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Research Article

Study of Obtaining Informed Consent in Pediatric Wards from the Viewpoint of Physicians and Children's Parents

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Abstract

Background: Obtaining informed consent for diagnostic and therapeutic procedures is of great moral and legal importance, which is more important in the field of pediatrics due to its specific issues.
Objectives: Obtaining informed consent in the pediatric field is specific because of many factors, including the age of the patients and the necessity of obtaining consent from parents or legal guardians. This study aimed to evaluate the process of obtaining informed consent from the viewpoint of substitute decision-makers (parents or guardians) and physicians. Attention to the differences between the views of these two groups by establishing appropriate and correct communication skills between them can lead to greater satisfaction and increased effectiveness of treatments.
Methods: In this descriptive study, the data were collected through questionnaires completed by 188 parents and 23 physicians. Finally, the statistical analysis was conducted using the one-sample t test method in SPSS 16.
Results: In 96.3% of the cases, parents believed that where the patient, their relatives, and the medical team disagreed about the kind of treatment, the final decision was made by the medical team. One-third of them did not receive enough information or received no information at all. Informing parents about other possible treatments, complications of the procedures, considering the patients and their relatives' opinions for the final decision, informing the child about his/her disease and treatment plans, and informing the parents about the possible outcomes were not in the favorable range. Physicians believed that decision about the treatment was made based on the opinion of the parents and the clinical committee, and only in 3.4% of the cases, their opinion was the basis for decision-making.
Conclusions: The results showed that there was a gap between the parents and physicians' opinions about informed consent, as the physicians believed that they act as the patients' parents wish and the parents believed that their opinion played no important role in the final decision regarding the health of their children. Thus, it seems necessary to institutionalize the culture of participatory decision-making by physicians and parents in decisions related to the diagnosis and treatment of children, and more emphasis should be placed on establishing the right relationship between treatment staff and patients and their relatives.

Keywords: Informed Consent, Children, Pediatric Ward

1. Background

Obtaining informed consent for medical procedures is of great importance from the perspective of law and medical ethics. Some physicians, especially in the pediatric field, seem to be not familiar enough with this concept, resulting in making decisions without paying special attention to patients' and their parents' rights regarding their health (1). Since children are highly vulnerable, when it comes to issues in medical ethics and lack the capacity to give informed consent (2), medical teams might falsely think that they are allowed to make a decision, and they deem appropriate or merely obtain the consent of children's parents without considering their age (3).

In statutory law, informed consent in its broad sense includes permission and consent. In other words, consent can be granted through a unilateral legal action (permission or release from obligation) or a bilateral legal action (condition of non-liability). Yet, permission and release from obligation are the two legal establishments mostly used for obtaining consent, and in Islamic fiqh and even in Islamic Penal Code, these two terms are commonly used to discuss the concept of patients' consent (4). Different legal systems disagree about the age of puberty or the age of maturity when individuals can assume legal control and decide about issues such as giving informed consent (4). It seems that the consent of the legal guardian should be a requisite for medical treatment (5). In Iranian law, the age of 18 is a requisite for an individual's consent to be valid. Yet, ethically, children should have the right to play a role in decisions about their medical treatments. Decisions concerning the capacity of children for making decisions about medical issues are made by the treating physician (6). In general, in the case of individuals without legal capacities, such as children, consent to medical treatment is granted by their guardians, but, in cases such as child abuse or negligence, such consent might not be required to be granted by the parents or the person who takes care of the child (7).

Nowadays, although children cannot make decisions on their own, it is ethically important to be informed about medical actions that are going to undergo; thus, they cooperate more and better result will be achieved. While legal parents should give consent to such medical treatment, children's assent can be of importance, as well (8, 9). On the other hand, most medical staff may know that they have to obtain informed consent for medical procedures, but how to obtain consent that is morally and legally valid is one of the less-discussed issues. The importance of this issue, especially in pediatrics, due to the patients' age and lack of competence to make decisions alone, makes it necessary to evaluate for diminishing the possible deficiencies in this field.

