Working Group on Sterilization
Review of Gudielines

As background review, we at CEHAT have conducted a comparative analysis of sterilization guidelines issued by the Govt. Of India, Govt. Of Maharshtra, Municipal Corporation of Greater Mumbai and International standards set forth by WHO and FIGO.

- Circulars studied include those we could obtain from Dr. Nikhil Datar. These are issued by the Directorate of Health Services [DHS], Govt. of Maharashtra and the Municipal Corporation of Greater Mumbai. In our analysis, we have focused on circulars that were issued after the year 2000.

- Review of National Guidelines includes:
  - "Standards for Female and Male Sterilization Services" issued by the MOHFW, Govt. Of India; October 2006
  - "Standard Operating Procedures for Sterilization Services in Camps" issued by MOHFW, Govt. Of India, March 2008
  - "Quality Assurance Manual for Sterilization Services" issued by the MOHFW, Govt. Of India; October 2006
  - "Operational Guidelines for FDS [Fixed-Day Static] Approach for Sterilization Services" issued by the MOHFW, Govt. Of India; November 2008
  - "Manual for Family Planning Insurance Scheme" Implemented by MOHFW, 2011.

A. Informed Consent

Criteria	Circulars	National Guidelines	Issues/Comments
Informed Consent Form	MCGM, 2009 1. No clause on Vasectomy even though informed consent form is for both men and women (E5). 2. Counsellor [can be any health personnel including doctor] is required to sign the undertaking which	1. Clause on Vasectomy states that "I understand that vasectomy does not result in immediate sterilization. *I agree to come for semen analysis three months after the operation to confirm the success of	• There are unexplained variations between the consent form mandated by the national guidelines and that provided by the state circular. • While compensation for failure is mentioned in the consent form, that for death or complications is not. •

	additionally states that: "Shri/Smt….*has been explained other methods of contraception available and the failures associated with other methods have been fully explained*" 3. No compensation mentioned for complications and death.	the sterilization surgery (azoospermia), failing which I shall be responsible for the consequences, if any." 2. No mention of failure rates of other contraception in National guidelines 3. There is a mention that compensation for complications including that for failure.	
<u>Issues related to Post-partum sterilization, and sterilization concurrent with MTP/C-section</u>	No guidelines for consent while doing TL with C-section or MTP.	No guidelines for consent while doing TL with C-section or MTP.	There are no specific guidelines for consent/counseling for doing TL with a normal delivery or C-section even though these procedures are performed commonly. The child's health, whether he/she dies or lives, may have an effect on the woman's choice to undergo sterilization and these must be considered. Further, MTP and TL are often performed concurrently and consent for this is sought prior to abortion. However, FIGO guidelines say that consent should not be requested when the woman is in a vulnerable position such as when seeking to terminate a pregnancy or in the aftermath of pregnancy. WHO guidelines: *"Immediate postpartum sterilization may have some advantages, but the chance that a woman will regret her previous decision after*

			undergoing sterilization is higher with women who undergo the procedure at this time, especially in cases of a child's illness or death or a change in marital status. Proper counselling is very important…Research suggests that regret after postpartum sterilization may be more common among younger women (less than 30 to 35 years old), women with few children, and those having caesarean sections. For postpartum clients with medical problems or for those who do not wish a permanent method, other long-term options exist. The IUD and Norplant may be inserted during the immediate postpartum." FIGO: *"Women's consent to sterilization should not be made a condition of access to medical care, such as HIV/ AIDS treatment, natural or cesarean delivery, or abortion, or of any benefit such as medical insurance, social assistance, employment or release from an institution. In addition, consent to sterilization should not be requested when women may be vulnerable, such as when requesting termination of pregnancy, going into labor or in the aftermath of delivery."*
<u>Consent of the Spouse</u>	The consent form issued by MCGM (2009) asks only for the acceptor's signature.	National Guidelines too require only the consent of the acceptor, not that of the spouse.	However, article 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, says that any procedure that results in sterility the consent of both husband and wife is required. As a result of this, the ICOG-FOGSI

			recommendation is that the signature of the client is required and that of the spouse is 'preferable'.
Mentally ill clients	No specific direction for mentally ill clients.	"Mentally ill clients must be certified by a psychiatrist, and a statement should be given by the legal guardian/spouse regarding the soundness of the client's state of mind."	What is meant by 'mentally ill'? How can the legal guardian/spouse be allowed to give consent? Need for guidelines in these cases.
Incentive for Motivator	Amount to be received by motivator is mentioned, for both public and private facilities.	Amount to be received by motivator is mentioned, for both public and private facilities.	Incentives provided to motivators provide scope for coercion, particularly when there are no incentives for other forms of contraception. Although the guidelines, consent form etc do mandate counseling and provision of choices of contraception, the tone of circulars is one that pushes for more sterilizations to be performed. For instance, one circular states that *"In every family, after they have 2 living children-advise sterilization. After 2 children, the sterilization rates should be 80-100%."*

