**A Survey of Current Practice of Informed Consent in an Iranian Hospital**

**Abstract**

**Aim and Background:** Informed consent is legal and ethical process which considered as important issue in quality of patient's treatment. The aim of the current study was to assess current informed consent of patients admitted in Rasoul Akram Hospital, 2014.

**Method:** This cross-sectional study was conducted on 300 patients admitted in Rasoule Akram Hospital. Data was collected using a dichotomous questionnaire with 30 questions. Statistical analysis was done using SPSS software (version 18).

**Results:** The results shown that 46% of patients had medium perception about informed consent, 44% believed to get insufficient information and 66% claimed to have active participation in treatment process. The significant associations were found between some dimensions and important parameters: Understanding of information dimension and education level (p<0.008), Participation (in decision-making) dimension and type of hospitalization (p=0.01), and level of patients' information dimension with resident adress (p=0.027) and medical specialty (p<0.001).

**Conclusion:** The current informed consent of patients wasn't in desirable condition and need to take proper actions such as give proper information, training, sufficient information and etc.

**Key words:** informed consent, Hospital, participation, Understanding ,information, patients.

**Introduction**

Informed consent is defined as a free and voidable agreement of patients in their contribution for medical (or research) decisions following their awareness about the procedure's nature, objective and consequences with belief that this contribution is for the selection of the most effective and useful medical treatment (1). Therefore, informed consent is a process that enables patients/individuals to voluntarily participate in treatment decisions (2,3). Informed consent is important not only from an ethical and legal perspective, it is also effective on the quality of care, patient understanding and cooperation, improved results and satisfactory medical treatments and contributes to the prevention of errors (2).

It is of high importance to achieve an effective informed consent plan due to its impression vulnerability from multiple factors (4). For instance, one of the most important factors is the cultural factor of a society which can therefore affect the relationship between patient and physician (2,5). Another influential factor is the patient's educational level and experience of the medical staff (6). For example, in Croatia, doctors and medical staff do not undergo necessary trainings for attaining and implementing informed consent (7). In addition to educating patients, medical staff should also be trained to improve their knowledge and skills in this field to obtain the required skill & knowledge about informed consent (8,9). Age, gender, state of health of patients, procedures, legal requirements, etc. can be considered among the factors affecting this process (10).

Since 1999 research regarding informed consent started in Iran and currently, based on the notification of health ministry, it is compulsory to observe patients' right as an important principle in medical centres (11). However, there are numerous challenges in this regard which could affect the efficiency and effectiveness of these plans. Informed consent is effective only when patients have sufficient information about different treatment options (12). Studies show that in some cases although patients long to be informed, they do not receive adequate information about their surgical procedure (11,13).

In a survey conducted July and et al three factors of patients unawareness of their rights are mentioned as barriers against the realization of their rights including lack of accountability in monitoring system, lack of human resources, time and facilities especially in teaching hospitals (14). Important to state that many informed consent forms that is used in Iran is predesigned and do not have specified and precise details about side effects and complaints (15).

While informed consent is an important and precise process and should be revised according to the changing circumstances (4). Therefore, various studies are required to address the quality of informed consent in different medical wards so that the roots for weaknesses are identified and problems would be fixed (16). The present study is with the aim of verifying the status of informed consent in patients treated in Rasousl-e-Akram Hospital in 2014.

**Method**

The present study is a cross-sectional research in 2014 carried out in Rasoul-e-Akram Hospital which is affiliated to Iran university of Medical sciences in I.R Iran. It is a General functioning hospital offering different medical specialties. To conduct this study, all in-patient admissions were considered as the research population. According to the existing statistics of the hospital, in-patient admission of the hospital is approximately 1,900 patients per month on average. And so, using Cochran formula 5% error was considered and 300 people were selected as sample size in this study. For sampling, simple random sampling method was applied.

To collect data a questionnaire was used which was first developed by amini and et al and its validity and reliability was approved (17). However, in order to be applied in this study its psychometric was again examined. To obtain face validity, it was distributed among nine experts and their points of views enhanced the questionnaire. To determine content validity, Content Validity Ratio (CVR) was used. Given the number of nine experts and using [Lawshe table](https://www.google.com/search?safe=off&q=lawshe+table&spell=1&sa=X&ved=0ahUKEwjfjOW8oqLMAhWHWCwKHZA4CYQQvwUIGigA), questions with CVR values less than 78.0 were removed or modified. Cronbach's alpha test was used to determine the reliability of the questionnaire, resulting in the numerical value of 86.0 its reliability was approved.