2. Objectives

Therefore, due to the importance of this item and the fact that a few studies have been conducted in Iran to show how consent is normally obtained from children, the main objective of this study was to evaluate the opinion of parents and physicians regarding informed consent. It is hoped that according to the results, the process of obtaining consent in children, which is one of the important issues in medical ethics, is improved.

3. Methods

The present descriptive-analytical study aimed to examine the ideas of children's parents and physicians about giving informed consent in children's wards of hospitals. The data were collected through questionnaires. Two questionnaires were utilized in the present study to evaluate the opinion of patients' parents and that of physicians about obtaining consent in the hospitals affiliated with Shahid Beheshti University of Medical Sciences. These questionnaires were designed based on relevant books and articles and with the help of some experts. The validity of the questionnaires was assessed by 10 experts, and the content validity ratio (CVR) and content validity index (CVI) were used to investigate the validity of the final version of the questionnaires. Each item on the parents' questionnaire showed a CVR of more than 80%, and that of the physicians' questionnaire was about 71%. Based on the four-part spectrum (irrelevant, somewhat relevant, relevant, and very relevant), the CVR of each item in the parents' questionnaire and the physicians' questionnaire was more than 85% and 80%, respectively. Using Cronbach's alpha, the reliability of the parents' and physicians' questionnaires was calculated to be 90% and 86%, respectively. Thus, the questionnaires showed acceptable validity and reliability. The questionnaires were made up of two main parts. In the first part, the demographic characteristics and in the second part, the participants' opinions about obtaining consent in medical centers were examined. In the second part of the questionnaires, which included 14 questions for the parents and 15 questions for the physicians, the answers were offered in a five-point Likert scale format. The questionnaires were completed by 188 parents and 23 physicians according to the statistics expert and through the census. Sampling was conducted based on the simple random sampling method. Then, the procedure of the study was explained to the participants, and their verbal informed consent was obtained by explaining the aim of the study and answering their questions about it. They were guided on how to fill out the questionnaires and finally, the questionnaires were distributed among the participants and then collected. Parents whose children were hospitalized for more than three days and were willing to take part in the study entered the study and physicians who were specialists or sub-specialists in a field related to children's medicine and were faculty members and willing to participate in the study entered the study. Finally, the statistical analysis was conducted using SPSS 16 with the one-sample t test method.

4. Results

Since two groups of parents and physicians were examined in the present study, the results will be presented in two sections.

4.1. Findings from Information Obtained from the Patients' Parents

Of 188 children whose parents filled out the questionnaires, about 72.2% were aged less than seven years old. The average age of the hospitalized children in this study was 1.31 years, with a standard deviation of 0.539. Besides, 72.2%

of these children were less than seven, 23.6% were between seven and 14, and 3.7% were over 14 years old. Also, 51.1% of them had been hospitalized only once, 22.9% had been hospitalized twice, 7.4% three times, and 18.6% had been hospitalized for more than three times. The mean score of hospitalizations for the patients was 1.94, with a standard deviation of 1.154. In the majority of the cases (83.5%), the children's mothers filled out the questionnaires, while only in 3.2% of the cases, the patients' fathers answered the questions. In a few cases (13%), it was a sister, brother, or grandparents of the patients who completed the questionnaires. The results obtained from the information provided by the patients' relatives about how consent is obtained in medical centers are presented in Table 1.

Questions 12, 13, and 14 were only asked from those companions (guardians) whose patients were less than seven years old. In 96.3% of the cases where the patient, their relatives, and the medical team disagreed about the kind of treatment, the final decision was made by the medical team, and only in 3.7% of the cases, the treatment was based on the patient's relatives' opinion. In no cases, the hospital's ethics committee made the final decision about the type of treatment. About the kind of consent, written consent was obtained in 85.5% of the cases, verbal consent was obtained in 16 (9.3%) cases, and implied consent was obtained in nine (5.2%) cases.

4.2. Findings from Information Obtained from Physicians

About two-thirds of the physicians were men, and about one-third (30.4%) were women. About two-thirds (65.2%) of the physicians had practiced medicine for more than 15 years, and 21.7% of them had worked as a physician for 10 to 15 years. The physicians participating in the study had practiced medicine for a mean of 3.43 years, with a standard deviation of 0.945. The information obtained from the physicians is presented in Table 2.