B. Eligibility of Providers

<table>
<tr><th>Criteria</th><th>Circulars</th><th>National Guidelines</th><th>Issues</th></tr>
<tr>
<td>Eligibility of providers</td>
<td>. Circular issued by ADHS, F.W.M.C.H. and S.H. Pune on 30/10/2006

• MBBS doctor can conduct mini-lap, abdominal tubectomy or routine vasectomy after 5 years of practice and training in any civil hospital/ medical college hospital/private teaching hospital.

• M.B.B.S. doctor CAN perform laparoscopic tubectomy.

• MBBS doctor can conduct NSV [no scalpel vasectomy] after 5 years of practice and NSV training in any civil hospital/ medical college /private training hospital.

• The doctor with D.G.O., M.D. (General Surgery) can conduct laparoscopic sterilization operation only after completion of Phase-I, Phase –II training in recognized hospital.

. Guidelines issued by the GoM-</td>
<td>a. As per the “ Standards for Female and Male Sterilization Services” issued by MOHFW, GoI; October 2006:

Female Sterilization:
<table>
<tr><th>Service</th><th>Basic qualification requirement of provider</th></tr>
<tr><td>Minilap services</td><td>Trained MBBS doctor</td></tr>
<tr><td>Laparoscopic sterilization</td><td>DGO, MD(Obs/Gyn), MS (Surgery) (trained in laparoscopic sterilization)</td></tr>
</table>
• Male Sterilization:
<table>
<tr><th>Service</th><th>Basic qualification requirement of provider</th></tr>
<tr><td>Conventional vasectomy</td><td>Trained MBBS doctor</td></tr>
<tr><td>No-scalpel vasectomy</td><td>Trained MBBS doctor</td></tr>
</table>
b. As per Annexure 13 of “Operational Guidelines for FDS Approach in Sterilization Services;” issued by MOHFW, GoI; November 2008
The nature of trainees for laparoscopic training includes a team comprising gynecologist/ surgeon (of 3 years’</td>
<td>• Ambiguities and contradictions exist in the National guidelines itself, resulting in varied interpretations by individual State stakeholders, as well as potential for confusion among providers.

• Unclear why MD [Obs/Gyn] who are expected to receive training in laparoscopic procedures during their residency require additional training.

• State guidelines in addition to not adhering to national standards, lack insight wherein a MBBS doctor is allowed to perform laparoscopic sterilization, while a DGO/ MD [Gen. Surgery] requires training in the same.</td>
</tr>
</table>

	Public Health Dept. on 29/4/2005 to comply with Supreme Court orders to all States on 1st March 2005 Doctors having post-graduate qualification as M.D. Obstetrics and Gynecology or D.G.O are competent to perform routine vasectomies, minilap tubectomies and laparoscopic sterilizations. Doctors having postgraduate qualification as M.S. General Surgery are competent to perform laparoscopic sterilizations only after the specified training. They can however perform other procedures listed above. Doctors with M.B.B.S. degree can perform routine vasectomies, non-scalpel vasectomies and minilap tubectomies only after the prescribed training and have 5 years experience. Laparoscopic sterilizations cannot be carried out by M.B.B.S. doctors. . Circular issued by DHS, GoM	standing) who is already performing or who is trained in Minilap, and OT Nurse and OT technician . As per "Quality Assurance Manual for Sterilization Services" issued by MOHFW, GoI; October 2006 • Female sterilization by minilap tubectomy should be performed by a trained MBBS/ post graduate doctor. • Laparoscopic sterilization for females should be performed by a gynaecologist with DGO/MD/MS qualification or by a surgeon with an MS degree; these doctors should be trained in laparoscopic sterilization. • Male sterilization procedures, both conventional vasectomy and no-scalpel vasectomy (NSV), should be performed by a trained MBBS doctor/or a post graduate doctor.	

