From : Issues in Medical Ethics

In Public Interest

Introduction - Female sterilization is the mainstay of contraceptive methods in India. Every year over 4 million female sterilization operations are conducted in the country. Like all surgical procedures female sterilization, despite being a relatively low risk procedure has its attendant risks and failure rates. According to international authorities the failure rate, ie. the chance of becoming pregnant after operation is around 1 in 200, the rate of complication around 1 in 100[1], and the risk of death around 3 in 100,000[2] procedures. According to these estimates there is a possibility of over 20,000 failures, 20,000 women with complications and about 150 deaths due to these operations. However there are no specific provisions for dealing with these acceptable risks within the programme.

Healthwatch UP Bihar is an advocacy network on women's health and rights in the four northern which originally comprised of Uttar Pradesh and Bihar. Healthwatch UP Bihar has been actively involved in tracking the changes in the state Family Planning programme delivery as a result of the adoption of the Target Free Approach and the Reproductive and Child Health Programme[3]. The state unveiled its population policy in July 2000, and this policy had a set of escalating annual targets which ranged from 600,000 to 1.2 million cases per year. In the process of reviewing the policy directives members of the network came across a large number of cases of sterilization failures, complications and deaths[4]. Site visits to sterilization camps revealed that bicycle pumps were being used to introduce air into the abdomen for laparoscopic ligation[5].

Public Interest Litigation for ensuring quality of care in sterilisation services- The Department of Family Welfare of the Government of India had prepared a manual of standards in the case of Female and Male Sterilisation[6]. Using these standards ten sterilization camps were rigorously documented. The documentation revealed that most of the standards were not being followed. The average operating time was between two and five minutes for laparoscopic ligation. Against the prescribed limit of twenty cases per team per day, teams were found to perform seventy five cases. Non trained doctors were allowed to perform surgeries and training of doctors was also being conducted even though this was strictly forbidden[7].

A study of sterilization related failures and complications in Maharashtra and Bihar had been conducted by IWID earlier. Using the Healthwatch UP Bihar and the IWID study as evidence and the Department of Family Welfare guidelines as the basis a Public Interest Litigation was filed in the Supreme Court by Healthwatch UP Bihar through its convenor, under Article 32 of the Constitution. The PIL (Writ Petition (Civil) No 209 2003) was admitted and the Supreme Court asked all the state and Union Territories to file their affidavits. It is exactly one year since the Supreme Court gave its order to the states and since then only seven states and union territories have filed their affidavits. These include Daman and Diu, Dadra and Nagar Haveli, Andamans and Nicobar, Sikkim, Manipur, Haryana and Orissa. Among these except for Haryana none have acknowdged that there are any cases of failure, complication or death and have solemnly sworn that all the

procedures are being followed according to the said standards. Haryana has been the sole exception because of the well-known Santara case[8] where the Government was made to pay compensation for a failed case of tubectomy.

It is interesting to note that a performance audit by the CAG on the National Family Wefare Programme in 2001 reported that 9 states had reported 762 failures and no investigations had been carried out to establish the reasons for the failure. A five district study in Uttar Pradesh[9] conducted in 1999 had reported a failure rate of 4.7 percent which would amount to over 15,000 failures in that state alone.

Quality of care, ethics and law in the case of sterilisation - Sterilisation campaigns have earlier been in the centre of controversies. Forced sterilsations in Nazi Germany, in the US in the early 40's and the Sterilisation Act of Sweden are well known cases of human rights violations. There were forced sterilizations during the Emergency in India too. However after the International Conference on Population and Development (Cairo 1994), family planning programmes are supposed to have become more development centred and women friendly. India too has changed its policies and programmes through the adoption of National Population Policy (NPP 2000), Reproductive and Child Health Programme (1997) and the Community Needs Assessment Approach (1999). In the wake of these changes the findings of the two studies raise a number of legal and ethical questions regarding the conduct of individual operations, mass sterilization camps as well as programme design and accountability.

