Are Patients Aware Of The Importance Of Reading The Informed Consent Form Before Radiologic Examination?

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Abstract

Purpose: This study aimed to evaluate the importance, perceptibility, and adequacy of the informed consent form.

Methods: A questionnaire was administered to 174 adult patients who provided informed consent before radiologic examination and had completed the radiologic examination. Patients who volunteered to participate in this survey were asked to answer the survey questions after a 15-minute pre-interview. They were asked to choose one of the options suitable for them.

Results: The education level of the participants was primary level at most 68.4%. Of the participants, 59.2% stated that they filled out the forms themselves, and 32.2% of them stated that the consent form was informed by verbal explanation. Approximately 46% of the participants stated that they did not know why they had to fill out the form, and 58% of them stated that they did not know its legal significance.

Conclusion: The fact that most of the participant population consisted of middle-aged patients and their education level was predominantly at the primary education level is the most important reason for not knowing the purpose and legal significance of signing the form. More comprehensive visual and written awareness training is required for patients to understand the purpose of signing the consent form and the legal situation in undesirable situations that may arise from signing this document.

Introduction

Since the discovery of X-rays in 1895, radiological techniques using X-rays have become increasingly important tools in medical diagnosis and treatment. With the widespread use of imaging, other non-radiation-based imaging techniques (ultrasound and magnetic resonance imaging (MRI)) have also been developed. The use of image-guided interventional methods to treat patients has also become common. The benefits of these diagnostic and treatment methods for patients cannot be compared with their side effects. As with all areas of medicine, appropriate assessment of the relative benefits and risks is necessary in radiology (1).

In routine clinical settings, the referring physician has a closer relationship with the patient and has more information about the patient's general history and current condition than the radiologist. On the contrary, the patient and radiologist may come face-to-face for the first time while the patient goes for imaging (2). Therefore, in the field of radiology, an important part of patient-physician communication includes an informed consent process. The standard informed consent form is typically an information leaflet or a form describing the procedure and listing the steps and possible complications of the procedure (3). Radiologists who perform interventional procedures have an ethical and legal responsibility to provide patients with adequate information about the examination while obtaining informed consent from the patients before the procedure (4).
Although there are remarkable differences in the international level of informed consent arrangements, the practice of the informed consent process with a signed document has been adopted worldwide (5). However, obtaining written consent not only shows the patient's willingness to undergo the examination but also provides documented evidence that it has been thought about (6). However, for the patient's consent to be valid, it must be voluntary and informed, and the person giving consent must have the capacity to make decisions (7).

The ideal format for informed consent provides patients with consistent and complete information regarding the nature of the procedure, its risks/benefits, alternative treatments, and complications. Moreover, it should be easily understood, should not unnecessarily affect the anxiety levels of the patients, and should ensure that the healthcare provider uses his/her time in the most efficient way (8).

Although many studies have suggested identifying deficiencies in the consent form and improving the process, a routine approach cannot be provided for the optimization of the process (9). While informed consent is an important component of a clinical trial, it remains unclear how to ensure that this consent form, which must be obtained prior to medical procedures, actually informs patients (10).

While studies evaluating the awareness and legibility of consent forms used in radiology by patients are abundant, studies evaluating the importance of the forms and their legal awareness in terms of patients are scarce. This study aimed to determine the comprehensibility and adequacy of the consent forms signed by patients before radiological procedures and to investigate whether the patients were aware of the reason for signing the consent form. Based on the data obtained, we aimed to determine the editing requirements in terms of the content of the form and possible problems experienced in the application.

Methods
This prospective questionnaire-based study was approved by the institutional research ethics board. The study was approved by the [redacted] Human Research Ethics Committee (approval no. ……). All participants provided written informed consent.

