

RESEARCH ARTICLE

Evaluation of Sterile Supply Cycle at One of The Malaysia Government Hospital in Perak

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ABSTRACT

Healthcare-associated Infections (HAIs) are normally mentioned as nosocomial infections, which usually occurs when the patients are hospitalized for a long time. One of the ways to reduce the number of HAIs is that hospitals should prepare their own Central Sterile Supply Department (CSSD). In CSSD, the authority should follow the guidance that is provided. Due to the uncooperative of the hospital that did not follow the guidelines that are provided by the government causes these infections to grow significantly. This research was carried out the CSSD in one of the government hospitals in the state of Perak. The data of this research was gain through interviews and observation to determine was this particular hospital had already followed the guideline that is provided by the Ministry of Health, Malaysia. The study concluded that the Malaysia Government Hospital in Perak, aspects that do not meet the requirements are design requirements, handling of used items, disinfection, packaging, and wrapping of used items before sterilization, sterilization methods, monitoring of sterilizer, quality management, selection and care of instrument, care of operating room textiles.

Keywords: Centre Sterile Supply Department, Healthcare-associated infections, Malaysia Government Hospital, Perak.

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INTRODUCTION

Every time numerous surgical procedures are formed at hospitals all around the world. Infection is a major risk for patients if medical instruments are not reprocessed the way they should be.¹⁻³ During the year 2013, according to the database from the Ministry of Health of Malaysia from all the hospitals in Malaysia shows that there are 2,110,628 admissions. As the report shows that respiratory disease is 11.50%, injury and certain external causes are 8.77%, certain infectious disease 7.8%, and circulatory disease is 7.65%. Ten principal cause death in a government hospital in 2013 shoes that circulatory disease is the highest percentage which is 24.38%, respiratory disease is 22.13%, and certain infectious disease is 13.96%.⁴⁻⁶

Infectious disease is a type of disease that caused by a pathogenic microorganism. Microorganism tends to grow in a compatible reservoir. To find a new compatible reservoir, they transmit or spread. Transmission of pathogenic microorganisms through a certain mechanism through direct transmission and indirect transmission. Indirect transmission consists of vehicle-borne, waterborne, airborne and etc.⁷⁻⁹

Central Sterile Supply Department (CSSD) is a special department in the hospital that helps to provide a full package of sterilization service for all the hospital equipment.^{10,11} CSSD provides services from washing, decontamination, packaging, sterilization, storage, and distribution.¹¹ Form the previous study, the functional flow of CSSD in Hospital Pulau Pinang Malaysia shows that part of the process does not reach all the requirements that are set by the Ministry Of Health Malaysia. Aspects that do not meet the requirements are processing linen, quality control, and storage process.¹² According to Rosenthal *et al.* that are collected by Kanayya showed that Healthcare Associated Infectious (HAIs) widely happens globally and majorities; it happens in the third country and developing country. The amount of cases in the third country and developing country is 3 to 5 times higher than the international standard. HAIs causes a time-consuming treatment, high costing and even death.^{13,14}

METHOD

In this study, qualitative design is used through observation techniques and interviews. Observation slip is used to record

the result of observation by making a checklist regarding the functional flow of CSSD according to the aspect and requirements that are set by the Ministry of Health Malaysia.¹⁰ Interviews are done to get data by asking and listening to the respondent. This technique is done by recording all the questions to the respondent.

Quantitative analysis by collecting data through interview are done through five phases:

- Transcript interview result
- Data Reduction
- Coding Process
- Categorization
- Verification/ Finalization

Table 1: Categorization of the Factors that affect the Sterility of CSSD in one of the Malaysia Government Hospital in Perak

No	Category	No	Attribute
1	Design Requirement	1	Length and width of the rooms does not meet the requirement
		2	Ventilation not measure
		3	No mechanical ventilation
2	Handling of Used Items	1	Not using automatics washer
		2	Temperature of rinsing water is not measured
3	Disinfection	-	-
5	Sterilization Methods	-	-
6	Loading of Sterilizer	-	-
7	Unloading of sterilizer	-	-
8	Storage of Sterile Items	-	-
9	Maintenance of sterilizers and validation of sterilization process	-	-
10	Quality Management	1	Biology test is done in the lab
		2	No ventilation
11	Cleaning of sterilizers	-	-
12	Selection and care of instrument	1	Not all personnel get intensive courses
13	Care of operation room textiles	1	Operation textiles handles by another department

