



The Survey Conformity between the Centers for Disease Control and Prevention's standards and Center Sterile Department's standards in selected operation rooms in Ayatollah kashani Shahrekord University of medical sciences

samaneh dehgha abnavi - 1, Instructor, Department of Operating Room, Community-Oriented Nursing Midwifery Research Center, Nursing and Midwifery School, Shahrekord University of Medical Sciences, Shahrekord, Iran;

leila ebrahimi sheikh shabani - 2. Instructor of medical surgical nursing, school of allied medical sciences, Shahrekord university of medical sciences .

Fatemeh Aliakbari - 3. Assistant Professor, Community Oriented Nursing and Midwifery Research Center, Shahrekord University of Medical Sciences, Shahrekord, Iran .

ali kazemipour - 4. Department of Mathematics, Aliabad Katoul Branch, Islamic Azad University, Aliabad Katoul, Iran

maryam khusravi* - Social Security Organization, Golestan Province Treatment Management, Khatam Al-Anbia Gonbad Kavous Hospital, Golestan, Iran .

Introduction: The Central Preparation and Sterilization Unit has a vital function that supports the operating room and other sections by providing tools for cleaning, disinfection, assembly, packaging and sterilization. The aim of this study was to determine The Conformity between the Centers for Disease Control and Prevention's standards and Center Sterile Department's standards in selected operation rooms in Ayatollah kashani Shahrekord University of medical sciences

Methods:

The present study is a descriptive-analytical study that was conducted in 2009-2010, which was done cross-sectionally. Census method was used for sampling. A researcher-made checklist was used to collect the data, the validity of the checklist was approved by 10 faculty members of the School of Nursing and Midwifery, and the test and retest method was used to verify the checklist. The data obtained by the tests were used. Descriptive statistics (mean and standard deviation ...) and independent t-test were analyzed by SPSS 21.

Results:

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

Conclusion:

The central sterilization ward of the operating room complied with CDC criteria in most cases. And it seems. Cases of non-compliance are due to insufficient budget and training, so cases that were inconsistent with the standards should be identified and a positive step should be taken to fully adapt the methods to the standard cases to prevent complications in the patient and possible damage.

Key Words: prevention and control , Sterilization, compliance, , operating room



Introduction:

Hospitals are one of the important centers for treating and caring of patients, but if health and safety issues are not paid attention to in the hospital, it leads to diseases called nosocomial infections [1].

Nosocomial infections refer to an infection that occurred during hospitalization and was not present when the patient was admitted [2]. Among the hospital departments, operating rooms have special conditions due to patients have in these rooms, heavy workload, numerous personnel, high traffic, serious condition of referred patients, bleeding and infectious secretions of patients, open surgical site and Increasing the chance of contamination of the internal tissues of the body, which are susceptible to various types of microbial infections, is more sensitive in this sense [3].

Prevention of infection in the post-operative stage requires cooperation between the post-operative nurse and the infection prevention specialist in order to prevent the infection of the surgical site and provide a healthy environment for 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 disability [5].

One of the most important sources and ways of spreading and transmitting hospital infections is not paying attention to the correct sterilization of surgical tools and equipment, because contaminated medical equipment causes many cases of hospital infections every year.

The instruments used in surgery must be properly cleaned and their contamination removed. Tools that are dirty or not working properly can compromise patient care. After the operation, the personnel should prepare the tools for use according to the manufacturer's written instructions. Cleaning and disinfection prevent transmission of pathogenic organisms to patients or health care personnel [4].

In order to minimize the chance of infection, all surgical instruments must go through the following steps: cleaning, disinfection, inspection and monitoring, pegging, sterilization, transportation, storage and use of equipment [6]. Central sterile services department has a vital function that supports the operating room and other departments by providing tools in the form of cleaning, disinfection, assembly, packaging and sterilization [7, 8].



The central preparation and sterilization department has a busy and high-pressure environment where technicians perform their primary duties of ensuring the decontamination of patient care equipment, cleaning and sterilizing surgical instruments, and sterilizing instruments. Although CSSD personnel are not directly related to the field of surgery, but their correct performance is effective in preventing infection and surgical results [9].

The use of surgical tools contaminated with microorganisms, which may not have been properly cleaned and sterilized, directly leads to infection of the surgical site in patients. The purpose of the sterile process is to break the cycle of infection at the surgical site. The sterile process includes a series of decontamination of surgical instruments, correct pegging of instruments for sterilization through a sterilizer or autoclave, etc., proper maintenance of instruments. When the sterilization process is done correctly, the possibility of transferring microorganisms from the instrument to a patient or other patients or treatment personnel is reduced and the chance of infection of the surgical site through the instrument is reduced [10, 11].

