Title: Informed Consent As A Process: A Hospital Administrator’s View

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Abstract: Informed Consent is generally viewed as a proof of communication between a doctor and a patient, that all the relevant information regarding any planned procedure is “provided to” and “understood by” the patient. Still we face complaints against doctors and administration by the dissatisfied patients in the form of a grievance or a legal notice. Despite doing what is legally right, we fail to prevent such discontentment. What is the root cause of it? Are we viewing it wrong? Must not an Informed Consent be viewed as a “process of communication” rather than “a mere document” which is not just one sided activity of providing information but also ensuring that the information is comprehended by the receiver. Administration must reach out to doctors and patients to understand the barriers of a relevant communication starting with the assessment of their awareness level, in order to make amends in the hospital policy with a scientific evidence.

Key Words: Informed Consent, Legal, Communication barriers, Scientific evidence, Root Cause, Communication process.

Introduction:

Informed Consent being such a contemporary issue, lacks proper research on the applied part of the law. Many studies have been conducted regarding the case discussion and their landmark judgement recent being made by Disputes Redressal Commission (DSCDRC), which states that “*Merely asking patients to sign a consent form is not enough as they ought to be informed the consequences of a surgery”* (1). There are not many studies which assess the awareness level of care providers and care seekers about Informed Consent in a hospital. This study endeavours to carry out an objective assessment of the awareness of surgeons and their patients about the legal and practical aspects of Informed Consent.

AIM : To assess the awareness regarding Informed Consent amongst surgeons and surgical patients in a tertiary care hospital.

OBJECTIVES

1. To assess the awareness regarding informed consent amongst surgeons in a tertiary care teaching hospital.

2. To assess the awareness regarding informed consent amongst surgical patients in a tertiary care teaching hospital.

3. To study the impact of demographic factors on the responses of doctors and patients.

4. To study differences in the responses of doctors and patients .

METHODOLOGY

1. Study Design: Prospective and Cross-sectional study.

2. Study Place: Tertiary care teaching hospital of Pune.

3. Study Period: One month

4. Sampling Technique : Non probability sampling

5. Study Population: All patients admitted to and doctors working in surgical wards of a tertiary care teaching hospital

6. Inclusion Criteria: (a) All adult surgical patients admitted during the study period

(b) All surgeons (including surgery residents) working in the hospital

7. Exclusion Criteria: Patients and Doctors who were unable or unwilling to participate in the study.

8. Study Methods: The study was carried out by using following methodology:

(a) Questionnaire based analysis for the assessment of :-

(i) Awareness regarding informed consent amongst doctors (Questionnaire attached as Annexure ‘A’ )

(ii) Awareness regarding informed consent amongst patients. (Questionnaire attached as Annexure ‘B’ )

(b) Development of Questionnaire: From the review of landmark cases and rulings on Informed Consent by Law, a semi-structured Questionnaire was developed which contained eleven closed ended questions regarding general awareness related to Informed Consent and one open ended question to cover the concerns of doctor and patients that cannot be covered by closed ended questions. The preliminary tool was then administered to 10 faculty members and 10 surgical ward patients to address issues like:

(i) Ability to comprehend the instructions on covering letter

(ii) Understanding of Questionnaire items

(iii) The format including font and layout

(iv) Length of questionnaire (time taken to complete the question).

All the comments were taken into consideration and errors were amended and the Revised Questionnaire was adopted

(c) Validation: Validation of the Final tool was done by Senior Member of Ethical Committee of Medical Research of the teaching college.

(d) The questionnaire was self-administered by the surgeons through e-mail and for patients, the responses were received on interview basis

9. Sample size: The questionnaire was distributed to a total of 52 surgeons (including residents), out of which 45 responded, and simultaneously. The questionnaire for patients was administered amongst 75 surgical patients, all of whom responded.

10. Data Analysis: Data was analyzed using SPSS version 20:0 statistical software. Data was analysed for demographic differences. The responses of surgeons and their patients were compared for statistical significance by applying unpaired T-test.

Results & Discussion

Objective 1: Assessment of the awareness regarding informed consent amongst doctors in a tertiary care teaching hospital.

1. Demographic Profile of the Surgeons:

(a) Gender: Out of 45 responses , 42 are male (93.3%) and 03 (06.7%) are female.

(b) Age Group: Out of 45 responses, 35 responses (77.8%) are of 25-35 yrs age group, 08 responses (17.8%) are of 46-55 yrs age group, 02 responses (4.4%) are of 36-35 yrs age group.

2. Scoring of responses for correctness: The score was calculated as shown below:

% of correct responses = No. of correct responses X 100

Total No. of responses

3. Grading: Criteria used to grade the awareness was based on percentage of correct responses. 100% correct response is Complete Awareness, 90% to 99% is Very good Awareness, 80%-90% is Good Awareness, 60%-80% knowledge is Average Awareness, 40% to 60% is Below Average Awareness, 20% to 40% is Poor Awareness and < 20% is scaled as Very Poor Awareness.

4. Final Result: As per the study findings the overall mean percentage of correct responses is about 95.57 % that amounts to Very Good Awareness level of the doctors as shown in Table 1

Table 1 : Mean result of Awareness level amongst Surgeons

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S. No. | Question | Proportion of correct responses (out of 45) | % of correct response | Remarks |
| 1 | Patient’s consent is required before procedure. | 44 | 97.8 | Very Good Awareness |
| 2 | When is consent not required? | 44 | 97.8 | Complete awareness |
| 3 | Who should obtain consent? | 40 | 88.9 | Good Awareness |
| 4 | Who should give consent? | 44 | 97.8 | Very Good Awareness |
| 5 | Who should give consent for children? | 40 | 88.9 | Good Awareness |
| 6 | Who should give consent for comatose patient? | 40 | 88.9 | Good Awareness |
| 7 | Should type of illness be told to patient before taking consent? | 44 | 97.8 | Very Good Awareness |
| 8 | Should type of procedure be told to patient before taking consent? | 44 | 97.8 | Very Good Awareness |
| 9 | Should benefits of procedure be told to patient before taking consent? | 44 | 97.8 | Very Good Awareness |
| 10 | Should risks of the procedure be told to patient before taking consent? | 44 | 97.8 | Very Good Awareness |
| 11 | Should alternative treatment be told to patient before taking consent? | 44 | 97.8 | Very Good Awareness |
|  | Mean | | 95.37 | Very Good Awareness |

Objective 2: Assessment of the awareness regarding informed consent amongst Surgical Patients in a tertiary care teaching hospital.