In cases where the child, the relatives, and the physician disagreed about treatment, the decision about the treatment was made based on the opinion of the relatives and the clinical committee, and only in 3.4% of the cases, the physicians believed that their opinion was the basis for decision-making.

Spearman's correlation (SPSS 16) was used to examine the relationship between demographic characteristics and how informed consent was obtained in the case of hospitalized children. There was no significant association between how informed consent was obtained and the child's age, the number of hospitalizations, and the relation of the person giving informed consent to the child, with the statistical results being $r = 0.05$ and $P > 0.05$, $r = 0.08$, and $P > 0.05$, and $r = 0.03$ and $P > 0.05$, respectively.

5. Discussion

The results of this study showed that although obtaining informed consent in a current way has many strengths from the parents' viewpoint, some parts should be emphasized more, such as informing parents about other possible treatments, complications of the procedures, considering the patients and their relatives' opinions for the final decision, informing the child about his/her disease and treatment plans, and informing the parents about the possible outcomes. In the parents' questionnaire, some parts got higher scores, such as deciding freely and independently, having enough time to make a decision, and giving necessary information by the physician about the treatment and disease. In this questionnaire, some questions directly concerned providing enough information (questions 1, 2, 5, 6, 8, 9, and 10). Although in the majority of the cases, the children's parents received enough information from the medical team, still one-third of them did not receive enough information or received no information at all. This legal and ethical problem has been pointed out in a similar study (10).

The same problem can be detected in providing the guardians with information about the kind of treatment, its advantages, and anticipated results, and also the fact they can refuse to allow treatment to go ahead. In a study on children undergoing LP procedures in the children's emergency ward, only 45.9% of the parents were provided with information about the diagnostic procedure. Also, only in 36.1% of the cases, the advantages of this procedure were explained, and alternative methods were mentioned in 12.5% (10).

Similarly, about half of the children's guardians stated that they had never been informed about the possible complications of the medical treatment, which can be due to some reasons: (1) Physicians might have been unaware of the necessity of delivering such information; (2) physicians might have been concerned that providing such information could cause the guardians not to allow the treatment to begin because it may have unwanted consequences for the child; (3) they have not enough time to provide each patient's guardian with the necessary information; and (4) physicians might argue that most of the possible complications can be controlled, and serious problems arise only in rare cases. A study on children who had undergone a cataract operation revealed that their parent had not been adequately informed about the possible complications of the surgery, the reason for which was reported to be the overwhelming information given to the parents and parents' stress and deep concern about their children's safety (11).