	on 27/10/2007 For performing NSV/Vasectomy:MBBS + 5 years experience is required as per Supreme Court orders.		
Training plan	Guidelines issued by DHS, GoM to District Health Officers, District Civil Surgeons and Medical Officers; 2000 • Permanent medical officers should be trained in tubectomy within 4 months and such training should be organized. • For medical officers who have received training but are hesitant to perform tubectomies, they should be given the opportunity to work with experts in tubectomy, and learn from them. Despite this, if they refuse to do tubectomy, they should be relieved of their duties and sent them to DHS for further orders. • Trained doctors who lack confidence should be sent again for training. • Medical officers who refuse to go for training should be		• Despite male sterilization being a relatively safer and easier procedure, female sterilization is being made the focus of family planning programs. 37% of women who have opted for any method of family planning have undergone sterilization themselves, and only 1% have had male sterilization done as the family planning method. The focus clearly needs to shift to counsel couples about the benefits and ease of vasectomy as a choice; and on training doctors in the same. • The nature of these guidelines is punitive and authoritarian with a single-pointed focus on increasing the number of sterilizations, and not on quality per se.

	relieved from their duties, and sent to DHS for further orders. • All MBBS, general surgeons, gynecologists, medical officers will have to perform tubectomies. It is binding on them as per DHS order. • Retd. Medical officers who received training of tubectomy can perform tubectomy after their retirement.		

C. Timing and Selection of Procedure, and Case Selection

Criteria	Circulars	National Guidelines	Issues/ Concerns
Timing & Selection of Procedure	a. Circular issued by DHS, GoM; 2/4/2004 • Not to perform laparoscopic sterilization with first trimester MTPs/abortions/for 6 weeks after delivery. • The institutions which desire to seek permission for performing MTP with laparoscopic sterilization should send application to the DGHS. Permission can be granted after inspection by the committee of experts consisting of representatives from the Govt., FOGSI and FPAI. • No individual practitioner will be granted permission but only a hospital, institution	**Interval sterilization** should be performed within 7 days of the menstrual period (in the follicular phase of the menstrual cycle). **Post-partum sterilization** should be done after 24 hours up to 7 days of delivery. **Sterilization with medical termination of pregnancy (MTP)** can be performed concurrently. **Sterilization following**	• National guidelines lack clear directions for when Minilap TL is to be performed/not; and when laparoscopic TL is the preferred procedure. • State guidelines do not provide basis for why certain procedures are not to be performed during the given period or at a particular institution. They appear ad-hoc in response to complications/ deaths, rather than being based on

	having a number of specialists will be considered. • Before giving the permission, the HOD Gyn-Obs, and also the head of the institution should give an undertaking that in case of any death or complication, they will be liable for legal action with payment of compensation to the deceased. b. <u>DHS, GoM guidelines; 21/10/2003</u> • Laparoscopic sterilization should be discontinued at PHCs. It may be continued at rural/cottage hospitals/corp. hospitals if only all the facilities are available. • Laparoscopic sterilizations with MTP/abortion/delivery should not be performed at any health institution including medical colleges/private hospitals during camps. • Laparoscopic sterilizations should not be performed for up to 6 weeks after delivery and 2^{nd} trimester abortions/MTPs in all health institutions including medical colleges and private hospitals. • Laparoscopic sterilization with 1^{st} trimester abortion/ MTP may be performed only in government medical colleges in routine and not during camps. • Abdominal tubectomy should be performed 48 hours after delivery.	**spontaneous abortion** can be performed provided the client fulfils the medical eligibility criteria. **Laparoscopic tubal ligation should not be done concurrently with second-trimester abortion and in the post-partum period**.	scientific evidence. • As per the State guidelines institutions are granted permission to perform MTP with laparoscopic sterilization. However, an empanelled surgeon may not be granted permission for the same in a particular institution, and may require to seek separate permission to perform the same surgery in a different institution. • Contradictions exist between National and State guidelines, and within State guidelines themselves. • National guidelines lack protocols for sterilization in case of non-institutional delivery, cesarean section and re-sterilization.

