Dasgupta, in his interview with Saheli clarified that he had not approved Quinacrine for sterilisation. Consequently, State Drugs Controllers of various states do not have the authority to issue import/manufacture licences for drugs which have not been licensed in India by the DCI. Although Kini claimed that doctors in the Bangalore Medical College used the Quinacrine method, Frontline's inquiries revealed that this was not true (Frontline 2 May 1997).

Dr JAIN CLINIC PRIVATE LIMITED, NEW DELHI : Un-limited Power To Promote Quinacrine.

Over the last 6 years, one name has gained prominence for the distribution and promotion of the Quinacrine method of chemical sterilisation of women in India : Dr JK Jain, a general surgeon, owner of Jain Medical Centre and Dr Jain Clinic Pvt Ltd, New Delhi. But Jain is no ordinary doctor. He has a wide range of what he himself defines as "medical and commercial interests". Besides holding powerful positions in various national and international medical organisations, Jain is a BJP MP and the owner of JAIN TV, the satellite channel best known for the inflammatory video films it produced and aired on the Ayodhya-Ram Janmabhoomi issue. Naturally, his position within the medical fraternity and the political arena give him considerable power to remain secure in midst of all the controversy surrounding his illegal and unethical practice of promoting Quinacrine.

In an interview with Saheli on 9.5.97, Jain said that he first decided to popularise Quinacrine after he learnt of it at the First International Symposium on the Quinacrine Pellet Method of Nonsurgical Female Sterilisation at

Bandung, Indonesia (Sept 15, 1991). As a member of the Consultative Committee on Health, Ministry of Health and Family Welfare, he claims that he raised the issue upon his return, but failed to receive a positive response from the government. But that did not deter him, and he decided to take matters into his own hands. In a statement to women's organisations in Delhi who staged a demonstration outside his clinic on 2nd May 1997 against his involvement with Quinacrine, he clearly states, "Population is a major problem for this country and neither the Government of India nor WHO have come up with workable solutions. It has, like so many other exigencies, been left to others to tackle". In fact, he went on to tell the women's groups that he was promoting Quinacrine "as a national service for the good of women". The first question this raises is, how does a general surgeon see himself in what he calls "the population control movement of the country"? Fortunately, one doesn't have to look far for an answer.

Jain has, for the last 6-7 years been President of IFFH (International Federation for Family Health) - a US-based right wing organisation whose Secretary General, Kessel has, alongwith Mumford of the Centre for Research on Population & Security (CRPS) been the major proponent of Quinacrine in the world. Like the IFFH, one of Jain's main contentions is that his work with Quinacrine is purely philanthropic, and that Quinacrine is an old drug that pharmaceutical companies don't gain anything from promoting, especially in terms of patents. But the argument fails to hold water on both grounds. Firstly, the prime objective of IFFH and its funders to control Third World populations for the sake of their imagined threat to First World nations like the USA can hardly be called philanthropic. Secondly, while we were unsuccessful in determining the scale of money at stake for people like Jain, he cannot claim to have no profit motive in promoting Quinacrine when he kept referring to it, during his interview with Saheli, as his "commercial interest".

By his own admission in the said interview with Saheli, Jain became President of IFFH in recognition of his 'pioneering work in health education and family planning awareness through information technology', i.e. propaganda on his own satellite channel, JAIN TV. Subsequently, Jain has had direct access to ample supplies of Quinacrine and the resources to facilitate its distribution. Anupam Agarwal, Co-ordinator, Jain Medical Group, interviewed in the documentary film, *The Yellow Haze*, has clearly stated that "we also use our own media to promote Quinacrine".

As publisher of 11 international medical journals including *Population Reports*, *Journal of the American Medical Association*, etc in India, Jain has added substantial credit to his profile as a responsible, scientific and medical person. Yet, his arguments in favour of promoting Quinacrine are not responsible, and nor are they based on sound scientific or medical grounds.

On one hand, Dr Jain told Saheli that his appointment as President of IFFH "is not only recognition for me, but it is an honour for India". But on the other hand, he blatantly refuses to take cognizance of the laws of the land. In his interview with Saheli, the Drugs Controller of India had asserted that according to the Drugs & Cosmetics Act, even though Quinacrine was approved for oral use as an anti-malarial drug or as a cure for giardiasis, in the eyes of the law it is a new drug that requires new approval and licenses when converted into a pellet form for insertion into the uterus for the purpose of sterilisation. As a surgeon and President of the Delhi Medical Association, Jain can hardly be unaware of such a basic legal requirement that needs to be fulfilled. Yet, when we asked him whether he had the necessary license, his response was aggressive. "What do you mean by a license? Aren't MBBS, MD, FRCOG, all licenses?" Obviously, Dr Jain thinks mere medical degrees are licences to do as he pleases!

In his written statement, Jain has taken the liberty to quote from a communication between the DCI and the Indian Council for Medical Research (ICMR) that refers to the fact that the former 'has no objection for clinical trials of Quinacrine sterilisation'. What he fails to mention is that the DCI's permission was solely for a very limited trial of 50 women by ICMR. A study that was in fact, terminated due to unacceptably high failure rates. The DCI, in his letter to Saheli (No.12-19/92 dated 8th May, 1997) and through public statements has categorically denied having granted any other approval or licence for clinical trials, mass use, distribution, import or manufacture of Quinacrine. When we confronted Jain with this fact, he exploded, "You people don't know the law of the land. Why do I need a licence? What will you do, *challan* me?"

Further, compounding the gross legal and ethical violations is the fact that Jain's arguments in favour of promoting Quinacrine are not medically and scientifically sound. For instance, he freely quotes the 'results' of the field trial in Vietnam involving 31,781 women to prove the safety and efficacy of Quinacrine, but we have already seen how misleading and unscientific such interpretation of data is. Also, it is common knowledge that prior to clinical trials involving thousands of human subjects, there must be adequate laboratory and animal experimentation and sufficient information on short and long term effects. Yet, in his interview with Saheli, Jain declared, "What do you mean by clinical trials? Quinacrine is being used all over the world!" This, despite the fact that the packages distributed by him clearly state: Distributed for clinical trials by Dr Jain Clinic Pvt. Ltd.

Jain also shrugs off the fact that in 1994, the WHO Consultation on Female Sterilisation Methods called for 4 pre-clinical toxicology studies on Quinacrine before approval of the drug for clinical trials on women. In fact, the WHO categorically stated that 'human trials be stopped forthwith pending the outcome of these tests'. Yet, when Jain was responding to a question on the critical issue of toxicity of Quinacrine, his 'scientific'

response was, "Toxicity? Where's the question of toxicity? When 2mg. of mepacrine (Quinacrine) is taken orally it isn't toxic; but how come if you put 0.2mg in the uterus it suddenly gets toxic?"

Even on the issue of reversibility of the method, Jain substitutes lack of definitive information with bluster. The findings of his own mentor and friends, Kessel, Zipper, Hieu, Mullick and Mumford (Quinacrine pellet method of non-surgical sterilization, Proceedings of VIII World Congress on Human Reproduction Joint IV World Congress on Fallopian Tube in Health and Disease, Bali, Indonesia, April 1993) are that as compared to an 80% success rate of reversal of surgical sterilisations, Quinacrine sterilisations only offer a 50% success rate. Contrarily, Jain confidently told us that Quinacrine sterilisations are easily reversible by using a catheter to open the blockage.

But if the scientific principles on which Jain advocates Quinacrine are suspect, his practice of acquiring and distributing it is even more dubious. When the Saheli team first asked Jain whether he was distributing Quinacrine, he initially denied it, and then finally, when pushed into a corner, accepted that he was doing so. When we questioned him about his source for supplies of Quinacrine, he refused to answer us. When asked whether he imported them, his response was, "Anyone can buy mepacrine for just a few rupees per kilo, it is freely available in the country. Then, it just has to be turned into pellets. That's how Quinacrine just costs a few annas per user". This despite the fact that Anupam Agarwal told the filmmakers of the video documentary *The Yellow Haze* that they received their supplies from Kessel. This is further corroborated by the fact that the packages (of 7 Quinacrine pellets @ 36 mg = 252 mg) distributed by Dr Jain Clinic Pvt Ltd are clearly marked "Manufactured by Sipharm Sisseln Ltd., CH-4334, Sisseln, Switzerland". Interestingly, after the Quinacrine controversy hit the headlines, the DCI not only clarified that no licences for the import/manufacture of Quinacrine had been granted by him, he also claimed to have run a computer search for any import of Quinacrine by any physician, NGO or institution at every international port in the country, but drew a blank everywhere. Obviously both, the import and manufacture of Quinacrine pellets in India is blatantly illegal, amounting to smuggling. And yet, Jain openly supplies Quinacrine for sterilisation to Kini and Bhateja in Bangalore, Lady Hardinge Medical College in Delhi and innumerable other NGOs, practitioners, etc.

