

THE EFFECT OF SIX SIGMA PROGRAM ON IMPROVING MEDICAL EQUIPMENT MANAGEMENT OF OPERATING ROOMS IN ONE OF THE HOSPITALS IN ISFAHAN IN 2016

Ashkan Karimi¹, Soheila Mojdeh^{2*}, Marzieh Adel Mehraban³

1. *M.sc student in Operating Room, Student Research Committee, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran*
2. *Corresponding author: MSc -Ulcer Repair Research Center, Nursing and Midwifery School, Isfahan University of Medical Sciences. Isfahan. Iran. Email: S.mojdeh@mail.nm.mui.ac.ir*
3. *Ph.D. (Assistant Professor), Department of Community Health Nursing, Management and Aging, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran*

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ABSTRACT

Introduction: Nowadays, medical equipment plays a major role in the diagnosis, treatment and medical education, and the major share of hospital expenditures is annually paid to purchase medical devices from domestic sellers and abroad, and in order to maintain and repair the medical equipment, 10 to 20 percentage of their purchase price should be forecasted in the current year's budget. The Six Sigma system as the newest quality management system, in addition to providing a more robust map, provides solutions to solve management problems. The present study aimed to investigate the effect of six sigma program on improving medical equipment management of operating rooms in one of the hospitals in Isfahan in 2016.

Method: The present study is quasi-experimental study and performed at two stages and its direction was towards future. The data was collected from operating rooms of one of the hospitals affiliated to the Isfahan University of Medical Sciences at two stages. The samples were selected by census method. In the present study, the data was collected using data collection form and the questionnaires were filled out at two stages by researcher and the users of medical equipment of operating room. At the first stage, characteristics of equipment, costs and frequency of their repairs in the three months before the intervention (by the data collection form) and assessment of the users' knowledge of medical equipment of operating room (by questionnaire). At the second stage, after implementing six sigma program and taking the measures required, the form and questionnaires were filled out again. SPSS V.16 software was used to analyze the data. Average, standard deviation, frequency and percentage were used for descriptive data and pair t-test was used to analyze the data.

Results: After implementing the Six Sigma program, the incidence of malfunctions was reduced and the frequency of equipment failures also declined. The average interval between repairs was zero. It was also observed that the average total repair cost of the equipment significantly decreased after the implementation of the Six Sigma program ($P = 0.002$). In addition, the average first repair cost of equipment significantly decreased after the implementation of the Six Sigma program. Also, the average performance score of the users of the operating room equipment significantly increased after the implementation of the Six Sigma program ($P = 0.002$).

Conclusion: Since the Six Sigma program has played an effective role in reducing malfunctions and the repairs costs of equipment, it is recommended to implement this program on a wider scale and in greater period of time to manage hospital equipment.

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Introduction

Medical services are one of the most basic and most important needs of human societies and medical devices play a very important role in providing the services [1]. Nowadays, medical equipment plays a major role in the diagnosis, treatment and medical education, and the major share of hospital expenditures is annually paid to purchase medical devices from domestic sellers and abroad [2]. Since 2001, the World Health Organization has made a major effort to develop and improve the policies of medical equipment management. It should be noted that the costs of hospital property is between 30% and 40% of the total hospital expenditures. The proper maintenance of equipment, supplies and devices of the hospital not only makes them easily accessible when needed but also increases their durability and enhances their efficiency [3].

Annually, the major share of the hospital expenditures (about 5-15% per year) is devoted to purchasing medical equipment such as surgical microscopes, operating room monitors, ventilators, anesthetic machines, defibrillation, electrocutter, etc. [4]. According to the studies conducted in Iran, in order to set up a new hospital, about one third of the costs of building and equipping the hospital is devoted to purchasing medical equipment and in order to maintain and repair the medical equipment, 10 to 20 percentage of their purchase price should be forecasted in the current year's budget, so that about 20% of the projected costs of the hospital are allocated to the medical equipment sector [5].

