



International Journal of Applied Business and Economic Research

ISSN : 0972-7302

available at <http://www.serialsjournals.com>

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Volume 15 • Number 23 (Part 2) • 2017

Investigate the Efficacy of Setting Patient Safety Standards on the Quality of Obtaining Informed Consent in Baharloo Hospital in Tehran

Description of the Disadvantages of the Procedure, Description of Alternative Methods Available, Description of the Possible Risks, Possibility Declare Dissatisfaction with the Procedure

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ABSTRACT

Fields and Goal: Patient safety is a global concern in all aspects of health services. Unsafe care and services bring huge economic costs to humans in addition to the infliction of suffering on them. Therefore, this study conducted with the aim of efficacy of setting patient safety standards on the quality of obtaining informed consent process in one of the hospitals of Tehran University of Medical Sciences (from 1389 to 1393).

Materials and Methods: This study is a descriptive - survey and quasi-experimental. The sample size targeted and accessible and using the Cochran formula were 200 patients, which at least one time in one of the hospital wards have undergone surgery. Information was collected using a 9-item checklist, through direct observation of researcher and interviews with patients or caregivers and by nurses in case of necessary. Data was analyzed using SPSS 18 software and paired *t*-test.

Findings: Setting patient safety standards in under study hospital have significant and positive impact on the quality of obtaining informed consent ($p = 0/001$), as well as on four variables, namely; (1) Description of

the disadvantages of the procedure to patients by doctor ($p = 0/001$), (2) Description of alternative methods available to patients by doctor ($p = 0/001$), (3) Description of potential risks arising from the failure to perform the procedure from the doctor ($p = 0/001$) and (4) Possibility of dissatisfaction with the procedure for patients ($001/0 = p$).

Conclusion: Setting patient safety standards and observance of the required principles are effective on the quality of obtaining informed consent from patients and will increase the quality of informed consent in all aspects.

Keywords: Patient safety, informed consent, standards of patient safety, hospital.

1. INTRODUCTION

Patient safety is a serious public health problem in the world. (2016 Bueno). It is estimated that approximately one person is injured in every 10 patients, which are receiving care in the hospital with high technology. (Classen, 2011 and, 2016 Bueno). According to the World Health Organization reports, annual millions of patients around the world suffer of disability, injury or death resulting from unsafe care (WHO, 2012). Unsafe care can include medication errors, surgical errors, diagnostic errors, nosocomial infections, patient falls, bedsores, wrong treatment and such other items (Abdi 2012). Therefore, we can say that the provision of patient safety is an important strategy in this field, which attempts to achieve reliable and accurate health care system by applying knowledge and scientific methods. In other words, the patient safety is identical with avoidance, prevention and improvement of unpleasant consequences or damage caused by health care process and in the meantime, safety, culture, quality and management are effective together (Emami Razavi, 2012).

Patient safety standards are a set of requirements that are vital for the implementing the patient safety program at the hospital. These standards provide the operational framework that enable hospitals for evaluating patient care in terms of safety, enhance skills of staffs in this category and participation of clients in the health care safety improvements (Khuri, 2007).

Three types of standards are classified: mandatory or vital (20 standards), basic (90 standards) and advanced (30 standards). Patient safety mandatory standards are set of requirements that are essential for the implementing the patient safety program at the hospital that categorized in 5 groups and 24 sub-groups, and for each area defined set of standards. One of the mandatory standards is in the participation seeking and interaction with the patient and the community standards group, which is defined in the field of obtaining informed consent before any remedial action and invasive diagnostics (Ganji & et al, 2011).

One of the most fundamental patient rights, is to give consent to accept treatment procedure. Any medical action according to law must be allowed by the patient and giving informed consent, and the most important principle of consent is, it's consciously (Batani, 2009). The patient has the right to have appropriate information. Without having the data, valid consent (consciously) cannot be achieved to him. Therefore, failure to give adequate and accurate information to him is a breach of contract whereby the patient can sue for any resulting damages (Druml, 2009). As a general rule the treatment without consent is illegal except in cases of real emergency (2010 Vora).

Ethical basis of informed consent is based on respect for the rights of patients. Regarding this right there should be enough information to select an option and discretion to refuse or accept medical interventions without coercion and prejudice. (Hajavi & Khoshgam, 2009).

A clinical examination will be complete, when it's various stages be done standard classical, although patient had minor complaint. For this reason, in addition to the license and obtaining the written consent of the patient in extensive surgery, it is necessary to achieve patient satisfaction in other examinations after an adequate description of necessary measures. Therefore, the patient's consent is considered the single most important laws on medical law. (Macintosh, 2010)

Informed consent is ethical and legal requirements for surgery and treatment of patients. It also is a moral form of modern practice, taking part, decision-making and attention (care) of the patients is the center (Bernat, 2006).