However, Jain's connections with the establishment that give him the legitimacy and might to adopt any measures whatsoever in order to promote Quinacrine. In his interview with Saheli, Badri Saxena, Addl. Director General, ICMR, distanced himself from people like Jain and their zeal to promote Quinacrine by saying, "ICMR is a responsible research agency that promptly terminated clinical trials on finding unacceptably high failure rates. We have nothing to do with those people". Yet Jain had in fact, been a Consultant to the ICMR study on Quinacrine.

Similarly, the DCI chose to sound equally righteous about not having granted any approvals or licences to this 'hazardous method'. At the interview with Saheli, when he was asked why he had failed to institute any enquiry/investigation into Jain's activities involving Quinacrine, the DCI said, "Which Dr Jain are you talking about? There are so many Jains!" Yet, a short while later, the DCI shared with us the fact that during the few days that the BJP government was in power at the Centre, Jain, then a BJP MP, had approached the Union Health Minister for approval of Quinacrine, but the DCI had declined to grant it. Further, in spite of widespread coverage in the newspapers which even quoted Jain and members of his staff, the DCI said, "It has not been brought to my notice until today. Give me something in writing with all of Dr Jain's details and I'll see what I can do". This, despite the fact that 3 weeks prior to the interview, Saheli had already sent the DCI a letter urging him to take action against those involved in the promotion of Quinacrine, including Jain. Subsequent to the interview, another letter was sent to the DCI, but no action has been taken until this report went to the press.

It is precisely such tacit support of the authorities, alongwith Jain's own position in associations like the DMA and the IFFH, and his power as an MP that come together to give him the confidence to continue to propagate the Quinacrine sterilisation of female sterilisation with impunity, despite numerous reports in the media that indict him, as well as considerable pressure from women's groups. At the demonstration of women's groups outside his clinic on 2nd May 1997, Jain declared, "I am a political man, and this is all just a conspiracy to malign me!"

But the veneer had begun to crack even before the controversy blew up to its present proportions. After the makers of the documentary video, *The Yellow Haze* had completed their interview of Anupam Agarwal, they were requested to send back the footage they had shot, so that portions that they were not to use could be removed by Jain's staff. The sections removed were those where Anupam Agarwal had clearly stated that Jain was distributing Quinacrine, that Kessel was supplying Quinacrine, that they were using the JAIN TV channel to publicise Quinacrine, etc. And yet, Jain would have us believe doing the nation proud by promoting Quinacrine! Similarly, at the interview with Saheli, when we started asking him uncomfortable questions about details of approval, licence, import, etc, Jain exploded at us, "You ladies do not know the law of the land. I feel sorry for you. May God help you", and immediately terminated the interview, and hustled us out of his office.

LADY HARDINGE MEDICAL COLLEGE, NEW DELHI : Endangering More Women's Lives

When the makers of the documentary video, *The Yellow Haze* were researching the use of Quinacrine in Delhi, they chanced upon the information that Dr Anita Sabarwal, an M.D. student of the Gynaecology and Obstetrics Department of Lady Hardinge Medical College (LHMC), New Delhi was conducting clinical trials of Quinacrine for her thesis. In their interviews in the film, Sabarwal and the head of her department, Dr Maya Sood are strong advocates of the Quinacrine pellet method of female sterilisation. The makers of *The Yellow Haze* also met and interviewed the staff of the Palam Primary Health Centre (Palam PHC - the rural outreach centre of LHMC), and several women who had been part of this trial. By doing so, they raised vital issues like selection of women, their informed consent, the side effects suffered by the women and issues of the success/failure of the method.

Though the study conducted at LHMC consisted of a relatively small number of women, it assumes a great importance in terms of attempting to find answers to many issues. Hence, in preparation of this report, Saheli decided to investigate the matter further, especially in additional areas like the ethics of the trial, the scientific validity of its protocol, its legality, the nature of follow-up, the mode of acquiring Quinacrine pellets, etc. Towards this end, we met Dr Maya Sood, HOD, Dept. of Gynaecology & Obstetrics (18.6.97), Dr. Kusum Sahgal, Principal, LHMC (23.5.97), Dr Uma Goyal, Professor, Dept. of Gyn. & Obs. (7.5.97) and officiating HOD in Sood's absence, Dr Girish Tayal, HOD Pharmacology and Chairperson, Ethical Committee, LHMC (8.5.97), Dr Dharam Prakash - Chief Medical Officer, Palam PHC, and D Sengupta, Social Worker and Extension Educator, Palam PHC (6.5.97). Also recounted here are experiences of six of the women who were part of the LHMC trial study, on the basis of their written accounts.

LHMC & Sucheta Kriplani Hospital are a joint teaching cum public hospital facility, one of the largest in the city of Delhi. It caters to thousands of men, women and children everyday, many of whom are from a lower socio-economic strata of society.

The study on Quinacrine sterilisation was carried out by Sabarwal, under the guidance of Sood on 32 women who Sabarwal describes as "belonging to the lower socio-economic strata" [*The Yellow Haze*]. Participants of the trial were enrolled either at the LHMC or at the Palam PHC. Sabarwal was personally responsible for carrying out the study and completed it over a period of 6-12 months.

When Saheli met faculty members of LHMC, most of them were upset with what they called "irresponsible reporting in the press by journalists who did not do their homework". Goyal took great pains to assert that at LHMC, no-one "could even dream of harming women".

Yet, from protocol to procedure, the LHMC trial is problematic all the way. So we decided to speak to her guide, principal investigator and Head of Dept., Sood. Early in the interview, Sood revealed a disturbing fact. She had started using Quinacrine for sterilisation of women nearly 4 years ago, and her maid-servant was her first case. We tried to ascertain whether these sterilisations were also part of a study, or whether Sabarwal's was the first formal trial Sood had been involved with; but she refused to commit herself to an answer. Yet, the first question that comes to mind is, "in what capacity did Sood use Quinacrine for sterilisation of all these women including her maid servant? Is the fact that she is a doctor sufficient to justify any experiments on any women she has access to?"

The research protocol followed by Sabarwal essentially follows the IFFH protocol, and therefore unthinkingly duplicates the use of Depo Provera as an additional contraceptive cover for three months after the first insertion of Quinacrine. Even if we set aside concerns of side effects of Depo Provera, given that even one injection of it is enough to cause delay in return of fertility for more than 6 months, how was Sabarwal's research (with field work of only about 6 months) expected to assess efficacy of the method? When questioned about this, Sood failed to take cognizance of the contradiction.

Lack of proper 'informed consent' is one of the other major problems with the LHMC trial. Despite all the claims of being a perfect study, none of the six women who recounted their experiences of the LHMC trial, were told anything about Quinacrine or its potential short and long term side effects. Yet, while Sahgal told Saheli, "The whole thing that no consent was taken is absolutely wrong", Sood refused to share with us the details of the protocol for consent.

Further, the ICMR guidelines for clinical research clearly says that informed consent should be obtained, not by a doctor who exerts considerable influence, but by a social worker who can help the subject make her decision. Yet, when Saheli met Sengupta, social worker at the Palam PHC where a number of Quinacrine sterilisations were performed he said that he didn't even know that such a trial was being conducted at the PHC, much less had he been involved in helping women make their decision or obtaining their consent. In *The Yellow Haze*, Shama Khanna, the lady health visitor of the PHC, said that she had been sending women in for copper-T insertions, but then she discovered that they were being given something new that she hadn't heard of. It was only then, that she asked and learnt the name of Quinacrine.

The testimonies of Sengupta and Khanna explode two myths. Firstly, that informed consent was obtained from the women in the recommended manner. Secondly, it also belies Sabarwal's claim that "only women who wanted sterilisations were enrolled". [*The Yellow Haze*].

