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

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KEYWORDS :

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 burden[2].

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

Characteristics	Public Hospital	Private Hospital
Number of beds	500	510
No of Surgery beds	50	60
No of ICU beds	24	32
Number of worker in CSSD	13	24
Area of CSSD	900 Sq Ft	1200 Sq Ft

Infrastructure		
Located in a delineated area where there is less or no external traffic movement.	No	Yes
Location of CSSD should be either close to OT or should be connected to OT with safe & quick transfer mechanism, like dumbwaiters.	Yes , manual transfer mechanism	quick transfer mechanism dumbwaiters ++
Entry to CSSD should be restricted to only staff working in CSSD	Yes But not so strict	Yes
layout should have well demarcated zones, which includes Collection zone (or soiled zone) , Cleaning zone , Sterilization zone ,Storage zone	Yes	Yes
Zones must lead to unidirectional movement of people and supplies.	No	Yes
Entry to sterile zone should be after taking necessary infection control precautions such as hand washing, wearing of gowns/aprons, gloves etc.	No	Yes
The sterilization zone (specially storage) should have a higher air pressure to prevent outside air to enter in this area	Yes	Yes
Emergency exit route should be identified and displayed	No	Yes
Easy access to fire fighting measures (like extinguisher, or hose pipe) should be available	No	Yes
Equipment: CSSD should have required sterilization and cleaning equipment in well-functioning condition.	Yes	Yes
Processes		
SOP should be documented for each activity done in CSSD. These activities include • Procedure of cleaning • Procedure of packin	Yes	Yes
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 • o Safety precautions and guidelines	Yes	Yes

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) • o Processing required before reuse of the items	No	Yes
Sterilization equipment must be calibrated at a regular interval. A preventive maintenance checklist should also be available for each equipment	Checklist is there but not calibrated regularly	Yes and calibrated regularly
Each pack, that is being sterilized must be labelled with following information • Date of sterilization • Date of expiry • Equipment number in which it was sterilized • Load number in which it was loaded for sterilization	Yes	Yes
Record of each load sterilized in CSSD should be maintained. The record must contain • Date • Load number • Description of contents that were included • Temperature, pressure and time-record chart	Not updated	Yes
Validation tests must be done in CSSD. The validation tests must include • Physical/Chemical test – should be done for each load • o Biological spore test – at-least weekly basis for each equipment	Yes	Yes
List of hazardous chemicals in CSSD should be available	No	Yes
Staff knowledge3		
Staff working in CSSD must have knowledge of following • Infection prevention practices to be followed in CSSD • Zones and unidirectional movement • Hand hygiene practices and other standard precautions • Validation tests done in CSSD • When sterilization breakdown should be considered • Procedure to recall when sterilization breakdown occurs • Relevant staff should know their work SOP • Occupational health hazards of working in CSSD • Hazardous chemicals and its spill management • o Other general topics like, employee rights, use of fire extinguisher, emergency codes etc.	Not adequate	Yes
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 • o How to send soiled/used items	Not adequate	Yes
Sterilization by saturated steam under pressure4		
Number of items of equipment	3	4
N. of cycles/day	20	28
N. of packages/month	24000	32000
Sterilization by hydrogen peroxide plasma		
Number of items of equipment	Nil	1
N. of cycles/day	Nil	4
N. of packages/month	Nil	1200
Sterilization by ethylene oxide		
Service tertiarized	Yes	Yes
N. of packages/month	2000	15000

Fig 1 : CSSD of Private hospital

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 1 stated endpoint value at which a color change occurs. However, Class V CIs was having 3 stated values: at 121°C, at 135°C, and at 1 temperature between these values (at which killing of the biological indicator is achieved). Class VI CIs was only have 1 stated value for cycle-specific sterilization, depending on the plateau time. All of the chemical indicators were tested using a chemical indicator evaluating resistometer, and each manufacturer follows the ISO 11140-1 standard.

Table 2 : Type of sterilizer and indicators used in both hospitals[5-7]

Name of sterilizer	Physical monitoring	Chemical indicator and location	Biological indicator
Steam sterilizer	Temp.: 134°C Holding time: 4 min	Class I (exposure control tape): outside every set	Geobacillus stearotherm ophilus

	Pressure: 2 bars OR Temp.: 121°C Holding time: 15 min Pressure: 1 bar	Class II (B–D test pack): 1st cycle of the day Class III (single variable): Inside a pack Class IV (multiple variables): Inside a pack Class VI (emulating indicator): Inside a pack	Geobacillus stearotherm ophilus
Gas sterilizer (Eto)	Temp.: 37°C or 55°C; Relative humidity: >60% Pressure: 0.8–1.8 bar Holding time: 3 h at 37°C Holding time: 1 h at 55°C	Class I: Outside every set Class III: Inside a pack Class IV: Inside a pack Class V: Inside a pack	Bacillus atrophaeus
Plasma sterilizer (H2O2)	Temp.: 50°C Pressure: (500 mtorr) Time: ~ 1 h	Class I: Outside every set Class III: Inside a pack	Geobacillus stearotherm ophilus

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 CSSD[8,9,10]

Sr no	Quality Indicators for CSSD	Public multi spl Hospital	Pvt multi spl Hospital
Presence and implementation of quality indicators for structure of CSSD			
1.	Written policy	Yes , but not in details	Yes
2.	Work flow chart	Yes	Yes
3.	Job assignment	No	Yes
4.	Practice manual	No	Yes
5.	Human resource development plan	No	Yes
6.	Annual health check Up	No	Yes
7.	Budget plan	No	Yes
Presence and implementation of quality indicators for sterilization process			
8.	Complying to sterilization guideline	Yes but not always	Yes
9.	Validation of sterilization instrument	Yes	Yes
10.	Use of chemical indicator	Yes	Yes
11.	Use of biological indicator	Yes	Yes
12.	Precautions of sharp injury	No	Yes
Presence and implementation of quality indicators for sterilized products			
13.	Percentage of Negative chemical test	74 .4 %	92 %
14.	Percentage of Negative Bowie Dick test	77 %	94 %
15.	Percentage of Negative biological test	68 %	91 %
16.	Percentage of Satisfaction of customers	64 %	96 %
17.	Percentage of retrieved products	No data Avlb	12 %
18.	Percentage of undelivered sterilized products	No data avlb	14 %
19.	Percentage of wet packs	29 %	3 %
20.	Percentage of technical failure of sterilizer	28 %	11 %
21.	Incidence of accidents at work.	12 times in study period	4 times in study period
22.	Percentage of expired products in stock	14 %	8 %
Others11, 12			
23.	% of HAI happening due to instrument/devices used on patients	No data avlb	0.05 %
24.	Number of times of sterilization failure	4 times in study period	Once
25.	% re-sterilization required due to improper storage	3 %	1%
26.	% of non-compliance to sterilization practices	6 %	1 %

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 hospital. 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 the 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 of process indicators such as chemical test and Bowie-Dick test.

RECOMMENDATION[11,12]

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.

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