Table 2: Observation result regarding the design requirement of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Visitor established with dress code	√		
2	Wall and partitions should separate functional work areas to control traffic flow	√		
3	Routine checks on electrical plumbing, and mechanical steam system	√		Every month
4	Floors and walls should be constructed of materials that will withstand periods of wet vacuuming or washing	√		
5	Edge of all the floors and ceilings should be curve	√		
6	Pipes above works areas should also be enclosed	√		
7	Ventilation using exhaust or filter partial recirculation system		√	using Air-Con
8	Negative air pressure	√		
9	Temperature 20°C-24°C	√		
10	Storage area 18°C-22°C	√		
11	Humidity 50%-60%	√		
12	Mechanical ventilation in the washing area		√	No mechanical ventilation
13	Handwashing facilities	√		
14	Decontamination area separate with others	√		
15	Air in washing area exile by recirculation		√	No recirculation
16	Sufficient space for clean textile storage	√		
17	Ventilation of sterilizing area have to be balanced by an exhaust fan		√	Using Air-Con
18	Ethylene Oxide sterilization is separate with others	√		
19	Sterilization area is adjacent to a storage area	√		
20	Floors are clean every day	√		

RESULT AND DISCUSSION

Observation Result

Refers to the tables above, it showed that there were a few aspects that do not meet the requirement that is set by the Ministry of Health Malaysia. Aspects that do not reach the requirements are:

Design requirement

Through the results from observations and interviews, it shows that the CSSD of this hospital does not use any exhaust fan or filter partial recirculation system, in this hospital only uses Air conditioning. Refer to the interviews, and the respondent also

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Table 3: Observation result of handling of used items requirement of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Water hardness is test weekly		√	Did not test
2	Personnel wearing uniform that is provided, mask, apron, boots, and glove	√		
3	Sharp item is clean separately	√		
4	Different types of equipment is wash separately	√		
5	Weak alkaline detergent pH 8-10		√	No recorded
6	Temperature of rinsing water 15°C-30°C		√	Not recorded
7	Dry in an oven	√		
8	Oven temperature 65°C-75°C	√		

Table 4: Observation result of disinfection of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Check the expiry date of the solutions	√		
2	Always clean instruments before disinfection	√		
3	Disinfectant is not allowed to refill	√		
4	PPE follows fully	√		
5	Disinfection is document	√		
6	Instrument is soak at 75°C for 10 minutes		√	Temperature is not recorded.

Table 5: Observation Result of Packaging of Used Items Prior to Sterilization of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Inner wrap are compatible	√		
2	Instrument or dressing should be corporate to textile	√		
3	Instrument follows the size	√		
4	Pack should not exceed the accepted minimum size 30cm x 30cm x 50cm nor should weigh 5.5kg	√		
5	Seal with indicator tape	√		
6	2.5 cm space in between instrument and pouch		√	Do not measure
7	Seal is folded properly to avoid gap		√	
8	Tape with pressure-sensitive, non-toxic, and clean surface		√	
9	Width tape not less than 22 mm ± 2 mm		√	
10	Instrument name is above the package		√	
11	Arrange according to sterilizing method		√	
12	Arrange by types and size		√	
13	Labeling information: instrument number, code, load number, autoclave number, sterilizing date, batch control data		√	Instrument number, load number, autoclave number not label
14	Reminder on cooling and drying time after sterilization		√	