The next important question that arises is the legality of the LHMC trial. Since Quinacrine is not a drug licensed for transcervical use, the Drugs & Cosmetics Act requires that specific permission be sought from the Drugs Controller of India (DCI) prior to the commencement of the trial. The DCI confirmed this at his interview with Saheli. Yet, within the LHMC compound, there seemed to be no unanimity on the matter. Tayal, the Chairperson of the Ethical Committee which had cleared the protocol for the study clearly said to Saheli members, "where any new drug, new formulation of an old drug, or new application of an old drug is concerned, permission of the DCI is mandatory. But this is the responsibility of the principal investigator". However, the principal investigator, Sood denied that this was the case. She told us, "This is a study, not a trial, so it can be undertaken without the DCI's permission. Strangely enough, the Principal of the college, Sahgal concurred, but on different grounds. "We are a medical college, we don't need to go through the DCI". But within Sood's department itself, there was yet another opinion. Goyal, specifically told Saheli that permissions for such trials even for MDs, have to be sought from the DCI, and that she was certain Sood would have done the same.

LHMC Trials : Some Women's Experiences

Woman #1, the mother of 4 children who had gone seeking permanent sterilisation, was one of the few lucky ones who has not experienced any problematic side effects. But although she had been told that Quinacrine was a new method, she was told nothing of the possible side-effects, nor warned about any symptoms she should look out for.

Some other women who were part of this trial and underwent Quinacrine insertions in a well-equipped public hospital like LHMC under the concerned and caring eyes of the experienced gynaecologists were not very lucky either! A 34-year old woman with 4 children [Woman #2] approached doctors to replace her old copper-T. Doctors at LHMC advised her to try a new drug. According to her she was told that this method is part of some study being carried out at LHMC., and that this method will put a stop to having babies. However, she was not told what to expect as possible problems associated with the Quinacrine insertion. Like everybody else who was part of this trial, she also received an injection of Depo Provera to protect herself from getting pregnant until the effect of Quinacrine takes place in a few weeks. She stopped having periods about 1 year after Quinacrine insertion. Since she was told that the new treatment would mean no more pregnancies, she ignored the missed periods without feeling concerned. Unfortunately for her, the missed periods was indeed a sign of pregnancy for her. Not only did she become pregnant but she started bleeding profusely about 2 months after her last period. She was admitted to the hospital and abortion took place. She came to know only later that the bleeding episode was an abortion - result of failure of the new method! She was indeed very upset and angry because she felt cheated about the doctor's promises of providing a simple and effective method of sterilisation and not warning her about the potential side effects. Now she has gone back to using copper-T again. The doctor told her that the drug did not work for her and that she had an ectopic pregnancy. However, when we talked to Sood she claimed that there was no case of ectopic pregnancy associated with their study.

Woman #3 who underwent Quinacrine sterilisation at the hands of Sabarwal had, in fact, gone to the PHC only for a copper-T insertion; not a sterilisation. Unfortunately, although she was told that a new method was being tried on her, she was not told that Quinacrine is a method of sterilisation. It was not until much later that she found out that the new drug they gave her has made her permanently incapable of having another child even if she wishes to! She complained of numerous side effects including yellow discharge and stoppage of periods for 6 months in her interview. She also claimed that she went back to the PHC with her problems but the doctor was not available. As it turned out, finding a doctor canvassing for Quinacrine pellet insertion was easy but no doctor could be found to talk about or solve problems arising out of the new method! Her experience of not finding a sympathetic / knowledgeable doctor was probably not an exception but a rule as we figured out after talking to Sood. When we asked Sood whether there is regular arrangement for a gynaecologist to visit Palam PHC, she sounded extremely unsure and could not give us an answer.

Woman #4 had serious complaints of swelling in feet subsequent to insertion of Quinacrine. When she sought help from the doctor for her complaints she was told that the swelling of her feet is because of swelling in the uterus! On the face of it, such a connection seems highly unlikely.

A young woman in her twenties [Woman #5] approached doctors for sterilisation but was scared of surgery. Instead of trying to dissuade her from getting sterilised at such an early age and using a method of contraception until her young children grow up, it seems that Sabarwal et al were happy to include her as one of the 32 women who underwent Quinacrine instillation.

Woman #6 was also fortunate enough to have an experience similar to that of Woman #1. No side effects, but no information on which her 'consent' was based, and no prior preparation in case she had suffered any side effects.

Like every other woman contacted, she was also told that it was a new method; but like all of them even she was given no information about the potential short and long term side effects of the method - a clear violation of norms to be followed for obtaining an informed consent!

The manner in which LHMC trial has been conducted is clearly violative of accepted norms of medical practice. When any trials are being conducted at a PHC or an extension counter, it is essential for the medical officer to be kept abreast of plans for its commencement, be prepared for the potential eventualities and finally, be in the know of the progress of the trial. Yet, the Chief Medical Officer, Dr Dharam Prakash told Saheli that he had no idea that any such trials were being conducted at the Palam PHC until he heard complaints from some of the women. However, he could not tell us what those complaints were.

Sood brushed aside concerns of lack of follow-up in the LHMC trial by telling us that women do not have any problems subsequent to the procedure of Quinacrine sterilisation. But Sahgal maintained, "There is no question of follow-ups not being done, it is part of every protocol because you can't ignore any problem that may crop up". Conversely, all Sood would say on the issue was, "My doors is always open and I am here to solve their problems", trying to sound magnanimous. But such an offer hardly constitutes planned follow-up that should be an essential part of any research protocol.

On the matter of follow-up care, Dharam Prakash is categorical. He says, "They have no business trying out new drugs in a place like this, where if a woman has problems we cannot help her because we don't know anything about it, and as you can see we don't even have the necessary facilities".

When asked about the possibility of conducting further trials on Quinacrine sterilisation, Sood mentioned that hospitals like LHMC do not have any money for research and that this study could only be carried out because Jain supplied Quinacrine pellets free of cost. Yet, in *The Yellow Haze*, she says that she would like to continue these studies if she gets funds for it from Kessel. When doctors associated with public hospitals are constantly on the lookout for ways to fulfil their own agendas, the access they have to poor and underprivileged women becomes a dangerous weapon in their hands.

Big lessons to be learnt from a small trial: Sahgal repeatedly told Saheli, "There is a major difference between using any drug just anywhere and in a well-controlled situation like a gynae. department in a teaching facility where there is a whole host of facilities and team of specialists looking after the patient". But despite her tall claims, the truth is that the LHMC trial cannot stand scrutiny on scientific, legal and ethical grounds. The implications of such malpractices get even more terrifying in the context of mass use.

DRUGS CONTROLLER OF INDIA : PRETENDING TO BE POWERLESS

Ever since the controversy surrounding the use and trials of Quinacrine has become public, all those engaged in it have been taking great pains to project themselves as upright and responsible medical practitioners working for the good of the nation. Yet, behind this respectable facade lies a maze of questionable motives and dubious means that have been employed to promote Quinacrine. Not the least of these has been that none of them have the necessary legal sanctions to use Quinacrine as a method of female sterilisation in India.

The legislation that governs the import, manufacture, distribution and sale of drugs in India is the Drugs and Cosmetics Act, 1940 alongwith the Drugs and Cosmetics Rules, 1945 (hereafter referred to as the DC Act and DC Rules respectively). The apex drug approval and licensing authority in the country is the Drugs Controller of India (DCI), Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi. In the matter of Quinacrine use for sterilisation in India both, the DC Act and the DCI (through his public statements, correspondence with Saheli and interview with Saheli members on 7.5.97) clearly hold all involved parties as having broken the law. As we have seen before, this report is investigating i) clinical trials and use of Quinacrine in the NGO sector by the likes of Mullick, Kini, Bhateja, and Jain, and ii) clinical trials by the teaching faculty of a public hospital like Lady Hardinge Medical College or Kasturba Medical College. The following are the claims commonly made to deny that Quinacrine sterilisation is illegal, alongwith the actual legal position on the matter.

Claim 1. Quinacrine is an old, approved drug that does not need any fresh approvals for use as an agent for chemical sterilisation.