	c. Circular issued by DHS to Health Officers, MCGM; 2001 • Laparoscopic tubectomy should be performed at least 6 weeks after delivery. If MTP has been done, then minilap tubectomy will be appropriate. • Non-institutional delivery: After 6 weeks sterilization can be performed. The beneficiary should receive 2 TT doses and to prevent infections, antibiotics are to be given. • Sterilization should be done within 7 days after the menstrual periods. d. State Family Welfare Office; 1995 • For re-sterilization [after failed] preference is to be given to mini-lap tubectomy.		
Case selection		• Clients should be married (including ever-married). • The couple should have at least one child whose age is above one year unless the sterilization is medically indicated.	• No scope exists in National guidelines for sterilization as a contraceptive choice of in unmarried/ nulliparous women. It is not clear if practitioners are simply to refuse such women. • National guidelines do not advise extra caution in young women, with emphasis on counseling about the permanency of sterilization and the

			availability of alternative, long-term, highly effective methods. Caution has been advised as per WHO guidelines due to higher incidence of regret and request for reversal in this age group. Given that the median age for sterilization in Maharashtra is 26 years, it would be important to stress this point.

D. Guidelines related to Pre-op, Procedural and Post-op issues with Sterilization

Criteria	Circulars	National Guidelines	Issues/ Concerns
Admission	Beneficiary should be admitted one day before the surgery. [Circular issued by State Family Welfare Dept., Pune on 6/6/2009]	Prior to the surgery, compilation of the client's medical history, physical examination, and laboratory investigations need to be done in order to ensure the eligibility of the client for surgery. It is essential to ensure that the consent for surgery is voluntary and well informed. However, no specific guidelines are provided on whether/ when the beneficiary is to be admitted.	Increasingly sterilization is being done as a day surgery, not requiring admission. The national guidelines do not state if the beneficiary is to be admitted. It is not clear if the State guidelines issued in 2009 should override the National guidelines [2006], and there may be ambiguity for practitioners on the protocol to be followed.
Anesthesia	• Local anesthesia should be used for family planning sterilization. Xylocaine [lignocaine] and penicillin sensitivity test to be done before surgery and documented on case papers.	• Skin sensitivity testing for local anaesthetic agent (lignocaine) has no established predictive value for anaphylactic reaction. Therefore, it is not mandatory to perform a skin sensitivity test prior to infiltration	• Contradiction exists between State and National guidelines regarding sensitivity testing for local anesthetic and dosage/use of lignocaine.

	• Use only 1% xylocaine for local anesthesia. [Circular issued by State Family Welfare Dept., Pune on 6/6/2009]	of lignocaine. • Lignocaine without adrenaline is the local anaesthetic that is to be infiltrated on the OT table. The maximum dosage is 3 mg per kg body weight. • General Anaesthesia: This is rarely necessary. However, it may be required in the following conditions: • Non-cooperative patient • Excessive obesity • History of allergy to local anesthetic drugs	• State guidelines do not explicitly state conditions when use of general anesthesia may be acceptable.
Discharge	• Patients should be hospitalized for 7 days after abdominal tubectomy, till stitches are removed for proper healing. [DHS, GoM guidelines: 21/10/2003] • The beneficiary is to be examined daily after sterilization in the morning and evening; findings to be noted and treatment/ dressing given. After mini-lap tubectomy, the wound should be examined on the 7th day and then only the patient should be discharged. [Circular issued by DHS, GoM to	The client may be discharged when the following conditions are met: • After at least 4 hours of procedure, when the vital signs are stable and the client is fully awake, has passed urine, and can walk, drink or talk. • The client has been seen and evaluated by the doctor. Whenever necessary, the client should be kept overnight at the facility. • The client must be advised to: • Return home and rest for the remainder of the day. • Keep the incision area clean and dry. Do not disturb or open the dressing.	National guidelines clearly do not require that beneficiaries be kept admitted after the procedure. Even though the State guidelines have been issued prior to the National guidelines coming into force, there is no circular to that effect of the protocol to be followed post-2005.