The questions were divided into two parts: general and specific questions: the general section includes background information such as age, gender, marital status, education, occupation, residence location, number of hospitalizations, method/reason for hospitalization and medical expertise. 20 questions were designed for Specific section in which 18 questions had a response range with six options of no (with a value of zero), very low (with a value of 1), low (with a value of 2), medium (with a value of 3), high (with a value of 4) and very high (with a value of 5), and the other two questions had three choice answer options.

In order to collect the data the questionnaires were distributed among individuals in person. Before completing the questionnaire, they voluntary participation was assured and they were assured that the information the share would remain completely confidential. Afterwards, necessary explanations were provided to patients to fill the questionnaire.

The obtained data was analyzed using a version 18 SPSS. Descriptive statistics were used to report descriptive data and to report analytical data parametric tests such as two-sample t-test and one way ANOVA test were used. The significance level for all tests was 5%.

**Results**

Table 1 shows the information of individuals participated in the study. 66% of the participants were male, mean and Standard Deviation of their age were 43 and 19 years respectively, 70% were married, more than half of them had education under senior high school and 54% percent of them were hospitalized for the first time.

Table 2 indicates the quality status of three dimensions relating to informed consent of patient. Accordingly, most people (46%) had an average understanding of informed consent, while 33% of them expressed their perception and understanding in a range of low to nothing and only 21% of the participants expressed a high or very high level for it.

44% of the patients stated that the information given to them by medical staff was little or nothing at all, while only 16.7% of patients announced that the information they received was "a lot" and "very much". In the dimension of patients' participation level in decision making 66% of the patients claimed that they had a good contribution in the decision-making and 13% did not state any participation.

The relationship between informed consent and other parameters (Table 3) shows that the patients' understanding has only a significant relationship with their education level (P>0.008). Patients' participation dimension in the treatment period was significantly correlated (P=0.01) only with the type of hospitalization (normal or emergency). There was a significant relationship between the patients' information intake and their residence location (P=0.027) and medical expertise related with the patients (P<0.0001). A significant difference was found in the information received concerned the patients living in rural areas.

**Discussion**

Informed consent is a key element in modern patient-centered medicine approach and represents informed decision making of individuals to receive health services. In addition to the patient's participation and their role in culture building, it is necessary that the health system lay essential infrastructures. This study aimed to evaluate the status of informed participation of individuals in Rasoul-e-Akram Hospital and was conducted with the participation of 300 patients.

The results showed that the majority of patients (44%) considered the provided information insufficient or nothing at all. Several studies also suggest the inadequacy of the information in this field. For instance, in Sheikh Taheri study nearly 83% (18) and in Amini and et al study 60% of the participants believed that the information they received was insufficient (17). In the study of Kigoba and et al (2012) only 9% of individuals has stated that during the study or treatment they have received inadequate information (19). Systematic review of studies published over the period of 1961 to 2006 showed that level of consent was 58% from the information received (20). These differences may be due to different procedures in different hospitals and locations, monitoring systems and monitoring, level of staff awareness and training and etc.

There was a significant relationship between the information received about the participants’ residence location and the ward of hospitalization. Accordingly, the information received by rural residents is less in comparison with urban residents. This shows that in order to promote informed consent, rural and urban segregation should also be considered and appropriate training should be given to rural residents. This training can be organized at the location of rural residents by the relevant organizations or at the visiting location of the patient by the medical team. Study of Vosugh and et al in Ardebil shows that informed consent can be affected by the residence location (21). Thus, in the methods and measures to obtain informed consent it is essential to take spatial and temporal conditions into consideration.

Moreover, it should be noted that most people participated in this survey had an education level lower that senior high school and there was a significant relationship between the values of their understanding from informed consent and level of education. With increase in the level of education average value for the understanding of information increased too. It challenges the people about the issue of what kind of information they need for their treatment. Even if there is a proper interaction between the medical system and patients, individuals’ differences in terms of education level and awareness should be considered (10).

Therefore, it is necessary that the amount of receiving information which is required to be commensurate with the level of participants’ education and provide the people at the time of need since it seems that the participants’ expectations vary depending on their level of education (22). Therefore, it is essential to adopt appropriate measures so that informed consent becomes informed choices. Kumanka and et al study showed that among 2026 surveyed patients only 19% had enough health literacy. This study also indicated to an important issue; having enough health literacy and providing necessary information to the patients can facilitate treatments in addition to affecting the satisfaction of medical care they receive (23).