Reality: Part X-A of the DC Act deals with *Import or manufacture of new drug for clinical trials or marketing*. Rule 122-E Para (b) of this part of the DC Act titled *Definition Of A New Drug* states: *A drug already approved by the licencing authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.* As the DCI elaborated during his interview with Saheli, "Quinacrine, or mepacrine, the name under which it is sold in India, is only approved for oral use, in tablet form, for treatment of malaria, giardiasis and amoebiasis. But for sterilisation, Quinacrine is used in the form of a pellet and inserted into the uterus. Hence it is a new formulation of an old drug, with a new route of administration for a new usage. It is therefore, classified as a new drug, requiring fresh approvals and licence.

Claim 2. No more trials are required for a drug like Quinacrine that has been used all over the world.

Reality: The first section of Schedule Y of the DC Act titled *Requirement and Guidelines for Import and Manufacture of a New Drug* deals with Clinical Trials. Para 1.1 states: *Nature of trials: The clinical trials required to be carried out in the country before a new drug is approved for marketing depend on the status of the drug in other countries. If the drug is already approved/marketed, Phase III trials as required under Item 7 of Appendix I are required. If the drug is not approved/marketed trials are generally allowed to be initiated at one phase earlier to the phase of trials in other countries.*

Contrary to what the advocates of Quinacrine would like us to believe, Quinacrine has not been approved for chemical sterilisation by any drug authority in the world, including the WHO and the US Food & Drug Administration (USFDA). Hence, in 1993 the ICMR started a limited Phase II-A trial of Quinacrine. During his interview with Saheli, the DCI acknowledged that the ICMR trials had in fact been terminated, not just on the basis of the high failure rate, but also based on global data on the inefficacy and hazardous effects of Quinacrine. Therefore, the status of the Quinacrine method of sterilisation is that clinical trials from Phase II still need to be carried out and cleared before it can gain the status of an approved drug. Yet, the people and organisations involved in the promotion of Quinacrine, including the Principal of LHMC persist with treating Quinacrine as an internationally accepted drug.

Claim 3. No approval/licence is required for conducting clinical trials of Quinacrine in India.

Reality: Para 1.2 of Schedule Y of the DC Act states: *Permission for trials: Permission to initiate clinical trials with a new drug may be obtained by applying in Form 12 for a test licence to import or manufacture the drug ... In addition, the protocol for proposed trials, case report forms to be used, and the names of investigators and institutions should also be submitted. Permission to carry out clinical trials with a new drug is issued along with a test licence.*

Any physician, hospital or Non Governmental Organisation wishing to conduct trials of Quinacrine in India cannot choose to pretend that there are no legal requirements for them to fulfil. In the case of the clinical

trials at LHMC, New Delhi, for instance, while Prof. Goyal and Prof. Tayal are clear that the DCI's permission needs to be sought before embarking on any such clinical trial - a fact that is clearly stated in the DC Act. Yet, the Principal, Sahgal, and HOD, Sood, told Saheli at two separate interviews, "We are a medical and teaching facility, we don't need to go through the Drugs Controller". In an interview with Saheli on 18.6.97, Sahgal stated, "Clearance from Ethical Committee is all we need to carry out clinical trials". The DCI has confirmed that no permissions were sought for the clinical trials of Quinacrine by LHMC. Such utter disregard for the law, especially by 'organisations, institutes and individuals of repute' must be penalised immediately by the law enforcing machinery of the State.

Claim 4 Although Quinacrine is not approved for sterilisation, it is not disapproved either. Therefore, it is not illegal to import, manufacture or use it in India.

Reality: In his interview with Saheli, the DCI said that under the DC Act, 3 kinds of import licences may be granted for a drug that is not approved. i) For clinical trials on the basis of an approved protocol, ii) A test license for the import of small quantities for physicians/institutions to use on select patients/volunteers against personal consent forms signed for/by the patient, and iii) A permit issued for direct use by individuals (usually in the case of new treatment for rare diseases/syndromes). The DCI repeatedly confirmed that none of these licences have been sought or granted. Nor has any import of Quinacrine (even a small quantity legally declared) been recorded at any international port of entry into India.

Further, the DCI said that although the State Drugs Controllers (DCs) have the power to grant manufacturing licenses, they can only do so for drugs approved by him. This brings into focus the falsity of the claim of the CHIP Trust, Bangalore that they have all the necessary approvals from the state government of Karnataka. Also, if as Jain claims, mepacrine tablets are being converted into Quinacrine pellets for sterilisation, that too is occurring outside the law. Thus, according to the DCI, "any import or manufacture of Quinacrine into India is illegal".

However, what the DCI conveniently failed to mention was that the DC Act clearly states that in order that any legal action be initiated against those who have committed the offence of importing or manufacturing Quinacrine, *the Central and State Governments need to prohibit the import and manufacture (respectively) by notification in the Official Gazette.* As far as we could gather, no such notification has been issued. This piece of inaction by the DCI, and subsequently, State DCs, has left a gaping legal loophole that allows the promoters of Quinacrine to continue their practice of importing, manufacturing and/or conducting Quinacrine trials without any fear of being prosecuted, much less being held guilty.

Not surprisingly, when Saheli met Dr Sneha Vishwanathan, Consultant, Parivar Seva Sansthan (and Marie Stopes), India she said, "After I met Dr Kessel in Karachi in 1994, we were planning to offer Quinacrine at some of our rural clinics. At that time I spoke to some private practitioners in Delhi who were offering Quinacrine and they told me that it is not illegal to do so". Significantly, they did not tell Vishwanathan that it was legal to do so.

All the rules are broken to promote Quinacrine, none are used to punish the guilty

Although Saheli was unsuccessful in tracing exactly how Quinacrine pellets are acquired by all those involved in its trials all over India, some indications do exist. Some of the probabilities voiced by the DCI were that they may be carried undeclared into the country by individuals in their personal baggage; or that they may actually be coming in branded as Quinacrine tablets which are approved for various purposes. The other possibility the DCI stated was that "it could be underground operations where people are turning mepacrine into Quinacrine pellets in their garages or kitchens". He concluded by saying, "In all these cases, there's nothing I can do". But this is far from the truth.

Firstly, the DC Act clearly empowers the DCI to prohibit the import and manufacture [under Sections 10(f) and 18(c)] of Quinacrine in India. Secondly, various provisions of Section 22 of the DC Act also empower him to appoint Inspectors to carry out investigations, conduct searches and confiscate goods. Subsequent to such a prohibitory order, the law awards penalty of imprisonment and/or fine for cognizable offences like the import and manufacture of prohibited drugs.

Yet, the DCI's 'investigations' have so far failed to gather any definitive information even from NGOs and physicians who have publicly admitted to using Quinacrine, or conducting its trials. No enquiry has been conducted on the way in which Quinacrine pellets are acquired by Jain, or what Sood means when she says, in her interview in the documentary, *The Yellow Haze*, "If Kessel gives me more funds, I can do more"; and yet tells Saheli that "I don't get anything directly from Kessel". In fact, the DCI amply illustrated the quality of his investigations when he generously excused Mullick for having given the inspectors a wrong name of his suppliers' source on the grounds that, "Dr Mullick is an old man, he must have forgotten, so what can we do?".

During his interview with Saheli, the DCI went a step further to 'share his helplessness' with us. "We are just a licencing body", he said, "we cannot enforce the law. But I am very disturbed after all that you have told me today. Please give me a complaint in writing and I will see what I can do. Also, you must yourself complain to the relevant authorities". Surely, the DCI must be well aware that the Section 32 of the DC Act specifies that *'No prosecutions under this Chapter shall be instituted except by an Inspector or by the person aggrieved or by a registered consumer association whether such person is a member of that association or not'*. Making it apparent that it is very much his responsibility to lodge such a complaint.

It is painfully obvious that tacit approval of the authorities alongwith their wilful inaction and inefficiency is what is giving the promoters the courage to brazenly pursue their trials and usage of Quinacrine. As a matter of fact, when Saheli asked Dr Jain what he thought of the DCI's statement to us on the legal position of Quinacrine trials in India, he went so far as to say, "These officials are weak-kneed, they say one thing to us and another to you", clearly implying that he had an informal okay from the DCI.

With so much evidence of the continuing illegal practice of Quinacrine sterilisations all over the country, authorities like the DCI and the Ministry of Health & Family Welfare can no longer turn a blind eye. They must take cognizance of the situation immediately. They cannot try to gain scientific credibility and social respectability by saying, "We haven't approved Quinacrine because it is unsafe for women", when they are doing nothing to prevent its widespread use. They must act today, because the health of tens of thousands women is at stake.

