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Original Article

The Conformity Between the Centers for Disease Control and Prevention Standards and Central Sterile Services Department Standards in Shahrekord, Iran

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Abstract

Background: The central preparation and sterilization unit plays a vital role in supporting operating rooms and other departments by providing tools for cleaning, disinfection, assembly, packaging, and sterilization. This study aimed to determine the conformity between the standards of the Centers for Disease Control and Prevention (CDC) and the practices of the Central Sterile Services Department (CSSD) in selected operation rooms at Ayatollah Kashani Hospital, Shahrekord University of Medical Sciences.

Methods: This descriptive-analytical study was conducted from 2019 to 2020 using a cross-sectional approach. The census method was used for sampling. A researcher-made checklist was used to collect the data, the validity of which was approved by 10 faculty members of the School of Nursing and Midwifery. Furthermore, test-retest reliability was used to verify the checklist. The obtained data were analyzed using descriptive statistics (mean and standard deviation) and independent t-tests via SPSS software version 21.

Results: The findings showed that the scores for safety and personal protection measures ($P=0.35$) and equipment packing, sterilization, and storage practices did not comply with CDC standards at Kashani Hospital in Shahrekord. However, there was conformity in the physical score, environmental control, decontamination, transfer of contaminated items to the CDC department, device arrangement, and recall process for non-sterile items ($P=0.038$).

Conclusion: The central sterilization ward of the operating room complied with CDC criteria in most cases. Cases of non-compliance were due to insufficient budget and training; therefore, cases that are inconsistent with the standards should be identified, and positive steps should be taken to fully align the methods with the standards to prevent patient complications and possible damage.

Keywords: Prevention and control, Sterilization, Compliance, Operating room

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Introduction

Hospitals are vital centers for treating and caring for patients, yet inadequate attention to health and safety issues can lead to nosocomial infections (1). Nosocomial infections refer to infections acquired during hospitalization that are not present when the patient is admitted (2). Among the hospital departments, operating rooms have special conditions and are more prone to these infections due to patients in these rooms, heavy workload, numerous personnel, high traffic, serious condition of referred patients, exposure to bleeding and infectious secretions of patients, and open surgical site, all of which increase the risk of the contamination of the internal body tissues with microbial infections (3).

Preventing infections in the post-operative stage requires cooperation between the post-operative nurse and the infection prevention specialist to prevent the infection of the surgical site and provide a healthy environment for both patients and staff (4). Infections caused by surgery are one of the types of hospital infections that are acquired

from the hospital environment. These infections are painful and deadly, with a prevalence of 2%-10%, and are costly due to the increase in hospitalization time and disabilities (5).

One of the most important sources and ways of spreading and transmitting hospital infections is the incorrect sterilization of surgical tools and equipment because contaminated medical equipment causes many hospital infections each year. Surgical instruments must be properly cleaned to remove their contamination. Dirty or malfunctioning tools can compromise patient care. Post-operative personnel should prepare tools for use according to the manufacturer's written instructions as proper cleaning and disinfection prevent the transmission of pathogenic organisms to patients or healthcare personnel (4).

To minimize infection risks, all surgical instruments must undergo the following steps: cleaning, disinfection, inspection and monitoring, pegging, sterilization, transportation, storage, and use (6). The Central Sterile Services Department (CSSD) plays a vital role in supporting the operating room and other departments by providing services such as cleaning, disinfection, assembly, packaging, and sterilization (7,8).

The central preparation and sterilization department is a high-pressure environment where technicians perform their primary duties of ensuring the decontamination of patient care equipment and the cleaning and sterilization of surgical instruments. Although CSSD personnel are not directly involved in surgery, their proper performance is effective in preventing infections and ensuring successful surgical outcomes (9).

Using surgical tools contaminated with microorganisms, which may not have been properly cleaned and sterilized, directly leads to surgical site infections (SSIs) in patients. The purpose of the sterile process is to break the infection cycle at the surgical site. This process includes decontaminating surgical instruments, correctly pegging instruments for sterilization through a sterilizer or autoclave, and properly maintaining instruments. Performing the sterilization process correctly reduces the risk of transferring microorganisms from instruments to patients or other treatment personnel, thereby decreasing the chances of SSIs through the instrument (10,11).