In the hospital, operating room ward is a costly and special unit, and the promotion and increase of its productivity and quality are essential for the survival of any medical institution [6]. In recent years, significant progress has been made in the medical equipment management, especially in dealing with chemical and physical agents and in the areas of monitoring, engineering, and services. However, these devices have not significantly improved in terms of performance and safety compared to the previous two decades [7]. Since medical equipment plays a significant role in promoting the health and safety of the community, its correct and optimal management can have a significant impact on the national development of each country in terms of healthcare economics, medical education and research [8].

Preventive maintenance can reduced the cost of repairs by 45 to 50 percent [9].

Improving the process of maintaining medical equipment is important for some reasons such as: reducing patient's dissatisfaction, increasing staff's job satisfaction, reducing dispatch costs, reducing the cost imposed on the patient, timely patient treatment, and reducing mortality and dangers during deployment [10]. For this purpose (proper management and cost reduction), implementation of measures such as comprehensive quality management of organizational improvement, ISO standards and Six Sigma has been proposed. Among these, the Six Sigma system as the newest quality management system, in addition to providing a stronger map, also provides stronger techniques. It also seems that the use of this method is a new systematic and statistical qualitative approach to prevent the occurrence of errors in processes that directly and indirectly deal with human lives [11]. Because Six Sigma, in its philosophy and vision, has a fundamental difference with other traditional and modern quality systems, so that it knows quality improvement as a factor in increasing the speed and reducing the costs, rather than knowing increasing the speed and reducing the costs as a factor in improving the quality [12]. Understanding the importance of identifying and solving process problems through culture-building in care institutions, attracting all the hospital staff, hospital director and management commitment, providing permanent education in the field of process-centralization and customer-orientation, establishing a continuous improvement process in the care institutions are considered as the infrastructure and underpinnings of the Six Sigma implementation mechanism [13].

In a simpler sense, this cycle is a systematic way to solve problems and promote projects. it includes 5 stages of define, measure, analyze, improve, and control. This cycle is a structured, coherent, and comprehensive approach to process improvement, and the five stages listed logically relate to their previous and next stages. Features of Six Sigma Plans are as follows:

- A clear focus on achieving measurement, assessment and productivity
- Emphasis on strong and passionate leadership, management and support
- Clear and transparent commitment to decision making based on verifiable information and not on hypotheses and speculation
- Improving the quality of the output process by detecting and eliminating the false causes (14).

Given above, we find that medical equipment accounts for a large part of the hospital expenditures and its improvement and quality can have a significant effect on the satisfaction of patients and physicians, achievement of optimal therapeutic outcomes, savings on hospital expenditures, etc. It also seems that the Six Sigma program is a new approach to managing health centers and has been implemented with different goals such as cost reduction, increased satisfaction, etc. And in most cases, positive results have been achieved. For this purpose, the researchers have tried to conduct the present study to provide the results to the related authorities to avoid the waste of money and other problems associated with it.

Method

The present study was conducted as two-stage quasi-experiment and interventional research in the operating rooms of one of the hospitals affiliated to the Isfahan University of Medical sciences. The research environment was the operating rooms of the hospital and had 13 surgical rooms. Due to the design of two separate parts of personnel and equipment, the population included all the medical equipment of operating room and their users. The samples of the medical equipment were selected according to the inclusion criteria. Inclusion criteria were including at least one year of its life time passed, being used at least

once per day, being classified in the electrical equipment of operating room. Exclusion criteria was replacement of equipment during the study. In the present study, the samples were selected by census method. First, all the medical equipment of operating room was selected by convenience method and then, it was selected according to the inclusion criteria.

About the samples of operating room personnel, they were selected by census method and in the case of they opted out the research, they were excluded.