ETHICAL ISSUES CONCERNING THE PROMOTION OF QUINACRINE

In addition to the Hippocratic oath they take when qualifying as doctors, medical practitioners all over the world are also bound by certain national and international Codes of Ethics that define their duties towards patients and the public and lay specific guidelines down for clinical research of any drug, especially on human subjects. In this section, we will look at some of the primary Indian and international guidelines and see how, by any standards anywhere in the world, the practice of promoting Quinacrine and using it for human trials without scientific reason or official sanction is grossly unethical.

Code of Ethics of the MEDICAL COUNCIL OF INDIA (MCI). Approved by the Central Government u/s 33 of the Indian Medical Council Act 1956, (vide letter # F 17-44 MPT dt. 23 Oct 1970), this Code lays the foundation for the ethical practice by medical practitioners in India.

i) **Basic issue of priority:** Declaration 6 of the MCI Code is a very simple, basic vow that every registered practitioner is meant to keep. It states, "*The health of my patient will be my first consideration*". Yet, in the case of Quinacrine sterilisation, we have seen how the prime consideration of its promoters is their agenda of 'population control' (e.g Jain) and personal gains like recognition of their work (e.g. Anita Sabarwal and her MD thesis). All, at the cost of the health of their patients who they have vowed to take care of.

ii) **Unethical business practice:** General Principle #6 of the Code states: "*A physician should not run an open shop for sale of medicine for dispensing prescriptions prescribed by doctors other than himself or for sale of medical and surgical appliances.....*". Obviously practitioners like Jain have failed to stop and consider the ethical aspects of getting involved in the business of distributing Quinacrine for sterilisation when as a surgeon, he could not possibly prescribe it.

iii) **Responsibilities as a specialist:** The last entry in the List of Duties of Physician to the Public, No.18 clearly states: "*Do not claim to be a specialist unless you have put in a good few years of study in that branch. Once you say you are one, do not undertake work outside your speciality even for your friends*". However, it is obvious that surgeons like Jain have no compunctions in actively promoting gynaecological procedures like Quinacrine sterilisations, and that too on such a large scale. Although they argue that technically they do not perform such sterilisations themselves, they cannot refute the fact that the chemical sterilisations that they are promoting are totally outside their area of specialisation!

Recommendations of the WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI. At the end of World War II, the Nuremberg Trials held a number of German doctors and scientists guilty of appalling and inhuman experiments carried out on inmates in the Nazi concentration camps. Subsequently, in June 1964, the first international set of guidelines on the ethics of medical research, the "Recommendations Guiding Physicians in Biomedical Research involving Human Subjects" was documented in the "Declaration of Helsinki" and adopted by the 18th World Medical Assembly, Helsinki, Finland. This was later amended in 1975, 1983 and 1989. The Declaration of Helsinki has also served as the basis for ethical guidelines formulated all over the world, including the ICMR guidelines, 1994.

Ironically, the guidelines that came into being in response to the atrocities committed at the Nazi concentration camps are today, being flagrantly violated by a drug whose original record of abuse also traces back to the Nazi concentration camps: Quinacrine.

1. Recommendation on Scientific Basis for Human Trial: *Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and a thorough knowledge of the scientific literature.* [Basic Principles - para 1].

Violation: As has been amply illustrated, all the human trials of Quinacrine, be they of 32 women at LHMC in Delhi or the proposed sterilisations of 25,000 women by the CHIP Trust in Bangalore are NOT based on adequate laboratory tests or animal experimentation. In fact, despite having been in use as a sterilising agent for more than three decades, adequate studies on its toxicity, mutagenicity, teratogenicity and carcinogenicity have not been carried out. Of the four such tests carried out by Family Health International, 3 indicated positive results for teratogenicity, mutagenicity and carcinogenicity. It was on the basis of these results that the WHO called for immediate suspension of all trials of Quinacrine, worldwide. Clearly this does not qualify as 'scientific basis' for the large scale Quinacrine trials that are currently under progress all over the country.

2. Recommendation on Approval of Research Protocol: *The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee*

independent of the investigator and the sponsor, provided that this independent committee is in conformity with the laws and regulations of the country in which the research is performed. [Basic Principles - para 2].

Violation: In India, under the Drugs And Cosmetics Act, all research protocols, after being approved by the Ethical Committees of respective institutions, must be sent to the DCI for approvals, before a licence for clinical trials is granted. While all the other organisations involved in Quinacrine sterilisation have merely chosen to ignore this requirement, Tayal, Chairperson, Ethical Committee, LHMC concurred that even a clinical trial conducted as part of an MD thesis needs to be approved by the DCI. However, as we have seen the college sought no such approval, choosing instead to unethically and illegally proceed with the trials.

3. Recommendation on Risk-Benefit Assessment preceding Human Trials: *Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison to foreseeable benefits to the subjects or to others. Concern for the interests of the subject must always prevail over the interests of science and society.* [Basic Principles - para 5].

Violation: The first premise of this guideline is that prior to human trials there will be adequate information based on laboratory and animal experimentation on which to base a risk-benefit assessment of the human trials. However, we have seen how this is not true in the case of Quinacrine trials. Instead, proponents of Quinacrine like Kessel repeatedly use this term to support their 'population control' agenda. They claim the benefits of Quinacrine sterilisation to 'diffuse the population bomb in Third World nations which would otherwise pose a security risk to First World countries'. Not only does such justification fail to look after the 'interests of the subject', it even falls outside the realm of 'interests of science and society' at large. And, obviously, the risks that women undergoing Quinacrine sterilisation are exposed to, are of no concern to Kessel et al!

4. Recommendation on Predictability of Hazards: *Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable.* [Basic Principles - para 7].

Violation: As we have seen, the short terms effects of Quinacrine sterilisation include change in menstrual pattern, itching of the vagina, pain in lower abdomen, perforation of the uterus, cervical stenosis, psychic stimulation, motor acceleration, restlessness, insomnia, changes in the EEG and increased risk of ectopic pregnancy. Research has also shown considerable indication of long term effects like teratogenicity, mutagenicity and carcinogenicity. In the absence of sufficient information, it is impossible for physicians to engage in human trials of Quinacrine sterilisation with the certainty that the health hazards it will pose to the woman are predictable and treatable. Yet, Drs. like Mullick, Jain, Sood and Sabarwal are not only conducting such trials, they are also actively advocating that Quinacrine sterilisation be made available to poor women in rural areas who don't even have access to basic healthcare much less, the facilities required to diagnose some of effects of Quinacrine sterilisation. So much for the ethics of their medical practice!

Guidelines of the COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES:

In 1993, the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organisation prepared international ethical guidelines for biomedical research involving human subjects. In addition to defining the essential information that must be given to all participants/volunteers of trials, these guidelines also focus on critical issues surrounding human trials in underdeveloped countries, the responsibilities of sponsors and compensation. The trials of Quinacrine sterilisations in India violate many of the provisions of these internationally accepted recommendations. Some glaring examples are given below.

1. Guideline for Research in developing countries: *Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that : - persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities.* [Guideline 8: Research involving subjects in underdeveloped communities].

Violation: While the animal and laboratory tests on Quinacrine sterilisation are grossly insufficient to justify any human trials, whether in the developed or developing world, the sad fact is that all trials of Quinacrine sterilisation have been carried out in Third World countries.

The reasons for this are manifold. Firstly, there is the matter of pure economics. As one of the key promoters of Quinacrine sterilisation, Kessel says in the video documentary film, *The Yellow Haze*, "If you do a risk-benefit analysis in America they will say we have to go through all the toxicological studies ... it would take 8

years and US\$ 8 million to take it through the US Food and Drug Authority... and no pharmacological company, no foundation and no government has planned to put the money in". Obviously, the cheaper option is to take it to Third World countries through the non-governmental network. Additionally this serves to work in tandem with their population control agenda, especially in an age when institutions like the World Bank and IMF are pushing Third World governments into a spot by tying up issues of aid with population control. Further, the blatant advocacy of Quinacrine sterilisations in the Third World is clearly capitalising on the fact that liberalisation is resulting in the breakdown of existing health services and increased privatisation resulting in widespread deregulation. And, as Kessel himself puts it in his interview in *The Yellow Haze*, "...doctors, particularly those working with contraceptives are very worried about the lawsuits. ... may be India is going to move in the same direction."