	Health Officers, MCGM, 2001] • Post-lap sterilization, the patient should be kept under observation for 24 hours. Do not give discharge before that or send the beneficiary home. [DHS, GoM guidelines, 2001]	• Bathe after 24 hours following the surgery. If the dressing becomes wet, it should be changed so that the incision area is kept dry until the stitches are removed.	
No. of surgeries	• Number of sterilizations cannot exceed more than 25 per surgeon per day. [Circular issued by State Family Welfare Dept., Pune on 6/6/2009] • For a single laparoscopic team, 2 laparoscopes should be available. 6 laparoscopic sterilizations should be done in 2 hours and 24 in 8 hours in a day by a single team as per guidelines from GoI dated 3/2/2003. [DHS, GoM guidelines: 21/10/2003]	• Estimation of likely number of clients to turn up for accessing services will help in determining number of teams for the camp. For maintaining quality service, each surgeon should restrict to conducting a maximum of: • 30 laparoscopic tubectomy (for 1 team with 3 laparoscopes) **OR** • 30 vasectomy (NSV or conventional) **OR** • 30 minilap tubectomy cases * With additional surgeons, support staff, instruments, equipment and supplies, the number of procedures per team may increase proportionately. However, the maximum number of procedures that are performed by a team in a day should not exceed 50. • Camp timings should preferably between 9 am and 4 pm.	• Contradictions between National and State guidelines regarding maximum no. of surgeries that can be performed by a surgeon, and the no.of laparoscopes to be available per operating team. • While National guidelines state the maximum no. of surgeries that can be performed per surgeon in a camp, they do not mention the maximum no. of surgeries per surgeon per day; as stated in the State guidelines. • As per the National guidelines, the maximum no. of surgeries per team should not cross 50/day with additional surgeons/staff/equipment available. However, the exact additional resources required to target 50 surgeries/ team is left to conjecture.

		• It is the responsibility of the camp manager [in-charge of the facility where the camp is being organized- sub-district hospital/FRU/CHC/PHC] to ensure the OT has been disinfected in advance and emergency medicines and other supplies are available at designated places. However the visiting team of surgeon/gynecologist is required to fill the checklist before conducting the procedure, signing that infection-prevention practices have been followed as per laid down standards.	• While the State guidelines state the no. of surgeries possible every 2 hours, given the constraints of equipment and autoclaving requirements; the National guidelines do not state how 30 surgeries/ surgeon would be possible in a 7 hour day from 9 am to 4 pm. • Person in-charge for a certain responsibility should be required to sign for it, that the given responsibility has been accomplished.
<u>Follow-up</u>	• After discharge, follow-up is to be done on an OPD basis or through home visits. • If the beneficiary is from another area, the medical officer/worker in that area should be informed about the case details and treatment in writing on the discharge card. • Health worker should visit the patient at home on the next day after sterilization/discharge and examine for any complaints. The medical officer of PHC should visit the patient of laparoscopic	• Follow-up contact with all tubectomy clients at home by the female health worker in a government health institution or reporting by the client to the clinic should be established within 48 hours of surgery. • The second follow-up should be done on the seventh post-operative day for the removal of stitches and post-operative check-up. A pelvic examination may be done, if indicated. • The third follow-up should be done after one month or after the client's	• Contradictions between National and State guidelines on protocol and responsibility for follow-up. • It is unclear how these follow-up requirements are to be adhered to in a large government hospital setting or private healthcare setting, given the existing staffing constraints.

	TL within 48 hours. • After a month or after the next menstrual period, another follow-up visit is to be made. [Circular issued by DHS, GoM to Health Officers, MCGM, 2001]	first menstrual period, whichever is earlier.	
Others	If the fallopian tubes are not found, this should be recorded and communicated to the patient in writing. In such a case, the patient should be taken to the nearest hospital, and the procedure should be performed. If this is not possible, explain clearly to the beneficiary in writing. [Circular issued by DHS, GoM to Health Officers, MCGM, 2001]	No guidelines are mentioned for protocol to be followed in such cases.	National guidelines lack directives for such situations.

E. Quality Assurance and Compensation for Death/Complications/Failures

Criteria	Circulars	National guidelines	Issues
Amount of Compensation	Compensation for death within 7 days of surgery is 2 lakhs and that for death between 8-30 days is 50,000.	Compensation for death within 7 days of surgery is 2 lakhs and that for death between 8-30 days is 50,000.	It is unclear why compensation for death within 0-7 days more than that within 8-30 days, if the death after 7 days is also resulting from the surgery.
Documents required to claim compensation	Consent form is required to claim compensation	Consent form required to claim compensation	While the consent form is required to claim compensation as per both State Circulars and National Guidelines, it is unclear if a copy of this form is to be provided to the client.
Providing MTP free of cost in cases of failure		1.6.3 states: “To detect failure leading to pregnancy at the earliest,	Contradiction within the National Guidelines regarding whether

