DOI: https://doi.org/10.53350/pjmhs20221612681

**ORIGINAL ARTICLE**

# Medicolegal Aspect of Consent

MUHAMMAD MUSHTAQ[1], ZOYA IMRAN[2], IMRAN JAWAAD[3], URVA MARYUM[2], HUMAIRA MUKHTAR[2]
[1]*Associate Professor, Forensic Medicine Department, University College of Medicine & Dentistry, The University of Lahore*
[2]*Final year MBBS Student, Shalamar Medical College, Lahore*
[3]*Professor, Forensic Medicine Department, University College of Medicine & Dentistry, The University of Lahore*
*Correspondence to: Muhammad Mushtaq, Email: drmushtaqap12345ucmd@gmail.com, Cell: 03224053774*

## ABSTRACT

**Introduction:** Consent is a legal requirement for all medical procedures whether surgical or non-surgical. Different types of consents are discussed in books, all fulfill legal requirements which totally depends upon the nature and type of case under process.

**Objective:** Main objective of the study is to determine the awareness of public about consent and its legal value.

**Material and Method:** It is a cross sectional observational study conducted at orthopedic department of Services Hospital Lahore, from 1st January 2019 to 29th December, 2019. A total of 125 patients were selected for this study.

**Study design:** It is a cross sectional observational study.

**Setting:** Study was conducted in the orthopedic department of Services Hospital Lahore.

**Duration:** Study was conducted from 1st January 2019 to 29th December 2019.

**Data Collection:** Data was collected through a questionnaire which was modified after pilot study.

**Results:** Majority 60% of the patients believe that consent is a formality for any medical procedure. 76% of the patients have a feeling that consent is a medical document and has no legal value. 40% of the patients believe that by signing consent they forgive their right for any compensation. 48% of patient's view consent as protection of their rights whereas 36% of them are unaware about this fact.

**Conclusion:** This study concludes the ignorance of the people about the legal value of consent. A vast gap exists between the informed consent and the knowledge of the people signing this document. In the current situation inform consent need to be modified so that public should be aware about its importance.

**Keywords:** Consent

## INTRODUCTION

Consent is a legal contract and is a prerequisite to many procedures(1), it is an action of a person or a patient who authorizes the dealing person to perform any procedure, research or to start a treatment as per requirement of the patient/person. Consent literally means to agree upon the matter under consideration whether medical or non-medical(2). Once consent is obtained the treating physician informs the patient about diagnosis, its treatment options, treatment plan, complications if any and in-depth nature of the illness the patient is suffering.

Majority of the patients think it is a formality which they are supposed to fill before the start of treatment as without signing any such document which is a consent form, treatment shall not be initiated(3). Consent is an agreement between the treating physician and the patient by virtue of which patient allows the treating physician to take history he can ask questions which normally a person don't want to answer, he allows the physician to examine his body even the most private parts. So, the presumption that it is just a formality is not true. It is the right of the patient he can refuse to continue with the treatment or examination at any stage when he withdraws consent(4).

Consent generally can be classified into different types, it could be in oral or written, both are acceptable in the eyes of law(5). The most common type is the informed consent in which patient is informed in detail about the disease, investigation treatment and the most likely outcome, all the queries of the patient are addressed to his satisfaction. In Pakistan the consent which is most prevalent is blanket consent in which patient or his guardian is asked to sign a form which is a consent form so that his treatment is started, he is not told about any procedure or treatment plan and pretended to be a routine matter and surprisingly patient or his guardian also do not ask what they signing for as everyone presume it to be part of the treatment(6).

In a research, informed consent is an agreement between the researcher and the person on whom research is going to be conducted. The participant is informed completely about the project, its duration, benefits and hazards. The primary goal of informed consent is that it safeguards the rights of the participant. It has often been observed that patient feels helpless ethically and legally as the information regarding consent provided to the patient is very limited(7).

The prime objective of this study is to evaluate patient's awareness about legal and ethical privileges regarding informed consent an added objective is to ascertain the interest of the patient about consent, whether they wish that they should be well informed about all the process and procedure they are going to be involved as the literacy rate in our country is not good, many patient feel are more comfortable when they are not aware about the harms of the process.