2. Guideline for *Right to Compensation*: *Research subjects who suffer physical injury as a result of participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability... The right to compensation may not be waived. [Guideline 13: Right of subjects to compensation].*

Violation: The trials of Quinacrine sterilisation in India are marked by the glaring absence of follow up. While the concerned doctors at LHMC, New Delhi claim to have provided sufficient follow-up and care, we have already seen how untrue the claim is. As for the other centres of Quinacrine sterilisations, follow-up is not even part of their protocol, and every paper published or interview given by them, cites "lack of funds" as the cause. In such a situation, women being subjected to Quinacrine sterilisations are not even diagnosed for the problems arising as a result of the procedure, much less, receiving treatment or compensation for their suffering.

3. Guideline for *Standards of Clinical Trials*: *An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in case of research carried out in that country. [Guideline 15: Obligations of sponsoring and host countries].*

Violation: As in Vietnam, Chile, Iran and Bangladesh, we have seen how human trials of Quinacrine sterilisation fail to meet even basic medical, legal and ethical requirements. Naturally, they fall far short of international standards that the investigators would be required to meet in developed countries.

Guiding Principles of the INDIAN COUNCIL OF MEDICAL RESEARCH: The Indian Council of Medical Research (ICMR) is the premier research body in the country. In 1994, it developed a Policy Statement on Ethical Considerations involved in Research on Human Subjects that was based largely on the Helsinki Declaration, but that also raised some crucial issues regarding informed consent and the importance of back-up health services.

1. Guiding Principle on *Preparations to Protect Subjects*: *The ethical committee should review every proposal for human subjects to assess, among other considerations, whether ... proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.*

Violation: All those involved in the trials of Quinacrine sterilisation in India claim lack of funds as the reason of lack of follow-up. Mullick, who has carried out more than 10,000 Quinacrine sterilisations is content with the claim that no women have come with complaints. He is not even interested in knowing their problems, much less in treating them. The CHIP Trust is speedily farming out the job of Quinacrine sterilisations to practitioners all over Karnataka — the only criteria being that they should be 'interested in Quinacrine sterilisations', not that they should have the facilities and the ability to deal with any medical crisis that the women might face. Even LHMC, which professes to be committed to 'quality medical care, and the woman's health', carried out many Quinacrine sterilisations in a Primary Health Centre (PHC) which has bare minimum of basic facilities. In fact, Dr Dharam Prakash, Chief Medical Officer at the PHC was dogmatic. He told Saheli, "They should not do such trials in such rural areas because when there are problems, we can't deal with them".

2. Guiding Principle on *Obtaining Informed Consent*: *Although the procedure of obtaining the signatures of the person giving his/her consent cannot be dispensed with, at the same time, it must be emphasized that in the context of the conditions prevailing in the country, mere signatures would not ensure the requirements of informed consent ... the proposed participants in a clinical research programme should be made aware, by a person not in a position to influence the patient such as a treating physician but for example, by a social worker, of the fact that a new drug or procedure is being evaluated.*

Violation: Obviously, the manner in which the trials of Quinacrine sterilisations are being carried out in India leaves much to be desired. Claims that 'of course, we have the informed consent of the women', fail to ring true in the face of other evidence. Private practitioners like those carrying out Quinacrine sterilisations for the CHIP Trust clearly bank on their power-positions to influence women's consent. And of course, they do not have social workers in their clinics who can serve as an independent party to facilitate a free and fair decision by women. At the PHC where a LHMC carried out many Quinacrine sterilisations, the Chief Medical Officer, social worker and even the Lady Health Visitor sending women in for the procedure had no information of the method, the fact that trials were being conducted, or the possible consequences of Quinacrine sterilisations. Not surprisingly, Goyal declared, "These women are so ignorant, they don't know anything, so we have to decide for them!". In the video documentary, *The Yellow Haze*, Kessel took such arrogance one step further when he said, "Do they understand the risks and benefits? It is doubtful; that is the problem in any developing country".

If such blatant unethical practice is to be brought to an end, national and international medical associations, councils and other scientific forums in India and abroad must break their silence. They must reaffirm their commitment to such codes of ethics. They must act immediately by debarring offending practitioners and organisations. Or else, all the world's codes of ethics will remain worthless words on paper, while the people of the world continue to suffer at the hands of such unethical medical practice.

CONCLUSION

"100,000 women sterilised by Quinacrine", the proponents of the method proudly declare; yet they have no definitive knowledge of the fate they have consigned these women to.

"Low risk option", they call Quinacrine sterilisation; but even after all these decades of its use as a sterilising agent, information on its long term effects is grossly insufficient, and what does exist, is cause for concern.

"The potential to defuse the population bomb", they pronounce - clearly revealing their obsession with population control, rather than their commitment to women's health.

For more than three decades now, the campaign to promote the Quinacrine method of female sterilisation has consistently been based more on hyperbole than on solid scientific grounds. Insufficient research has not stopped the worldwide spread of the method. Dubious interpretation of data has been used to support vested interests. Unscrupulous medical practice has been unabashedly encouraged. And the final result has been a relentless attack on women's bodies all over the Third World.

In India, the story of Quinacrine sterilisations is almost twenty years old despite the fact that the method has never received official approval. Today, the majority of Quinacrine sterilisations are being carried out by the NGO sector and private practitioners all over the country : A practice that they cannot defend either on medical, social, legal or ethical grounds. It is obvious that in the rush to promote Quinacrine sterilisations as widely as possible, they have completely lost sight of the women who are subjected to the procedure.

Medical Issues : Too Many Questions with No Answers

From the earliest experiments in which Quinacrine was used as a possible agent for chemical sterilisation of women, controversy has dogged its footsteps. The very proposal that a corrosive agent be used to create scar tissue in order to effect sterilisation has always been problematic. Yet, the practice of Quinacrine sterilisation has survived. But over the years, the dangers that it poses to women's health have become more apparent and consequently, the voices against it much louder.

The blind procedure of instilling Quinacrine for sterilisation has always been one of the first causes of concern. Problems associated with the procedure itself include possible adhesions between the anterior and posterior uterine walls, perforation of the uterus, cervical stenosis and the like.

The basic question of efficacy of Quinacrine sterilisation has always been worrisome. Even the promoters of the method acknowledge that failure rates vary substantially depending upon the skill of insertion of Quinacrine, the additional contraceptive cover included, etc., and that the efficacy of the method is yet to achieve a satisfactory rate. Yet, women all over the world are being freely subjected to the procedure.

Another serious issue is that of the high risk of ectopic pregnancies. This potentially fatal possibility has also received insufficient attention. The advocates of the method brush the issue aside by saying that the rate of ectopic pregnancies is equivalent to that of IUD insertions. But the fact remains that high incidence of ectopic pregnancy was one of the main reasons for termination of the ICMR trials of Quinacrine sterilisation. In fact, even in the LHMC study, out of a sample of just 32 women, at least one ectopic pregnancy was reported. With approximately 100,000 women all over the world having undergone the procedure, the prospects are frightening.

Long terms effects is the other critical area of study that has been systematically ignored. Three decades after its introduction, animal testing is still inadequate and hardly any data are available about the mutagenic potential (potential to cause changes in tissue), teratogenicity (effect on the foetus), carcinogenicity (potential to cause cancer) and the ability of Quinacrine to persist in the tissues. The few studies that have been done, indicate that Quinacrine can cause mutations, and the need for further testing. There are no documented studies on the teratogenic potential of Quinacrine and this lack of information has been conveniently portrayed as absence of the effect. And despite the worrisome 'scientific information' available on the method, it is being aggressively promoted as the ideal method for Third World countries.

Even the claim of 'no fatalities due to the method', the basis on which Quinacrine is called the safer option to surgical sterilisation, cannot be backed up with proper data because no adequate follow-up have been done. Absence of proper data maintenance may be the other reason for no 'reported' deaths due to the method. Additionally, the side-effects and long-term risks that could contribute to morbidity have not been measured nor can they be predicted, since they have not been sufficiently studied.

The reversibility of Quinacrine sterilisation is another area of concern. In the developing countries where it is being promoted, poor healthcare systems, high infant and child mortality rates and an early age of female

sterilisation, makes the option of reversibility important. But all the available data indicates an unacceptable low return of fertility rate of just 50%. Yet, Jain confidently told Saheli that Quinacrine sterilisations are easily reversible by using a catheter to open the blockage. So much for the scientific basis of their arguments!