Over half (55.7%) of the guardians participating in the

Table 1. Parents' Responses to the Questionnaire

Questions	Number of Answers	Never, No. (%)	In Most cases No, No. (%)	Sometimes, No. (%)	In most CASES Yes, No. (%)	Always, No. (%)	Mean ± SD
1) Did the medical team provide you with the necessary information about the disease?	188	35 (18.6)	30 (16)	34 (18.1)	35 (18.6)	54 (28.7)	3.23 ± 1.483
2) Did the medical team provide you with the necessary information about the treatment procedure?	186	35 (18.8)	24 (12.9)	39 (21)	31 (16.7)	57 (30.6)	3.27 ± 1.487
3) Did you have enough time to make decisions?	186	31 (16.7)	21 (11.3)	35 (18.8)	28 (15.1)	71 (38.2)	3.47 ± 1.559
4) Did the medical team consider your decision in the treatment?	184	72 (39.1)	23 (15.5)	35 (19)	17 (9.2)	37 (20.1)	2.59 ± 1.559
5) Did the medical team inform you about the advantages of the treatment?	184	50 (27.2)	22 (12)	27 (14.7)	30 (16.3)	55 (29.9)	3.10 ± 1.603
6) Did the medical team inform you about the possible complications of the treatment?	184	92 (50)	23 (12.5)	25 (13.6)	16 (8.7)	29 (15.2)	2.27 ± 1.515
7) Could you act freely and independently when giving consent?	186	29 (15.6)	18 (9.7)	32 (17.2)	24 (12.9)	83 (44.6)	3.61 ± 1.507; the highest
8) Did the medical team inform you about other possible treatment methods?	185	103 (57.7)	23 (12.4)	24 (13)	13 (7)	22 (11.9)	2.07 ± 1.430; the lowest
9) Did the medical team inform you about the possible outcome of the treatment?	185	61 (33)	22 (11.9)	39 (21.1)	25 (13.5)	38 (20.5)	2.77 ± 1.534
10) Did the medical team inform you about your right to refuse to give consent to the treatment?	186	58 (31.2)	18 (9.7)	20 (10.8)	13 (7)	77 (41.4)	3.18 ± 1.748
11) Was the information provided by the physician clear enough to you?	185	48 (25.9)	14 (7.6)	32 (17.3)	33 (17.8)	58 (31.4)	3.21 ± 1.586
12) Did you or the physician provide the child with information about the disease?	45	18 (40)	5 (11.1)	8 (17.8)	5 (11.1)	9 (20)	2.60 ± 1.587
13) Did you or the physician provide the child with information about the treatment?	45	16 (35.6)	5 (11.1)	10 (22.2)	4 (8.9)	10 (22.2)	2.71 ± 1.576
14) Was the child's opinion considered in the treatment?	46	20 (43.5)	4 (8.7)	13 (28.3)	1 (2.2)	8 (17.4)	2.41 ± 1.499

study said that they had never been informed about other alternative treatments (the lowest mean score in this questionnaire), which can be due to the following reasons: (1) Physicians might have been unaware of the necessity of providing such information; (2) there might have been too many patients and not enough time to provide information about these alternatives; (3) physicians might have feared that providing such information might cause more stress and pressure for guardians at a time when prompt decision-making is important; (4) children's guardians might have been unaware of their right to know about alternatives, which might have helped the medical team in making the best decision; and (5) children's guardians might have trusted the medical team and asked them to make all decisions needed for a better result. In a similar study in the US, it was reported that for pediatric endoscopy, in only 17% of the cases, children's relatives were informed about possible complications, and only 14% were given information about alternative treatments (12). While giving enough time to guardians and helping them to make decisions are part of the ethically acceptable procedure, only 3.47% of the guardians in this study said they had this chance, and about 16.7% of them said that they had not enough time to make up their mind.

The results of this study showed that 39.1% of the children's guardians believed that their opinion had never been considered in the decision-making, which reveals that physicians and guardians have failed to establish a good relationship and communicate their ideas properly. The final decision about the kind of medical treatment should be the outcome of interaction and cooperation between the child, the guardian, and the physicians. A mean of 2.59 in this study indicates that the situation is not favorable. As can be seen in Table 1, the highest score (a mean of 3.61) belonged to guardians' free and independent decision-making about giving informed consent, which is acceptable.

The explanations provided by the physicians were "never clear" to 25.9% of the participants and, in "most cases unclear" to 7.6% of them, amounting to 33.5% of the children's guardians. Information provided by the medical team should be clear and understandable for the guardians so that they make the right decision when giving consent to treatment. However, about one-third of the people who gave consent to treatment in this study had not understood the explanations regarding consent, which is clearly unacceptable. Since questions 12 - 15 concerned children of seven years of age or over, only 53 participants answered these questions, an analysis of which indicated that neither physicians nor children's guardians (parents) pro-