Considering the importance of complying with the standards and the important position of CSSD in healthcare centers, not complying with any of the CDC standards related to CSSD can cause the transmission of infection and the occurrence of disease caused by the transfer of microorganisms from contaminated tools to personnel and hospitals. Also, considering the importance of monitoring and inspection from the point of view of managers as an important tool of environmental control and that no study has been done in this regard in research environments, we decided to conduct a study with the aim of determining the compliance level of operating room sterilization procedures with valid Scientific guidelines in central sterilization department of the operating room of Ayatollah Kashani Shahrekord Hospital

Methods:

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

The criteria for entering the research include 1. The treatment centers have a separate CSSD department, which means that there is a separate CSSD department inside the hospital. 2. Permanent

personnel in the CSSD department and exclusion criteria: 1. The samples received information about the objectives of the study before starting, and it gave an impression, the researcher started working based on the questionnaire and checklist whose validity and reliability were confirmed.

The data of the research was collected by a questionnaire and a two-part checklist made 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 based on the test and retest method. The CSSD department of Ayatollah Kashani Hospital was questioned by two different observers for one week after the initial visit, and the information from the checklists was entered into SPSS 16 to determine the reliability of the questionnaire by determining the Cronbach's alpha of the questions by a statistician.

The questionnaire included details about the hospital. The checklist contains 82 questions, in which the level of compliance with the standards of the Centers for Disease Control) 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 number 16 and descriptive statistics methods (mean and standard deviation...) and independent t test were used.

First, the researcher completed and reviewed the criteria and standards of Kashani hospital's CSSD center based on the standards and 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 in the checklist.

When filling out the questionnaire based on the current situation, the researcher will score 2 (complete) if all the steps and conditions are met for each of the items mentioned above, if a number of items are missing (or not done) and If a number of them are present and observed, score 1 (incomplete) and if they are completely absent, score 0 (absent). The information was kept confidential and ethical considerations were taken into account when expressing the results, and the results were published with the permission of the ethics committee.

Results:

In the physical design part of CSSD, the score of this part is according to CDC standards (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, presence of positive pressure In the clean area, the temperature is 18-22 degrees Celsius, humidity is 35-70%, compliance with safety measures is standard in the operating room of Hospital ($p=0.038$) Therefore, according to this score, the physical design of CSSD according to CDC standards in the operating room is standard.

The amount of CSSD environmental control score according to CDC standards (daily disinfection of surfaces and floors, weekly disinfection of walls and equipment storage shelves) in the operating room of Hospital, is standard. Considering that the standard error difference is equal to zero, so there is no need for correlation coefficient and t-test. That is, the CSSD environmental control score is standard according to CDC standards in the operating room of Hospital.

The score of 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 this department) in the operating room of Hospital is not standard ($p=0.356$).

The score of 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, use of shoe covers) is not standard ($p=0.104$).

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

In relation to the decontamination item (separation of garbage and disposable items, separation of large 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) due to the fact that the standard error difference is equal to zero, so there is no need for correlation coefficient and t-test.

The item score of packing and arranging equipment (putting equipment in a tray, placing equipment in an open manner, observing the proper distance between equipment, placing concave trays) according to CDC standards in the operating room was not standard (Table No. 1).

Scores of different items with CSSD standards Table No. 1

	Test Value = 2				
	t	df	Sig. (2-tailed)	تفاوت میانگین	فاصله اطمینان
					%۹۵ کمترین
Physical design 1	-3.105	10	.011	-.8182	-1.405
Physical design 2	-2.193	10	.053	-.4545	-.916
Safety measures 1	-1.549	6	.172	-.286	-.74
Protective equipment 1	-1.922	6	.103	-.571	-1.30
Protective equipment 2	-1.000	6	.356	-.286	-.98
Packing items 1	-1.567	3	.215	-.750	-2.27
Packing items 2	-1.000	3	.391	-.500	-2.09
Sterilization 1	-2.449	3	.092	-1.000	-2.30
Storage of equipment 1	-3.055	14	.009	-.400	-.68
Storage of equipment 2	-2.779	14	.015	-.533	-.94
Arrangement of equipment 1	-1.000	2	.423	-.333	-1.77
Arrangement of equipment 2	-1.000	2	.423	-.333	-1.77
Reminder method 1	-1.491	10	.167	-.182	-.45
Reminder method 2	-1.000	10	.341	-.091	-.29
Sterile process 1	-1.000	3	.391	-.250	-1.05
Sterile process 2	-1.000	3	.391	-.250	-1.05

مستقل با سطح معنی داری ۰/۰۵ T آزمون

The score of different items with CSSD standards, Table No. 2

	Test Value = 2
	%۹۵ confidence interval
	بیشترین

Physical design 1	-.231
Physical design 2	.007
Safety measures 1	.17
Protective devices 1	.16
Protective devices 2	.41
Packing items 1	.77
Packing items 2	1.09
Sterilization 1	.30
Storage of equipment 1	-.12
Storage of equipment 2	-.12
Arrangement of equipment 1	1.10
Arrangement of equipment 2	1.10
Reminder method 1	.09
Reminder method 2	.11
Non-sterile process 1	.55
Non-sterile process 2	.55

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

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

The score of the reminder method item (sending a warning, recalling the produced product via fax or letter to the head of the purchasing service, checking the CSSD after receiving the warning information) according to CDC standards in the operating room of Hospital was standard.

