



Research Article

**WORKFLOW MANAGEMENT AND STERILIZATION PROCEDURE IN CENTRAL STERILE SUPPLY DEPARTMENT (CSSD) OF A TEACHING HOSPITAL OF HARYANA**

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**ABSTRACT**

**Introduction-** Hospital-acquired infection remains the hospital's single most serious concern. CSSD ensures availability of reliably sterilized articles at the required time and place in the hospital as economically as possible, having regard to the need to conserve the time of users. **Aim and objectives-** This study was conducted with the aim of studying functioning, workflow and process of sterilization employed in CSSD of a teaching tertiary care institution of Haryana. **Material and methods-** This observational study was conducted in CSSD of a tertiary care teaching hospital of Haryana over a period of three months i.e. February 2018 to April 2018 using an observation checklist. Prior permission for the study was obtained from appropriate authorities. **Observations-** CSSD is centrally located in the hospital premises and has 11 staff members. Workflow ranges from receipt, cleaning, sorting, packing, sterilization and storage of articles. Steam sterilization and gas sterilization is performed by a total of seven autoclaves and 2 ETO machines. **Conclusion-** CSSD of the institution is contributing its part towards reduction of nosocomial infections and quality of standards for sterilization is well maintained. Staff must be provided refresher training to update them.

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**INTRODUCTION**

Despite the unprecedented advances made in the medical field, hospital-acquired infection remains the hospital's single most serious concern that negates some of its otherwise good work. Their impact ranges from increased length of hospital stay, emotional stress, disability, death of the patients as well as increased hospital cost for the patients as well as the providers. Studies in India have reported nosocomial infection rates ranging from 58% to 8% <sup>(1,2)</sup>. To combat this ubiquitous menace of infections caused by pathogenic micro-organisms, hospitals have over the years developed a scientific method commonly referred as Central Sterile Supply Department (CSSD). During the Second World War the British Army established a CSSD in Cairo for supply of sterile items to mobile units. In India, one of the earliest CSSDs was established by Safdarjung Hospital, Delhi and Christian Medical College, Vellore during 1957-60 <sup>(3)</sup>.

The objective of establishing a Central Sterile Supply Department is to make reliably sterilized articles available at the required time and place for any agreed purpose in the hospital as economically as possible, having regard to the need to conserve the time of users <sup>(4)</sup>.

Broadly, the functions of the department are to receive and sterilize used and unsterile supplies and sets from nursing units, OPD, operation theatres and labour rooms, to maintain an uninterrupted supply of bacteriologically safe supplies at all time, to impart training to hospital personnel in safe hospital practices and to provide advice to hospital administration on suitability of supplies and equipment from sterilization point of view <sup>(5)</sup>. Workflow management in CSSD ranges from receipt of articles, cleaning, assembly, packing, sterilization, storage, issue and distribution <sup>(6)</sup>.

The aims of CSSD are to maintain high quality of sterilization services and several indicators like mechanical indicators, chemical indicators and biological indicators are used to assess the quality of services.

Considering the paucity of similar studies in Haryana, this study was planned to evaluate the functioning, workflow and

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process of sterilization employed in CSSD of a teaching tertiary care hospital of Haryana.

## MATERIAL AND METHODS

The study was conducted in CSSD of a 1700 bedded tertiary care hospital of Haryana over a period of three months i.e. February 2018 to April 2018. An observation checklist based on CSSD standards prescribed by World Health Organization and the Ministry of Health and Family Welfare (MoHFW), Government of India. Prior permission was obtained from appropriate authority for conducting the study. The investigator visited the CSSD and collected data regarding infrastructure, staffing pattern, workflow management, items sterilized, process of sterilization, maintenance and quality control operation in CSSD. Confidentiality of information was maintained.

### Observations

The CSSD of the institution is situated on the ground floor of the hospital building, centrally located and convenient to all operation theatres and wards. Only restricted access is permitted. CSSD operates from 7 a.m. to 6 p.m. and also on Sundays and holidays.

