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ORIGINAL ARTICLE

Evaluation of surgical instrument and medical device decontamination and sterilisation practice in healthcare facilities

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Abstract

Effective cleaning and disinfection/sterilisation using a properly validated washer-disinfector/steriliser will protect patients and staff from infection; prolong the life of the equipment and ensure the quality of the diagnostic/therapeutic procedure. The purpose of this study was to evaluate how instrument trays were received in the decontamination area, checked, sorted, cleaned, inspected, wrapped, sterilized and how each processing stage was validated. An audit of the CSSD facility was also conducted. This study was conducted at Tygerberg Hospital during the period of 18th of June to 18th of July 2013 as part of the Intermediate course in decontamination and sterilisation for Postgraduate diploma in Infection prevention and control. This was a descriptive survey, whereby an audit tool and other observational tools for capturing the required information were developed and used to collect information. The results from the audit conducted at CSSD from 21st June to 5th July 2013 indicated 86% compliance. The control of instruments before and after use was not documented in 37% and 60% cases respectively. There was lack of displayed written SOPs for reusable instruments on wards, and for instruments manual cleaning in CSSD. A good program of decontamination and sterilization was observed in the CSSD of TBH. However, some improvements are still needed such as proper use of detergents, hand hygiene practice, use of PPE and record keeping. Staff training, developing and displaying of required SOPs, regular monitoring and evaluation of activities should also be tackled to enhance the compliance.

Keywords: Disinfection; Sterilization; Healthcare facilities manpower and services and microbiology and instrumentation; Health personnel and education.

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Introduction

Health facilities are places with a high incidence of disease-causing micro-organisms, which are easily spread from patient to patient by the staff and equipment and other materials used for patient care. Moreover, many people visiting hospitals are weak and, therefore are extra susceptible to acquire disease.[1] It is the task of the health facilities not only to cure diseases of its patients, but also to prevent transmission of diseases from one patient to the other.[1] An important measure against spreading of diseases is the requirement that all medical supplies, such as instruments, swabs, drapes etc, which are used on open wounds or will be in touch with the inner fluids of the body, are free of any viable micro-organisms. They have to be sterile.[2] Some of these materials are sterilized at the factory and are designed for single use. However, many instruments and materials used for medical interventions are very expensive and are designed such that they can be re-used. A high-quality reprocessing cycle is necessary in which the used materials are treated such that they can be used safely again.[1-3]

Background

Effective cleaning and disinfection/sterilization using a properly validated washer-disinfector/sterilizer will protect patients and staff from infection; prolong the life of the equipment and ensure the quality of the diagnostic/therapeutic procedure.[2-3] The purpose of this study was to evaluate how dirty items were handled and cleaned, how clean items were inspected, wrapped, sterilized and how was validation carried out.

Methods

This study was conducted at Tygerberg Hospital during the period 18 June to 18 July 2013 by a PDIC student as part of the Intermediate course module in Decontamination and Sterilisation for Postgraduate Diploma in Infection Prevention and Control (PDIC). This is a 1310 beds academic tertiary referral hospital, located in Parow, Cape Town. The hospital was officially opened in 1976 and is the largest hospital in the Western Cape and the second largest hospital in South Africa. The CSSD of Tygerberg Hospital is a modern unit fitted with arguably the most recent advances in decontamination technology and it is operational since November 2009. There are two sterilization methods to reprocessing medical devices and instrument trays. The main one is steam sterilization method. The building of steam sterilization is equipped with 3 washer-disinfectors (one washer-disinfector of type 1 and two washer-disinfectors of type 2) and 10 pre-vacuum steam sterilizers type auto sliding door. The second one is low temperature sterilization method by ethylene oxide. The ethylene oxide sterilization building is self-contained with 4 ethylene oxide machine (STERIVAC). The CSSD of TBH is serving 30 theatres and other different clinical/hospitalization wards, ICUs and Trauma department. It is also serving KARL BREMER District Hospital by reprocessing its thermo-labile medical devices. 74 staff including 49 operators and 7 supervisors had been serving in the CSSD during the study period. Average of packs reprocessed per week was 790 packs for steam sterilization and 483 packs for ethylene oxide. This was a descriptive survey, whereby audit tool and other observational tools were developed and used for data collection. This study looked only on steam sterilization method. The audit tool used for data collection was adapted from Sterile Processing Best Practices Audit Checklist of SEAVEY HEALTHCARE CONSULTING accessed from www.seaveyhealthcareconsulting.com. National standards, international standards and CSSD local situation were considered during the audit tool development. It contained seven main sections: Facility/space design, staff training and competence, personal protective equipment (PPE), reprocessing of surgical devices (sorting of items prior to cleaning, manual cleaning, mechanical cleaning, and housekeeping), inspection, assembly and packaging (IAP), sterilization process, sterile storage and documentation (policies and procedures in place). The CSSD was visited and visual inspection of practices done. Instrument control slip completeness checked. Inventory of equipment, wraps, instruments, detergents/disinfectants was conducted and analysed. The wrapping methods available are textile sheets (non-linting linen), paper sheets and laminated film pouches (for sharp instruments). The instrument tray packaging was based on a three-layer wrapping system, whereby the first layer was made by non-linting linen, the second and third layers were made by soft wraps type STERISHEETS. The scoring was dichotomous; answers were "yes" or "no". The final score was obtained by adding the total number of "Yes" answers and divide by the total

