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INTRODUCTION
The Central Sterile Supply Department (CSSD) is defined as a technical support unit whose purpose is to provide appropriately-processed medical-hospital articles, thus providing conditions for direct attendance and health care provision for ill and healthy individuals.1 Central Sterilization and Supplies Department (CSSD), has its importance in prevention of cross infection in hospitals. An effective functioning of CSSD will reduce the HAI traceable to use of instruments on patients’ care. For this CSSD must follow standard practices in its sterilization and supplies operations. The department is responsible for cleaning, decontamination and sterilization of all reusable instruments and supplies. Defects in sterilization can lead to catastrophic consequences and economic burden2.

OBJECTIVE
The objective of this study was to describe and analyze the quality indicators used in the CSSDs of Multispecialty Public and Private Hospital in Delhi NCR and suggest corrective measure to improve.

METHOD
Quality control of CSSD is prime importance in controlling hospital infection. The various parameters of CSSD like infrastructure, process and various validated quality indicators were checked on ground from data and interview with key personals of both hospitals. Data collection was undertaken in the period of Jan to Dec 2018 in two hospitals which had given authorization in the time period stipulated. All of the interviewees signed the Terms of Free and Informed Consent. The data was compiled and analyzed. The gap was studied and recommendation given to hospital for further improvement.

RESULTS
Both Hospitals were well equipped modern central sterilization and supply department (CSSD), which caters to the needs of patients and health care workers in the hospital. CSSD is the nerve center of the hospitals which ensure safety to the patients who are undergoing various surgical and non surgical procedures in the hospital. The sample studied was characterized as Large-Size Hospitals with structure and capacity directed at higher complexity care, showing us that its organization was initially devised with quality in mind. Both hospitals were approximately 500 bedded with adequate infrastructure as shown in Table 1.

Table 1: Infrastructure and process characteristics of CSSD of Hospital

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Public Hospital</th>
<th>Private Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of beds</td>
<td>500</td>
<td>510</td>
</tr>
<tr>
<td>No of Surgery beds</td>
<td>50</td>
<td>60</td>
</tr>
<tr>
<td>No of ICU beds</td>
<td>24</td>
<td>32</td>
</tr>
<tr>
<td>Number of worker in CSSD</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>Area of CSSD</td>
<td>900 Sq Ft</td>
<td>1200 Sq Ft</td>
</tr>
</tbody>
</table>

EVALUATION OF QUALITY CONTROL IN CSSD IN PUBLIC AND PVT MULTISPECIALTY HOSPITAL IN DELHI NCR

KEYWORDS

- Infrastructure
- Location of CSSD
- Entry to CSSD
- Layout of CSSD
- Sterilization zone
- Storage zone
- Zone transition
- Equipment
- Processes
- SOP documentation
- Sterilization
- Disinfection
- Cleaning

<table>
<thead>
<tr>
<th>Infrastructure</th>
<th>Located in a delineated area where there is less or no external traffic movement.</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of CSSD</td>
<td>Should be either close to OT or should be connected to OT with safe &amp; quick transfer mechanism, like dumbwaiters.</td>
<td>Yes, manual transfer mechanism</td>
<td>quick transfer mechanism + +</td>
</tr>
<tr>
<td>Entry to CSSD</td>
<td>Should be restricted to only staff working in CSSD</td>
<td>Yes</td>
<td>But not so strict</td>
</tr>
<tr>
<td>Zones</td>
<td>Must lead to unidirectional movement of people and supplies.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Entry to sterile zone</td>
<td>Should be after taking necessary infection control precautions such as hand washing, wearing of gowns/aprons, gloves etc.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>The sterilization zone (specially storage)</td>
<td>Should have a higher air pressure to prevent outside air to enter in this area</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Emergency exit route</td>
<td>Should be identified and displayed</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Equipment: CSSD</td>
<td>Should have required sterilization and cleaning equipment in well-functioning condition.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Processes

- SOP should be documented for each activity done in CSSD. These activities include
  - Procedure of cleaning
  - Procedure of packing

- SOP should be documented for each activity done in CSSD. These activities include
  - Procedure of cleaning
  - Procedure of packing
  - Procedure of disinfection
  - Procedure of sterilization (separate SOP for each type of sterilization equipment)
  - Procedure of storage and issue
    - Safety precautions and guidelines

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A policy should be there on reusable devices/items which specifies following:
- List of items that can be re-used (items not in list should automatically be considered, non-reusable).
- Number of times it can be re-used.
- On whom can it be re-used (like on same patient or on different patient).
- Processing required before reuse of the items.