There are a total of 11 staff members including the Incharge of CSSD, CSSD Supervisors, Sterilization Technician, Attendants, store keeper and other support staff. CSSD of the institution follows clean for dirty exchange system i.e. soiled items from the user department are replaced by another set of sterilized articles.

### Workflow in CSSD

- a. Receiving of items- Soiled items are received from user departments through receipt window and records are maintained by CSSD attendants. Precleaned linen is received from laundry and further sterilized. Staff wears gloves at the time of receipt of items but other personal protection equipments (PPEs) are not worn.
- b. Cleaning- Soiled instruments or instruments used in case of HIV/Hepatitis B patients are soaked in 1% sodium hypochlorite solution for 3 days in CSSD.
- c. Drying- Items are either air dried or dried within the drying cabinet.
- d. Packing- Linen is folded and packed in CSSD. Instrument trays are prepared. Plastic and rubber items are packed in paper before sterilization.
- e. Sterilization- Articles are sterilized either by steam sterilization (Autoclave) or gas sterilization (ETO machine).
- f. Storage- Sterilized articles are stored in racks located in sterile store. Racks are labeled according to the name of user departments. Records are maintained.
- g. Issue of sterile items- It is done through issue window. Record is maintained regarding number of items issued and person receiving it. Sterilized items are transported back over carbolized trolleys.

**Table 1** Equipments available in CSSD are as follows

S. No.	Name of equipment	Number
1	Gauze cutter	2
2	Autoclaves (Rectangular horizontal type)	7
3	Ethylene oxide sterilizer (8XL)	2
4	Work benches with marble or stainless steel top	
5	Storage cupboards and racks	34
6	Linen folding table	
7	Soaking sinks	2
8	Drying cabinets	1
9	Trolleys	10

**Table 2** List of items sterilized in CSSD

S. No.	Items	Numbers sterilized	Method of sterilization used
1	OT linen	27 packets/day	Washed linen is received from laundry and sterilized by steam sterilization
2	Bowls and trays	86/day	Steam sterilization
3	Dressing drums	6-8/day	Steam sterilization
4	Other item like dressing, sponges, gauze and cotton material		Steam sterilization
5	Ward articles	200/day	Steam or gas sterilization (depending upon the type of article)
6	Instruments	Rubber and plastic articles- 400/month	Gas sterilization
7	Gloves	Not reused	

### Methods of sterilization employed

*In the CSSD, two methods of sterilization are employed namely*

- a. Steam sterilization- It is done using autoclaves.
- b. Gas sterilization- Done by ETO (Ethylene oxide) machine using ethylene oxide gas.

**Autoclave (Steam sterilizer)-** There are seven rectangular horizontal type autoclaves. Ideally there must be one attendant for each autoclave but there are only two attendants in CSSD. Autoclaving is mainly done for metal instruments, trays, linen, dressing material and drums. Autoclave operates at three ranges of temperature which are-

- 121 to 124°C for minimum holding time of 18-20 minutes
- 126 to 129°C for minimum holding time of 8-10 minutes
- 134 to 138°C for minimum holding time of 3-5 minutes

Autoclave is operated mostly at a temperature of 121°C and 15lb/in<sup>2</sup> of pressure.

It is ensured that the autoclave is clean and dry before operation. Articles are packed inside double layer of linen and a chemical indicator is applied over the label. Clean, dry and packed articles are loaded in chamber, lid and safety lock is closed and steam inlet is opened. Steam reaches from the jacket to chamber (made of stainless steel). After completion of sterilization cycle, steam is allowed to drain and articles are allowed to cool. Later, sterilized articles are loaded on carbolized trolleys and transported to the sterile store. Shelf life of sterilized packs is 72 hours (if unwrapped). Record of autoclaving process is maintained till 10 years. Autoclave is

operated for 3-4 cycles per day depending upon the load. A large sized autoclave can sterilize approximately 27-30 packets/cycle while a small sized autoclave sterilizes 12-14 packets/cycle.

