A study of quality of care of sterilization services in Madhya Pradesh

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Abstract

Background: In a country with a high demand for contraception such as India, one of the most common methods is surgical sterilization, which is delivered by two approaches namely the camp approach and the fixed day static approach. The quality of services for sterilization in India for both the approaches has remained questionable. Objectives: This paper seeks to determine the quality of sterilization services at fixed day static centers of Madhya Pradesh. Methods: It was a descriptive observational study done between September 2017-December 2017 in 10 districts of Madhya Pradesh. One District Hospital and 2 Community Health Centers were randomly chosen from each district. The study was carried out using a prestructured, pretested, and prevalidated tool which used the Ona Platform. Results: Two of the facilities conducted more than 30 operations on the day of the visit. In only 18.3% of the cases was the patient informed about all contraception options. The duration between the start of surgery and the signing of consent was less than 2 h in 42% of the patients. The surgical protocol for proper surgical wear was not followed in most cases. Conclusion: The quality of care of sterilization services was found to be substandard in the fixed day static centers. The guidelines for the sterilization services were not being followed, and follow up of the patients was also neglected. Better training of the staff with strict and timely supervision is required for the better quality provision at the fixed day static centers.

Keywords: Fixed day static, Madhya Pradesh, quality of care, sterilization

Introduction

Background and problem statement

The burden of unplanned pregnancy and unmet needs of contraception is quite high in a developing country such as India, where sterilization remains the most familiar contraception choice, with a magnitude of 75.3% of the women undergoing the procedure. Owing to India’s mountain of a population, it has always been a big challenge to meet the demands of sterilization services numerically, and this has been tried to be catered to in the form of mostly camp approaches till recent times.

However, these approaches could barely satisfy the quantitative needs, and another bigger challenge rose up in the form of provision of quality service provision, at which the camps failed miserably, and a few years back a huge gap in the quality of services was highlighted when there were deaths in a certain sterilization camp due to substandard medicines and lack of following protocol in spite of well laid down standards for sterilization. Even the quality assurance guidelines are clearly dictated, but have not been followed which has led to many mishaps like these. Even basic necessities for the service provision is lacking in some areas of India.

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Received: 20-08-2020 Revised: 27-09-2020 Accepted: 14-10-2020 Published: 31-12-2020

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How to cite this article: Bali S, Yadav K, Alok Y. A study of quality of care of sterilization services in Madhya Pradesh. J Family Med Prim Care 2020;9:6005-11.
Measures to tackle the issue
The government of India laid down the provision of fixed static services in order to provide quality sterilization services in the country, and it was seen that they helped achieved replacement level fertility in the areas they were set up. However, in a study conducted by Achyut et al. it was found that there were unsatisfactory levels of hygiene, a severe want of staff and facilities, and a wanton disregard for protocol and patient care. Such findings warrant further studies in other parts of the country to assess the quality of care provided in the facilities of the state. The quality of care is an important determinant of the satisfaction and the trust that the populace has in the governmental facilities, as well as it is a measure of policy implementation at multiple levels. The provision of sterilization services at the primary health centers (those that have the provision), community health centers, and district hospitals is a fundamental requirement of primary health care as per the Indian Public Health Standards. It is relevant to the practice of primary care because this study addresses the issue of the lack of evidence based policy formulation for provision of quality sterilization services, especially in the state of Madhya Pradesh, where evidence on such topics is minimal.

Aim and Objective
To study the quality of sterilization services in selected static centers in Madhya Pradesh.

Methodology
Study design: Descriptive observational study which was executed as a cross-sectional survey of facilities by a team which observed the process of sterilization at the facilities starting from the preoperative period to the time of discharge of the patient.

Study period: September 2017 to December 2017 (a total of 4 months).

Sampling units: The sampling units in the study were healthcare facilities that provided the services of sterilization.

Study setting: The study took place in 10 districts of Madhya Pradesh that were randomly selected out of each of the 10 divisions of the State. Within each district, one district hospital and two randomly selected Community Health Centers were included in the study. These selected units provided sterilization services on a fixed day basis.

Sample Size: The total facilities selected for the study were 30 (10 district hospitals and 20 Community Health Centers).