There is a very close relationship between quality of care, ethics and legality. While quality of care can be considered to relate to technical aspects, ethics relate to the moral responsibility and law binds with legal accountability.

Sterilisation operations are non-therapeutic procedures and being such they warrant extra care and caution[10] . The ethical responsibility of the practitioner is more in the case of non-therapeutic operations, because it is possible to cause harm to someone who did not have a problem to start with. Many women undergo tubectomy as a result of the subtle pressures of the health workers and the absence of knowledge and access to other services. The ethical considerations in the case of female sterilization have more than one dimension. Firstly one has to consider the manner in which women are recruited for the procedure. While this responsibility of the paramedics and outreach worker, it is finally the responsibility of the team headed by the operating surgeon to ensure that all medical eligibility criteria and ethical (informed consent) requirements have been met. In the conduct of the operations the operating surgeons must ensure that minimum acceptable technical standards are met. Besides, women who come to camps deserve to be treated with dignity. Our experience at the camps shows that heavily sedated women are picked up roughly and dumped on the operation table. In the operation theatre there is little concern for the women's privacy and finally she is picked up and dumped outside equally unceremoniously at the conclusion of the operations with little concern for post operative care. As a program of high national priority the family planning program owes the women who agree to undergo sterilization operation minimum respect and quality services and the medical personnel associated with the camps need to ensure it.

Doctors often justify the very shoddy treatment of women at sterilization camps by referring to the pressure of targets that they have to fulfill or because of the lack of time. This is a dilemma that doctors must resolve at the personal level as well through professional organizations like the IMA (Indian Medical Association) and FOGSI (Federation of Obstetrician and Gynaecologists Societies in India). The accountability to the employer (the government) in terms of various pressures has to be balanced against the ethical responsibility towards the individual patient. It is also not the matter of ethical principles alone, but the consequences of poorly conducted operations have legal dimensions as well. Indian Courts have admitted cases of tubectomy failure and deaths and have taken steps to compensate women both for medical negligence and fixed accountability of the state for negligence of the doctor in cases of failure[11] as well as tubectomy deaths[12].

It is time that the simple tubectomy operation is examined more closely not only because it is perhaps the largest surgical procedure conducted in the country but also because it is a major surgical procedure and the potential (and actual) harm it can cause women.

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[1] Rotimi A K Jaiyesimi, Padma Eedarapalli, **Female Sterilisation** downloaded from http://www.sexualhealthmatters.com/v2iss2/article4.html

[2] Chapron C, Querleu D, Bruhat MA, et al. **Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases**. Hum Reprod 1998; 13: 867–72

[3] For details see Healthwatch UP Bihar (1999) ***Voices from the Ground,*** Healthwatch UP, Bihar, Lucknow

[4] Details of these cases have been reported in Healthwatch UP Bihar (2002) ***Priorities of the People*** , Healthwatch UP Bihar, Lucknow

[5] Later reported by Rashmi Saxena, in **Theatre of the Absurd,** The Week, Dec 22, 2002.

[6] **Standards for Male and Female Sterilisation**, Division of Research studies & standards, Department of Family Welfare, Ministry of Health and Family Welfare, Government of India, October 1999

[7] Report of the study is forthcoming.

[8] Supreme Court in State of Haryana v. Santra [(2000) 5 *Supreme Court Cases* 182].

[9] **Lapascopy Sterilisation: A study of Success rate in the state of Uttar Pradesh**, State Innovations for Family Planning Services Agency (1999),(mimeo) Lucknow , UP

[10] For a discussion on distinction the distinction of therapeutic and non-therapeutic procedures please see Sommerville Margeret A (1981) **Therapeutic and Non- Therapeutic medical procedures – What are the distinctions** . Health Law in Canada vol.2 no.4 pp 85 – 90

[11] See Reference 8 above

[12] Achutrao Haribhau Khodwa v State of Maharashtra , 1996 Acc CJ 505 : (AIR 1996 SCW919)