#### **Precautions and safety**

- It must be ensured that the lid of autoclave is not opened in between the cycle.
- Attendants must wash hands and wear PPE at the time of operations but CSSD staff was seen only wearing gloves among the PPEs.
- Autoclave label must change colour from green to brown/black after completion of sterilization cycle.

#### **Quality control/Sterilization checks**

Pre-vacuum is ensured by Bowie Dick test must be ideally performed daily. It consists of a series of air removal and steam penetration barriers. A uniform change of colour from yellow to blue/purple on the indicator sheet indicates that all air was removed and replaced by steam. Seven culture tubes with cotton plugs containing *Bacillus stearothermophilus* i.e. one culture tube for each autoclave are used for sterility checks. This is done weekly and these culture tubes are tested in Microbiology Department Laboratory for growth of any organism.

#### **ETO sterilizer (Ethylene oxide) /Gas sterilizer**

There are two ETO machine in the CSSD of the institution which are 8XL type. ETO machine must be ideally located in the clean zone of CSSD but due to space constraints, it has been kept in receiving area of CSSD (i.e. soiled zone). Gas sterilization is mainly done for heat sensitive and moisture sensitive articles like rubber and plastic goods. Article must be clean and dry before sterilization and packed in medical grade paper before placing into the sterilization chamber. ETO gas cylinder (170 grams) is inserted into the port. Air conditioner is switched on to remove excess heat generated during the process.

ETO machine operates at two ranges of temperature i.e. 37°C and 55°C at 450 mbar of pressure. The machine operates in three stages i.e. pre-conditioning stage, gas exposure stage and aeration stage. Pre-conditioning stage lasts for approximately 1 hour 20 minutes while the gas exposure stage is of 1.5 hours which also includes purge time of 45 minutes. No attempt should be made at opening the door of sterilization chamber during gas exposure stage because ethylene oxide gas leakage may pose many health risks (skin rash, carcinoma and even death). Finally, aeration stage is of 3 hours after which the door of sterilization chamber is opened. Gas exhaust is released through chimneys. Shelf life of sterilized packs is six months (if unwrapped). Record of autoclaving process is maintained till a period of three years.

#### **Precautions and safety**

- It must be ensured that the door of sterilization chamber is not opened.
- Hand washing is ensured before operations.
- Attendants must wear PPEs at the time of operations.

*Quality control* is ensured by biological indicator which is placed inside the sterilization chamber during the sterilization process and further tested in Microbiology Department Laboratory. Articles are distributed only when biological indicator tests negative for the presence of any microorganism.

#### **Process of storage and distribution of sterilized items**

Sterilized articles are stored in racks within the sterile store which are labeled according to name of user departments. Sterilized articles are distributed through the issue window of the CSSD and transported back to the user departments over carbolized trolleys.

#### **Return of unutilized packs**

If any sterilized pack is not utilized within the given time (3 days in case of autoclaved packs and 6 months in case of ETO sterilized packs) then it is returned back to CSSD where it undergoes the complete cycle of disinfection and sterilization.

#### **Other standard operational aspects followed in CSSD**

##### **Operating policy**

The CSSD of the institution has its own Standard Operating Procedures (SOPs) and operates accordingly.

##### **Recall procedure**

There is no mention of recall procedure in the SOPs of the CSSD.

##### **Biomedical Waste management**

The Colour coded bins are available and biomedical waste generated is disposed according to biomedical waste management guidelines

##### **Maintenance and repair of equipments**

Machineries are under Annual Maintenance Contract. Minor machinery faults are repaired by the workshop of the institution while in case of major ones, supplier repairs the equipments.

##### **Monitoring and evaluation**

Periodic internal audits and monitoring is performed by the Incharge and supervisor of CSSD. Yearly financial audits are undertaken to assess the utilization of budget. Records are maintained by the Store keeper.