The data was collected using data collection form (checklist) for recording the characteristics of the equipment and a questionnaire (about users' knowledge). The form and questionnaire were filled out at two stages by the researcher and the users of the operating room medical equipment. The form used to record the fix and variable characteristics had three parts:

Part A: the fixed characteristics of the equipment including name, serial number, year of production, manufacturing factory and country, duration of its use in the operating room from the date of purchase until now, warranty period, the person responsible for the device, the room used

Part B: The frequency of failures and repairs of medical operating room equipment and the costs paid for them in the three months before the implementation of the Six Sigma program

Part C: The frequency of failures and repairs of medical operating room equipment and the costs paid for them in the three months after the implementation of the Six Sigma program

The questionnaire used to evaluate the operating room equipment users' knowledge was researcher-made questionnaire and had 15 4-option questions that each of them had 1 score. The first stage of filling out the data collection forms, including recording the characteristics of the equipment and collecting the statistics on the frequency and costs of medical operating room equipment repairs in the three months before the intervention, was performed by researcher and the second stage was performed three months after the implementation of the Six Sigma program and doing the actions required. Before intervention, the questionnaires of assessment of operating room equipment users' knowledge of medical operating room equipment, were distributed among the users and filled out by them. At the end of the intervention, the questionnaires were again filled out by the users of medical operating room equipment.

In order to determine the validity of the questionnaire for assessing the level of knowledge of the users of the medical operating room equipment, 10 faculty members of the operating room and nursing department of the Isfahan Nursing and Midwifery faculty were asked about the relevant items of the survey and the corrections were made so that its validity (content validity) was confirmed.

In the present study, the data was collected at two stages using data collection form and questionnaire and by the researcher and operating room equipment users. The first stage included recording the characteristics of the equipment and collecting the statistics on the frequency and costs of medical operating room equipment repairs in the three months before the intervention (October, November and December 2016) which was performed by researcher and the second stage was performed three months after the implementation of the Six Sigma program (March, April, May) and doing the actions required. Before the implementation of the Six Sigma program, the questionnaires on operating room equipment users' knowledge of medical operating room equipment, were distributed among the users and filled out by them. After intervention and implementation of the Six Sigma program, the questionnaires were again filled out by the users of medical operating room equipment.

During the intervention, the researcher proceeded on the basis of six sigma steps. At first, the problem was defined (stage one) and all the statistics and figures, and the consequences of the medical equipment repairs costs were described to the authorities and the problem was expressed to them. In this section, the hospital management, the head of the medical equipment office, the operating room officer and the medical engineering department of the hospital were spoken and after obtaining their consent and attracting their cooperation, the next stages were followed.

At the stage "Measure" (stage 2): by referring to the part of the statistics of medical and hospital facilities retrospectively, frequency of repairs and expenses paid for repairing the medical operating room equipment in the three months before the implementation of the Six Sigma program were collected and recorded. The number of equipment, specifications, and the frequency and costs of medical operating room equipment repairs are carefully collected and analyzed.

At the stage "analyze" (stage 3): all the causes of the failures of the medical operating room equipment were investigated and 60 equipment were selected and, an improvement program was designed for them according to the identified causes. Problems were divided into three categories.

- a) The items that could be prevented by personnel (such as a lack of complete awareness of the device's functionality, uses, and how it works).
- b) The problems related to the operating room management, such as regular checks of the equipment by the manufacturer and its after-sales services.
- c) The problems of documentation of equipment, provision of its certification, and accurate record of the number of failures and repairs that were attributable to the hospital's property section.

At the stage "Improve" (stage4): according to the causes identified at the stage 3, some strategies were taken in order to improve the management. In order to improve the management, the strategies were provided in three following categories:

- a) The part related to the operating room personnel: at this stage, a training course was held for personnel in two 1-hour sessions. The course was held as lecture and practical training.

In the first session, a questionnaire was firstly distributed among the personnel to measure their performance and then, with the help of the representative of the manufacturer and the medical equipment engineering department, the equipment was fully introduced and the reason for its use during the surgery and its importance in the positive results of the surgery and patient health were explained. The statistics on the failures and repairs of the medical operating room equipment were interpreted so that they can properly understand the importance of the subject. The sources of this session were from the reference books for the medical operating room equipment.

In the second session, how to work with the device and how to maintain it were taught to the users practically and by presenting the film.