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Staff in patient care areas who receive CSSD supplies must know following:
- About the labels on sterile packs, specially expiry date.
- Storage condition that should be maintained.
- Condition under which sterile packs must not be used.
- What to do in case a sterile pack has been recalled.
- How to send soiled/used items.

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Sterilization by saturated steam under pressure:

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Chemical Indicator</th>
<th>Biological Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Ethylene oxide</td>
<td>Geobacillus</td>
</tr>
</tbody>
</table>

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Both hospitals are using physical and chemical monitoring system. The physical monitoring system was depends upon sterilization time, temperature, and pressure. In daily work practice, this monitoring was performed by visual inspection of the gauge-glass in an analog meter, via a program-linked control (PLC system), or with an automatic printout mechanism. The system was calibrated by inserting thermocouples inside the chamber or using a data logger with the manufacturer's predetermined specifications. The data printouts from each sterilizer were documented in the register along with the data for other items sterilized in the same load.

The chemical monitoring system were composed of a set of various indicators based on specific requirements such as equipment monitoring (Bowie-Dick test pack, Class II CI), pack monitoring (internal chemical indicators, Class III-VI), and exposure monitoring (exposure control tape, Class I CI), and others. Every chemical indicator (CI) was having 3 stated values: at 121°C, at 134°C, and at 135°C, and at 1 temperature between these values (at which killing occurs). However, Class V CIs was having 3 stated values: at 121°C, at 134°C, and at 1 temperature between these values (at which killing of the biological indicator is achieved). Class VI CIs was having 1 stated endpoint value at which a color change occurs. However, Class V CIs was having 3 stated values: at 121°C, at 134°C, and at 1 temperature between these values (at which killing of the biological indicator is achieved). Class VI CIs was having 1 stated endpoint value at which a color change occurs.

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**Table 2 : Type of sterilizer and indicators used in both hospitals**

<table>
<thead>
<tr>
<th>Name of sterilizer</th>
<th>Physical monitoring</th>
<th>Chemical indicator and location</th>
<th>Biological indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam sterilizer</td>
<td>Temp: 134°C Holding time: 4 min</td>
<td>Class I (exposure control tape): outside every set</td>
<td>Geobacillus stearotherophilus</td>
</tr>
</tbody>
</table>
Various quality indicators of both the hospital were assessed and results of all these indicators shown in table 3.

Table 3: Various quality indicators of CSSD²⁸⁻¹⁰

<table>
<thead>
<tr>
<th>Sr no</th>
<th>Quality Indicators for CSSD</th>
<th>Public multi spl Hospital</th>
<th>Pvt multi spl Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Written policy</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2.</td>
<td>Work flow chart</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3.</td>
<td>Job assignment</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4.</td>
<td>Practice manual</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5.</td>
<td>Human resource development plan</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>6.</td>
<td>Annual health check Up</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>7.</td>
<td>Budget plan</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>8.</td>
<td>Complying to sterilization guideline</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>9.</td>
<td>Validation of sterilization instrument</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>10.</td>
<td>Use of chemical indicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>11.</td>
<td>Use of biological indicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>12.</td>
<td>Precautions of sharp injury</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>13.</td>
<td>Percentage of Negative chemical test</td>
<td>74.4 %</td>
<td>92 %</td>
</tr>
<tr>
<td>14.</td>
<td>Percentage of Negative Bowie Dick test</td>
<td>77 %</td>
<td>94 %</td>
</tr>
<tr>
<td>15.</td>
<td>Percentage of Negative biological test</td>
<td>68 %</td>
<td>91 %</td>
</tr>
<tr>
<td>16.</td>
<td>Percentage of Satisfaction of customers</td>
<td>54 %</td>
<td>96 %</td>
</tr>
</tbody>
</table>

DISCUSSION
Satisfactory quality control of sterilization processes is of paramount importance in maintaining the reliability of sterile supplies in a Central Sterile Supply Department (CSSD). The common practices included the setting of a work flow chart and job assignment. However, the written policy, practice manuals, and budget plan was not there in the structure of CSSD in public hospital.