Study team: The team consisted of one Principal Investigator and one Public Health Expert (MPH), and two field investigators (MSW) for collection and recording of field data.

Study tool: Data were collected using a pre-structured, pre-tested, and pre-validated tool. This tool was converted to a digital format and uploaded on the software Ona. Consent was taken from each center in-charge and beneficiaries if interviewed. The privacy of the data, its confidentiality, and the patient information was maintained to the highest degree possible.

Variables: To assess the quality of sterilization services the variables were broadly grouped into the following categories: details related to pre-operative examination of the clients, obtaining consent, observation of surgical procedure in OT, and utilization of personal protective devices.

Data analysis: The analysis of data was carried out using SPSS v21, and the results were reported in percentages, proportions, and graphs. Association between various independent variables was calculated using Pearson's Chi-square test.

Ethical Clearance: Ethical clearance was obtained from the Institutional Human Ethics Committee (IHEC). (LOP/2017/EF0069 dated 14th October 2017) Permissions from each district’s Chief Medical and Health Officers (CMHOs) were also taken prior to the visit of the selected facilities.

Results
Basic counts and observations
The study was done in 30 facilities in 10 randomly selected divisions of the state of Madhya Pradesh. In the present study, on the day of the visit, 384 clients were enrolled in 16 of the facilities. Nine facilities did not have any enrolment and five facilities had their cases postponed by the surgeon. About 29 patients were found unfit for the surgery owing to different causes. About 355 sterilization operations were carried out on the day of the visit, in which the research team could observe 306 operations.

Frequency of sterilization services
Most facilities (63%) had the provision of weekly sterilization services. Among the 10 district hospitals, a half of them provided daily and the others provided weekly sterilization services. Among the 20 CHCs, weekly services were being provided by 15 centers, 1 center was providing fortnightly and 4 facilities were giving monthly sterilization services to the clients.

Among all the facilities, five of the centers have conducted more than 30 sterilization procedures in a single day. Two of the facilities had conducted 56 and 58 cases in a day which is a significant finding.
Attending personnel

Regarding the main findings of the study, with respect to the accompanying person, most of the clients (71%) were accompanied by ASHA workers, about 18% by AWWs, 9% by ANMs, and 2% by other workers like LHV, AYUSH worker, etc. These workers acted as motivators and accompanied patients at each step of the sterilization process along with the family members and relatives.

Preoperative assessment protocol

With respect to the preoperative examination procedures, among 306 patients, about two thirds of the patients were assessed in the preoperative room. The preoperative examination was carried out in more than half of the cases by the staff nurse followed by the medical officer, the operating surgeon, and even the ANM. However, in only 18.3% of the patients was the client fully explained about all the contraceptive methods. In most cases, the ASHA was present during the physical examination of the clients apart from the doctor (56.9%). Regarding the examinations that were carried out during the physical assessment process, most women had a hemoglobin estimation and a urine pregnancy test carried out, and Blood Pressure and Pulse were examined in 76.5% and 84.6% of the patients. An abdominal examination was carried out in only 62.7% of the patients and a pelvic examination only in 20.3% of the patients. [Table 1]

Consent

Regarding the consent, the most common places of taking the consent were the waiting area (39.9%) and the pre-operative room (35.3%), however, a few consents were also obtained in the Operation Theater. The person who took the consent was most often the staff nurse (62.1%), followed by the ASHA, ANM, and even the OT Technician and other people. The Medical Officer only took consent in a very few cases. A relative was present with the patient at the time of taking the consent in 46.4% of the cases, and the ASHA was present in 36.3% of the cases. Only about 30.4% of the patients were explained about the consent in their local language. About 14% of the patients asked questions after the consent was explained to them. In most cases printed consent forms were available and all of them were in Hindi. A notable finding was that while 32% of the patients had a gap of 5 hours or more between the signing of the consent and the procedure, about 42.8% of the patients lay in the category of 0-2 hours duration between consent signing and the operation. [Table 2] The consent was signed by both the doctor and the patient in more than 70% of the cases. Another important thing to note here was that most of the patients did not, or only partly understood the process explained in the consent.