Table 2. Physicians' Responses to the Questionnaire

Questions	Number of Answers	Never, No. (%)	In Most Cases No, No. (%)	Sometimes, No. (%)	In Most Cases Yes, No. (%)	Always, No. (%)	Mean ± SD
1) Do you normally inform patients' guardians about the diagnostic and treatment procedure before embarking on it?	23	-	1 (4.3)	1 (4.3)	14 (60.9)	7 (30.4)	4.17 ± 0.717
2) Do you provide patients' guardians with the necessary information about the diagnostic and treatment procedure?	23	-	-	1 (4.3)	14 60.9 ()	8 (34.8)	4.30 ± 0.559
3) Do you explain the possible complications of the diagnostic and treatment procedure to patients' guardians?	24	-	-	2 (8.3)	16 (66.7)	6 (25)	4.17 ± 0.565
4) Do you explain the advantages of the diagnostic and treatment procedure to patients' guardians?	24	-	-	1 (4.2)	12 (50)	11 (45.8)	4.42 ± 0.584; the highest
5) Do you let the patients' guardians decide freely?	24	-	1 (4.2)	7 (29.2)	12 (50)	4 (16.7)	3.79 ± 0.779
6) When a medical treatment coincides with a research project, for which of them do you obtain separate consent?	24	-	3 (12.5)	4 (16.7)	10 (41.7)	7 (29.2)	3.88 ± 0.992
7) Do you give patients' guardians enough time to consult somebody and make decisions?	24	-	-	3 (12.5)	16 (66.7)	5 (20.8)	4.08 ± 0.584
8) Do you consider the opinion of patients' guardians in your decision-making?	24	-	2 (8.3)	8 (33.3)	11 (45.8)	3 (12.5)	3.63 ± 0.824
9) Do you inform patients about other possible treatments?	24	-	-	7 (29.2)	14 (58.3)	3 (12.5)	3.83 ± 0.637
10) Do you adequately inform patients' guardians about the anticipated outcome of the treatment?	24	-	-	3 (12.5)	16 (66.7)	5 (20.8)	4.08 ± 0.584
11) While you are explaining the procedure, do you let patients' guardians know that they can decide not to allow the treatment?	24	-	1 (4.2)	9 (37.5)	10 (41.7)	4 (16.7)	3.71 ± 0.806
12) Do you make sure that your explanations are clear enough to patients?	24	-	-	-	16 (66.7)	8 (33.3)	4.33 ± 0.482
13) Do you inform the child about the diagnostic and treatment procedure?	24	1 (4.2)	8 (33.3)	10 (41.7)	4 (16.7)	1 (4.2)	2.83 ± 0.917
14) Do you consider the child's opinion in the final decision?	24	1 (4.2)	12 (50)	10 (41.7)	-	1 (4.2)	2.50 ± 0.780; the lowest
15) Is a nurse witness to the process of obtaining consent?	19	3 (15.8)	4 (21.1)	5 (26.3)	3 (15.8)	4 (21.1)	3.05 ± 1.393

Table 3. Physicians' Opinions About How Decisions Are Made in Cases Where the Child, Their Guardians, and Physicians Disagree

Number of answers	Based on the Opinion of the Child's Relative, No. (%)	Based on the Child's Opinion, No. (%)	Based on the Physician's Opinion, No. (%)	Based on the Opinion of the Clinical Ethics Committee, No. (%)	Mean ± SD
23	8 (34.8)	0 (0)	7 (3.4)	8 (34.8)	2.65 ± 1.301

vided children with enough information about the disease and medical treatment, which shows that children are not given an important part in this process.

As can be seen in Table 3, the children's guardians and physicians had very different ideas about "disagreements between the medical team and children's relatives about kind of treatment", which shows the process of obtaining consent is unfavorable in some ways, probably due to the following reasons: (1) Patients' relatives believe that the physicians have better knowledge and experience to make the right decision; (2) in such emergencies, patients' relatives do not know about their legal rights in giving consent and easily allow the physicians to decide for them; (3) because of the critical situation of their children and the stress and pressure they face, the relatives of children prefer to speed up the process of decision-making and giving consent rather than trying to know about the procedure; and (4) the inappropriate relationship between physicians and patients' relatives usually makes the relatives act passively and accept the physicians' ideas.

Although different scholars have stressed the importance of obtaining consent from children, it seems that children have been ignored, as this study indicated. In a similar study in Japan, it was shown that four in every five parents were not familiar with the word "assent" in medical and research procedures (13). When different groups involved in the decision-makings process disagree, the clinical ethics committee can play an important role. Yet, in the present study, neither physicians nor patients' relatives pointed to the role of this committee, which might be due to the following reasons: None of them (parents and physicians) was aware of the duties of such committees, and physicians might have been unwilling to use the capacity of this committee.