- b) The part related to the operating room management: A meeting was held with the operating room management and the representative of the medical equipment manufacturer. At the meeting, the company was asked to provide its program for regular checking of equipment and it was decided to reduce the intervals between the checks to reduce the failures of equipment. Their recommendations on the maintenance of registered equipment were developed and provided to the hospital's medical equipment department. With the help of the operating room officer, a checklist was prepared to accurately record the number of failures, repairs, and repair costs, and to provide available statistics.
- c) The part related to the hospital's property and medical equipment: in this section, hospital property management and the head of the medical equipment office were talked to obtain complete information about each of the equipment, and in collaboration with both of them, a certification was prepared for each equipment. The certification contained complete information on the device, such as name, serial number, model, country of manufacture, manufacturer, year of production, and warranty period. Three copies of it were provided for each equipment. A copy was hung on the device. A copy was kept in the hospital property management and a copy was given to the operating room officer to collect all the certificates in one place availablely.

Also, in this section, the catalog and guide of the equipment were read and translated and a paper containing the manual for use and maintenance was made and attached to each equipment. After taking instructions from the representative of the manufacturer to provide the tools and materials needed for maintenance, cleaning and disinfection of medical equipment, a list of them was developed and provided to the medical equipment management to be prepared and delivered to the operating room officer.

Then, in the stage "Control" (stage5) until the end of the study, all stages of improvement were monitored and followed up. The frequency of failure of the medical operating room equipment and their costs in the three months after the intervention were recorded and the questionnaire on the users' knowledge of the medical operating room equipment was completed by the users and finally the data collected before and after the implementation of the Six Sigma program was compared.

Results

In the present study (quasi-experimental and two-stage research), all the medical equipment of operating room of one of the hospitals affiliated to the Isfahan University of Medical Sciences (n=60) and their users (n=35) were studied in order to investigate the effect of six sigma program on the improvement of operating room equipment management in 2016.

It was observed that none of the 60 operating room equipment, including 3 C-ARM devices, 12 electrocutters, 2 defibrillations, 8 monitors, 13 anesthetic machines, 3 microscopes, 16 suction devices and 3 tourniquets, had certification before the Six Sigma Program. After implementing Six Sigma Program, the 60 operating room equipment (%100) had certification.

After implementing the Six Sigma program, the incidence of malfunctions was reduced. Before the Six Sigma Program, %61.7 of equipment (37 devices) didn't fail but after implementing the program, %78.3 of equipment (47 devices) didn't fail and the frequency of equipment deterioration also declined after implementing the program so that %21.7 of equipment (13 devices) failed just one time (Table 1) and (Figure 1).

Table 1: Frequency of equipment failures before and after the implementation of the Six Sigma program

	Number of failures Before the implementation of the Six Sigma program				Total	Number of failures After the implementation of the Six Sigma program		Total
	Healthy	1 time	2 times	3 times		Healthy	1 time	
C-ARM	1	1	1	0	3	3	0	3
	33.3%	33.3%	33.3%	0.0%	100.0%	100.0%	0.0%	100.0%
Electrocutter	6	3	2	1	12	10	2	12
	50.0%	25.0%	16.7%	8.3%	100.0%	83.3%	16.7%	100.0%
Defibrillation	2	0	0	0	2	1	1	2
	100.0%	0.0%	0.0%	0.0%	100.0%	50.0%	50.0%	100.0%
Operating room monitor	7	1	0	0	8	8	0	8
	87.5%	12.5%	0.0%	0.0%	100.0%	100.0%	0.0%	100.0%

Anesthetic machines	7	2	4	0	13	9	4	13
	53.8%	15.4%	30.8%	0.0%	100.0%	69.2%	30.8%	100.0%
Microscope	2	1	0	0	3	3	0	3
	66.7%	33.3%	0.0%	0.0%	100.0%	100.0%	0.0%	100.0%
Suction device	10	4	1	1	16	10	6	16
	62.5%	25.0%	6.2%	6.2%	100.0%	62.5%	37.5%	100.0%
Tourniquet	2	0	1	0	3	3	0	3
	66.7%	0.0%	33.3%	0.0%	100.0%	100.0%	0.0%	100.0%
Total	37	12	9	2	60	47	13	60
	61.7%	20.0%	15.0%	3.3%	100.0%	78.3%	21.7%	100.0%