Despite previous studies regarding with the obtaining informed consent of the patient, there is not performed any codified research about the impact of setting patient safety standards on the quality of informed consent as yet. Study of Taghaddosi nezhad and et al showed that patient's awareness of possible complications of surgery and success percentage is evaluated fairly weak. Also, it is necessary to emphasized the importance of obtaining informed consent and informed acquit before any treatment modality, due to the majority attitude of patients based on relative fault of doctors in case of complications (Taghaddosi nezhad, 2008).

Melissa and colleagues (2009) research shows that unfortunately, consent forms support and approve the treatment of hospital and doctors, instead of giving information to patient to participate more in making decisions. (Vaskooei Eshkevari, 2009).

A study in England found that 95 percent of patients were satisfied with explanations provided before obtaining consent. (Houghton, 2010).

In a study, which performed in Christchurch Hospital (India) the majority of patients have mentioned, that the most important type of information are providing information about major risks and complications of surgery, and alternative methods are also described (93%). Moreover, Yang in 2010 showed that cancer patients participating in the research were aware of their incurable disease and its complications (Vaskooei Eshkevari, 2009). Also Siddiqi et al (2012) in study to assess the patients safety standards required, in 7 developing countries mentioned the realization of standards required, between 8 to 78 percent. Study Baines et al (2015) found a positive relationship between the variables of patient safety with improvement preventable side effects existing in England comprehensive safety program.

Havladr study (2004) showed that most patients are aware of the complications and even death, according to a study in South Africa, patients were not informed from other serious health risks and costs of treatment. Patients in Clifford et al's study (2005) felt that they have received enough information about the process. Despite this feeling, only 16 percent of patients were able to recall more than five of the 24 adverse side effect. Patients hardly remember potential risks and alternative methods. The majority of patients had tried physical and medication therapy that was not effective. The majority of patients were satisfied with the received information, but some offered suggestions for change or completion method, the most common suggestions by patients to improve this process was make a video of spinal process. (Clifford, 2005).

Teaching and learning (education) patient safety is of the most important tasks in order to guarantee providing safe care to the patient that this case has been confirmed in the Declaration of Helsinki (Rall,

2011) and the findings of the study Simon et al in 2015 also show that there are meaningful relationship between led improving the quality of care and patient safety with continuous training. This study conducted in 1393 in one of the selected hospitals of Tehran University of Medical Sciences aimed to assess the quality of the obtaining patient's informed consent after the setting of safety standards and disadvantages of the procedure, description alternative available methods, description of probable risks and possibility dissatisfaction with the procedure. Of course, these hospitals has achieved first place in terms of setting patient safety standards in country. The findings of this study can be used as a model for other health centers in this case and researcher hope that the results of this research can be used in future planning of health-care policy makers.

2. ANALYSIS METHOD

This study is a descriptive - survey and the quasi-experimental studies that was done early in setting of standards of patient safety, and after it.

Instruments used in this study are 9-questions checklist as 3 choice (poor, average, well), scored respectively, with scores (zero, half and one). Currently checklist for validation were available to specialists, professors, hospital quality improvement responsible, patient safety responsible expert, doctors Department of Forensic Medicine and senior ministry valuator. Score from checklist was considered between zero (minimum) to 9 (maximum). The standard of mentioned checklist were 5 groups according to the Table 1 (Table 1). Checklist was performed through direct observation of research, interviews with patients or their families and, if necessary, by nurses.

Table 1
Groups, subgroups and patient safety mandatory standards

<i>Sum</i>	<i>Mandatory standards</i>	<i>Subgroups</i>	<i>Groups</i>
36	9 standards	4	Governance and leadership
28	2 standards	2	Participation and interaction between patients and community
44	7 standards	4	Safe and evidence-based clinical services
21	2 standards	1	Safe environment
11	-	3	Continuing Education

The study population were 200 patients chosen by Cochran formula, targeted and accessible since the beginning of the setting of patient safety standards till ever, which at least one time in one of the hospital wards have undergone surgery and invasive procedures. After collecting the information, data was analyzed using SPSS 18 software and paired t-test.

3. FINDINGS

Based on the findings of present study, each 4 investigated assumption average increased compared to early establishment and a significance level of all four assumption is less than 0.05, which indicates the effect of patient safety standards establishment on quality of obtaining informed consent and its assumptions.