Observations inside the operation theater

During the observation of the surgical procedure in the operation theater, it was found that the door of the OT was shut in 13 facilities during the surgery, but in 3 facilities it was open and the entire procedure could be seen by an outsider. [Table 3] The OT was found to be overcrowded in 40% of the facilities. In 2 of the facilities there were non medical people going inside and outside the OT. In 3 facilities ASHAs and AWWs were also present inside the OT during the procedure. In 3 places (around 19%) sterilization procedures were undertaken even after 6 PM.

Adherence to protocol during surgery

With regards to the utilization of personal protective devices during the procedure, a general disregard for the standard norms was found. In most facilities, people were present inside the OT without the gown, and more than one-fourth of them also did not have the cap, mask and OT shoes. Also, the surgeon did not scrub again for another patient undergoing the procedure in 65.5% of the facilities as well as did not change gloves which are a very significant finding. In one of the facilities the surgeon left the OT in between the surgery. [Table 3] In most facilities patients were wearing surgical gown over their routine clothing. In some facilities it was observed that the clothing of the patients was unhygienic, yet the procedures were performed while patients were wearing them.

As per the observational findings, all surgeries that were observed were laparoscopic and the anaesthesia provided was local. The surgeon waited for 1 min after the painting of the area in about two thirds of the cases. Sterile drapes were used in all surgeries. In 94.4% of the surgeries, the patient winced in between the procedure. Most surgeries ended within 10 min. Only in about 11.1% cases, the insufflation apparatus was present, and the gas insufflation was carried out using mostly a hand pump, and in about one sixth of the cases a bicycle pump was also used.

| Category                  | Sub-category             | Number (%) |
|---------------------------|--------------------------|------------|
| Place for pre-operative assessment | Pre-operative room       | 196 (64.1%)|
|                           | OPD                      | 98 (32%)   |
|                           | Other                    | 12 (3.9%)  |
| Personnel who carried the pre-operative examination | Staff Nurse | 169 (55.2%)|
|                           | MO                       | 107 (35%)  |
|                           | Operating Surgeon        | 21 (6.9%)  |
|                           | ANM                      | 9 (2.9%)   |
| Client was explained fully about all contraceptive methods | ASHA                  | 174 (56.9%)|
|                           | ANM                      | 48 (15.7%) |
|                           | Staff Nurse              | 30 (9.8%)  |
|                           | AWW                      | 22 (7.2%)  |
|                           | Relative                 | 15 (4.9%)  |
|                           | Ward aaya                | 7 (2.3%)   |
|                           | None                     | 10 (3.3%)  |
| Examinations done during the preoperative assessment | Pulse                  | 259 (84.6%)|
|                           | BP                       | 234 (76.5%)|
|                           | Abdominal Examination    | 192 (62.7%)|
|                           | Pelvic Examination       | 62 (20.3%) |
|                           | Hemoglobin test          | 291 (95.1%)|
|                           | Urine pregnancy test     | 298 (97.4%)|
Regarding the cleaning of the laparoscope, in most cases it was immersed in cidex for less than 20 min (77%) which is again a very important finding, and in only 10.8% of the cases was the standard procedure followed. [Table 4]

**Postoperative observations**

With regards to the postoperative observations, the postoperative checkup was done and postoperative instruction was given in only in 68.8% of the facilities. Majority of the facility did not have a duty doctor/duty staff in the afternoon so the post op care mostly relied upon the ASHA/relatives, and at times the ANM. The average number of patients present in the postoperative ward was 19 patients among all the facilities. Men, children, other female members, ASHAs, ANMs, and other health workers were also present in the postoperative area, which can suggest and overcrowding of the postoperative area in most facilities.

**Quality assurance**

About 26 (86.7%) facilities have DQAC (District Quality Assurance Committee) team visit records of the past year. The visits were conducted by only some of the members of the committee, as well as there was no note of any recommendations. No reports that were supposed to be sent to the higher centers were found since one of the tasks of the committee is regular monthly reporting of indicators regarding sterilization to the state. On detailed examination, only 10 facilities had records of DQAC visit on the day of sterilization. The paperwork showed that only 2-4 members of the committee were present in the visit of that specific center in the previous 6 months. There was no facility that was visited by a complete committee. The few suggestions given by the DQAC were general in nature and reiterated at the other centers. No specific comments were available.

