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Quinacrine Sterilization in India: Women's Health and Medical Ethics Still at Risk

By Rajashri Dasgupta

Women's groups in India are only too aware that the "real battles" are fought outside the court room. In 1998, when the Supreme Court of India banned quinacrine sterilization (QS) because its long-term effects on women are unknown and are potentially harmful, activists knew they had to continue the struggle outside the courts. Their fears proved true when a group of medical practitioners violated the ban on the use of the drug for female sterilization.

A study conducted in 2003 found that five years after the ban, medical practitioners in India were still using quinacrine to sterilize women.[1] None of the women interviewed knew that QS was an unauthorized method, with potential health hazards. Most of the women who underwent QS said that the provider never asked them to sign or give their thumb-print on any consent form or other document. The few who did sign forms said that they were not aware why they were asked to do so. "It calls into question any claim that informed consent was given by these women, thus violating their human rights," stated Shree Mulay, Director, Centre for Research and Teaching on Women, McGill University, Canada, who led the team of researchers based in Kolkata, the capital city of West Bengal, the Indian state bordering Bangladesh.[2]

QS is a non-surgical, permanent method of sterilization by the synthetic anti-malarial chemical quinacrine. When quinacrine pellets are inserted into the uterus through an intra-uterine device, they dissolve, form scars and block the fallopian tube to prevent fertilization.

In 1997, women's health advocates around the world were alarmed to discover that large-scale clinical trials had been conducted with QS on over 100,000 women in 25 countries. An ardent proponent of QS, Dr. Ashi Sarin, claimed in a telephone interview that at least one-fifth of the QS cases in the world were done in 26 centers in India before the ban. Sarin herself has conducted 134 QS procedures among 'high-risk' women and found it to be effective. "In most countries like India the trials were covert. We are concerned that women are being targets of unethical drug trials," said Mohan Rao of the Public Health faculty of Jawaharlal Nehru University (JNU) in Delhi.

It was this concern that led to intense campaigns by women's groups in several parts of the country. Protest demonstrations were held in front of clinics of doctors practicing QS in the cities of Delhi and Kolkata. Saheli, a prominent women's rights group, published an in-depth study that countered the arguments put forward by QS advocates and media reports questioned the government's failures in regulating and monitoring illegal drug trials. To further strengthen the growing movement, the faculty of Public Health at JNU joined hands with the All India Democratic Women's Association to file a public interest litigation that finally led to the Supreme Court ban on QS.

Two years later in a workshop in Kolkata, a study with a feminist perspective was developed to document women's experiences of QS, determine if there are any deleterious effects, investigate whether QS is being used after the ban and find

out whether women were aware that QS was an experimental method. The workshop participants were women's health advocates, academics and media personnel, many of whom had been involved in the movement against QS in India, Bangladesh, the USA and Canada; they supported the study team with ideas and advice during the entire research period.

Given limited resources, a larger population-based study was not possible. Instead the study in West Bengal would conduct in-depth interviews with 32 women in one region who had undergone quinacrine sterilization, followed by medical examination offered to those who wanted one. An equal number of women who had undergone surgical sterilization (SS) were selected using parity parameters such as socio-economic status, current age, age during the sterilization procedure, and reproductive history at the time of the study.

In 2003, the study was released in Kolkata with the support of women's activists and the Women's Commission of West Bengal, a statutory body. It found the striking difference between the QS and SS women was that the former had several cases of cervical erosion and inflammation, requiring long-term follow up. Thirteen of the 32 QS women "bled on touch" during internal examination, and the cervices of 13 were diagnosed as "clinically unhealthy" and "ulcerated," and had "growth," therefore requiring further microscopic investigations, according to Dr Sanjeev Mukherjee, a Kolkata-based gynecologist who conducted the medical examination.

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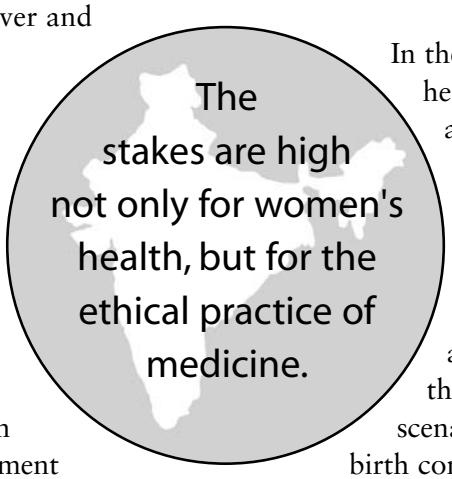
In the last decade worldwide unethical QS trials received a series of setbacks. In 1998, the U.S. Food and Drug Administration (FDA) asked the two Americans, Dr. Elton Kessel and Stephen Mumford, the spirit behind the trials, to halt immediately the distribution, import, manufacture and export of quinacrine pellets for female sterilization. Earlier in 1994, the World Health Organization (WHO) had cautioned researchers to stop all human trials until laboratory and animal testing was complete, the first essential steps in the development of any new drug. But it was the Indian ban that was an "enormous setback" for QS worldwide, said Dr. Mumford, as it "undermined the efforts of individuals in numerous other governments to have their own governments undertake national clinical trials."

QS is promoted in countries like India by a network of doctors (like Sarin) in urban areas, who in turn train rural practitioners and supply them with pellets. In West Bengal, gynecologist Biral Mullick claimed to have done 10,000 QS procedures; he trained hundreds of rural practitioners and set up the Indian Rural Medical Association (IRMA) that claims a membership of 40,000. The rural practitioners have a smattering knowledge of allopathic drugs and combine it with traditional medicine and homeopathy.
"The doctors are my friends and I only teach them the technical know-how and provide them with pellets," admitted Kessel when he was in Kolkata in 1998 to convince doctors to appeal to the Indian government to rescind the ban. "I do not do anything illegal, I do not do trials in your country."