		the client should be advised to report to the facility immediately after missed periods. The client should be offered MTP and repeat sterilization surgery or should be medically supported throughout the pregnancy if she so wishes." Annexure 4 (Informed Consent form) in the same document states: "*If, after the sterilization operation, I/my spouse experience (s) a missed menstrual cycle, then I/my spouse shall report within two weeks of the missed menstrual cycle to the doctor/health facility and may avail of the facility to get an MTP done free of cost.* *If I/my wife get (s) pregnant after the failure of the sterilization operation and if I am not able to get the foetus aborted within two weeks, then I will not be entitled to claim any compensation over and above the compensation offered under the Family Planning Insurance Scheme from any court of law in this regard or any other compensation for the upbringing of the child."*	MTP/medical support through pregnancy should be provided to clients who report after 2 weeks.

Role of QAC	No mention of regular audit in the QAC meeting minutes.	National guidelines specify the number of facilities and cases that are to be audited every quarter. Detailed checklist for this has also been provided.	All discussion in QAC meetings is around specific cases of complications, failures or deaths. Apart from investigating cases of death, failure and complications, facility and case audit is an important mandate of the QAC. As per the Supreme Court order, the role of the QAC is not just to investigate complications (although that is one way of quality control), but to ensure that pre- and post- guidelines are being implemented. Yet, it seems that focus on adherence to standards seems to come in only when a death is reported. For instance, in one meeting it was reported that a death had occurred in a camp where 55 sterilizations had been performed in one day [Minutes of State QAC meeting: 26/10/2005]. As a result, the committee recommended that the guidelines be re-circulated. However, no effort seems to be made to ensure that standards are being followed routinely and that deaths do not occur to begin with.
Indemnity for Doctors	No specific circular with mention of indemnity for doctors.	Provides for indemnity insurance for "doctors/facilities" for up to 4 cases a year.	It is unclear whether indemnity insurance for 4 cases is for an individual doctor or the facility.
Awareness generation about FPIS	No mention of awareness generation.	Mechanism for awareness generation includes only that for state agencies.	No systematic plan for awareness generation among clients.
Empanelment of Private Facilities	"*For sterilizations, 2 private hospitals in every group/Taluka*	No such mandate in National Guidelines. The National	Specific need for accrediting private hospitals in each Taluka is unclear.

	need to be authorized. If there is only one private hospital accredited in a Taluka, then neighboring Talukas must be seen for authorizing hospitals there." (Circular M9 - 13.12.07)	Guidelines only say that the State should prepare a district-wise panel of doctors who are authorized to carry out sterilizations.	
<u>Cost of care in private facilities</u>	(Circular M9 - 13.12.07) says *"It is the decision/choice of beneficiary to do in govt./private hospital. If done in authorized private center, no incentives will be offered. However, the surgery will be done for free. If beneficiary goes to private facility on their own, then they will receive the motivator amount."* Then goes on to say *"Authorized private facilities/NGO should display their authorization certificate, services provided by that facility, that no fee will be charged for sterilization, and the incentives for motivator. Should be easily visible. It is not binding on pvt./NGO facilities to give free care to above poverty line and SC/ST females for sterilization."*	Nothing regarding fees to be charged by Pvt facilities in National Guidelines.	Contradictions within the same circular regarding fee to be charged in private facilities.

Defining Complications	---	The National guidelines recognize 'complications' of sterilization as just those immediately related to the procedure such as stitch abscess, hematoma, intestinal obstruction, tetanus or incisional hernia – only those who are hospitalized are to be reported to the QAC and are eligible for compensation.	Others such as menstrual irregularities are not even recognized as impacts of sterilization! The national guidelines categorically dismiss them as "conditions not related to sterilization". There are two major problems with this: 1) These conditions may indeed be related to sterilization per se. Women actually narrate this as part of their experience, and it is not just their 'perception'. Subsequent infections may be a consequence of poor quality of care, infection control etc. Interestingly, 'psychological problems' are recognized as related to male sterilization, but not female sterilization. 2) Because the National Guidelines do not consider that these are related to sterilization, there is no effort made to report these. And since the QAC does not seem to do any facility or procedure audit to ensure infection control (except in case of death, complications or failure), there is a high chance that these complaints must be quite common, yet are not being recognized as related to sterilization!