

# Medical Negligence and Rights Violation

*The poor quality of care that women receive in tubectomy camps in UP translates into a heavy burden of failure, morbidity and often mortality. There is an urgent need to ensure that standards of care are implemented and some form of redressal mechanism established.*

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India started the first national family planning programme in the world soon after independence, in 1951-52. Over the years, the nature of the programme has changed. Female sterilisation has emerged as the method of choice, and despite having a policy of a 'cafeteria approach' and informed consent, the proportion of contraception adopters using female sterilisation is an overwhelming 98 per cent of all sterilisations each year and roughly 62 per cent of all contraceptive users. The most popular method used in female sterilisation, or tubectomy, in India is the laparoscopic tubal occlusion. Over four-fifths (85.3 per cent) of all persons who have adopted this method of contraception availed this service from government facilities.

As with all surgical procedures, the operation carries some degree of risk. According to international sources, with tubectomy the risk of failure (becoming pregnant again) is roughly one in 200, the risk of post-operative complications is one in 100 [Jaiyesimi and Edarapalli, undated] and the risk of death is three in 1,00,000 [Chapron et al 1998]. In the past, there has been some degree of concern about the higher failure rates in India [SIFPSA 1999]. In April 1999, the ministry of health and family welfare convened a meeting of experts to lay down standards for male and female sterilisation. The document that emerged as a result of this consultation, 'Standards for Female and Male Sterilisation' [GoI 1999] is the current standard of care prescribed by the department of family welfare for performing sterilisation operations in India.

This paper compares the current practice of tubectomy in Uttar Pradesh against the standards prescribed by the division of research and standards, department of

family welfare in 1999, using secondary data as well as direct observations from 10 RCH camps. The findings indicate that most 'standards' are being breached. This failure has grave ethical, legal and human rights implications, especially since tubectomy is an elective, non-therapeutic intervention.

## Experiences of Tubectomy in UP

Uttar Pradesh is the most populous state, accounting for nearly a sixth of India's total population. It also has some of the poorest socio-economic indicators of all states, and the population growth rate in the state is high. It is often referred to as one of the 'problem' states. UP has an extensive family planning programme, which receives support from USAID and World Bank. Tubal ligation continues to be the most widely used contraceptive in the state and over 4,50,000 tubal ligations are performed each year.

The quality of care of sterilisation services in UP has been studied earlier [Townsend et al 1999] and found wanting. A study of laparoscopic failure conducted by the State Innovations in Family Planning Services Agency [SIFPSA 1999] concludes that the failure rate is 4.7 per cent. The study also reports that half (50.5 per cent) of the women suffered post-operative complications.

Death is a known complication of tubectomy and reports of death in India are as high as 19 per 1,00,000. In a study conducted in a medical college in Ahmedabad, 77,563 tubal sterilisation operations resulted in 16 deaths [Patel et al 2002]. Reports of deaths during sterilisation are not uncommon in UP. A couple of cases which were investigated by the health advocacy network Healthwatch UP, Bihar include Leelavati, who died during sterilisation in December 2000 at the district women's hospital in Kushinagar

district (Healthwatch 2002), and Sheila, who died during operation in March 2003 at Deendayal Hospital in Varanasi (*Dainik Jagaran*, November 29, 2002). The post-mortem report for Leelavati reads, "Incision of the inferior vena cava causing three litres of blood in the peritoneum", and for Sheila Devi it reads, "Vaso vagal and peritoneal shock due to peritoneal and mesenteric over stretch".

In order to understand extent to which the standard practices recommended by the department of family welfare were being followed on the field, a study was conducted by the health advocacy network, Healthwatch UP, Bihar, on 10 reproductive and child health (RCH) camps in Uttar Pradesh between December 2002 and February 2003, using convenience sampling. Camps were selected based on the availability of a field-based NGO member of Healthwatch and the list of camp dates provided by the office of the chief medical officer of the district. A checklist-cum-questionnaire was prepared based on ministry guidelines and field researchers were briefed and trained. In addition, a team comprising a doctor with 10 years experience in supervising family planning programmes and a public health practitioner visited eight of these camps, conducted interviews and made detailed observations. The findings are summarised below.