Table 6: Observation Result of Sterilization Methods of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Pre-vacuum sterilizer operates at 132°C-138°C	√		Operate at 134°C
2	Operating time depends on the weight and size of the instrument	√		
3	Dry heat sterilizer use on enclose instrument at 160°C for 60 minutes	√		
4	Sterilization temperature is control at 180°C	√		
5	Sterilizer will go off when is overheat		√	Alarm will ring and personnel off it
6	Ethylene oxide sterilizer has a different exhaust	√		
7	Gas concentration is not less than 400mg/mL	√		
8	Temperature for cool cycle 36°C, warm cycle not greater than 60°C	√		
9	Humidity 40% - 100%		√	Not record
10	Metal sterilization tray is used	√		

Table 7: Observation Result of Loading of Sterilization of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Pre-vacuum sterilizer, packs should put vertically		√	
2	Items shall be loaded within the boundaries of the carriage is in transit		√	
3	Heavy packs should be beside on light packs		√	
4	Loading carriages shall be loosely loaded a capacity		√	
5	Racks used to allow adequate separation		√	
6	Dry heat sterilization preheat at 160°C		√	
7	Temperature is monitored and regulated		√	
8	Space shall be left between items to allow adequate air circulation		√	
9	Chemical indicator is used		√	
10	Space between each package items and basket		√	
11	Items is placed in a basket for ethylene oxide sterilization		√	
12	Items are arranged accordingly		√	

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Table 8: Observation result of unloading of sterilizer of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Recording charts is check before unloading	√		
2	Loading carts with cooling item kept away from the high activity area	√		
3	Item is no force cooling	√		
4	Items is clean and no water droplets	√		
5	Documentation on temperature, humidity, expose time, and concentration sterililant	√		
6	Items properly aerated in the mechanical aerator	√		
7	Combination of system sterilizer and aerator, both cycles have to be complete before unloading	√		
8	Unloading carts is pull not push	√		
9	Butyl gloves is worn	√		

Table 9: Observation Result of Storage Area of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	All items stored above floor level by at least 25cm, at least 44 cm from ceiling, 5cm from an outside wall	√		
2	Items kept clean, dry, and in good condition	√		
3	Walls, floors, ceiling are easy to clean	√		
4	Floors construct with material that is easy to clean and strong	√		
5	Overhead lighting fitted to minimize dust entrapment	√		
6	Temperature 20°C - 22°C	√		
7	Humidity 50% - 60%	√		
8	Away from traffic	√		
9	Appropriate PPE	√		

Table 10: Observation result maintenance of sterilizers and validation of sterilization process of CSSD in one of the Malaysia Government Hospital in Perak.

No	Observational Aspect	Yes	No	Notes
1	Calibration on machines, timer, gauges, and displays handle by experienced personnel.		√	
2	Routines checks, calibration, and results is record.			
	a. Daily and monthly maintenance	√		
	b. Visual Inspection	√		
	c. Monthly Thermocouple test	√		
	d. Gauges calibration	√		
	e. Residu detergent and pH		√	
3	Dry heat sterilizer: overlook	√		
	a. Chamber free of debris	√		
	b. Temperature gauge and timer function correctly	√		
	c. Door gasket	√		
	d. Loading trays	√		
	e. Weekly cleaning	√		
4	Ethylene oxide sterilizer			
	a. Accuracy of concentration airborne	√		
	b. Experience personnel handle EtO	√		
	c. Documentation on EtO strilizer	√		

mention that the whole CSSD are close up without any window and exhaust fan to reduce air particle and to create ventilation using air condition. Therefore there's no measurement on ventilation in the CSSD.

Handling of Used Items

All the water that are used to either wash or soak comes from tap water; this is a factor that may cause contamination on those items. Detergents are used to wash away residues and organic components. According to the guideline, weak alkaline pH 8.0–10.8 is better than pH neutral. The container of the detergent had to show the pH of the detergent. According to the observation, result pH is not shown on the container, and the pH is not recorded. Therefore the rinsing process had to be done a few times to wash away the chloride and prevent corrosion on the items.

Disinfection

Preparation of the disinfection process had to display on the disinfection area, but in this CSSD, they did not show.

Sterilization Method

In this CSSD, there are three types of sterilization method can be seen, which is dry hear, steam and ethylene oxide sterilization. When the sterilizer overheats, it should cut off automatically, but in this CSSD, the sterilizer's alarm will be a trigger, and the personnel will switch it off. There is a risk towards the sterilizer and the safety for the personnel. Furthermore, in this area, there is not measurement showing the humidity.