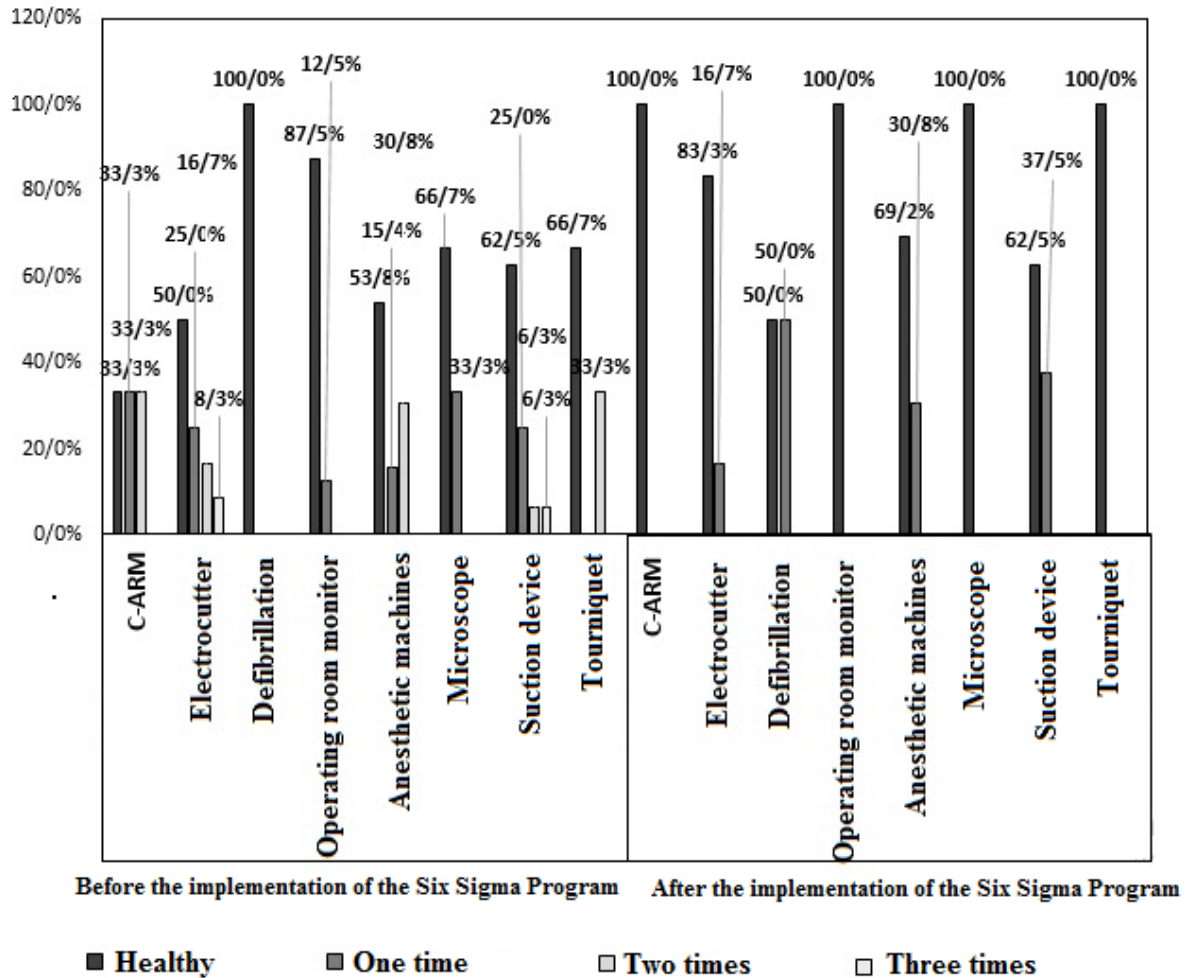


Figure 1: Frequency of incidence of equipment malfunctions before and after the implementation of the Six Sigma program

On the other hand, since some dives failed just one time after the implementation of the Six Sigma program, average time interval between the repairs was zero, therefore there was significant difference between the average time interval between the equipment repairs before (5.45 days) and after (0 day) the implementation of the Six Sigma program (Table 2). The results were presented based on the pair t-test.