This was a single-center prospective survey study. Between October and November 2020, a questionnaire was administered to patients who underwent contrast-enhanced examination or interventional procedures in the computed tomography (CT), MRI, Fluoroscopy, and interventional radiology units of XXX University Faculty of Medicine, Department of Radiology. A questionnaire was administered to 174 volunteer patients who filled out the consent form and then completed the radiologic examination. The patients included both inpatients and outpatients. Patients who met the inclusion criteria and volunteered to participate in this survey were asked to answer the survey questions after a 15-minute pre-interview about the content of the survey. The questionnaire forms were given to the patients by hand, and they were told that they had to answer and submit the questionnaires at the place of their choice in 10–15 minutes. The survey consists of 19 questions. The patients could mark the appropriate boxes as they wished. While they were asked to choose between the “yes” and “no” options in the questions, some were asked about their reasons in addition to these options. The first 3 questions were designed to determine the demographic structure of the patients, and the next 12 questions were designed to indicate their experiences and opinions at the current stage. In the last two questions, the patient's reason for signing the consent form and their knowledge regarding the legal importance of the form were also questioned.

Inclusion criteria:
1. Patients who had an examination to be performed by giving contrast material or those who underwent invasive application in CT, MRI, Fluoroscopy, and interventional radiology of the radiology department.
2. Patients who completed the consent form and the examination before the examinations were performed in the MR, CT, Fluoroscopy, and interventional radiology departments.
3. Patients with age 18 years and above
4. Patients who could communicate or had relatives with whom they could communicate

Exclusion criteria:
1. Patients with age below 18 years
2. Patients whose radiological examinations were performed without the need to fill out a consent form
3. Patients with CT and MRI examinations performed without contrast agent
4. Uncooperative patients

Statistical Analysis
The answers to the age questions asked to each participant were statistically defined as ±± SD. Qualitative data were defined as percentages. Differences between variables were analyzed using the chi-square test. The significance level was set at P < 0.05. All analyses were conducted using TURCOSA (Turcosa Analytics, Ltd. Co. XXX: http://www.turcosa.com.tr). Statistical significance was set
Results

Between October and December 2020, questionnaires were distributed to 174 participants who voluntarily participated in the survey. The ages of the participants in the survey were between 18–91 years and their mean age was 51.13±14.61 years. Of the participants, 50.6% (n:88) were men and 49.4% (n:86) were women. The educational level of the participants was 54.6% primary school, 13.8% secondary school, 14.9% high school, 14.4% university, and 2.3% postgraduate.

Of the participants, 37.9% stated that they signed the consent form without explanation, 29% benefited from the consent form, and 32.2% stated that they made a verbal explanation. Approximately 23% of the participants stated that the person who provided information about the form was a doctor, 13.8% a radiologic technologist, 11.5% a nurse, 28.2% a secretary, and 23.6% did not know. A statistically significant difference was found between the sex of the participants and their knowledge of the person who gave the consent form. (p<0.01) (Table 1)

**Table 1: Demographics of survey respondents**

<table>
<thead>
<tr>
<th>Age</th>
<th>Percent (%)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-40 years</td>
<td>15.795</td>
<td>52</td>
</tr>
<tr>
<td>41-65 years</td>
<td>47.7064</td>
<td>52</td>
</tr>
<tr>
<td>65 years and above</td>
<td>48.1481</td>
<td>13</td>
</tr>
<tr>
<td>N</td>
<td>32</td>
<td>57</td>
</tr>
<tr>
<td>%</td>
<td>84.2105</td>
<td>52.2936</td>
</tr>
</tbody>
</table>

**Table 2: The relationship between filling out the form according to age groups and knowledge of the legal significance of the form**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Fill out the form yourself</th>
<th>Chi-Square</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-40 years</td>
<td>No</td>
<td>7.5904</td>
<td>0.022</td>
</tr>
<tr>
<td>41-65 years</td>
<td>Yes</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>65 years and above</td>
<td>No</td>
<td>12.5969</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

Among the participants, 49.4% read the entire form, 27.6% did not read it, 16.1% read some of it, and 6.9% read the form with help. A statistically significant difference was found between the educational level of the participants and their reading of the form (p<0.03). Of the participants, 63.2% stated that they were not helped when they wanted to ask questions in the form, while 36.8% were helped.