A policy and practice in human resource development was low in public hospital. The personnel in CSSD need continuing professional development through education otherwise they will be left behind in the advancement of knowledge and technology of new machines. The calling-back of sterilized products that do not meet the standard was also lacking in both hospitals. The heads of CSSD were not automatically selected as a member of ICC. This widens the gaps between CSSD and ICC and costumers.

Indicators were used to assess the quality of sterilization process in both hospitals surveyed (Table 3). It is to be noted that validation of sterilization instrument is far less in public hospital as compared to private hospital. Even though it was validated, it was done by CSSD personnel who were not engineers. Defects of the instrument could easily occur and are not easily detected in daily practice leading to unsterile products. The use of process and outcome indicators were satisfactory in both hospitals. These monitoring processes provide quality assurance to healthcare workers and patients that the instruments have been properly processed. Certain important guidelines were not available in the both hospitals; these included guidelines on: cleaning, packaging, loading, unloading, delivery of sterilized products and maintenance of sterilized instruments.

The quality indicators for sterilized products were very limited. The result of biological (spore) test was the major indicator. Process indicators were less recognized in public hospital. Positive feedbacks from users were almost absent in both hospitals. Many useful indicators were to be introduced, for example, the proportion of retrieved products, defective products, undelivered products, wet packs, expired products in stocks, incidence of technical failure of sterilizer and events of work-related accidents.

The quality indicators for process of sterilization were also studied in both hospitals. Both the hospitals were using process indicators such as chemical test and Bowie-Dick test.
RECOMMENDATION

1. Facility should be design as per laid down protocol and environmental requirement
2. All the policy and procedures should be in place
3. Cleaning and verification of reusable medical equipment / devices should be done with all precaution
4. Calibration and maintenance of repossessing equipment and records to be maintained
5. The hospital should have policies and procedures for all aspects of reprocessing based on current recognized standards / recommendations and should review at least annually.
6. All policies and procedures for sterilization should review and approval by infection control committee.
7. Procedures for disinfection and sterilization must include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure and physical and chemical properties that might have an impact on the efficacy of the process. It should be included in policy.
8. A procedure should be established for recall of improperly reprocessed medical equipment / device.
9. There should be a policy that prohibits eating / drinking , storage of food , smoking , application of cosmetics or / and handling contact lenses in the reprocessing area.
10. Measures and procedures shall be written to prevent and manage injuries from sharp objects , exposure to blood and body fluids.
11. Annual health checkup and vaccination should be done strictly.
12. Sterile / clean and used items shall not be transported together.
13. Transport carts shall be cleaned and dried between uses. There should be a physical barrier between the bottom shelf and the floor.
14. Reusable medical equipment / devices must be thoroughly cleaned prior to before disinfection or sterilization.
15. Personnel must use appropriate PPE.
16. Audit of cleaning process shall be done on a regular basis.
17. Reusable medical equipment / device must be thoroughly inspected , prepared before packaging and sterilized ready to use and ensure patient safety.
18. Rigid container systems should be cleaned after each use.
19. Non critical medical equipment / devices are to be cleaned then disinfected using a low level disinfectant.
20. Semi critical medical equipment / devices require at a minimal , high level disinfection but sterilization should be preferred.
21. A preventive maintenance program for pasteurizing equipment must be implemented and documented.
22. A log of contents , temperature and time should be maintained for each pasteurizer cycle.
23. Policies and procedures for sterilizing processes should include loading and unloading the sterilizer , operation of the sterilizer , testing and monitoring and documented and available.
24. Written policies and procedure should available for storage , handling , rotation and labeling of sterile packs.
25. Rotation of stock should be done on first in first out ( FIFO ) basis.
26. Calibration of instruments should be periodically to control and monitor the equipment.

CONCLUSION

The quality indicators for assessing the performance of CSSD by checklist, situation analysis, feasibility study and final refinement will yield a better outcome of CSSD performance and control in Hospital Infection control.

REFERENCES