Table 2: Comparison of the average time interval between the equipment repairs before and after the implementation of the Six Sigma Program

Average time interval between the equipment repairs	Mean (Day)	N	Std. Deviation	Std. Error Mean	P-value
Before the implementation of the Six Sigma program	5.45	60.00	13.12	1.69	0.002*

After the implementation of the Six Sigma program	0.000	60.00	0.000	0.000	
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It was observed that the average equipment repairs costs significantly decreased from 2.48 to 0.38 million Tomans after the implementation of the Six Sigma program (P-value=0.002<0.05). After the implementation of the Six Sigma program, on average, 2 million Tomans were saved at the equipment repair cost. Before the implementation of the Six Sigma Program, some of equipment failed more than one time (2 and 3 times), the first equipment repair cost was 1.38±0.342 million, the second and third repair costs were 0.883±0.278 and 0.058±0.041 million, respectively, but after the implementation of the Six Sigma Program, average total cost was equal to the first equipment repair cost, as listed in [Table 3]. The results were presented based on pair t-test.

Table 3: Comparison of the average equipment repairs costs before and after the implementation of the Six Sigma Program

Average equipment repair costs	Mean (million)	N	Std. Deviation	Std. Error Mean	P-value
Before the implementation of the Six Sigma program	2.48	60.00	3.78	0.490	0.001*
After the implementation of the Six Sigma program	0.380	60.00	0.800	0.100	

Additionally, comparing the first repair cost of equipment before and after the implementation of the Six Sigma program showed that the average first repair cost of equipment significantly decreased from 1.38 to 0.38 million Tomans after the implementation of the Six Sigma program (P-value=0.005<0.05) [Table 4].

Table 4: Comparison of the average first repair cost of equipment before and after the implementation of the Six Sigma Program

Average first repair cost of equipment	Mean (million)	N	Std. Deviation	Std. Error Mean	P-value
Before the implementation of the Six Sigma program	1.38	60.00	2.66	.340	.005*0
After the implementation of the Six Sigma program	.380	60.00	.800	.100	

Finally 35 operating room users were studied in order to determine their performance scores before and after the implementation of the Six Sigma program, frequency of their demographic characteristics are listed in [Table 5].

Table 5: Frequency of the demographic characteristics of the operating room users

	Frequency	Valid Percent
Male	8	22.9
Female	27	77.1
Total	35	100.0
Associate's degree	8	22.9
Bachelor's degree	25	71.4
Master's degree	2	5.7
Total	35	100.0
	Age	Working experience
Mean	33.10	11.04
Std. Error of Mean	1.45	1.42

It was observed that the average performance score of the users of the operating room equipment was 7.34±0.33 before the implementation of the Six Sigma program and it significantly increased after the implementation of the Six Sigma program (14.43±0.11) (P-value = 0.001<0.05). Before the implementation of the Six Sigma program, the average knowledge scores of the users of operating room equipment was less than the criterion value and it indicated the moderate-to-low performance

of the users. After the implementation of the Six Sigma program, the average knowledge scores of the users of operating room equipment significantly increased and showed the high performance of the users (Table 6).

Table 6: Comparison of the average knowledge scores of the users of operating room equipment before and after the implementation of Six Sigma program

Performance of the users of equipment	Mean	N	Std. Deviation	Std. Error Mean	P-value
Before the implementation of Six Sigma program	7.34	35.00	1.92	.330	.001*0
After the implementation of Six Sigma program	14.43	35.00	.650	.110	

Discussion

The present study aimed to investigate the effect of six sigma program on improving medical equipment management of operating rooms in one of the hospitals in Isfahan in 2016.

Over the past 30 years, the dramatic increase in medical costs has forced researchers and medical businessmen to explore the ways to improve operational efficiency or reduce the costs. In fact, these changes are a major challenge that proper decision-making is required for its proper management [15]. Also, in recent years, significant progress has been made in the medical equipment management, especially in dealing with chemical and physical agents and in the areas of monitoring, engineering, and services. However, these devices have not significantly improved in terms of performance and safety compared to the previous two decades [7].

The results of the present study showed that after the implementation of the Six Sigma program, the incidence of malfunctions was reduced and the frequency of equipment failures also declined. Ghaisari et al. (2014), in their study, have reduced the number of surgical cancellations using the Six Sigma model and this result is consistent with the result of the present study [6].