## MATERIAL AND METHODS

This is a cross sectional observational type of study conducted at orthopedic department of Services Hospital Lahore, from 1st January 2019 to 29th December, 2019. A total of 150 patients were selected who had undergone surgery after passing information about their surgery and signing consent form, out of these 150 patients 125 consented for the study and was included in the study, patients who did not consented were not included in the study. Before the study 15 patients were chosen who were given an interview schedule as a pilot project. After making appropriate changes through input of the patient interview schedule was finalized with modifications in the questions. The questions were designed what patient want to know about consent and the procedure for which they are admitted to the hospital. (This questionnaire was prevalidated through a pilot study, appropriate modifications were made under recommendations of the consultants and finally circulated through the patients)Questions were framed about the awareness of the patient what they have understood about the information passed to them. Those patients whose understanding was less than 25% were categorized as poor understanding. Those whose understanding was between 25-50% were categorized as general understanding. Those whose understanding was between 51-75% were categorized as well understood and those above 75% were judged as good understanding. Analysis of the data was done using SPSS version 20wherever appropriate chi-square test was applied.

## RESULTS

Consent is a legal document and is the only document which is accepted in the court of law if there is a legal issue. In our society 60% of the patients believe that it is just a formality for any medical procedure and is considered to be a requirement before any

procedure whether medical invasive procedure or a surgery. 76% of the patients have a feeling that consent is a medical document and has no legal value. 40% of the patients believe that by signing consent they forgive their right for any compensation whereas same %age of the patient is unaware about any compensation. 48% of patient's view consent as protection of their rights whereas 36% of them are unaware about this fact. 36% of patient agree that by signing consent they become aware about all the relevant information whereas 32% of the patient believe that even after signing consent they can change their opinion about the treatment. Majority of the patient are aware about 84% that consent can be signed by any close relative on their behalf. 64% believe that if consent is not signed their treatment cannot be started which can even result in their death Table-I.

Table 1: Opinion of patient about consent and its after effects (n=125).

| Opinion of patient about consent form | Agree | Disagree | Unaware |
|---|---|---|---|
| Consent is a routine formality | 75(60%) | 30(24%) | 10(8%) |
| Consent is a requirement for a procedure | 90(72%) | 20(16%) | 15(12%) |
| Consent signing has nothing to with legal issues | 95(76%) | 10(8%) | 20(16%) |
| Signing consent waves right for compensation | 50(40%) | 25(20%) | 50(40%) |
| Consent is for protection of medical community | 72(57.6%) | 18(14.4%) | 35(28%) |
| Consent protects patient rights | 60(48%) | 20(16%) | 45(36%) |
| Signing a consent form justifies that all relevant information is known to the patient | 45(36%) | 10(8%) | 70(56%) |
| Without signing consent operation shall not be conducted | 100(80%) | 12(9.6%) | 13(10.4%) |
| After signing consent form your opinion can be changed | 40(32%) | 22(17.6%) | 65(52%) |
| Consent form can be signed by your guardian | 105(84%) | 13(10.4%) | 7(5.6%) |
| No matter what is the situation without signing consent surgery cannot be done even if the patient dies | 80(64%) | 20(16%) | 25(20%) |

More than 75% of the patients believe they are aware of their surgical procedure. 72% are aware of the facts about their surgery what surgeon will do. 88% are aware about the expected duration of their surgery. 92% of patients are aware of the risks involved in their surgery. Less %age of the patients 56% were aware of postoperative problems. Approximately 80% of the patients are aware of their expected stay at hospital. 84% of the patients had an idea when they are going to go back to work after surgery. 88% of the patients are aware of the success rate of their surgery. 96% were well aware about the precautions in their habits and dietary precautions they are supposed to take after surgery. All patients undergoing surgery were completely aware about the cost of their surgery Table-II.

Table 2: Information of patient about their surgery (n=125)

| Patient awareness/information | Agree | Disagree |
|---|---|---|
| Why surgery is performed | 95(76%) | 30(24%) |
| What surgeon will do during surgery | 90(72%) | 35(28%) |
| What is the time duration of surgery | 110(88%) | 15(12%) |
| Is any serious risk involved in surgery | 115(92%) | 10(8%) |
| What are possible complications | 85(68%) | 40(32%) |
| What will happen after surgery | 70(56%) | 55(44%) |
| What is the probable time of hospital stay | 100(80%) | 25(20%) |
| When patient can get back to work | 105(84%) | 20(16%) |
| Success rate of surgery | 110(88%) | 15(12%) |
| Precautions to be taken after surgery | 120(96%) | 05(4%) |
| Dietary precaution after surgery | 115(92%) | 10(8%) |
| Total cost of surgery and hospital stay | 125(100%) | 0(0%) |

Approximately 96% of the patients agreed to follow the decision of the doctor who is taking care of their medical problem. 100% of the patients showed full faith and confidence in their doctor. Whereas 28% of the patients told that after discussion with their doctor they are going to take decision about their treatment Table-III.