### Table 2: Details related to the consent (n=306)

| Category                          | Sub-category       | Number (%)       |
|-----------------------------------|--------------------|------------------|
| Place of taking consent           | Waiting area       | 122 (39.9%)      |
|                                   | Pre-operative room | 108 (35.3%)      |
|                                   | OPD                | 66 (21.6%)       |
|                                   | OT                 | 10 (3.3%)        |
| Personnel who took consent        | Staff Nurse        | 190 (62.1%)      |
|                                   | ASHA               | 31 (10.1%)       |
|                                   | ANM                | 28 (9.2%)        |
|                                   | OT Technician      | 22 (7.2%)        |
|                                   | MO                 | 20 (6.5%)        |
|                                   | Other/AWW          | 15 (4.9%)        |
| Personnel present at time of consent | Relative      | 142 (46.4%)      |
|                                   | ASHA               | 111 (36.3%)      |
|                                   | Staff Nurse        | 22 (7.2%)        |
|                                   | Ward Aya           | 17 (5.6%)        |
|                                   | AWW                | 14 (4.6%)        |
| Client was explained about consent in local language | Yes | 93 (30.4%) |
| Language of consent form          | Hindi              | 306 (100%)       |
| Client asked question after the consent was explained | Yes | 45 (14.7%) |
| Printed consent forms             | Available          | 273 (89.2%)      |
| Interval between signing of consent and start of operation | <1 hour | 40 (13.1%) |
|                                   | 1 hour             | 65 (21.2%)       |
|                                   | 2 hours            | 26 (8.5%)        |
|                                   | 3 hours            | 33 (10.8%)       |
|                                   | 4 hours            | 44 (14.4%)       |
|                                   | 5 h and more       | 98 (32%)         |
| Consent signed by both client and doctor | Yes | 217 (70.9%) |
| Client understood the process explained in consent | No | 173 (56.5%) |
|                                   | Yes (partially)    | 73 (23.9%)       |
|                                   | Yes (fully)        | 60 (19.6%)       |
| Sterilization procedure           | Laparoscopy        | 306 (100%)       |

### Table 3: Observation of operation theater at facilities and utilization of personal protective devices by the staff (n=16)

| Variable                                      | Category          | Frequency, n (%) |
|-----------------------------------------------|-------------------|------------------|
| OT door Shut during the procedure             | Yes               | 13 (81.2%)       |
| Person from outside can see the inside of OT  | Yes               | 3 (18.8%)        |
| Non-medical person going in and out of OT     | Yes               | 2 (12.5%)        |
| Person present in OT during the procedure     | OT Staff Nurse    | 15 (93.8%)       |
|                                               | OT Technician     | 4 (25%)          |
|                                               | Aaya/Ward Boy     | 15 (93.3%)       |
|                                               | ANM               | 7 (43.8%)        |
|                                               | ASHA/AWW          | 3 (18.8%)        |
|                                               | Relative          | 0                |
| People were present in OT Without Gown        | Yes               | 9 (56.3%)        |
| People were present in Without OT Cap         | Yes               | 6 (37.5%)        |
| People were present in Without OT Mask        | Yes               | 4 (25%)          |
| People were present in Without OT shoe        | Yes               | 4 (25.5%)        |
| Surgeon and assistant did scrubbing before start surgery | Yes | 16 (100%)       |
| Surgeon Scrubbing Frequent                    | After 1-5 case    | 3 (18.8%)        |
|                                               | After more than 6 cases | 3 (18.8%)       |
|                                               | Did not Scrub again | 10 (65.5%)       |
| Surgeon and assistant leave the OT_B/W procedure | Yes           | 1 (6.3%)         |
|                                               | No                | 15 (95.7%)       |
Discussion

The present study aimed at analyzing the quality of care of sterilization services in the state of Madhya Pradesh. According to the Framework by Bruce J,[10] the six key elements that determine quality of services include: Method choice, information imparted to clients; technical skill; person to person relations; follow-up, and mechanisms maintaining continuity; and the appropriate constellation of services. The study is centripetal to these six points, and the findings are discussed with regards to these.