Approximately 71.3% of the participants stated that the written language was simple, easy, and understandable; 9.8% stated that it was confusing and difficult to understand; 16.1% stated that it was very long and took time to read; and 2.9% stated that it looked like it was written in another language because it contained too many medical words. After reading the form, 20.1% of the participants stated that they did not have sufficient information, 53.4% received sufficient information, 25.3% stated that they were partially informed, and 1.1% stated that the form itself was insufficient. Of the participants, 93.7% stated that they did not think of giving up after reading the form and 6.3% stated that they thought of giving up.

Of the participants, 48.3% stated that they did not complete a similar form, whereas 51.7% stated that they did. Among those who filled out similar forms, 89.1% said that there was no difference between the forms and 10.9% said that they were different.

All participants were treated with contrast material. The participants stated that 89.1% of them did not experience any problems related to the procedure or contrast material, and 10.9% had problems related to the procedure or contrast material. Among these, 47.7% marked the other
option, followed by nausea and vomiting (21.1 %), contrast allergy (15.6 %), and vascular access problems (15.6 %). Among the procedures that developed complications, tomography was the most common (74.1%), followed by MRI (15.7%), and interventional procedures (10.2%). It was marked according to the way the problem experienced during the examination was resolved, with 47.3% of the measures taken in which I stated my medical history in the form, 47.3% the intervention was done as written in the form, and 5.4% as no one was interested.

While 54% of the participants knew the reason for completing the form, 46% did not know why they had to fill out the form. A statistically significant difference was found in the education level of the participants and their knowledge regarding the reason for completing the form (p=0.03).

While 42% of the participants knew the legal importance of filling out the form, 58% did not. A statistically significant difference was found in the education level of the participants and their knowledge of the legal significance of the form (p=0.03).

**Discussion**

Numerous examinations that require legally informed consent are performed on patients examined daily in the radiology department (11). For simple examinations like plain radiographs, the presence of a patient is sufficient for implicit consent. However, informed consent should be obtained for more invasive procedures such as biopsy, catheterization, angiography, and complex procedures that involve different amounts of radiation dose depending on the duration of the procedure and have obvious and known risks (12). Although there are publications that argue that the fulfillment of the duty of informing radiology is better framed in light of laws and ethical guidelines that support respect for patient honour (13), providing information and patient education against the risks associated with medical imaging has been found to be largely inadequate (14). Various factors can limit the informed consent process, including patient competence, limited information provision, ineffective patient-physician communication, hospital environment itself, and privacy issues (15). In routine clinical settings, time constraints, emergencies and spatial difficulties often make it difficult to conduct a calm and focused pre-examination briefing (11). With the responsibility of being a central hospital, our hospital serves patients in the region as well as those from the surrounding provinces. Unfortunately, this situation results in a heavy workload and may disrupt verbal communication with patients during the consent process. In the study, 37.9% of participants stated that they signed the consent form without explanation, 29% stated that they were informed by reading the consent form, and 32.2% stated that they provided an oral explanation. There is a general belief that the consent form itself can be a part of the documentation about the procedure, but it can never replace conversations with the patient (16).

Across the studies reviewed, the average reading level of consent forms was well above the recommended sixth-to eighth-grade level. The difficulty in forming the consent form is due to the inability to strike a balance in ensuring that consent forms are at the sixth to eighth grade reading level while covering all regulatory and legal requirements (17). In a study at the University of Dundee, 69% of patients stated that they signed without reading (18). Akkad et al. determined that the majority of patients did not read the consent form and were content to sign an unread form based on verbal information (19). In this study, 49.4% of participants read the entire form, 27.6% did not read it, 16.1% read some of it, and 6.9% read the form with help. Those who did not read the form stated that they signed the consent form regardless of what was written in it. A statistically significant difference was found between the education level of the participants and their reading of the form (p=0.03). By using the small notes they wrote on the questionnaire, the participants stated that they did not read it because they had completed the examination as soon as possible without wasting time or because they had recently filled in a similar form.