The item score of the recall process for non-sterile items according to CDC standards in the operating room of Hospital was standard.

Item score of 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 Ayatollah Kashani Hospital of Shahrekord University of Medical Sciences was standard (Table No. 2).

Considering that the standard error difference is equal to zero, so there is no need for correlation coefficient and t-test.

Discussion:

The present study was conducted with the aim of investigating the compliance of the standards of the Center for Disease Control and Prevention with the central sterilization department of the Shahrekord Teaching Hospital's operating room.

Basu in 2016, in a study entitled Reasons for using wet pack after steam sterilization and its consequences, an overview of the preparation and central sterilization department of a cancer center in eastern India, concluded that identification of wet packs is very important because the reasons Many factors are effective in creating it. 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.

CSSD personnel should document all the products as the basis of the recall and consider them as non-sterile materials [12]. The results of this study were not consistent with the present study, and it is probably due to the lack of space in Kashani Hospital's CSR. .

In foreign studies, they investigated the use of wet packs after steam sterilization and 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.

In internal studies, they 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 their storage conditions[10]. In the current study, the shelf life of the sterile equipment was not according to the standard, and there is a possibility that the Kashani Hospital does not have performs all surgical procedures.

In 2012, Morriya and his colleagues conducted a research called the evaluation of the sterility of packaged items on 175 samples with cloth, V-pack, and crepe paper packaging, and concluded that if

the conditions of storage and transportation be observed properly the packages will remain uncontaminated for more than 6 months [14].

In 2012, Dancer and his colleagues concluded in a study titled surgical site infection related to surgical instruments that instrument contamination after the sterilization process increased the rate of surgical site infection in orthopedic and eye patients.

Among the reasons that can be attributed to the increase of infection in the operation site are: insufficient supervision, lack of training or low manpower, poor transportation methods during and after the sterilization process through the autoclave, moisture remaining inside the packages. Sterilized due to rapid cooling of packages. This research suggests that close cooperation between sterile department personnel, managers and clinical staff can reduce the contamination of surgical instruments [15].

In 2012, Bruna & Graziano concluded that the influence of environmental factors, temperature and humidity in maintaining the sterility of the stored materials, but what is more important is the correct packaging of the tools. May it protect them against environmental factors such as temperature and humidity [16].

In 2013, in a study titled "Clinical investigation of the rate of contamination of sterile instruments with *Staphylococcus aureus*" in long-term orthopedic surgeries, Pirmeradian and his colleagues concluded that out of a total of 110 samples taken immediately after opening the sterile cover, 5 cultures were positive. was obtained (54.4%). The rate of contamination recorded for 91 samples taken, one hour after the operation, was 10 cases (10.98%). Also, out of 32 samples taken 2 hours after the operation, 5 infected samples were recorded (15.62%), and in 12 samples taken 3 hours after the operation, one *Staphylococcus aureus* infection (8.33%). It was reported. Due to the high rate of contamination with *S. aureus* in sterile instruments, it was suggested that trays containing sterile instruments should not be opened until they are specifically needed (17).

Dr. Seyed Sadat Mansouri and his colleagues in 2007, in a research titled comparing the amount of sterile durability in 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, showed 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 keeping the equipment sterile up to nine months of follow-up (18).

In the cases examined in the current study, it was found that there was mostly compliance with CDC standards, and in cases where there was no compliance, the main reason is the hospital's financial and budget issues, as well as the lack of necessary training.

The degree of compliance of the central sterilization department of the operating room of Ayatollah Kashani Hospital with CDC standards was observed in most cases. Therefore, it seems that other items that have less compliance are due to insufficient budget and training, so it is necessary to identify the items that were inconsistent with the standards and take a positive step in order to prevent them and fully adapt the methods to the standard items. To prevent the occurrence of complications in the patient and the possible damages that will follow.

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Ethical approval:

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

Conflict of interest:

This study has no conflicts of interest for any of the researchers.

Contribution of the authors:

Samaneh Dehghan Abnavi (first author) preparing the draft of the article, supervising and approving the final version of the article 50%; Fatemeh Ali Akbari (second author) preparation of the first version of the article 10%; Leila Ebrahimi (third author) data analysis and preparation of the first version of the article 10%; Kazemipour (fourth author) data collection and preparation of the initial version of the article 10%, Maryam Khosravi (fifth and responsible author) data collection, supervision and approval of the final version of the article 20%

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