Table 3: Patient decision about his treatment (n=125)

| Patient opinion about his treatment | Yes | No | Don't know |
|---|---|---|---|
| I shall follow the doctors decision about my treatment | 120(96%) | 5(4%) | - |
| I have faith in doctor and shall follow his instruction | 125(100%) | - | - |
| After discussion with the doctor I shall make a final decision | 35(28%) | 90(72%) | - |

## DISCUSSION

When a person gets ill he wants to know a lot of things about his illness, unfortunately he has limited knowledge about consent, a study conducted in 2018 by Molina-Pérez A, Rodríguez-Arias D, Delgado-Rodríguez J, Morgan M, Frunza M, Randhawa G, et and another study conducted by Al Demour S, Alzoubi KH, Alabsi A, Al Abdallat S, Alzayed A in 2019 about informed consent on resident doctors supports our study[1,2]. For any surgical procedure it is a fundamental right of the patient to get full information about informed consent, a study conducted in 2021 by Millum J, Bromwich D and other study conducted in 2020 by Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, et al is in favor of our study[3,4]. The basic information which all the patients should be aware of their disease or surgical procedure is the nature of disease, investigation involved, benefits of the surgical procedure, risk and complications, likely outcome. What alternatives are available other than surgical procedure and why surgery is preferred above other treatment options, a 3-year multicentre randomised controlled trial in 2017 by Gastaldi G, Felice P, Pistilli R, Barausse C, Trullenque-Eriksson A, Esposito M. supports the finding of our study[5].

Consent whether it is oral or written are equally given weightage by the court of law, however, written consent is better in a way it can be produced as a document and can be verified even in the absence of the person supposed to give consent, a study conducted in 2019 by Meade MJ, Weston A, Dreyer CW and another study conducted by Ciliberti R, Gorini I, Gazzaniga V, De Stefano F, Gulino M in 2018 in Italy favors our study[6,7]. The present study has shown that majority of the people believe that consent before any medical procedure is a formality and have got no legal value, a qualitative interview study conducted in 2020 by Minei AP, Arafia R, Kaipu SO, Minei JM supports our study[8]. They have no idea about any compensation if any medical procedure goes wrong or not according to the information provided to them by the surgeon, a study conducted in 2020 by Bersani G, Pacitti F, Iannitelli A supports the finding of our study[9].

In this study the interesting features emerged are that majority of the people want to know the duration of the surgery or medical procedure, how long they are going to stay in the hospital and what cost they have to bear for all such procedures, a study conducted in 2020 by Vikas H, Kini A, Sharma N, Gowda NR, Gupta A is in favor of this study[10,11].

This study highlights the limited amount of knowledge people have got about oral or written consent or its legal implication, in a Pilot Project with Dental Hygiene Students to Assess Student Knowledge, Perceptions, and Attitudes conducted in 2017 by Tarp HC, Sanderson T, Fore ME, Nies MA supports this study, another comparative study in 2018 by Al Azmi SF, Almutairi BA, Al Jafar AM supports the finding of our study[12,13]. Some doctors believe that passing complete information about the complications of the procedure shall raise the level of anxiety among patients or their relatives which is not going to provide any benefit so they conceal the facts which should be known to the patient or his guardian, a study conducted in 2017 by Abd El-Latif AA, Abd-El-Atty B,

Hossain MS, Rahman MA, Alamri A, Gupta BB and another study conducted by Parah SA, Ahad F, Sheikh JA, Bhat GM in 2017 supports our study[14,15]. On the other hand, some patient believe that their surgeon should make the decision about their treatment and leave the rest to God, in a qualitative study conducted in 2017 by Lin C, Cohen E, Livingston PM, Botti M and in another study conducted in 2017 by Mirmozaffari M supports the finding of our study[16,17].

One the limitation of this study is that majority of the patients were quite uneducated and ignorant belonging to low socio-economic group. Inspite of all the facts it is quite true that majority of the population is unaware about the importance of consent and its legal value

**Limitation of the study:** This study is delimited to a single department only if similar study is conducted to other departments such as gynecology, general surgery, neuro surgery, different results could be expected)

## CONCLUSION

It is concluded that this study highlights some very important facts, the ignorance of the people about the legal value of consent. A vast gap exists between the informed consent and the knowledge of the people signing this document. In the current situation inform consent need to be modified so that public should be aware about its importance.

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