*Eligibility/counselling/informed consent:* In all camps visited the clients were women. They were made to sign or put their thumb impression on the consent form without being read out its consent or the procedure explained as detailed in the standards manual. The question of using a language which the client understood did not arise. There were tables meant for counselling in three places, but these were out in the open and no client was seen being counselled. On informally talking to the clients the team found out that the latter had been informed that this was a safe and simple procedure [GoI 1999: Section 1.2.5.a], but none of the other points that 'must be explained to the client' (Sections 1.2.5.b to 1.2.5.h) had been explained. The women also said that they had only been informed of female sterilisation as the method they could adopt.

*Standards for female sterilisation:* Laparoscopic ligation was conducted in nine places and mini-laparotomy conducted in one camp. In one PHC, the surgeon who conducted the laparoscopic ligation operations did not meet the eligibility criteria

as he was only an MBBS. Medical history taking was confined to menstrual and obstetric history by an ANM and instructions for detailed history taking were ignored. Medical examination included blood pressure examination in a queue in the regular OPD. Pelvic examination was being done by a health visitor and/ or the ANM, but not for all clients. A comparison between the number of gloves used and the number of women examined showed large discrepancies. In only one camp (at Saharanpur) were separate gloves used for each examination.

Laboratory examinations included blood test for haemoglobin using a colour-matching chart, which was being done at all locations except one. Urine samples had been taken from all clients but there was no evidence of any test equipment. Toilets were present at seven locations but only three of them were in usable condition. The operating surgeon did not conduct any final assessment of the clients or confirm eligibility, except in one place. No clients were refused sterilisation on the basis of relative contraindication, clinical assessment or laboratory examination in any camp.

In the Khorabad PHC, medical termination of pregnancy (MTP) was done along with laparoscopic ligation, in contravention to standards. Pre-medication was given to all clients at the same time. In two places, clients were being taken into the operation theatre (OT) even five minutes after pre-medication, when the standards maintain that operation should begin at least 30 minutes after pre-medication. The infiltration of local anaesthetic over the incision site was given outside in the pre-operative waiting area in nine places, and in one place (Tilhar PHC), no local anaesthetic was given. This is in contravention of standards, which state that the infiltration of local anaesthetic should take place on the OT table. At Pandri, the team observed, "...The woman was lying on the table with her head turned upside down at an angulation of almost 45 degrees on the makeshift operating table. She is asked by the assistant 'side se kas ke pakar ke rakho' ('hold tightly to the sides') and rebuked when she slips down because of the steep angle 'upar utho...upar khisko' ('climb up...shift upwards'). Her petticoat was turned on her face and two persons firmly held one leg each. The surgeon is ready to give a nick and put in the trocar. The local anaesthetic and sedative had been applied over 30 minutes ago when she was

outside and she cries out as the nick is made" (field notes).

In Saharanpur, a bicycle pump with a nasal tube attached to its end was used to pump air into the abdomen, while in other places, where laparoscopic ligation was performed, the bulb of a blood pressure instrument was used to pump air. Carbon dioxide was not used in any location. Instead of gradually releasing the air before removing the trocar, the surgeon would pull out the trocar immediately after the rings were in place.

No evidence of pre- or post-operative monitoring (pulse, blood pressure or respiration at 15-minute intervals is mentioned as the standard) was found and the patient bed head tickets were only available at one location (Vijaypur PHC). Even this did not have any regular entry of pulse rates, respiration rate or blood pressure. Clients were discharged well before the minimum period of four hours. Discharge cards were provided, but these were filled along with the consent form at the beginning and handed over to the motivator.

*Standards for male sterilisation:* No male sterilisation operations were conducted in any of the camps visited, so no observations were recorded.