Storage and Handling of Sterile Items

The final results on the temperature of the storage area are 19.3°C, and the humidity is 53%. Both data show the two

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Table 11: Observation result of quality management of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Person in charge of sterilizing process with specific qualification	√		
2	Documentation			
	a. All test is done on every machine	√		
	b. Sterilizer Cycle	√		
	c. Employee records	√		
	d. Incident reports	√		
	e. Operational manual	√		
	f. Maintenance record	√		
3	Batch control number			
	a. Number Identification sterilizer		√	No record
	b. Date of sterilization	√		
	c. Cycle or load number	√		
4	Sterilization cycle note			
	a. Cycle date	√		
	b. Number and code sterilizer		√	No record
	c. Cycle and load number	√		
	d. Exposure time and temperature	√		
	e. Name loading operator	√		
	f. Identification of loading operator	√		
	g. Result for chemical and biology indicator	√		
5	Monitoring			
	a. Temperature, time, pressure and gauges	√		
	b. Graphic chart	√		
	c. Identification of chart	√		
6	Chemical indicator read every cycle	√		
7	Selection on a biological indicator			
	a. Steam sterilizer: <i>Bacillus stearothermophilus</i>	√		
	b. Ethylene oxide sterilizer: <i>Bacillus subtilis</i>	√		
8	Biological indicator record every sterilization cycle	√		
9	Biological indicator has done every cycle	√		
10	Using of <i>Bacillus stearothermophilus</i> at 56°C, <i>Bacillus subtilis</i> at 37°C		√	Did in lab
11	Bowie-Dick test done every day at 134°C-136°C for 3.5 hours	√		
12	Accurate PPE	√		
13	Apron plastic, mask, gloves, goggles used during decontamination	√		
14	All accessories not allow in CSSD	√		
15	All areas have hand washing area and sanitizer	√		
16	All machines are contracted with a company to maintenance	√		

Table 12: Observation Result Cleaning of Sterilizers of CSSD in one of Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Routine cleaning performed in accordance	√		Everyday
2	Written procedures for cleaning of all sterilizing	√		
3	Disposal container is prepares	√		
4	All waste removed from the sterilizing process via designated disposal exit	√		

Table 13: Observation Result Selection and Care of Instruments of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	All items in good condition	√		
2	Equipment that are not in good condition is replace	√		

Table 14: Observation Result of Care of Operating Room Textiles of CSSD in one of the Malaysia Government Hospital in Perak

No	Observational Aspect	Yes	No	Notes
1	Inspection, folding and assembly of linen perform dedicated	√		
2	Air conditioning is remove of airborne	√		
3	Linen is inspected over the illuminated linen inspection table	√		Every month

aspects meet the requirement from the Ministry of Health. Temperature and humidity play a significant role in the metabolism reaction of an organism. For bacteria, if the temperature is high will cause it to denature, while if too low

the membrane of bacteria will cause inhibition in nutrients transportation. For the humidity will affect the moisture of the microorganism.

Quality Management

This healthcare facility is responsible for sterilizing the equipment for handling the sterilization process personnel are educated and go through intensive training. All the personnel should be acknowledged to repair minor destruction while the professional mechanic will repair the major destruction. Form the result of the interview, it shows that only certain personnel get to follow the intensive training.

CONCLUSION

The functional workflow of the Central Sterile Supply Department of one of the Malaysia Government Hospital in Perak did not reach the requirements that are set by the Ministry of Health Malaysia. Aspects that does not reach the requirement design, handling used items, disinfection, packaging used items prior to sterilization, sterilization methods, maintenance of sterilizer, quality management, and care of operating textiles.

Recommendation

According to the result from the study that is carried out in the Central Sterile Supply Department in one of the Malaysia Government Hospital in Perak, a recommendation that are suggested is follow all the requirements that are list by the Ministry of Health Malaysia. The monitoring of the workflow can be stricter and perform a quantitative study to get a better understanding of the situation.

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