In the dimension for the level of participation they had 66% of participation. Also, participation of the patients during their hospitalization had a significant relationship with their type of hospitalization (normal or emergency) and the level of participation from emergency ward participants was less than others. Since generally patients at the time of their first visit to emergency ward may have a poor health status and stress they may be less inclined to contribute. A study carried out by Hoagland and et al also showed that level of participation was 60%.

A study conducted by Zafarghandi et al also reveals less participation to the level of approximately 42% (25). Individuals’ participation depends on various factors. For example, patients should be aware of their duties and the importance of their roles (26). However, alongside, physicians should accept the active participation of the patients as a major principle. Even if they are informed, they should be still receiving the essential trainings (27). In addition to these items, there should be comprehensive guidelines to obtain consent from patients and to explain details relating to the patients and their responsibilities.

It is therefore critical to consider various factors such as education level, residence location, and health status of patients in hospital wards and etc when obtaining informed consent and noting these factors give them appropriate trainings. Also it is important to be assured of the accuracy and completeness of the information entered in the forms.

**Conclusion**

The results of this study indicate that the informed consent of the individuals is not desirable and necessary measures is required to achieve a level that the patients’ informed consent convert to informed choices. In this direction more focus is essential with respect to parameters including providing information in accordance with the patients’ education level, inpatient ward in which they are admitted and their residence location (particularly rural).

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Table 1. Frequency distribution & frequency percentage of the study patients' background characteristics

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Components** | **Frequency** | **%** |
| Medical specialty | ENT | 38 | 12.4 |
| Urology | 4 | 1.3 |
| Surgery | 42 | 13.7 |
| Orthopedic | 41 | 13.4 |
| Obstetrics and Gynecology | 12 | 3.9 |
| Ophthalmology | 89 | 29.1 |
| Neurology | 15 | 4.9 |
| Cardiovascular | 65 | 21.2 |
| Geneder | Male | 202 | 66.2 |
| Female | 103 | 33.8 |
| Marital Status | Married | 216 | 70.8 |
| Single | 89 | 29.2 |
| Type of hospitalization | Emergency | 106 | 34.6 |
| Ordinary | 200 | 65.4 |
| Occupation | Unemployed | 26 | 8.5 |
| Studying | 38 | 12.4 |
| housewife | 73 | 23.9 |
| freelance | 95 | 31 |
| Employee | 35 | 11.4 |
| Other | 39 | 12.7 |
| Residency Address | Provincial capitals. | 139 | 45.6 |
| town | 85 | 27.9 |
| Village | 81 | 26.6 |
| Education | junior high school | 152 | 51 |
| Diploma | 90 | 30.2 |
| Associate Degree | 30 | 10.1 |
| Undergraduate and above | 26 | 8.7 |
| Number of hospitalizations | admitted once | 165 | 54.5 |
| 2 to 3 times | 122 | 40.3 |
| More than 3 times | 16 | 5.3 |
| Patient Age | 21< | 39 | 12.7 |
| 21-34 | 68 | 22.2 |
| 35-49 | 75 | 24.5 |
| 50-65 | 86 | 28.1 |
| 65> | 38 | 12.4 |

Table 2. Frequency distribution of quality status for each of the three dimensions of patients' informed consent

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Dimensions** | **None** | **very low** | **Low** | **Medium** | **High** | **Very High** |
| Understanding of information | 2.3% | 8.2% | 22.5% | 46.1% | 18.3% | 2.6% |
| Participation in decision-making | 13.1% | 0.3% | 2.6% | 18% | 29.7% | 36.3% |
| level of patients' information | 4.6% | 8.2% | 31.4% | 39.2% | 16% | 0.7% |

Table 3. Quality for each of the three dimensions of informed consent based on background characteristics