The blatant scientific inaccuracies, gross misinformation and utter irresponsibility that have characterised Quinacrine trials cannot be allowed to continue. Governments, national and international medical associations, councils and other scientific forums in India and abroad must break their silence immediately. Such medical practice directly contravenes accepted national and international code of medical ethics, and threatens to jeopardise the life and well-being of tens of thousands of women (and possibly, that of future generations as well).

Clinical Trials : Experimenting with Women's Lives

Even the manner in which the trials of Quinacrine sterilisation have been carried out are extremely problematic. The method of insertion changes midway through studies; combinations of drugs instilled in the uterus change dramatically (e.g. Quinacrine + ibuprofen, Quinacrine + tetracycline and Quinacrine + diclofenac) and yet, these wide variations in protocol do not deter the promoters from clubbing them together for analysis. In some studies, Depo Provera, a long acting hormonal contraceptive replaces the oral contraceptive pill as the additional contraceptive cover. Its inclusion as a contraceptive cover in a large number of trials, including the IFFH protocol is shocking because it is itself known to produce a large number of side-effects, including delayed return of fertility! And yet, such a protocol is approved and used even in a 'responsible medical college' like Lady Hardinge Medical College (LHMC).

Informed consent is also a contentious aspect of Quinacrine trials. While most of the individual practitioners and NGOs involved in trials of Quinacrine sterilisation publicly declare that requirements like informed consent are adequately fulfilled, the facts speak otherwise. International guidelines on informed consent for clinical trials clearly state that consent must be taken on the basis of complete information, including possible risks, complications, side-effects, etc. The lack of information on Quinacrine sterilisation makes it impossible for this basic requirement to be fulfilled.

The ICMR guidelines also specify that in a country like India, participants should be made aware of the trial by a person like a social worker, and not a doctor. This is a condition that few, if any, private practitioners or NGOs care to fulfil. At the PHC where LHMC carried out many Quinacrine sterilisations, neither the Chief Medical Officer, social worker nor the lady health visitor had any information of the method, the fact that trials were being conducted, or its possible consequences. Not surprisingly, one out of six women contacted had no information that she was being sterilised, much less that she was being used as a guinea pig for Quinacrine trials!

The trials of Quinacrine sterilisation are marked by the absence of follow-up. In writing and in interviews, on and off the record, the practitioners involved in Quinacrine sterilisation have cited lack of funds as the reason for lack of follow-up. In doing so, they are only revealing the fact that the people behind the promotion of Quinacrine sterilisations clearly have no commitment to women's health.

In India, this plea is echoed by the likes of Mullick who has, by his own admission, conducted more than 10,000 Quinacrine sterilisations, doctors in LHMC who claim that the interests of the woman is their only concern, and Kini who asserts that the Quinacrine sterilisations they offer are part of a study, and yet has no follow-up to show for it. Consequently, people like Mullick merely choose to claim that no women have returned to him with any complaints, and that therefore, Quinacrine sterilisations should be considered as having no side-effects or complications. Obviously, such claims are patently unscientific and totally unacceptable.

An immediate stop must be put to all such clinical trials. NGOs and private practitioners involved in the trials must immediately initiate follow-ups of all the women sterilised by Quinacrine, monitor them adequately and provide quality healthcare. Also, a basis must be evolved for providing compensation to all the women who have been subjected to the procedure.

Since Quinacrine trials are not legal in India, stern action must be taken and an example be set to deter such illegal and unethical practice.

A clearcut direction must be given to contraceptive research to ensure that it only strives towards providing safe solutions for the health and well-being of the women and men in the country.

Potential for Mass Use : Massive Potential for Abuse

Ease of use - the primary argument in favour of Quinacrine sterilisations is probably the strongest argument against it. There are two grounds for this assertion. Firstly, although the procedure is technically simple, the efficacy of the method is a direct function of the skill with which it is inserted. In spite of the fact that the promoters of the method never fail to stress the need for giving adequate training to experienced paramedics,

ANMs, etc., even practitioners like Mullick only carry out 2-day practical workshops. Given the scale at which they project the potential for Quinacrine sterilisations, how much training will be imparted, skill developed and efficacy reached remains a matter of conjecture. This matter gains even more serious proportions when the procedure is visualised as being conducted in a single visit, with no follow-up visits to check for efficacy, complications or even side-effects.

Secondly, since the method of insertion and immediate side-effects like pain in the lower abdomen, etc., of Quinacrine sterilisation are so similar to that of IUDs, it is highly probable that the woman undergoing sterilisation with Quinacrine actually mistake it for a Copper-T. An instance of this has already been seen in the case of Woman #3 of the LHMC trials.

This is precisely the 'potential' that promoters of Quinacrine sterilisation like Jain believe ought to be 'exploited'. Towards this end, they have established a nationwide network for the distribution of Quinacrine pellets for sterilisation. In the bargain unfortunately, it is the women, mostly those belonging to poorer, marginalised sections who are getting exploited.

Obviously, the only way to ensure that Quinacrine sterilisations are not [mis]used on a mass scale, is to ensure that they are not used at all. Whenever instances of Quinacrine sterilisation come to light, penal action must be initiated - irrespective of whether it is been conducted by private practitioners, 'charitable' trusts, NGOs or government hospitals.

Population Control: Vested Interest In Quinacrine Sterilisations

The case of Quinacrine sterilisations is a direct fallout of the population control lobby worldwide and the population policy of the Indian government. For the First World population control lobby, it is a permanent method that can help 'control the fertility of women in developing countries' that they believe poses a security threat to the First World. Although the procedure of Quinacrine sterilisation is simple, it is nevertheless, controlled by the provider of the method. Thus making it a powerful weapon in the hands of the population control lobby.

Not surprisingly, some of the most active promoters of Quinacrine sterilisation worldwide are Kessel and Mumford, whose respective organisations, IFFH and CRPS, are funded by right-wing anti-immigration groups. Mumford has gone on record saying, "If the borders of the US are not closed, the US would become a Third World country".

The promoters of Quinacrine sterilisation argue that the method is appropriate for developing countries because it can play an important role in lowering maternal mortality by preventing pregnancies. But this reasoning is obviously faulty. The only way to lower maternal mortality is to improve health services, not to introduce a hazardous means of sterilisation like Quinacrine.

They also contend that the gap between developing and developed nations is so wide in terms of health and contraceptive prevalence, that it is inappropriate to apply a single standard for clinical trials to both. In its place they propose the WHO "risk/benefit criterion for tropical diseases", i.e. that the risk of the disease is high enough to justify the use of inadequately tested drugs. This criterion is seriously problematic on two counts: In the first place, allowing the use of inadequately tested drugs even for treating diseases is itself unethical and medically unsound. Secondly, viewing reproduction as a disease to be 'treated' with untested drugs reveals the anti-woman bias of such research. Women's fertility is regarded here as uncontrolled and untamed, to be reined in by any means and at any cost to the woman.

Consequently, the 'trials' of Quinacrine in most developing countries follow a pattern - there is no evidence of informed consent, the research protocols are shoddy and unscientific, and there is a glaring lack of adequate follow up. Another common thread running through the 'trials' is that more often than not, they are carried out through private practitioners and/or NGOs, who have no accountability whatsoever.

Third World governments must stand up for the health and well-being of their populations, and bring Quinacrine sterilisations to an immediate stop.

Quinacrine Sterilisation in the Age Of Privatisation : Frightening Implications

The current story of the trials of Quinacrine sterilisation in India, is a real sign of the times. In fact, it is the process of de-regulation of the economy and privatisation of the health sector over the last few years, that is translating into the horrible reality of Quinacrine sterilisation today. And the machinations of the various organisations and individuals involved in the promotion of the method are a mere reflection of the extent to which the extra-legal terrain of medical practice has grown.

Today, it is the market that rules. Concern for peoples' health has been replaced by concerns of cost-efficiency. Long-term studies have given way to post-marketing surveillance programmes. And government responsibilities in the health sector are being hurriedly farmed out to the NGO sector.