## **DISCUSSION**

Recent advances in surgical techniques and the responsibility for the control of infections, have placed the CSSD in a prominent position within hospitals. It was common practice in the past to plan and provide autoclaves, boilers and sterilizers centrally for the main users but there was the ever present chance of tardy quality control because nursing staff could not devote full attention to these activities in addition to their direct patient care activities. Therefore, sterilization activities in a hospital are better centralized in one single department for efficiency and effectiveness. Sterilization is the complete destruction or removal of microorganisms, including bacterial spores while disinfection is destruction or removal of

microorganisms at a level that is not harmful to health and safe to handle <sup>(7)</sup>.

Shetty reported that steam sterilization (autoclave) was the only sterilization method practiced in the selected hospital of Mangalore.<sup>(8)</sup> CSSD of our institution not only practices steam sterilization but also gas sterilization. Utmost care is taken to maintain high quality standards in CSSD of our institution. Sakharkar states that the main equipment in the CSSD is the *autoclave* and at least one additional autoclave other than the main one should be provided to cater for failure or extra workload <sup>(9)</sup>. Autoclaves must function according to manufacturer's instruction, regularly cleaned and quality checks must be performed. In the CSSD of our institution, seven functional autoclaves are available which is quite a sufficient number. Autoclaves function according to SOPs of CSSD, regularly cleaned and quality checks of sterilized items are undertaken periodically.

Dunko *et al* in their study in USA reported that Bowie-Dick testing was reported to be performed at more than 90% of facilities, at least daily, after repairs and after shutdowns, respectively. <sup>(10)</sup> Bowie Dick Test must be ideally done daily in empty steam sterilizer at the beginning of operations to check for pre-vacuum but due to non-availability of test kits, this is not done daily in the CSSD of our institution. There is the need to focus upon logistic constraints to improve the standards and quality of sterilization operations.

Sakharkar recommends that CSSD attendants/operators must wear Personal Protective Equipments (PPEs) at the time of operations especially since ethylene oxide is poisonous gas but CSSD staff wears only gloves during working. Staff must be educated regarding the role of PPEs in prevention of occupational hazards. Precautions against ethylene oxide gas leak are taken by following strict protocol of uninterrupted completion of the whole sterilization cycle followed by the release of gas exhausts by chimney at the end. In our CSSD, there is strict monitoring of sterilization standards by ETO machine which is evident from the fact that the sterilized packs are issued/distributed only when the biological indicator tests negative for the presence of any microorganism. Shriyan *et al* in their study from Mangalore reported that almost all of the nurses were aware of the biological indicator though they did not know its name. There is need to educate the healthcare functionaries regarding sterilization and disinfection so as to reduce the prevalence of nosocomial infections. <sup>(11)</sup>

Though earlier gloves were recycled in our CSSD but now this operation has been discontinued. In a study conducted by Arora *et al* in a 1700 bedded teaching hospital of North India it was reported that that purchase of sterile disposable single-use gloves was cheaper than the process of recycling. Reprocessing of gloves was not economical on tangible terms even in resource-limited settings, and from the perspective of better infection control as well as health-care worker safety.<sup>(12)</sup> There is no mention of recall procedure in SOPs of CSSD. Recall procedures are of utmost significance in case of sterilization failure and must specify who to report first in case of failure of sterilization, actions to be undertaken (i.e. recall of whole batch of issued items within the given time frame) and format for recall report.

It may be emphasized that there is a need of conducting regular external audits i.e. apart from staff of CSSD; staff of user departments, administrative staff and senior health officials may be involved. External audits may provide a clearer unbiased picture of operations of CSSD and thus help in overall quality improvement.

## CONCLUSION AND RECOMMENDATIONS

Nosocomial infection cause significant health issues and economic loss to the patients as well as the health care facilities. CSSD ensures that reliably sterilized articles available at the required time and place. An efficient CSSD not only improves patient outcomes and reputation of the institution but also reduces the wastage of healthcare expenditure. CSSD of our institution is contributing its part towards reduction of nosocomial infections. Articles are sterilized using steam sterilization (autoclave) and gas sterilization (ETO). Quality of standards for sterilization and disinfection are well maintained and physical, chemical and biological indicators are regularly employed. Staff must be provided refresher training to update them regarding the advancements in the field of infection control.

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