Given the importance of complying with the standards and the important role of CSSD in healthcare centers, non-compliance with any of the CDC standards related to CSSD can lead to the transmission of infections and the occurrence of diseases due to the transfer of microorganisms from contaminated tools to personnel and hospitals. Given the importance of monitoring and inspection from managers' perspectives as an important environmental control tool and considering the lack of studies in this area within the research environments, we decided to determine the compliance level of operating room sterilization procedures with valid scientific guidelines in the central sterilization department of the operating room of Ayatollah Kashani Hospital in Shahrekord, Iran.

Methods

This descriptive-analytical study was approved by the Research Council and the Ethics Committee of Shahrekord University of Medical Sciences in 2019-2020. After receiving permission to conduct the research and a code of ethics from Shahrekord University of Medical Sciences, the researcher referred to the CSSD departments of Ayatollah Kashani Hospital and started the sampling procedure with a checklist.

The criteria for entering the research included treatment centers with a separate CSSD department and permanent personnel in the CSSD department. Exclusion criteria involved individuals who were informed about the study's objectives before starting, which may affect the results.

The data were collected by a questionnaire and a two-part checklist created by the researcher. The validity of the questionnaire and the checklist was approved by 10 faculty members of the Faculty of Nursing and Midwifery, and the reliability of the checklist was assessed based on the test and retest method. The CSSD department of Ayatollah Kashani Hospital was evaluated by two different observers for one week after the initial visit, and the information obtained from the checklists was entered into SPSS 21 to determine the questionnaire's reliability by determining Cronbach's alpha of the questions.

The questionnaire included details about the hospital, while the checklist contained 82 questions assessing the level of compliance with the CDC standards regarding physical design of CSSD (11 questions), environmental control of CSSD (2 questions), occupational safety measures in CSSD (7 questions), personal protective equipment (7 questions), transportation of CSSD-contaminated items (3 questions), decontamination of equipment (13 questions), packaging and assembly of equipment (4 questions), high-level sterilization/disinfection of equipment (4 questions), storage and maintenance of equipment (15 questions), arrangement of equipment (3 questions), reminder methods (3 questions), recall processes for non-sterile items (8 questions), sterilization monitoring and control systems (4 questions).

To analyze the data, SPSS software version 21 was used along with descriptive statistics methods (mean and standard deviation) and independent t-tests. First, the researcher reviewed the criteria and standards of Kashani Hospital's CSSD center based on the standards and a checklist made by the researcher. All items and sterilization monitoring and control systems were carefully observed and compared with the current situation in the hospital and the checklist. When filling out the questionnaire based on the current situation, the researcher assigned a score of 2 (complete) if all the steps and conditions were met for each item mentioned above, a score of 1 (incomplete) if several items were missing (or not done) but some were present and observed, a

score of 0 (absent) if the items were completely absent. The information was kept confidential, and ethical considerations were taken into account when expressing the results. Then, the results were published with the permission of the ethics committee.

Results

The score for the physical design part of CSSD was according to CDC standards (i.e., separation of contaminated, clean, and sterile areas, washable roof, non-porous work surfaces, air changes at least 10 times per minute, negative pressure in disinfection areas, positive pressure in the clean area, temperature of 18-22 degrees Celsius, humidity of 35-70%, and compliance with safety measures). The physical design of CSSD according to CDC standards in the operating room of Hospital was found to be standard ($P=0.038$).

The score for CSSD environmental control, according to CDC standards (daily disinfection of surfaces and floors and weekly disinfection of walls and equipment storage shelves) in the operating room of hospital, was standard. Since the standard error difference was equal to zero, there was no need for a correlation coefficient and t-test, suggesting that CSSD environmental control score met CDC standards in the operating room of the hospital.

The score for occupational safety measures in CSSD, according to CDC standards (doctor's permission for personnel with infectious symptoms, not wearing jewelry, regular hand washing, use of mechanical devices for sharp tools, compliance with personnel ergonomics, use of separate gloves and compliance sterility tips when leaving and entering the department) in the operating room of the hospital, was not standard ($P=0.356$).

The score for personal protective equipment, according to CDC standards (wearing special clothing, use of eye protection, use of hair cover, use of suitable mask, use of impermeable gown, use of normal gloves, and use of shoe covers), was also not standard ($P=0.104$).