Many proposed interventions to improve informed consent have focused on increasing excellent information. To date, these strategies for developing a participatory understanding have failed. Numerous studies have shown that shorter informed consent forms are as effective as longer forms for participants’ understanding (20). However, interventions that focused on reducing reading levels were generally successful (21). It is aimed to increase the level of intelligibility and reading rates by preparing the consent forms that we routinely use, based on people whose written language is low in health literacy, and by preparing a form with fewer pages. In this study, 71.3% of the participants stated that the written language was simple, easy, and understandable; 9.8% stated that it was confusing and difficult to understand; 16.1% stated that it was very long and took time to read; and only 2.9% stated that it was as if it were written in another language because it contained too many medical words.

In busy specialties, such as radiology, it is easy to see consent as a simple action or check box. Unfortunately, patients can also be defined as "consented" (9). As a result, while legal and ethical requirements are fulfilled by the patient’s signature, the extent to which the patient is informed can be ignored. In this study, 20.1% of participants...
stated that they did not have enough information after reading the form, 53.4% stated that they had enough information, 25.3% were partially informed, and 1.1% stated that the form itself was insufficient. Rather than leaving the patient alone with the form and asking them to hand the patients’ consent form and sign it, our primary duty is to provide detailed information about the content form by using verbal communication with the patient (22).

Predominantly, this requires providing patients with explanatory information regarding planned radiological procedures (indications, risks, benefits, and alternatives) while obtaining consent. This process has traditionally been performed by a physician or other health care provider in an oral manner, followed by the patient signing a consent form. The content and amount of information provided are usually at the discretion of the physician and may differ between different providers and even by the same healthcare provider (8). In one study, 48% of patients who remembered obtaining their consent from a physician prior to a CT scan in the emergency department reported that consent was obtained by a CT technician compared to 9% (23). In this study, 23% of the participants stated that the person who provided information about the form was a doctor, 13.8% a technician, 11.5% a nurse, 28.2% a secretary, and 23.6% did not know. A statistically significant difference was found between the sex of the participants and their knowledge of the person who gave them the consent form (p=0.01). As stated in the literature, consent providers may vary depending on the type of procedure owing to different reasons in radiology with a heavy workload. While consent providers are physicians or assistant assistants who perform the procedure depending on the severity of the procedure in interventional procedures, non-radiologist personnel, especially radiologic technologists, can be employed in other procedures, such as tomography and MRI. Just before the interventional radiology procedures, the radiologist explains in detail how the procedure is performed and possible complications to the patient or their relatives and answers any questions. If the patient agrees, they are asked to read and complete the consent form. In other areas of radiology, patients complete the consent process through auxiliary staff, perhaps without even meeting the doctor. The reason why patients specify different individuals as consent providers is that the duty to provide consent is left to non-physician personnel in some radiological procedures. Additionally, among the participants, there were also those who did not know who gave the form to a substantial extent (23.6% stated that they did not know). It is unclear whether this is because we do not adequately introduce ourselves or because patients do not care who gives them the form.

Substandard health literacy is prevalent in the United States, with half of the population reading at or below the eighth grade reading level (24). According to 2010 data, the average duration of education for XXX individuals aged 15 and older is 7.11 years, and it falls to 6.33 years among women (25). Since the patient population consists of elderly patients and the average literacy level is around 6–8 years, they can complete the consent form in the presence of their companion. In one study, 71% of the respondents completed the form themselves, while 29% completed it through their companion. Among companions, family members accounted for about 62%, and other relatives and friends accounted for 38% (23). In our study, 59.2% of the participants filled out the form themselves, while 40.8% filled out the form with their companions. A statistically significant relationship was found between the age group and the variables of filling out the form (p=0.002) (Table 2). A statistically significant difference was found between the education level of the participants and the completion of the consent form (p=0.004). Consistent with the literature, the majority of companions who filled out the form were family members (67.6%). The others were hospital staff (25.4%), friends (2.8%), and relatives (4.2%).

