

COMMENT

Negligence in sterilisation: the changing legal regime

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Abstract

Negligence in a sterilisation operation is a crucial issue in a country like India where sterilisation operations form an important part of government programmes. This article seeks to highlight the medico-legal dilemmas that surround this issue, and the legal pronouncements on it. The article also deals with a recent policy initiative - the Family Planning Insurance Scheme - that has been formulated in this regard, its legal implications, and its impact on the medical fraternity as well as on society as a whole.

Negligence during a sterilisation operation has diverse implications for patients, ranging from serious health problems and threat to life to extreme economic hardships. The implications of such negligence are particularly grave because sterilisation operations such as tubectomies are elective, non-therapeutic interventions (1). In India, sterilisation is a primary method of family planning and birth control and is an integral part of the National Family Planning Programme. Hence, the law relating to negligence in such operations becomes even more crucial. Negligence during sterilisation procedures can have two major consequences: serious health hazards including death of the patient, and unwanted pregnancy. In either case, the patient and his/her family ultimately have to undergo severe mental agony and suffering, the varied nature of which is reflected on a case to case basis.

The Government of India has issued guidelines for sterilisation procedures in India. Sterilisation services are provided free of charge in government institutions. Guidelines have been issued from time to time by the government covering various aspects of sterilisation. These are: a) The age of the husband should not ordinarily be less than 25 years nor should it be over 50 years. b) The age of the wife should not be less than 20 years or more than 45 years. c) The motivated couple must have two living children at the time of operation. d) If the couple has three or more living children, the lower limit of age of husband or wife may be relaxed at the discretion of the operating surgeon. e) It is sufficient if the acceptor declares having obtained the consent of his / her spouse to undergo sterilisation operation without outside pressure, inducement or coercion, and that he /she knows that for all practical purposes, the operation is irreversible and also that the spouse has not been sterilised earlier.

However, studies in India by non-governmental organisations such as Healthwatch (2) indicate high rates of death and failure of the procedure as a consequence of not following the government guidelines.

In order to understand the extent to which the standard

practices recommended by the department of family welfare are being followed on the field, a study was conducted by Healthwatch UP-Bihar on reproductive and child health (RCH) camps in Uttar Pradesh between December 2002 and February 2003. The discrepancies included absence of proper counselling, no reading out of consent form, no adequate examination of patient's medical history, inadequate and insufficient medical equipment and non-conducive pre and post operative environment (1).

A 1999 study of failures of laparoscopic procedures conducted by the State Innovations in Family Planning Services Agency concluded that the failure rate was 4.7 per cent. Half the women covered in the study also suffered from post-operative complications (3). The situation becomes worse in the absence of an adequately supportive legal regime.

Ascertaining negligence

It is an established fact that no sterilisation operation can guarantee success and there are always instances when conception may occur despite the surgery and in the absence of any medical negligence (4). Hence, the fact that a woman after having undergone a sterilisation operation becomes pregnant and delivers a child does not imply that her surgeon is liable; the claim can be sustained only if there is proof of negligence on the part of the surgeon (5). The doctor will be held liable for negligence if the patient offered himself/herself for complete sterilisation and was assured after the operation that no child would be conceived (6).

Failure of sterilisation: judicial response

There have been a number of judicial decisions from courts across the country attempting to define the legal standards of negligence in sterilisation operations and the loss suffered by patients. The Supreme Court of India has recognised the economic implications of having an unwanted child, which could have been avoided had the sterilisation operation been successful. The court has set a precedent by recognising the liability of the doctor as well as of the government, which advocates family planning as a way of relieving a couple of an economic burden they may not be able to shoulder (6). The courts have also recognised and compensated the non-pecuniary injuries that might result from such negligence, such as mental trauma and distress. In one case the court ruled that the government was liable to pay compensation to a woman who had become pregnant after her husband underwent vasectomy and had to face humiliation, insult and torture as her

integrity was doubted by her husband and his family who were led to believe that after the operation no child would be born (7). The courts have also granted compensation in instances of death of the patient during a sterilisation operation (8) and when severe complications arose after the operation (9).

The family planning insurance scheme

While it is apparent that the judiciary has been taking a reasonably pro-active stand in matters related to negligent sterilisation operations, the government had been more or less inactive in this matter until recently. One of the most significant steps in constructing a more supportive regulatory regime for victims of negligence in case of sterilisation operations is the Family Planning Insurance Scheme which was launched in 2005 (10). The scheme was launched in response to the exhaustive directives issued by the Supreme Court in its order dated March 1, 2005 in Civil Writ Petition No 209/2003 (*Ramakant Rai v. Union of India*) where it directed the Union of India and States/UTs to ensure enforcement of the union government's guidelines for conducting sterilisation procedures and norms for bringing about uniformity in sterilisation procedures (10).

Before the launch of this scheme, no compensation was payable for failure of sterilisation, and no indemnity cover was provided to doctors or health facilities providing professional services for conducting sterilisation procedures etc. The scheme does away with the complicated process of ex-gratia payment to those who suffered from post-operative complications, incapacitation or death attributable to the procedure of sterilisation.

The scheme grants a patient (or family as applicable) compensation of Rs 1 lakh in case of death due to sterilisation while in hospital, Rs 30,000 in case of death due to sterilisation within 30 days of discharge from hospital, a maximum of Rs 20,000 to cover expenses for treatment of medical complications due to the sterilisation operation (within 60 days of the operation) and Rs 20,000 in case of failure of sterilisation (including first instance of conception after sterilisation) (10). The scheme thus covers all sorts of damages that may be suffered by the victims of negligence during sterilisation operations.

Under the scheme all doctors/health facilities including doctors/health facilities of central, state, local-self governments bodies, other public sectors, and all accredited doctors/health facilities of non-government and private sectors rendering family planning services and conducting such operations shall stand indemnified against the claims arising out of failure of the sterilisation procedure, death or medical complication resulting from it, up to a maximum amount of Rs 2 lakh per doctor/health facility per case. The cover also includes the legal

costs and actual modality of defending the prosecuted doctor/health facility in court, which would be borne by the insurance company within certain limits.

Liability of the insurance company under this section would be limited to four cases of negligence per doctor, beyond which the doctor/health facility concerned would be himself/herself responsible for his/her lapse, apart from any other action that may be taken by the government against the doctor/health facility.

This was essential because doctors/health facilities were reluctant to conduct sterilisation operations fearing litigation if the procedure failed. The scheme provides an essential safeguard to ensure doctors participate in the sterilisation programme, which is essential for the success of the population policy in the country.

Conclusion

The adequacy of these measures is still under scrutiny and the quantum of compensation provided will inevitably be questioned. However, the insurance scheme is to be appreciated for removing the ambiguity and uncertainty of the law in this regard to quite an extent. The scheme provides for a uniform legal framework to deal with the issue of negligence in sterilisation procedures considering the ambiguity that has resulted from the wide range of judicial opinions in various courts across the country. The scheme presents a balanced approach and recognises the limitations of doctors and provides them with a reasonable safeguard. It is also crucial because it recognises the problems of the victims of negligence and makes an attempt to create a reasonably favourable legal regime for them too.

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