Table 2
Comparison statements of obtaining informed concept in studied hospital in the early patient safety standards establishment and afterwards at a glance (N = 200)

<i>Assumption</i>	<i>Statements</i>	<i>Early in the establishment</i>	<i>After the establishment</i>	<i>The average difference</i>	<i>Degrees of freedom</i>	<i>t</i>	<i>p. value</i>
Assumptions 1	Description quality of disadvantages (effects) of intended procedure to patients by doctor	0.85	2.81	1.95	199	16.62	0.001
Assumptions 2	Description quality of available alternative methods to patients by doctor	1.05	2.04	0.99	199	8.24	0.001
Assumptions 3	Description quality of the type and methods of performing the procedure to patients by doctor	0.40	0.67	0.27	199	5.85	0.001
Assumptions 4	Description quality of the intended procedure benefits to patients by doctor	0.21	0.98	0.77	199	36.94	0.001
Main assumption	Total score of all aspects	2.51	6.50	3.98	199	67.65	0.001

The establishment patient safety standards and has a significant positive impact on the quality of obtaining informed concept ($p = 0/001$). In addition, the establishment patient safety standards has a significant positive effect on the description quality of intended procedure disadvantages to patients by doctors and ($p = 0/001$).

The findings current study also showed that the establishment of standards quality for patient safety has a significant and positive impact on available alternative methods description quality to patients by doctor ($p = 0/001$). The results indicated that establishment patient safety standards quality has a significant positive effect on the description quality of risks arising from procedure disadvantages resulted by doctor. ($p = 0/001$). At the end, the establishment of quality standards for patient safety had a significant positive impact on the quality of possibility dissatisfaction with the procedure for the patient ($p = 0/001$). Also in Figure 1 through 5, respectively shows average difference resulting from the establishment of patient safety standard on the four hypotheses and main hypothesis.

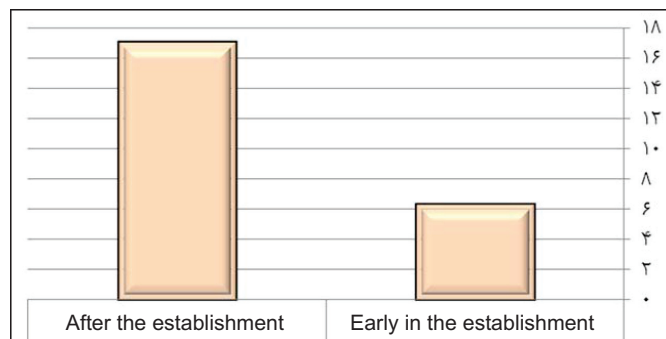


Figure 1: Average differences resulting from the establishment patient safety standards on the quality of obtaining informed concept

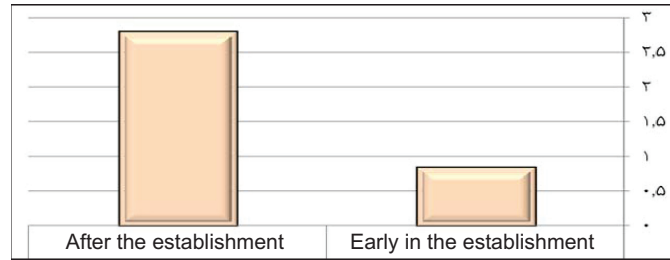


Figure 2: Average differences resulting from the establishment the quality of the patient safety standard on description quality of procedure disadvantages (complications) to patients

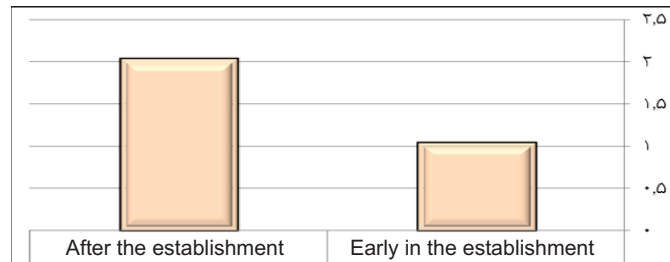


Figure 3: Average differences resulting from the establishment the quality of the patient safety standard on description quality of alternative methods available to patients

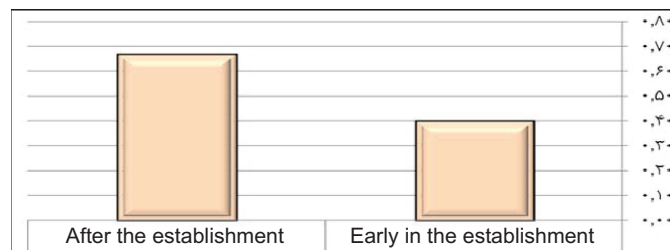


Figure 4: Average differences resulting from the establishment patient safety standards on description quality of risks arising from procedure disadvantages, to patients by doctor