What drives Kessel, founder of the International Federation for Family Health, and Mumford, director of the US-based Center for Research on Population and Security (CRPS), is their life-long devotion to fighting population growth in developing countries and increased immigration to developed countries. They promote QS as the answer to maternal deaths in poor countries while simultaneously promoting the need for sterilization by playing on upper-class fears of the "population problem."

"The explosion of numbers will come from the immigrants and their offspring and will dominate our lives. There will be chaos and anarchy. It's even more serious than the nuclear threat," said Kessel. "The threat of immigrants invading and taking over is real, they are swarming all over and draining the resources. Look at the chaos in India's eastern region with thousands coming in from Bangladesh and in the USA, Mexicans and Caribbeans are pouring in. No civilized government can allow this."



By exploiting fear of the "population explosion," Mumford and Kessel shift attention away from pressing issues of hunger, unemployment and rising costs of health care and education, according to economist Navsharan Singh, who co-authored the West Bengal study. Like national governments and the international population lobby, the duo do not take into account the impoverished lifestyles and gender inequality that rob most women of their choice on issues of marriage or repeated pregnancies.

The West Bengal study, for the first time, documented the actual experiences of women who have undergone QS. Apart from the health impact, it probes deeply the socio-economic context in which women are choosing to be sterilized and the issue of easy availability of QS from private medical practitioners in the context of deteriorating public health services. Rural medical practitioners who provide QS were interviewed to understand their informal networks and to provide a contrast to the information given by the women.

A major factor that influenced women's decision-making was that the rural medical practitioners who provide QS are locals and trusted members of the community. Moreover, they have a personal relationship with the women and their families since over the years they have treated them for various ailments. As one woman sterilized with quinacrine put it, "He (the provider) guaranteed that there would be no side-effects. And his medicines really work. He has treated me many times; I have faith in him." In contrast, surgical sterilizations are done in impersonal camps by unknown doctors with hundreds of women sterilized on one day with makeshift facilities and little counseling.

In the absence of adequate public health services, particularly in rural areas, the easy availability and accessibility of these providers make the community dependent on them. The IRMA of unregistered 'doctors' also provide essential services like abortion and thus endear themselves to women. In such a scenario, women who are desperate for birth control need little convincing to try QS after hearing positive things about these 'doctors' from relatives or neighbors who have undergone the procedure.

According to women's rights activist Laxmi Murthy, "The non-governmental organizations (NGOs) like IRMA providing QS tend to be better-behaved and have better services than the government-run clinics. So when NGOs use these banned procedures, people unfortunately tend to trust them more than the government, which they are more suspicious of. Since government services are almost non-existent especially in villages, NGOs fill the gap and are welcomed."

The use of banned drugs and procedures in India is possible because of weak regulations and lack of monitoring and enforcement. Two years ago, members of IRMA conducted trials on 700 women in Bengal by inserting crushed erythromycin tablets through an intra-uterine device to sterilize them. Last year, doctors experimented with chord blood on HIV/AIDS patients without their consent or following research protocols. "It's the lure of fame, foreign travel and the glamour of seminars that encourage doctors to pursue these so-called trials," said gynecologist Mukherjee.

Health and women's rights networks have used various opportunities to raise awareness about the campaign against quinacrine sterilization in India.

They have suggested to the state drug controller that medical professional bodies should be informed repeatedly and warned against its use. Following the public hue and cry, the rampant use of QS seems to have weakened among qualified doctors in the cities.

However, some doctors have appealed to the Drug Controller of India to rescind the QS ban. Last year Dr. Sarin filed a legal petition in the Punjab High Court to lift the ban on quinacrine. For the last six years, said Mumford, Dr. Kessel and he have "personally" talked to perhaps 20,000 American clinicians about QS, including physicians, nurse practitioners and nurse midwives. Since without FDA approval, there is little chance of QS being approved by any governments, least of all India, the International Federation for Family Health and CRPS have encouraged FDA-approved trials initiated by Dr Jack Lippes in the U.S. "We are now preparing to apply to the FDA for approval to undertake a much larger national trial," said Mumford.

If so, the struggle against QS is far from over. In India, the QS ban, the study to document the experiences of QS women, and the coalition of health activists and academics are a step forward in the campaign. However, while women continue to be sterilized with quinacrine, thousands of QS women are left without health follow-up, medical practitioners conducting the unapproved trials go scot-free and governments remain indifferent.

With the unholy alliance of right wing groups keen to stop the 'invasion' of third world immigrants and a group of dubious medical practitioners quick-fixing medical ethics, only a sustained campaign with a stronger and wider network of international solidarity backed by more feminist research can highlight how quinacrine sterilization exploits and harms women. The stakes are high not only for women's health, but for the ethical practice of medicine. QS threatens to be another infamous chapter in an ongoing saga of unethical medical experimentation on human beings.

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References

1 Mulay, Shree; Singh, Navsharan; Dasgupta, Rajashri (2003) "Quinacrine Non-Surgical Sterilisation In West Bengal: What We Have Learned From The Women On The Ground," A report presented in a workshop to discuss the research findings, Kolkata, India, November 28.

2 The interviews quoted in the text were conducted by the author either on phone or through email. Interview with Elton Kessel was conducted personally in November 1998 when he was in Kolkata to attend a medical conference. In March 2005 Dr Mumford replied to the set of questions I sent to April Mayberry referred to by Dr. A. Sarin. He said she was out of the office traveling.