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A Survey of Current Practice of Informed Consent in Iranian Hospitals

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ABSTRACT

Background: Informed consent is legal and ethical process which is 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 Iranian selected Hospitals, 2016.

Materials and Methods: This cross-sectional study was conducted on 2150 patients admitted in 11 public Hospitals. Data was collected using a dichotomous questionnaire with 30 questions. Statistical analysis was done using SPSS software (version 18).

Results: The results showed 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 address (p = 0.027) and medical specialty (p < 0.001).

Conclusion: In our study the current informed consent of patients wasn’t in desirable condition. The Necessary measures are required to achieve a level that the patients’ informed consent convert to informed choices. Hospital healthcare team need to take proper actions such as give proper information, patient training, sufficient information and etc.

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 (Parsapour, Parsapour, and Larijani 2005). Therefore, informed consent is a process that enables patients/individuals to voluntarily participate in treatment decisions (Barnett et al. 2008; Oduro et al. 2008). 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 (Barnett et al. 2008). It is of high importance to achieve an effective informed consent plan due to its impression vulnerability from multiple factors (Bhattacharya, Dhiman, and Chaturvedi 2016). 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 (Barnett et al. 2008; Smith 2016). Another influential factor is the patient's educational level and experience of the medical staff (Minnies et al. 2008). For example, in Croatia, doctors and medical staff do not undergo necessary trainings for attaining and implementing informed consent (Juki ´c et al. 2009). 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 (AL-RIYAMI et al. 2011; Leclercq et al. 2013). Age, gender, state of health of patients, procedures, legal requirements, etc. can be considered among the factors affecting this process (Molyneux et al. 2005).

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 (Joolaee and Hajibabaee 2012). 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 (Faghnipour, Joolaee, and Sobhani 2014). Studies show that in some cases although patients long to be informed, they do not receive adequate information about their surgical procedure (Farzandipour, Sheikhtaheri, and Sadeqi Jabali 2015; Joolaee and Hajibabaee 2012).

In a survey conducted by 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 (Joolaee et al. 2008). 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 (Joolaee and Hajibabaee 2012).

While informed consent is an important and precise process and should be revised according to the changing circumstances (Bhattacharya, Dhiman, and Chaturvedi 2016). 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 (Hall, Proc-hazka, and Fink 2012). The present study is with the aim of assessing current informed consent of patients admitted in Iranian selected Hospitals, 2016.

Materials and methods

The present study is a cross-sectional research in 2016 carried out in 12 Hospitals which is affiliated to Iran university of Medical sciences in I.R Iran. They are General hospitals offering different medical specialities. To conduct this study, all inpatient admissions were considered as the research population. According to the existing statistics of the hospitals, inpatient admission of the hospitals is approximately 19900 patients per month on average. And so, using Cochran formula 2% error was considered and 2150 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 (Amini, Moosavi, and Mohammadnejad 2009). 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, 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 should read their voluntary participation and they were assured that the information the share would remain completely confidential. Afterwards, necessary explanations were provided to patients to assist in filling the questionnaire.

The obtained data was analyzed using SPSS version 18. 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 who 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 a moderate 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.
Table 1. Frequency distribution & frequency percentage of the study patients’ background characteristics.

| Variable          | Components        | %    |
|-------------------|-------------------|------|
| Medical specialty | ENT               | 12.4 |
|                   | Urology           | 1.3  |
|                   | Surgery           | 13.7 |
|                   | Orthopedic        | 13.4 |
|                   | Obstetrics and Gynecology | 3.9 |
|                   | Ophthalmology     | 29.1 |
|                   | Neurology         | 4.9  |
|                   | Cardiovascular    | 21.2 |
| Gender            | Male              | 66.2 |
|                   | Female            | 33.8 |
| Marital Status    | Married           | 70.8 |
|                   | Single            | 29.2 |
| Type of hospitalization | Emergency     | 34.6 |
|                   | Ordinary          | 65.4 |
| Occupation        | Unemployed        | 8.5  |
|                   | Studying          | 12.4 |
|                   | housewife         | 23.9 |
|                   | Freelance         | 31.1 |
|                   | Employee          | 11.4 |
|                   | Other             | 12.7 |
| Residency Address | Provincial capitals | 45.6 |
|                   | town              | 27.9 |
|                   | Village           | 26.6 |
| Education         | junior high school| 51.1 |
|                   | Diploma           | 30.2 |
|                   | Associate Degree  | 10.1 |
|                   | Undergraduate and above | 8.7 |
| Number of hospitalizations | admitted once | 54.5 |
|                   | 2 to 3 times      | 40.3 |
|                   | More than 3 times | 5.3  |
| Patient Age       | 21<               | 12.7 |
|                   | 21–34             | 22.2 |
|                   | 35–49             | 24.5 |
|                   | 50–65             | 28.1 |
|                   | 65->              | 12.4 |

44% of the patients stated that the information given to them by medical staff was low, very low and nothing at all, while only 16.7% of patients announced that the information they received was “high” and “very high”. In the dimension of patients’ participation level in decision making 66% of the patients claimed that they had a good (high and very high) 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.

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

| Dimensions          | None  | very low | Low   | Moderate | 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%      |

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 Consent of inpatients in Selected Hospitals and was conducted with the participation of 2150 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% (Sheikhthaheri and Farzandipour 2010) and in Amini and et al study 60% of the participants believed that the information they received was insufficient (Amini, Moosavi, and Mohammadnejad 2009). In the study of Kiguba and et al (2012) only 9% of individuals have stated that during the study or treatment they have received inadequate information (Kiguba et al. 2012). Systematic review of studies published over the period of 1961 to 2006 showed that level of consent was 58% from the information received (Falagas et al. 2009). 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
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              | Mean                       | Standard Deviation | P-value |
| Medical specialty       | ENT                         | 2.68                         | 0.67                            | 0.68                        | 2.95               | 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          |                        |
| Education               | 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 | 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          |                        |
|                         | > 3                         | 2.56                         | 1                              |                            | 3.75               | 1.34               |                    | 2.42          | 0.91          |                        |
| 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                | 1.4                |                    | 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          |                        |

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 (Amani 2011). 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 than 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 (Molyneux et al. 2005).

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 (Jovic-Vranes et al. 2011). 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 (Komenaka et al. 2014).
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% (Heggland et al. 2012).

A study conducted by Zafarghandi et al also reveals less participation to the level of approximately 42% (Zafarghandi, Davati, and Sarv 2014). Individuals’ participation depends on various factors. For example, patients should be aware of their duties and the importance of their roles (Heggland and Hausken 2015). 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 (Mehmood et al. 2013). 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 are 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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