The degree of transfer of CSSD-contaminated items (use of containers with lids and covered trolleys and quick transport of half-package washing of contaminated containers in the decontamination area) in the operating room of the hospital was standard. Since the standard error difference was zero, there was no need for a correlation coefficient and t-test.

Regarding the decontamination items (separation of garbage and disposable items, removal of extensive pollution from the surface of tools, separation of parts of large tools, manual cleaning of tools, immersion of tools in cold water, use of disposable brushes consumption, use of enzymatic detergents, use of water after using detergents, immersion of instruments in disinfectant solution, following recommendations of endoscope manufacturers, use of lubricants for instruments, inspection of instruments for cleanliness, proper performance, and defects), since the standard error difference was zero, there was no need for a correlation coefficient and t-test.

The item score for packing and arranging equipment (putting equipment in a tray, arranging equipment in an open manner, maintaining proper distance between equipment, and placing concave trays) according to CDC standards in the operating room was not standard (Table 1).

The score for high-level sterilization and disinfection item (placing the sterilizing device near the packing area, using the appropriate disinfection solution, observing the appropriate time interval for cooling the equipment, and performing the aeration phase of the equipment) according to CDC standards in the operating room of the hospital was not standard.

The score for storage and maintenance was also not standard according to the CDC standards in the operating room of the hospital. Likewise, the score for equipment arrangement (correctness of the sterility life of the packages, checking the packages for integrity, color change, and no tears, and moving the equipment so that the old equipment is used first) according to the CDC standards in the operating room of the hospital was not standard.

However, the score for the reminder method item (sending a warning, recalling the produced product via fax or letter to the head of the purchasing service, and checking the CSSD after receiving the warning information) according to CDC standards in the operating room of the hospital was standard. Similarly, the item score for the recall process of non-sterile items according to CDC standards in the operating room of the hospital was standard. Additionally, the item score for sterilization monitoring and review systems (daily reporting, use of chemical indicators-paper strips impregnated with chemicals, use of Bowie-Dick device, use of biological indicators at the beginning of each day) according to CDC standards in the operating room of Ayatollah Kashani Hospital of Shahrekord University of Medical Sciences was standard (Table 2). Since the standard error difference was equal to zero, there was no need for a correlation coefficient and t-test.

Discussion

The present study was conducted to investigate the CDC standards' compliance with the CSSD of the operating room of Shahrekord Teaching Hospital. In a study entitled "Reasons for Using Wet Pack after Steam Sterilization and Its Consequences" at a cancer center in eastern India, Basu concluded that identifying wet packs is extremely important because many factors contribute to their formation. The presence of wet packs should be immediately reported to the CSSD and the hospital's infection control team, and a list of supplies should be prepared and returned to the CSSD for review (12). Furthermore, CSSD personnel should document all the products as the basis of the recall and consider them as non-sterile materials (11). The results of this study were not consistent with those in the present study, probably

Table 1. Scores of Different Items With CSSD Standards

	Test Value = 2				
	t	*df*	Sig. (2-tailed)	Mean Difference	95% Confidence Interval
					The Least
Physical design 1	-3.105	10	**0.011**	-.8182	-1.405
Physical design 2	-2.193	10	0.053	-0.4545	-0.916
Safety measures 1	-1.549	6	0.172	-0.286	-0.74
Protective equipment 1	-1.922	6	0.103	-0.571	-1.30
Protective equipment 2	-1.000	6	0.356	-0.286	-0.98
Packing items 1	-1.567	3	0.215	-0.750	-2.27
Packing items 2	-1.000	3	0.391	-0.500	-2.09
Sterilization 1	-2.449	3	0.092	-1.000	-2.30
Storage of equipment 1	-3.055	14	0.009	-0.400	-0.68
Storage of equipment 2	-2.779	14	0.015	-0.533	-0.94
Arrangement of equipment 1	-1.000	2	0.423	-0.333	-1.77
Arrangement of equipment 2	-1.000	2	0.423	-0.333	-1.77
Reminder method 1	-1.491	10	0.167	-0.182	-0.45
Reminder method 2	-1.000	10	0.341	-0.091	-0.29
Sterile process 1	-1.000	3	0.391	-0.250	-1.05
Sterile process 2	-1.000	3	0.391	-0.250	-1.05

Note. CSSD: Central sterile services department.