In a study on obtaining informed consent from patients before surgical operations in Iran, it was shown that information given to the patients was insufficient and patients were not provided with enough information about the operation, type of anesthesia, possible complications, alternative treatments, period of hospitalization, and post-surgery care (14), which is in agreement with the findings of the present study. As can be seen, in questions 13 and 14 (informing the child about diagnostic and treatment procedures and considering the child's opinion in the final decision), the physicians mostly answered "in most cases no" and "sometimes", respectively. In a study conducted in England in 2016, factors such as children's characteristics (their willingness and ability to participate in the process of making decisions), the family's willingness to involve the child in the decision-making process, the severity of the health conditions of the child, and national and regional rules and regulations were shown to play an important role in obtaining consent from children (15). A study on obtaining informed consent in non-emergency surgical operations revealed that informed consent was not obtained based on a standard procedure probably because of the shortage of time, lack of necessary skills for obtaining consent from the part of the physicians, and patients' unwillingness to participate in the diagnostic and treatment process (16).

In the physicians' questionnaire, the question concerning ensuring the clarity of explanations showed a high mean score (4.33), and the one about considering children's opinion in decision-making showed the lowest mean score (0.780), the possible reasons for which can be better explained in another study focusing on the amount of time the physicians and children's guardians spend together on discussing the situation and how well they communicate their ideas. The answer to this question is somehow disturbing, as it indicates that children do not play an important part in the process of giving consent. In other studies on the role of children in this process, it was shown that no consensus existed about the status and role of children in such processes, which might require the development of national and international regulations in this regard.

As already discussed, physicians and children's guardians had different ideas about dealing with a situation in which physicians and children's guardians disagree about the final decision. No one in the study believed that the kind of treatment was based on the opinion of the child, which, according to the findings of the present study and also based on clinical experience, is quite reliable. A comparison between the answers to different questions by the participants in the study can be important, as it reveals agreements and disagreements in their opinion about each item, which can help us to deal with possible challenges and make modifications in the process of obtaining consent for better results.

The lowest gap between the mean scores of the two groups of participants belonged to question 14 in the two questionnaires, indicating that both groups believe that probably due to the children's limited ability to make decisions, no important role should be given to children. The biggest gap, however, could be found between the mean score of the question concerning explaining the possible complications of the diagnostic and treatment procedure to the child (question 6 in the guardians' questionnaire and question 3 in the physicians' questionnaire). While physicians believed they offered the necessary information about such complications, children's guardians said that the explanations were not sufficient. This disagreement can be because the explanations might have been complicated, probably due to the use of technical words, insufficient, or less than what the parents expected.

5.1. Conclusions

The results of the present study highlight the necessity of making both the medical team and children's guardians fully aware of the importance of informed consent, its advantages, processes, and methods. The results also showed that there is a gap between the parents' and physicians' opinions about informed consent, as the physicians believe that they act as the patients' parents wish and the parents believe that their opinion plays no important role in the final decision regarding the health of their children. This shows that it is necessary to have good communication with each other, and participatory decision-making must be considered. Physicians and parents must know that if the child can understand the concept of disease and treatment (above 5-6 y/o), then she/he must gain degrees of information, and their assent should be obtained.

5.2. Recommendations

For teaching the public about the importance and content of valid consent, the government can use mass media, billboards, banners, and brochures and also teaching the necessary skills of communicating effectively with others to medical teams. As a large number of people visit medical centers, in addition to physicians, other members of medical teams who are well aware of such procedures and ethics committees at hospitals can help improve the process of obtaining informed consent. Conducting similar studies on how informed consent is obtained from children's parents at other medical centers and in different age groups can remedy the deficiencies of this procedure, which will bring about higher satisfaction for the medical team, patients, and their relatives. Prospective studies on the content of informed consent, communicating relevant information, and patients' satisfaction with how informed consent is obtained could be the focus of future studies in Iran (17).

Footnotes

Authors' Contribution: Study concept and design: SB, MF, and SR. Analysis and interpretation of data: SB. Drafting of the manuscript: SR. Critical revision of the manuscript for important intellectual content: SB, MF, and SR.

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