The Quality of Informed Consent After the Establishment of Patient Safety Standards: The Consent of the Physician, The Presence of a Third Party, The Description of the Type of Procedure, The Description of the Benefits of the Procedure

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Abstract

Objectives: The present study was to investigate the aim of establishment of patient safety standards' impact on quality of informed consent in Baharlo Hospital in Tehran.

Research Method: This is descriptive-survey research that was done by cross-sectional method. The statistical population of the study consisted of all patients who underwent surgical procedures since the establishment of patient safety standards from 2011 to 2016. 200 people were selected using target and convenient sampling method. The data were collected using a checklist and were analyzed using inferential statistics of paired t-test.

Findings: The findings of the study showed that the establishment of patient safety standards has a positive and significant effect on the quality of informed consent ($p = 0.001$) and also on 4 variables: 1) the consent of physician or the person performing the procedure ($p=0.001$), 2) presence of a third party (nurse or companion) at the time of obtaining consent ($p = 0.001$), 3) description of the type of procedure by the physician to the patient ($p = 0.001$), 4) description of the benefits of the procedure to the patient ($p = 0.001$) in Baharlo Hospital.

Conclusion: Establishment of patient safety standards as well as observance of their mandatory principles affects the quality of informed consent of patients and increases the quality of informed consent in all aspects.

Key words: Patient Safety Standards, Quality of Informed Consent

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Introduction

In the current world, the quality of health care and the improvement in hospital performance has been a global issue and one of the main goals of the health system of all countries. Among the most important reasons for addressing the issue of quality in health care, there are problems with the safety of providing these services (Emami Razavi et al., 2011).

Patient safety standards are a set of requirements that are critical to patient safety planning in the hospital setting. These standards provide operational forms that empower hospitals to evaluate patient care in terms of patient safety, empowerment of staff in patient safety, and empowerment of service users in promoting health in healthcare services (Emami Razavi et al., 2011).

Patient safety is a global concern in all health care settings. Inadequate care and services, besides imposing suffering on patients, cause heavy economic costs. Although significant advances have been made in the last decade in terms of patient safety, there are still many shortcomings; and the degree of damage inflicted on patients is unacceptably high (Parsapur et al., 2009).

The World Health Organization has recognized the importance of patient safety and prioritized it as a public health concern. The Eastern Mediterranean World Health Organization has launched a safety hospital program. This program is considered necessary to implement a set of patient safety standards for the hospital and staff to provide the best performance in this regard (Emami Razavi et al., 2011).

Patient safety standards are comprised of five main groups and subdivided into 24 subgroups. This section includes guidelines for assessors, including documentation to be reviewed for each standard, relevant interviews, guided visits and group visits, and rating guidelines. (Farkhondeh, 2010).

The five groups that meet the following standards are:
A. Leadership
B. Attracting patient and community engagement
C. Clinical-safety and evidence-based services
D. Safe environment
E. Continuous training

Every living human has life, health and death rights. One of the most fundamental rights of patients is the right of consent to treatment. Logically every person with a healthy mind has the right to decide on what action is conducted on his or her body (Farzandipour, 2012).

According to law any medical action should be permitted by the patient through informed consent, and the most important principle in obtaining consent is consciousness (Bateni, 2013; quarterly journal of Jamaran Heart Hospital) and the patient has the right to have the right information as without this, informed consent is not obtained. Therefore, the failure to provide adequate and accurate information to a patient is a breach of the contract, according to which the patient can lodge an action for any damages (Darmal, 2009)

As a general rule, patient treatment is unlawful without their consent, except in cases such as real-life emergency situations (Voura, 2010).

Conscious consent is not just signing the consent form, but also informed consent. There must be 6 conditions met: “Provide information, understanding, decision competence, consent signature or oral satisfaction, and factors relating to the interaction between the doctor and the patient”. (Sheikh Taheri, 2008).

The legal origin of informed consent lies within the context of the law, which is based on the principle that each individual “has the right to know what action is conducted on his body” (Sklundorf, the New York Hospital Association of 1914, quoted by Hiller 2008) and they must be medically satisfied. The legal aspect of more informed consent is used in negligence cases, so that the patient has permitted doctor to take steps to improve his condition when he / she consents to the intervention of the physician, but the physician may not describe the risks and possible consequences (Abbasi Nejad, 2011).

Despite research on patient consent, the research on the impact of establishing patient safety standards on the quality of informed consent has not been investigated. Therefore, the aim of this study is to answer this question. The research is carried out in Baharlo Hospital, the first ranked hospital in terms of establishment of patient safety standards. Therefore, the findings of this study can be used as a model for other health centers in this area.

There are few studies in Iran in this regard. In some studies, this topic has been partially discussed from the point of view of the patient rights charter. A study in Yazd has reported mediating the patient’s right to inform the nurses. (Nasiriyani, 2007)

Studies in Iran show that Iranian physicians generally provide general information about the illness to the patient. Doctors also seem to be more prudent in reporting side effects and other treatment options. In this study, 50% of the respondents believed that the information given was not understandable. (Vahdhani Nia, 2007; Amini, 2008; Taghadosi nezhad, 2008)

Studies in Iran have shown that generally enough information about diagnosis or treatment is not provided to patients, and patients do not understand the information provided (Tariqat, 2007; Davar Panah, 2002; Dengirz, 2007; Wahdadi, 2004).

The study of CD Coy (2009) also referred to the same subject. Though studying Jawf (2001) reported in America, 86% of patients considered the information understandable.

A study in Sydney showed that 74.6% of cancer patients knew that their disease was untreatable (Gatthalari, 2002). Hawolder's (2004) study also found that most patients were aware of the complications of surgery and even the possibility of death.