Table 2. Scores of Different Items With CSSD Standards

	Test Value = 2
	95% Confidence Interval
	The Highest
Physical design 1	-0.231
Physical design 2	0.007
Safety measures 1	0.17
Protective devices 1	0.16
Protective devices 2	0.41
Packing items 1	0.77
Packing items 2	1.09
Sterilization 1	0.30
Storage of equipment 1	-0.12
Storage of equipment 2	-0.12
Arrangement of equipment 1	1.10
Arrangement of equipment 2	1.10
Reminder method 1	0.09
Reminder method 2	0.11
Non-sterile process 1	0.55
Non-sterile process 2	0.55

Note. CSSD: Central sterile services department.

due to the lack of space in Kashani Hospital's corporate social responsibility.

Some foreign studies have investigated the use of wet packs after steam sterilization, factors for checking the storage time of sterilized items, the sterilization status of instruments, the infection of the surgical site, and the temperature and humidity of the instrument storage area (12).

Some studies conducted in Iran have investigated the microbial contamination of the work environment and the level of instrument contamination, but none of the studies investigated the compliance of CSSD with CDC standards. They conclude that the shelf life of the equipment depends on the sterilization process, checking the sterilization time, and storage conditions (10). In the current study, the shelf life of the sterile equipment did not meet the standard, possibly because Kashani Hospital does not perform all surgical procedures (13).

In 2012, de Araújo Moriya et al conducted research on the evaluation of the sterility of packaged items on 175 samples with cloth, V-pack, and crepe paper packaging, concluding that if storage and transportation conditions are properly observed, the packages will remain uncontaminated for more than 6 months (14).

In a study titled "Surgical Site Infection Related to Surgical Instruments", Dancer et al concluded that instrument contamination after the sterilization process increases the rate of SSI in orthopedic and eye patients (9). Factors attributed to the increase in infection in the operation site include insufficient supervision, lack of training, inadequate manpower, poor transportation methods during and after the sterilization process through the autoclave, and residual moisture inside the packages. This research suggests that close cooperation between sterile department personnel, managers, and clinical staff can reduce the contamination of surgical instruments (15).

De Moraes Bruna and Graziano observed that environmental factors, temperature, and humidity significantly affect the sterility of the stored materials. Moreover, they asserted that the correct packaging of tools is crucial for protecting them against environmental factors such as temperature and humidity (16).

In a study titled "Clinical Investigation of the Rate of Contamination of Sterile Instruments with Staphylococcus aureus" in long-term orthopedic surgeries, Pirmoradian et al found that out of a total of 110 samples taken immediately after opening the sterile cover, 5 cultures were positive (54.4%). The contamination rate recorded for 91 samples taken one hour after the operation was 10 cases (10.98%). Additionally, out of 32 samples taken two hours after the operation, 5 infected samples were recorded (15.62%), and among 12 samples taken three hours after the operation, one was infected (8.33%). Due to the high rate of contamination with *Staphylococcus aureus* in sterile instruments, it was suggested that trays containing sterile instruments should not be opened until they are specifically needed (17).

Sadat Mansouri et al conducted an investigation comparing the amount of sterile durability of different types of packaging for dental equipment on 1400 samples, including cloth bags, Roly-Percy and Tecno-Gaz sterile envelopes, and Segeva and Eline adhesive bags. They found that the type of packaging does not affect the results of sterilization, and the type of recent packaging, similar to cloth, showed a positive effect in maintaining the equipment sterile for up to nine months of follow-up (18).

Most cases examined in the current study exhibited compliance with CDC standards, and the main reasons for non-compliance in other cases were the hospital's financial and budget issues and the lack of necessary training.

Conclusion

The degree of compliance of the CSSD of the operating room of Ayatollah Kashani Hospital with CDC standards was observed in most cases. Therefore, for items with less compliance, the reasons seem to be insufficient budget and training. Therefore, it is necessary to identify the items that are inconsistent with the standards, take positive steps to prevent them, and fully adapt the methods to the standard items to prevent the occurrence of complications in the patients and the possible damages that may follow.

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Competing Interests

The authors declare no conflict of interests.

Ethical Approval

This study received ethical approval from Shahrekord University of Medical Sciences with the number IR.SKUMS.REC.1399.096.

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