A combination of vested and commercial interests are coming together to influence the procedures and decisions of governments and regulatory authorities. In the case of Depo Provera, the USFDA played into the hands of commercial interests and sanctioned its use as a contraceptive. Consequently, numerous regulatory bodies all over the world including the ICMR in India, granted approvals for the marketing of Depo Provera, subject only to a post-marketing surveillance. Needless to say, this only served to open the floodgates for the manufacturers and their Indian subsidiary.

In the case of Quinacrine sterilisation, international organisations like the WHO and USFDA may have played a responsible role. However, in the interests of the people of any nation, it is the governments and regulatory bodies that must independently maintain stringent standards for screening and licencing, rather than be subject to the pressures of international lobbies or authorities.

The dismantling of health services is an equally serious issue. When high infant mortality, maternal mortality, death during childbirth etc., are a function of the abysmal health infrastructure in the country, how can the consequences of replacing them with family planning centres or handing over the primary responsibilities to NGO programmes be anything less than disastrous? The government must evolve clear guidelines for all NGO functioning in these areas, and develop mechanisms to implement them.

If the government is to make credible its claims of being committed to the health and welfare of its people, it has no alternative but to halt the process of dismantling the health infrastructure, and strengthen primary healthcare services available in every part of the country.

Role Of The Government : No Governing Role At All

The controversy surrounding Quinacrine sterilisation in India has been marked by an interesting official response. Concerned officials like Dasgupta, DCI and Saxena, Addl Dir Gen, ICMR, met Saheli with confidence and righteousness, claiming that they had nothing to do with the ongoing Quinacrine sterilisations, and that they had both, in fact, played very responsible roles. However, Saheli's investigations revealed otherwise.

Saxena's claim that ICMR had called off its trials due to a high failure rate and that they have had no dealings with the private practitioners or NGOs involved was belied by two important facts. Firstly, despite these dissociations, the ICMR legitimised Mullick and his 'research' by quoting it in their protocol for Phase II clinical trials of Quinacrine. They also invited him to a meeting in 1992 on "The use of Quinacrine for Tubal Sterilisation". Similarly even though Saxena behaved as though he had no knowledge of Jain, the latter was a Consultant to the ICMR study on Quinacrine. Lending such credibility to the unauthorised and illegal activities of Mullick and Jain hardly qualifies as having had nothing to do with them.

Saxena is also quite righteous about the fact that ICMR abandoned its Quinacrine study in the interests of women's health. But this is one of the rare instances in which the ICMR has responded to problematic results in a study with such promptitude. Although it has formulated the national guidelines for clinical trials on human subjects in India, the usual practice of ICMR, be it in the area of research protocol, informed consent, screening for contraindications, etc., has always been problematic. The experience of the Norplant trials conducted on thousands of women all over the country, is replete with such accounts.

Unless governmental agencies and regulatory bodies themselves function in a legitimate, if not exemplary manner, it is unrealistic to expect that the norms they lay down can have any more value than empty words on paper.

The DCI's response to the Quinacrine situation was as much of a farce. At an hour-long interview with Saheli, he claimed that he was very perturbed with all that was happening. He repeatedly clarified that legally, Quinacrine pellets used for sterilisation are a new drug that requires new approvals. He also asserted that he had not given any approvals except for the ICMR study, and that every clinical trial, be it at a medical college like LHMC or at an NGO like Indian Rural Medical Association, needed his permission. Further, he said that without his approval, any import or manufacture of Quinacrine pellets is illegal. But he claimed that since he is "only a licensing authority", all he can do is investigate the matter, after that it was upto the law enforcing authorities.

The DCI is not as powerless as he would have us believe. The Drugs & Cosmetics Act specifically empowers him to conduct investigations into matters of illegal import and manufacture of drugs, confiscate stocks and even initiate proceedings. For a start, the DCI's investigations leave much to be desired. He revealed the bias of his investigations when he generously excused Mullick for having given the inspectors a wrong name of his suppliers' source on absolutely flimsy grounds. When questioned about why Jain's operations including his source of Quinacrine supplies had not been investigated, the DCI pretended he had never heard of Jain. A short while later he contradicted himself by revealing that during the short period that the BJP government was in power at the Centre, Jain, then an MP, had approached the Union Health Minister for approval of Quinacrine, but that he had declined to grant it. Until the publication of this report, the DCI has still not taken any action against Jain.

It is obvious that authorities like the DCI are well-aware of the trials of Quinacrine sterilisation being conducted all over the country, and that these 'experiments with women's bodies' do in fact, have his tacit approval. Only prompt action against those involved in this illegal and unethical practice, will serve as a deterrent against such dubious medical practice.

Despite its official position against the trials of Quinacrine sterilisation, the government is turning a blind eye to flagrant violations by the promoters and practitioners of Quinacrine sterilisation. This state of affairs clearly cannot be allowed to continue.

Protests Against Quinacrine Sterilisation : Legitimate Demands

The medical concerns compounded with the social implications of use of Quinacrine as an agent for female sterilisation has sparked off protests from women's groups all over the world and here, in India. In Calcutta, the Ganatantrik Mahila Samity was instrumental in getting Mullick to abandon his trials of Quinacrine sterilisation. In Delhi, several women's groups like All India Democratic Women's Association (AIDWA), Centre for Women's Development Studies, Joint Women's Programme, Saheli Women's Resource Centre, etc., jointly staged a demonstration at Jain's clinic to protest against his role in the promotion of Quinacrine sterilisation in India. Letters of protest, urging immediate action have also been jointly sent to the DCI and the Minister of Health & Family Welfare; but no action has yet been initiated. AIDWA and Dr Rao are also in the process of jointly filing a public interest litigation on the matter.

The need of the hour is that immediate action be taken to prevent the continuation of Quinacrine sterilisations on women all over the country. It is essential that women's groups and other concerned organisations and individuals strengthen their voice against such illegal and unethical medical practice.

SOME CORRECTIONS & ADDITIONS [13.8.97]

1. *The petitioners of the public interest litigation [now] filed in the Supreme Court [refer pg.4 and pg.39] are the All India Democratic Women's Association and the faculty of the Centre for Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi.*
2. *On the issue of dosage [refer pg.5], according to the training manual brought out by the IDT, a third instillation of Quinacrine is essential in case of any bleeding during the first or second instillation, whether due to menstruation or as a consequence of the procedure itself. According to Dr. Bhateja, bleeding during insertions is fairly common, thus necessitating a third instillation. This further belies claims of the promoters of the Quinacrine method of sterilisation, that the procedure is so simple that it can be administered in a single visit.*
3. *On the matter of fatality due to the Quinacrine method [refer pg.14 and pg.35], as mentioned in pg.17, three deaths due to the use of Quinacrine slurry were reported by the manufacturer of the drug. Additionally, Dr. Zafrullah Chowdhury, a renowned doctor from Bangladesh reported in a meeting on May 10, 1997 in Delhi that he was approached by Zipper 20 years ago to carry out a trial of quinacrine sterilisation in Bangladesh. Since he was very impressed with the "scientific" evidence put forth by Zipper, Kessel and Mumford, he obtained permission for the trial from the Bangladesh Medical Research Council. After carefully selecting a case and obtaining informed consent, he performed the quinacrine sterilisation in a fully equipped operation theatre. To his horror, the woman died almost instantaneously following the instillation of quinacrine. He immediately sent a cable to Kessel, but received no response. (Letter to the editor, Mohan Rao, Frontline July 11, 1997).*
4. *On pg. 17, in the list of countries in which large scale use of the quinacrine method of sterilisation has been carried out, kindly ignore the fact that China and Bangladesh appear twice.*
5. *On 30 May 1997, in response to a question [Unstarred Question No. 4045] raised in Parliament by Ashok Mitra, on the legality of the use/trials of the Quinacrine method of female sterilisation, Mr. Ramakant Khalap, Minister of State of the Department of Legal Affairs, confirmed that the method was specifically disapproved by the WHO and further stated, "Approval for trials on quinacrine pellets has not been granted to any investigator by the DCI." When asked whether the government was aware that a number of NGOs in association with some doctors in private practice have been distributing and experimenting with this drug in different parts of the country, Mr Khalap replied, "There have been some reports in newspapers about dissemination-use of quinacrine by some individual doctors, but no specific instance has been brought to the notice of the government". This is despite the fact that Saheli raised the issue citing specific instances of illegal use of quinacrine in several communications with the DCI dated 22.4.97, 17.5.97 and during a meeting with him on 7.5.97.*

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