Courts do not just emphasize seriousness; they recognize probability as an important component of risk. Serious risks (death, stroke, loss of cognition, amputation, and cancer) should always be disclosed, even if the probability of their occurrence is negligible (26). Most of the research in this area shows that a typical doctor says little to the patient, and their values and preferences for treatment are unexplored. Many patients avoid the responsibility of making decisions and defer their roles to the family or doctor (27). As stated in the literature, most patients in our society tend to regard the physician as their guardian before their family members and to keep their words. Therefore, 6% of the patients stated that they had to do this because they believed that the diagnosis or treatment would be delayed if they refused the application, even if they thought of giving up. While patients seem to be compelled to sign the consent form as a condition for receiving diagnosis and treatment, the consent process does little to ensure patients' active participation in decisions about their health. Habiba et al. highlighted the argument that patients understand the consent process as a routine in which doctors are expected to play a prewritten role in their interests (28).

Although the questionnaire tool identified different types of consent, there was no confirmation that patients knew the differences between the various types of consent (23). In this study, 48.3% of the participants stated that they did not fill out a similar form, while 51.7% stated that they did. Among those who filled out similar forms, 89.1% said that there was no difference between the forms and 10.9% said that they were different.
The need for understanding is based on the conditions for the successful execution of the consent process. The consenting person needs to understand three things: (I) whether he/she has consented; (II) how he/she will exercise his/her right to consent or not; and (III) what he/she consents to (29). A literature review by Leclercq et al. found that many patients were unaware of the informed consent process or their rights in relation to it (30). This study found that 46% of the participants thought that the primary function of informed consent forms was to protect the hospital, and only 41% believed they had reported their wishes. Sixty-eight percent felt that signing gave doctors control of their treatment (31). In our study, 46% of the participants did not know why they had to fill out the form and 58% did not know the legal significance of the form. In addition, similar to the literature, those who knew the legal importance of filling out the form (42%) thought that signing the consent form was mandatory to protect doctors and the hospital from legal action when something went wrong. A statistically significant difference was found in terms of the education level of the participants and knowing why they filled out the form (p=0.03). A statistically significant difference was found in terms of the education level of the participants and their knowledge of the legal significance of the form (p=0.03). A statistically significant relationship was found between the age group variable and legal significance of the form (p=0.022) (Table 2).

Despite its ubiquity and importance, research suggests that the consent process often lags behind theoretical ideals (32). If we treat informed consent as just a formality that needs to be done, we show that we do not respect the patients as individuals. However, we declare that we respect each patient's freedom and dignity if we not only sign a form but also have a real conversation that will equip patients to make informed choices (16).

Limitations

This study has several limitations. The small sample size may limit the generalizability of the results. This study was conducted in a single health care network in XXX. We limited it not to all patients who visited all units in radiology, but only to patients who underwent contrast and interventional examinations and MRI. Perhaps, in the future, larger surveys that include radiation awareness can be conducted. Although the patients said that the consent form was easy to read, no questioning was conducted to assess what they understood. While this study was carried out only to determine the awareness of patients, a study that includes the awareness of physicians or other health workers can be conducted in the future.

Main Points

- We should try to ensure that the consent form, which patients give voluntarily and that they know what legal responsibility they have as a result of signing it.
- Consent form should not be considered as a document that only needs to be signed.
- In the process of signing the informed consent form, it should be aimed to reinforce the trust of the patients to the healthcare providers, to provide transparent information to the patient about the process, and to make the patient understand the information given.

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References