number of questions answered (including all "Yes" and "No" answers) excluding the "N/A" and then multiply by 100 to get the percentage. The compliance levels were calculated by using the compliance categories (compliant 85% or above, partial compliance 75 to 84%, minimal compliance 74% or below).[3]

Results

The work flow in the CSSD of TBH is unidirectional from dirty to clean area, and most importantly the decontamination area is physically separated from other parts of the CSSD. There was mechanical ventilation in the CSSD, whereby negative pressure ventilation in decontamination area and positive pressure ventilation in IAP and sterile storage area. Both automated and manual cleaning methods have been observed, but automated cleaning by washer-disinfectors is the most commonly used method. The instruments are adequately wrapped with appropriate wrapping materials and instrument trays had been validated at each reprocessing stage. Physical, chemical and biological indicators were used for validation. There was sufficient steam-sterilizers, whereby two of them have own steam generation.

The audit conducted at CSSD between 21 June and 5 July 2013 (tables I to V and Figure 1) indicated 86% compliance with existing CSSD protocol. The control of instruments before and after use was not documented in 37% and 60% cases respectively. There was adequate equipment, appropriate and adequate wraps. Most of detergents used for cleaning of instruments were out of date. The shortage or stock out of most of surgical instruments was also noted. There was lack of displayed written SOPs for reusable instruments on wards, and for manual cleaning of instruments in the CSSD.

Table I. Hand washing practice in CSSD-Decontamination area, June 2013

Hand washing moment	Opportunities	Performance (%)
After manual cleaning dirty instruments	42	60
After checking of dirty instruments	21	19
After removing gloves used for other purpose	25	28
Overall	88	41

Table II. The use personal protection equipment in the CSSD of TBH, June 2013

	During Checking of dirty instrument trays (n=44)	During manual cleaning of dirty instruments (n=36)
Type of PPE	%	%
Domestic gloves	0	11
Clinical examination gloves	100	89
Apron	100	100
Face cover (eye shield)	2	0
Surgical mask	15	16
Headgear	82	83

Table III. Visual inspection of surgical instrument trays, TBH; June 2014

The average surgical instrument trays inspected per week was 575.

	Cleanliness		Completeness	
n	Clean and dry	Dirty	Complete	Incomplete
333	333	0	198	135
%	100	0	59	41

Table IV. The most likely missing instruments; CSSD-Tygerberg Hospital, June 2013

N	Type of instrument	Amount	%
1	Probe Silver	83	44
2	Cissors	75	39
3	Sleeve Lloyd Davies	13	7
4	Deppers Prep	9	5
5	Scalpel BP Handle	2	1
6	Forceps Artery Spencer Wells	2	1
7	Gillies Pinset	1	0.5
8	Handle Gigli Saw	1	0.5
9	Needle Holder	1	0.5
10	Plate	1	0.5
11	Bristow Elevator	1	0.5
12	Skel Steke	1	0.5
	Total	190	100

Table V. Documentation of instrument slip before and after instrument trays use (n=333)

Moment	Slip documented	Slip not documented	Compliance (%)
IAP-CSSD	333	0	100
Before use (Operating theatre)	209	124	63
After use (Operating theatre)	134	199	40
Return to Decontamination area-CSSD	333	0	100

Conclusion

Despite poor performance in some different areas such as hand hygiene (41%), documentation of instrument control (63% before use and 40% after use) and manual cleaning performance (64%), the overall performance of the CSSD was compliant (86%). Therefore, a good programme of decontamination and sterilization was observed (good CSSD design and workflow, enough equipment such as washer-disinfectors and sterilizers, procurement plan and staff training programme in place). Most of their activities are carried out according to the international standards (e.g., BS, EN 556; HTM 2030; ISO 11140; ISO 11138). The results ranked 86% compliance. However, some improvements are still needed such as proper dilution and use of detergents, hand hygiene practice, manual cleaning practice and records keeping. Operating theatre staff should always control instrument trays before and after use and document properly instrument control slips. Regular staff training, providing of required SOPs, regular monitoring and evaluation of activities should also be tackled to further improve compliance levels in the CSSD.

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