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Characteristics** | **Components** | **Understanding of information** | | | **Participation in decision-making** | | | **level of patients' information** | | |
| **Mean** | **Standard Deviation** | **P-value** | **Mean** | **Standard Deviation** | **P-value** | **Mean** | **Standard Deviation** | **P-value** |
| Medical specialty | ENT | 2.68 | 0.67 | 0.68 | 3.95 | 1.41 | 0.181 | 3.13 | 0.78 | 0.001≥ |
| Urology | 2.75 | 0.2 |  | 4.25 | 0.5 |  | 2.68 | 0.63 |  |
| Surgery | 2.65 | 0.77 |  | 3.19 | 1.53 |  | 2.13 | 0.82 |  |
| Orthopedic | 2.89 | 0.84 |  | 3.66 | 1.26 |  | 2.57 | 0.8 |  |
| Obstetrics and Gynecology | 2.44 | 0.8 |  | 3.08 | 1.68 |  | 2.5 | 0.61 |  |
| Ophthalmology | 2.67 | 0.94 |  | 3.67 | 1.66 |  | 2.34 | 0.88 |  |
| Neurology | 2.9 | 0.85 |  | 2.87 | 2.45 |  | 2.41 | 0.82 |  |
| Cardiovascular | 2.74 | 0.69 |  | 3.74 | 1.68 |  | 2.65 | 0.69 |  |
| Gender | Male | 2.79 | 0.77 | 0.25 | 3.54 | 1.63 | 0.461 | 2.58 | 0.83 | 0.103 |
| Female | 2.57 | 0.85 |  | 3.69 | 1.59 |  | 2.41 | 0.85 |  |
| Marital Status | Married | 2.74 | 0.81 | 0.451 | 3.63 | 1.65 | 0.544 | 2.53 | 0.83 | 0.8 |
| Single | 2.66 | 0.8 |  | 3.51 | 1.55 |  | 2.5 | 0.86 |  |
| Type of hospitalization | Emergency | 2.65 | 0.87 | 0.273 | 3.24 | 1.95 | 0.01 | 2.59 | 0.88 | 0.267 |
| Ordinary | 2.75 | 0.77 |  | 3.79 | 1.37 |  | 2.48 | 0.82 |  |
| Occupation | Unemployed | 2.6 | 0.77 | 0.142 | 3.81 | 1.39 | 0.741 | 2.45 | 0.78 | 0.2 |
|  | Studying | 2.64 | 0.6 |  | 3.61 | 1.46 |  | 2.56 | 0.76 |  |
|  | housewife | 2.55 | 0.94 |  | 3.58 | 1.74 |  | 2.34 | 0.83 |  |
|  | freelance | 2.88 | 0.72 |  | 3.74 | 1.56 |  | 2.61 | 0.84 |  |
|  | Employee | 2.82 | 0.86 |  | 3.4 | 1.52 |  | 2.74 | 0.83 |  |
|  | Other | 2.68 | 0.85 |  | 3.33 | 1.91 |  | 2.45 | 0.94 |  |
| Residency Address | Provincial capitals. | 2.69 | 0.85 | 0.263 | 3.45 | 1.75 | 0.24 | 2.41 | 0.85 | 0.027 |
| town | 2.66 | 0.79 |  | 3.61 | 1.43 |  | 2.53 | 0.78 |  |
| Village | 2.85 | 0.72 |  | 3.83 | 1.56 |  | 2.72 | 0.85 |  |
| Etionduc | junior high school | 2.6 | 0.86 | 0.008 | 3.69 | 1.57 | 0.641 | 2.46 | 0.9 | 0.108 |
|  | Diploma | 2.73 | 0.74 |  | 3.42 | 1.75 |  | 2.48 | 0.72 |  |
|  | Associate Degree | 2.93 | 0.57 |  | 3.57 | 1.63 |  | 2.52 | 0.79 |  |
|  | Undergraduate and above | 3.12 | 0.81 |  | 3.46 | 1.56 |  | 2.89 | 0.73 |  |
| Number of hospitalizations | admitted once | 2.7 | 0.83 | 0.699 | 3.45 | 1.75 | 0.233 | 2.51 | 0.83 | 0.874 |
| 2 to 3 times | 2.74 | 0.75 |  | 3.77 | 1.46 |  | 2.53 | 0.85 |  |
| More than 3 times | 2.56 | 1 |  | 3.75 | 1.34 |  | 2.42 | 0.91 |  |
| Patient Age | 21< | 2.66 | 0.64 | 0.514 | 3.64 | 1.53 | 0.641 | 2.58 | 0.89 | 0.841 |
| 21-34 | 2.77 | 0.86 |  | 3.35 | 1.8 |  | 2.5 | 0.9 |  |
| 35-49 | 2.82 | 0.74 |  | 3.6 | 1.41 |  | 2.6 | 0.83 |  |
| 50-65 | 2.61 | 0.88 |  | 3.77 | 1.64 |  | 2.46 | 0.8 |  |
| 65> | 2.72 | 0.82 |  | 3.61 | 1.72 |  | 2.48 | 0.78 |  |