Butachyara et al concluded that informed consent in admissions was associated with the risk of an increase in compensation (P ≤ 0.000). In other words, by increasing the risk of surgery, the team needs to be more responsible for providing appropriate information to patients and reducing future reimbursement. (Quotes, 2012).

Yang's study 2010, also revealed that cancer patients studied were aware of the untreatable nature of their illness and its complications. A study in Switzerland also found that patients considered the amount of information provided (both written and oral) to be good and adequate (Qulam, 2006) The study of CD Coy (2009) also referred to the same subject. A study by Jaff (2001) in the United States reported 86% of patients considered the information understandable.

Research method

The overall aim of this study was to investigate the effect of establishment of patient safety standards on the quality of informed consent in Baharlo Hospital in Tehran. This study is a descriptive-survey study that was conducted in Baharlo Hospital. This research was a semi-experimental study that was carried out before and after establishment of patient safety. This research was done on a field scale and the information gathering tool was a checklist for the standard of quality of information for informed consent. Through direct observation, interviews were conducted with the patient and, if necessary, with the nurses.
The tool used in this study was a checklist. The checklist is available to expert users (professors, responsible for improving the quality of the hospital, a patient safety expert, doctors of the Forensic Medicine Group and a senior evaluator of the ministry at Baharlo Hospital). For each statement, the check list has three weak options (zero score), average (score of 0.5) and good (score 1) and the score obtained from the check list is between zero (at least) and 12 (maximum)

The statistical population of this study included all patients who underwent surgical procedures since the beginning of the establishment of patient safety standards in all parts of the Baharlo hospital in Tehran (from 2010-2016).

Sample size: The sample number was estimated by Cochrane formula 200. The sampling method was targeted and available at the time of the study in Baharlo Hospital of the patients undergoing surgery.

To analyze the data of the present study, we use the inferential statistics of the paired t-test.

Table 1: Comparison at a Glance Informed consent centers in the hospital at the beginning and after the establishment of patient safety standards

Hypothesis	Items	Before establishment	After establishment	Mean difference	Degree of freedom	t	p value
Hypothesis 1	Obtain informed consent by the doctor or the person administering the procedure	1.02	2.98	1.96	199	22.279	0.001
Hypothesis 2	The presence of a third party (nurse or companion patient) at the time of consent from the patient	1.11	2.97	1.86	199	29.283	0.001
Hypothesis 3	The quality of the description of the type and manner of conducting the procedure by the physician to the patient	0.73	2.52	1.89	199	26.34	0.001
Hypothesis 4	Quality description of the benefits of the procedure by the physician to the patient	1.01	2.15	1.14	199	11.20	0.001
Main hypothesis	**Total score of all dimensions**	**3.87**	**17.12**	**10.47**	199	22.297	0.001

Findings

The findings of this study showed that the establishment of patient safety standards has a positive and significant effect on the quality of informed consent. (P = 0.001) Although patients in the hospital should be informed about their legal rights, the legal and ethical awareness of informed consent is often limited. Sufficient information before surgery is fundamental and the basis for patient's informed consent. Information should include the description of surgical usefulness, risk and complexity during the surgical procedure and various treatment regimens. Many studies have shown that providing information has a very beneficial effect. Patients who receive information in writing during treatment can better understand their information and recall after surgery (Rajesh, 2013). The results of this study indicate that the establishment of patient safety standards has improved all the information that was considered in the study, as well as the length of the treatment and information provided by the doctor or the person performing the procedure.

In studies in Iran, it has been shown that sufficient information about the diagnosis is not available to patients (Sheikh Taheri, 2010), while in the present study safety standards have affected this item. The doctor writes the type of diagnosis in the informed consent form, after a written explanation. In other countries, studies show that patients receive better information about their illness in this format which is consistent with the current study (Gatlari, 2002; Gulam, 2006; Jacick, 2009; McIntosh, 2010).

The findings of this study showed that the establishment of patient safety standards on the quality of third-party presence (nurse or companion) has a positive and significant effect on consent. (P = 0.001) According to Rajesh (2013) research, in the UK, the physician is obliged to obtain consent, and individuals over the age of 18 years are qualified to give consent. Patient consent is not just a signed form. Consent should be obtained regarding complications for as high a prevalence of 1%, which was congruent with the present study in which consent is obtained by physician except in rare cases, where it is obtained by nurses.

The study, by Golam (2006), found that patients considered the amount of information (both written and oral) to be good and adequate. A study by Gathlory in Sydney showed that 74.6% of cancer patients know that their disease is untreatable. Hawolder's (2004) study also found that most patients were aware of the complications and even the possibility of death.

Conclusion

The findings of the study showed the benefit of establishment of patient safety standards on the quality of informed consent (p = 0.001), as well as on 4 variables, namely, (1) obtaining consent by the practitioner or the person performing the procedure (p = 0.001) 2) The presence of a third party (nurse or companion) at the time of obtaining consent (p = 0.001); 3) Description of the type of procedure by the physician to the patient (p = 0.001); 4) Description of the benefits of the procedure, by the physician (p = 0.001) and it has a positive and significant effect in Baharlo Hospital. Establishing patient safety standards as well as observing its mandatory principles will affect the quality of informed consent of patients and will increase the quality of informed consent in all aspects.

Recommendations

Based on the results of the research and the achievement of the effect of establishing patient safety standards on the quality of informed consent, it is suggested that, with more comprehensive coordinated studies, a national medical consensus form could be designed and developed to be used in all treatment units which could help to unify the procedure. And the information forms of informed consent by the physician should be simple and understandable, with less use of medical terms. The complications and side effects of surgery should be explained by the doctor and the patient should be the ultimate decision maker.

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