*Physical requirements:* Of the 10 locations visited, nine were mobile settings with the mobile team coming from a different facility. An operation theatre was present in all locations. Pre-operative and post-operative areas were absent in six and four places respectively. Both pre- and post-operative clients were made to lie down in the same passage or verandah. In three locations, the examination was being conducted in a labour room. In seven out of 10 camps, there was no space for counselling and in two camps no laboratory was found.

Four camps were held in cramped operation theatres, two were dark, in three places the entrance was not clear, and in two places it was not clean. In eight locations where laparoscopic ligations were conducted, there were two or three tables being used for the operation so that two or more cases could be done simultaneously. At Gursarai, the scene at the OT was as follows: "The OT was roughly 16 feet square with no windows and damp walls. In this room there were three operation tables, three doctors, four nurses, four ANMs, one chowkidar-cum-instrument clerk and two ward boys working in it at the same time. Two persons were continuously going in

and out of the OT bringing in and taking out clients. There were gauze pieces soaked with blood and antiseptic as well as used gloves lying all around the OT. There was a continuous squishing noise as the slippers of the surgeons and assistants and OT boys stepped on these" (field notes).

While all the locations visited were clinical settings, examination of records at Gursarai indicated that weekly camps were being held at Markua School on Thursdays and 53 cases had been operated on December 18, 2002, which is a blatant contravention of standards.

The earliest that surgery began at a camp was 12 pm, and in one case surgery began at 4.30 pm and ended at 7.00 pm. The standards are that camps should be held between 1 pm and 4 pm and the optimum number of cases should be around 20. In the camps that the research team observed, the least number of cases were six and in four camps this number was exceeded, with a maximum of 75 cases in one camp. The average time per surgery at camps was as low as two minutes and in all but three camps the average time was within five minutes.

*Prevention of infection – asepsis and antisepsis:* Clients were not provided with OT clothes in any location. Clean clothes were available for surgeons and assistants at two places. At five locations, surgeons were changing their gloves after each case, but their assistants were not. At no location were the surgeons and their assistants were seen to do a surgical scrub after five cases, as recommended.

At Khorabar PHC, it was observed: "We were then taken to the pharmacist's room, (where the pharmacist) was busy giving test doses of penicillin. The syringe was full and all the test doses were given by a single syringe. However, the needle was being replaced, but from a bowl filled with water and containing three stainless steel and three disposable needles. In all 20 clients were injected using these six needles over and over again from this bowl of water" (field notes). At other places a similar practice was observed.

Autoclaving of surgical instruments was observed at two sites. However, the providers informed the team that the instruments had been autoclaved the previous day at the headquarters of the mobile team. The disinfection of used instruments was being done in a boiler kept in the operation theatre, in which instruments were being continuously added and taken out. There was one laparoscope in eight

places (except Bidhanoo, where there were three) and it was being dipped in a container with Cidex solution for a very short time before use once again. The trocar and the laparoscope were used once again without being washed or even wiped with sterile water or cloth.

Disposable syringes, needles, drip sets, gloves, drapes, medicine vials, gauze pieces, cotton swabs and broken bottles were found scattered around and even within the health centre.

### **Review of Sterilisation Practices**

The data emerging from all camps is very similar in that most of them, standards laid out by the central government are not being maintained.

*Quality issues:* The doctors were not aware of the standards, and the quality of services provided was found to be poor in all locations. This results in hundreds of deaths, thousands of repeat pregnancies and hundreds of thousands of chronic complications. In reply to a question<sup>1</sup> on standards of care in parliament in 2003, the minister of state for health and family welfare had mentioned that quality parameters had been framed and disseminated to all levels. Our findings, however, do not provide substance to this claim.