Choice of methods, Information Imparted to clients and Interpersonal relations

In the study, it was found that some of the facilities were conducting surgeries way above the recommended number in the guidelines given by the ministry of health and family welfare.[7] This act alone can lead to a serious compromise in the quality of services that are provided at the facility. Also it was seen that only about 18.3% of the clients were explained fully about all the methods of contraception that were available, and even the abdominal and pelvic examinations were carried out in a few patients only. The level of pre-surgery counselling and care given at the facility are minimal and substandard,[7,11,12] and amount to deprivation of knowledge and basic care to the patient, which could jeopardize the decision making capacity of the patients and may also introduce or augment a small degree of fear of the surgery among the patients. Similar situation has been documented in other studies done in Odisha and Bihar.[3,13] This is a serious matter that needs to be thoroughly investigated and rectified in order to improve the trust between the people and the public sector health facilities, and help the patients make decisions that comply with their satisfaction.

With regards to the consent, it was also found that the place of consent taking was in few cases, the OT. As per the personnel taking the consent, in some cases even the OT technician, the AWW took the consent, and the MO only took consent in very few cases. Also, most clients were not explained about the consent in their local language, hence most of them did not even understand the clauses in the consent. This shows that interpersonal interactions between health providers and clients – a key aspect of quality of care – are not emphasized. Similar findings are reported in a study done by Prakash RR, in his study in Chennai.[14] He reported that providers do not appear to prioritize informing clients about their test results as they consider this information useful for them clinically to make decisions about clients. This might be a missed opportunity as the act of sharing the results with clients can also build confidence and enhance interpersonal interaction.[14] Also we see that the duration between the start of surgery and the taking of consent is less than 4 h in many cases, which is similar to that reported by Pal et. al., and Prakash.[14,13]

Table 4: Distribution of observation of surgical procedure in operation theater at health care facility (n=306)

| Variable                                      | Category                  | Frequency n (%) |
|-----------------------------------------------|---------------------------|-----------------|
| Type of procedure                             | Tubectomy                 | 0               |
|                                               | Laparoscopic              | 306 (100%)      |
|                                               | Vasectomy                 | 0               |
|                                               | NSV                       | 0               |
| Type of anaesthesia                           | Local                     | 306 (100%)      |
|                                               | General                   | 0               |
|                                               | Spinal                    | 0               |
| Interval between injecting LA and starting surgery | <1 minute                | 59 (19.3%)      |
|                                               | 1-5 minute                | 204 (66.7%)     |
|                                               | 5-10 minute               | 39 (12.7%)      |
|                                               | More than 10 minute       | 4 (1.3%)        |
| After the scrubbing of skin, did the surgeon wait for at least 1 min | Yes                       | 197 (64.4%)    |
| Sterile drapes used                           | Yes                       | 306 (100%)      |
| Patient wince at any time during the operation | Yes                       | 289 (94.4%)    |
| Total duration of the surgery (from skin incision to skin closure) | <5 min                    | 3 (1%)          |
|                                               | 5-10 min                  | 284 (92.8%)     |
|                                               | 10-15 min                 | 6 (2%)          |
|                                               | More than 15 min          | 13 (4.2%)       |
| Gas insufflated                               | By Manual                 | 72 (23.5%)      |
|                                               | Insufflation Apparatus    | 34 (11.1%)      |
|                                               | Bicycle pump              | 57 (18.6%)      |
|                                               | Hand pump                 | 143 (46.7%)     |
| Laparoscope cleaned                           | Immersed in cidex for ≥20 min | 33 (10.8%) |
|                                               | Immersed in cidex for <20 min | 236 (77.1%) |
|                                               | Cleaned with antiseptic solution | 37 (12.1%) |
|                                               | Cleaned with water        | 0               |
Technical skills, adherence to guidelines, and services provided