The results of the present study showed that since some of the equipment failed just one time after the implementation of the Six Sigma program, average time interval between the repairs was zero, therefore, significant difference was observed between the time interval between the repairs before and after the implementation of the Six Sigma program ($P=0.002<0.05$). Nasiripour et al. (2010), in their study entitled "A study of the waiting time of people referred to the clinic of the Shariati Hospital using Six Sigma model", have reported the clients' average waiting time as much as 121 ± 33.37 minutes.

Maleki, Khoshgam and Goharinzhad (2008) have conducted a study to investigate the effect of the Six Sigma program on reducing the admission time of patients hospitalized in the orthopedic surgery ward in Firouzgar Hospital. Their sample size was 200 and they have reported that before the implementation of the Six Sigma program, the average admission time was 7.519 days that it reduced to 6.572 after intervention ($P=0.001$) [18]. Hool et al. (2006) have studied the admission time after hip surgery at the Amsterdam Red Cross Medical Center in the Netherlands through the Six Sigma approach. After resolving the problem, admission time reduced from 14 to 8 days [19]. The results of all the three studies are consistent with the result of the present study and all of them, admission time decreased using the Six Sigma program.

It was also observed that the average total repair cost of the equipment significantly decreased after the implementation of the Six Sigma program ($P = 0.002<0.05$). After the implementation of the Six Sigma program, the average total repair cost of the failures significantly decreased. In addition, comparing the average first repair cost of the equipment before and after the implementation of the Six Sigma program showed that the average first repair cost of equipment significantly decreased after the implementation of the Six Sigma program ($P=0.005<0.05$). Karen J. et al. (2007) have conducted a study to evaluate the results of the performance improvement project in a hospital complex using the Six Sigma model. The results showed a saving of more than \$ 300 million [20]. Lee, Kahn and Essan have conducted a study to investigate the integration of the Six Sigma program and continuous quality improvement for patient care and the results showed the reduced surgical costs [21].

The results of a study, entitled "the Six Sigma program and reduction in medical errors" by Able, showed that the Six Sigma program reduced the medical errors and costs [22]. Darvish Heidari, in his study entitled "application of the Six Sigma methodology", has concluded that implementing the Six Sigma program reduces the process time and costs and results in financial savings [23]. Gagner et al., in addition to expressing a saving of \$ 1.87 million per year for the Hospital, stated that Six Sigma program successfully improved the quality and reduced the costs [24]. The results of all the studies mentioned are consistent with the results of the present study. All of them could reduce the desired costs and this may be due to the ability of the Six Sigma program to find out the costly reasons of the organization.

It was observed that the average performance score of the users of the operating room equipment significantly increased after the implementation of the Six Sigma program (P -value = $0.001<0.05$). Nasiripour et al. (2008) have studied on the relationship between organizational culture and implementation of the Six Sigma program in the hospitals affiliated to the Kerman University of Medical Sciences and concluded that the Six Sigma program is a wave of promotion of quality culture in the organization [24]. The results of the study on the relationship between the Six Sigma and quality culture by Louis Davis, showed that implementing the Six Sigma program promotes the quality culture in the organization [24]. Mahmoudi Rad and

Astaki, have performed a study entitled “the effect of Six Sigma model implementation on the quantity and efficacy of patient education in CCU ward of Vali-e-Asr Hospital in Birjand” and concluded that the quality of patient education and their average knowledge score increased compared to the control group ($P < 0.001$). The results of the studies mentioned are consistent with the results of the present study which can be due to the promotion of people’ knowledge during the intervention that, contributes to problem-solving as a part of the program [25].

The limitations of the present study are a little time of monitoring the devices and also, the limited number of equipment.

Conclusion

Since implementing the Six Sigma program was effective in reducing malfunctions and the repairs costs of equipment and medical equipment plays a major role in the diagnosis, treatment and medical education, and the major share of hospital expenditures is annually paid to purchase medical devices and a lot of money is spent on maintenance and repair of medical equipment, it is recommended to implement this program on a wider scale and in greater period of time to manage hospital equipment.

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