*Legal dimensions:* The way sterilisation camps were conducted as witnessed in the study opens up a large number of legal issues. There is clear violation of the directions of the guidelines as well as violation of Section 90 of the Indian Penal Code relating to informed consent. The second legal issue concerns failure of tubectomy operation in itself. The Supreme Court, in a judgment<sup>2</sup> delivered on April 24, 2000, clearly stated that the doctor as well as the state must be held responsible if sterilisation fails on account of negligence. A third dimension is sterilisation-related severe morbidity and death as a result of medical negligence. The courts have ruled that in case of death after tubectomy, the state is responsible for the acts of its medical officers.<sup>3</sup>

*Human rights issues:* Coercive population control policies are known to violate human rights. This has been seen in Nazi Germany, in Sweden, in the US, as well as in India during the emergency period. However, there has been a sea change in approach as a result of the International Conference on Population and Development [Cairo 1994]. Contraception is now seen as a

subset of reproductive health, and human rights is considered one of its guiding principles.<sup>4</sup> However, the problem persists even today and in places like Peru and Slovakia sterilisation cases have been taken up in human rights courts.

*Way forward:* Tubectomy will continue to remain one of the most important contraceptives in India's family planning programme. The challenge is to provide this service safely to women and give them the option of choosing other services as well. In terms of national priority there needs to be a significant shift from the emphasis on tubectomy and terminal methods to increasing options and choices for spacing methods. Health workers should provide information on delaying and spacing children rather than terminal methods. Male involvement remains a huge and untapped area.

However, reducing the emphasis on tubectomy alone is not enough. The following suggestions are being made to improve quality and accountability of services and also ensure that women who do face some form of risk have the wherewithal to deal with what they see as misfortune.

*Wide dissemination of standards of care:* The standards of practice, which have been laid down with a considerable degree of detail, have to be adhered to. Copies of the guidelines must be available with all CHCs, PHCs as well as operating teams responsible for camp based sterilisation.

Pamphlets in the local language based on these guidelines should be distributed to leaders of local community-level groups and PRI institutions by the ANM and anganwadi workers. Posters summarising the norms should be prominently displayed at all PHCs and CHCs and other hospitals.

*Dealing with death, complications and failure:* There must be mandatory reporting of all sterilisation-related complications, failures and deaths. These figures must be published and discussed at the village/block/district-level PRI meetings. The ministry of health and family welfare in consultation with independent experts should set up acceptable risk levels for the operation, and an independent monitoring commission set up. The commission should also lay down clear criteria and norms for dealing with such exigencies, which should include compensation and essential medical follow-up support.

All women who undertake tubectomy should be covered under an insurance

scheme which will enable the compensation to be disbursed speedily. The insurance premium should be provided by the government. A small amount of premium per case can provide a reasonably large fund every year. This sum can be used for providing no-fault compensation to women who suffer from acceptable risks.

*Liability and punitive action:* There must be an independent enquiry into all reports of tubectomy-related deaths, and responsibility and liability assigned. It may be convenient to define what constitutes a tubectomy death, much in line with the definition of maternal death. In cases of negligence, doctors must be made liable and face punishment. According to the Supreme Court, the state itself also has responsibility for the negligence of its officers.

## Conclusion

The quality of sterilisation operations, especially that of tubectomy, is an important reproductive health concern. It affects 4.5-5 million women every year in India. These women are exposed to high failure rates, high rates of complication, and sadly, also to a high possibility of mortality. However, it is an area where there is widespread apathy. Women who undergo tubectomy contribute to the fulfilment of a national goal. These women through adoption of tubectomy contribute to the achievements of the family welfare department. Unfortunately, the health and well-being of these women is not a matter of concern either for the family welfare department authorities or for the doctors who perform these operations.

The study clearly highlights the fact that there is an urgent need to ensure that standards of care are implemented and some form of redressal mechanism established. This will not only enable poor women and their families to deal with the misfortune of a complicated operation, but will also go a long way towards ensuring quality compliance. This is perhaps the minimum that the state owes to some of its most vulnerable citizens. **EWJ**

## Notes

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1 Rajya Sabha Unstarred Question No 752 answered on 28.07.2003.

- 2 Supreme Court in State of Haryana v Santra ((2000) 5 *Supreme Court Cases* 182).
- 3 Achutrao Haribhau Khodwa v State of Maharashtra, 1996 Acc CJ 505: (AIR 1996 SCW919)
- 4 See Chapter 2 of Programme of Action of ICPD.

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