During surgical procedures, the OT door has to be shut during the entire course of the operation, but in some cases this was not the case. Sometimes even the ASHAs and AWWs were present in the OT during the procedure which have no relation with the surgery. The staff was also without proper OT wear in most cases which is in concurrence with the findings of Achyut et al.[8] This could be due to lack of proper training of the staff.[9] In most cases the surgeon did not scrub again after a surgery and wore the same OT garments, or scrubbed after 6 or more surgeries. In one of the cases the surgeon even left the OT during the procedure. The nonconformance to standard surgical guidelines is also a concurrent finding in another studies,[16,17] (in less than 17% cases) and is a gross violation of surgical principles and conduct, also a blatant disregard for aseptic precautions which could lead to iatrogenic surgical site infections and transmission of diseases spreading from contact with infected blood to an otherwise healthy patient, which defeats the very purpose of healthcare provision.

The total time taken in most surgeries was 5-10 min, which could indicate the fact that in order to meet the patient load, the surgeries were being conducted in a very short time interval and some amount of quality might have been compromised. During the procedure it was also seen that patients winced at least one time during the procedure. The equipment used for gas insufflation for the patients was also not proper in many cases, and devices like hand pump and bicycle pump were used for insufflation of the abdomen instead of the proper apparatus. Also, the aseptic maintenance of surgical equipment was found to be substandard as the immersion of the apparatus was below the recommended time in most cases. This could be due to the fact that the surgeons has to complete the target within few hours so most of the cases instruments were not sterilized as per the standard.[9] This again is an outright violation of surgical principles as well as the operational guidelines and may lead to hospital borne infections which are resistant to most antibiotics and difficult to cure.

Follow up

It was seen that the follow up was also not proper in the facilities, which is reported in other studies as well.[9] This could be due to a high workload in the facilities, or lack of manpower. But the lack of follow up indicates a negligence about the effects of the surgery, and its success and failures, and documentation; all three of which put the establishment and the relation of the facility with the community at risk. Also, none of the facilities had a DQAC visit by a complete team, which indicates that there are lacunae in the supervising system as well. This is a concerning problem and needs to be corrected because the deficits will gradually increase over time and halt the healthcare delivery system eventually at the respective facility if the supervision is not up to the mark.

Strengths and limitations

The strengths of the study include its unique feature to be among the few studies that have been conducted regarding the quality of care in fixed day static sterilization services. Also, the results could be generalizable to some extent because of the inclusion of all the divisions of the state. The limitations of the study include its snapshot nature inherent in a cross sectional study and its limited ability to find the reasons for the above mentioned findings for which an extensive study of a qualitative nature must be conducted.

Conclusion and Recommendations

From the study we can see that the quality of care of sterilization services is grossly substandard in terms of patient information and consent, maintenance of surgical protocol, follow up and supervision. There is a need for better pre surgery counselling so that the patient’s choice is respected, for which training sessions could be conducted. Supervision has to be strict to see that the number of cases in a facility do not exceed the limit provided in the standards, and proper surgical protocol is followed, for which monthly supervision reports of the facilities can be published. Better training of the staff about the handling of the instruments and the conduct in the operation theater can be conducted. A behavioural change intervention could also prove useful in the long run. Lastly, policy makers and public health officers can modify existing policies through discussion with the providers and the community which would lead to a strong bond between the people and the public health facilities, and will lead to continuity of care.

Key points

In the study, the quality of care provided in the facilities that provided fixed day static sterilization services were found to be grossly inept. The problems identified by the study will help to improve the quality of services provided in the public health institutions at all levels of implementation so that better usage of these facilities takes place at the level of primary and secondary healthcare, and people begin to have faith in the services that the government provides them.

Acknowledgements

The authors would like to extend our gratitude to the Principal secretary, Commissioner, Mission Director, National Health Mission, Department of Public Health and Family Welfare, Government of Madhya Pradesh for administrative support.

The authors would also like to convey heartfelt thanks to Mrs. Kirti Iyengar, (National Programme Officer) and Dr. Nilesh Deshpande (State Programme Officer), United Nations Fund for Population Activities, India for their technical support.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have
given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

**Financial support and sponsorship**
UNFPA, Madhya Pradesh, India.

**Conflicts of interest**
There are no conflicts of interest.

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