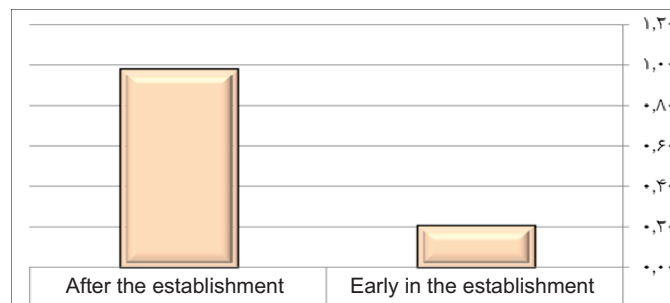


Figure 5: Average differences resulting from the establishment the patient safety standard on dissatisfaction with the procedure or choose alternative methods for the patient

4. DISCUSSION AND CONCLUSION

However, patients in hospital should be informed about their legal rights but moral and legal awareness in relation to informed consent are often limited. Sufficient information before surgery is fundamental to obtain informed consent from the patient. Information should include a description of the usefulness of

surgery, its complexity and risk during surgical procedures and different forms of treatment. Many studies have shown that writing of information is very useful.

In a study by Henley (1998) in South Africa, patients are not informed from other treatments and serious health hazard and treatment costs, while on present study methods and the risks of treatment explained by a doctor. In the study of Melissa et al (2009) also became clear, consent forms care consent treatment to support hospital and doctors, instead of giving information to patients to participate more in decisions. According to this, standards of patient safety considering patients' rights that in some ways is inconsistent with the findings of this research.

In a study, which performed in Christchurch Hospital (India) the majority of patients have mentioned, that the most important type of information are providing information about major risks and complications of surgery, and alternative methods are also described (93%). Moreover, Yang in 2010 showed that cancer patients participating in the research were aware of their incurable disease and its complications. That is consistent and aligned with results of this study and description of alternative methods to patients by doctors.

In addition, reviews of Razzaghi Kashani et al (1393) showed that the establishment of patient safety standards had a significant effect on the quality of preparation for the injection of blood products. In this study, Mahmoudi markid et al (1394) in the selected Emergency Department of Urmia Medical Sciences University also showed that nurses performance in 84/4 percent of cases had relatively good state in the application of safe injection standards before injection, in 15/2 percent injections were in the optimal range and did not receive any negative range.

Jenna et al (2012) in their study counted patient identification errors as one of the root causes medicinal side effects, surgery, diet and other medical errors and blood injection to the wrong person known as the major fatal error .

According to the results of Mazhari et al (1393), the average of observance standards in hospitals was 56/33%. This score indicates the average level of compliance with standards. To improve the points in this group, needs to promote health awareness in patients and their caregivers, to give power and the right to participate in decisions about their treatment and ensuring proper identification and authentication of the patient's identity at all stages.

Holler study (2004) showed that most patients are aware of the risk of death from complications of surgery. In this study explained the potential risks to patients resulting from failure to perform the procedure to patients by doctor. In this study, the early establishment of patient safety standards were in quite poor situation (40%), but after the establishment, the patient safety standard has better situation than before (64%), which is consistent with the Holler's study. Similarly, in the study of Taghaddosi nejad et al (1387) found amount of patients who become aware of possible complications and surgery success rate is evaluated fairly weak. Along with this study, obtained results from informed consent of the early establishment were 29%, which is consistent with poor condition. However, after the establishment of patient safety standard, this number reached 77%, which is in good condition.

Patients in Clifford et al's study (2005) felt that they have received enough information about the process. Despite this feeling, only 16 percent of patients were able to recall more than five of the 24 adverse side effect. Patients hardly remember potential risks and alternative methods. The majority of patients had

tried physical and medication therapy that was not effective. The majority of patients were satisfied with the received information, but some offered suggestions for change or completion method, the most common suggestions by patients to improve this process was make a video of spinal process. Moreover informing family members of patients can improve understanding all aspects of the provided information contained in the informed consent process.

According to the findings, it is necessary in medical ethics courses teach students the conditions of obtaining informed consent, and provide suitable time and appropriate field in hospitals.

It seems that the institutionalization of patient safety culture, focusing on patient in the way of service provision, training staff and patients and regulatory clearance, increased patient safety standards in the country. Therefore, the establishment of standards of patient safety and compliance requirements affect the quality of informed consent from patients and will increase the quality of informed consent in all aspects. Suggested more comprehensive study as coordinated action to design a single form of medical consent, to be used in all health units, which contribute to procedure unification.

Talents within the organization, senior management support and a positive attitude are essential in order to implement safety programs. The strong point of program is communication with the noble values of human that was reinforced with the systemic attitude of the authorities. In this context, the quality of success was in a relatively good place. However, intermittent training courses establishment, continuous monitoring and simultaneous change of personnel attitude, open an excellence way towards ideal levels.

Acknowledgments

This study is the result of MSc thesis, Tehran University of Science and Research, and we want give thanks, sincere appreciation for cooperation to all colleagues in Tehran University of Medical Sciences Complex, that helped us in any way to conducting this study.

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