1. Demographic Profile of the Patients: table

(a) Gender: Out of 75 responses, 44 responses (58.7%) are of Male patients and 31 responses (41.3%) are of Female patients

(b) Age: Out of 75 responses, 22 responses (29.3%) are of 18-25 yrs age group, 18 responses (24%) are of 26-35 yrs age group, 18 responses (24%) are of 36-45 yrs age group, 09 responses (12%) are of >55 yrs age group and 08 responses (10.7%) are of 46-55 yrs age group.

(c) Education: Out of 75 responses, 43 responses are 10th /12th level pass, 12 responses are of graduate patients, 06 responses are of Post graduate level patients and 14 responses are of uneducated patient

2. Scoring of correct responses: Percentage score was calculated as shown below:

% of correct responses = No. of correct responses X 100

Total No. of responses

3. Grading: Criteria used to grade the awareness was based on percentage of correct responses. 100% correct response is Complete Awareness, 90% to 99% is Very good Awareness, 80%-90% is Good Awareness, 60%-80% knowledge is Average Awareness, 40% to 60% is Below Average Awareness, 20% to 40% is Poor Awareness and < 20% is scaled as Very Poor Awareness.

4. Final Result: As per the study findings the overall mean percentage of correct responses is about 71.77 % that amounts to Average Awareness level of the patients as shown in the Table 2 .

Table 2 : Mean result of Awareness level amongst surgical patients

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S. No. | Question | Proportion of correct responses (Out of 75) | % of correct response | Remarks |
| 1 | Patient’s consent is required before procedure. | 58/75 | 77.3 | Average Awareness |
| 2 | When is consent not required? | 60/75 | 80.0 | Good Awareness |
| 3 | Who should obtain consent? | 64/75 | 85.3 | Very Good Awareness |
| 4 | Who should give consent? | 37/75 | 49.3 | Below Average Awareness |
| 5 | Who should give consent for children? | 31/75 | 41.3 | Below Average Awareness |
| 6 | Who should give consent for comatose patient? | 40/75 | 53.3 | Below Average Awareness |
| 7 | Should type of illness be told to patient before taking consent? | 57/75 | 76.0 | Average Awareness |
| 8 | Should type of procedure be told to patient before taking consent? | 54/75 | 72.0 | Average Awareness |
| 9 | Should benefits of procedure be told to patient before taking consent? | 64/75 | 86.5 | Good Awareness |
| 10 | Should risks of the procedure be told to patient before taking consent? | 55/75 | 73.3 | Average Awareness |
| 11 | Should alternative treatment be told to patient before taking consent? | 67/75 | 89.3 | Good Awareness |
|  | Mean | | 71.23 | Average Awareness |

Discussion: The information regarding Informed Consent, on the basis of which the questionnaire is being formulated is discussed below:

1. What is Informed Consent?

(a) As per International Law: “An informed consent is that consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all.” (2)

(b) As per Indian Law: Section 13 of The Indian Contract Act 1872 states that “two or more persons are said to consent when they agree upon the same thing in the same sense”. (3)

(c) In Clinical practice: Informed consent is defined as the permission a patient gives a doctor to perform a test or procedure after doctor has explained all the risks and benefits of the procedure, in the language that patient understands.

2. Relevance of Consent: The dictum of Justice Cardozo of the supreme court of United States of America states that “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages”. Consent has gained relevance with passage of time as now the law supports principal of “bodily autonomy” over the principal of “Sanctity of life”. (4)

3. Importance of awareness regarding Informed Consent for Doctors: The case of *Samira Kohli Vs Dr. Prabha Manchanda* is a perfect example of need for awareness regarding Informed Consent in which the doctor could not prove that a blanket consent of both diagnostic as well as operative procedure was obtained for performing Abdominal hysterectomy with Bilateral Salpingo-oophorectomy upon discovering the positive finding on diagnostic laparoscopy. In her defence the doctor claimed that she took consent from patient’s mother while patient was unconscious. The lack of evidence for consent for an operative procedure (which was not an emergency procedure) rendered the consent by ‘near relative’ invalid. (5)

4. Importance of awareness regarding Informed Consent for patients: On the other hand, the care-seekers i.e. the patients, especially in India, have different levels of perception of their rights as far as medical care is concerned. Some believe Doctors to be equivalent to God and others believe them to be money centred. It is to balance these varied level of perceptions and “Godly” expectations from doctors which may act as “fuel’ for future litigation against a doctor or hospital administration, a general awareness of law regarding ‘informed consent’ is essential from the seeker’s end as well.

5. Information about Informed Consent, on the basis of which general awareness amongst doctors and patients is assessed is discussed below:-

(a) Who should give consent?

(i) Person above 18 years of age: Section 11 of Indian Contract Act 1872 says that a person who is of the age of maturity and is of sound mind is competent to contract, thereby also implying that he is competent to give consent. The Indian Majority Act states that every person attains the age of majority on completing 18 years of age (6)

(ii) Parent or Guardian: As per IPC 1860, for child and the person of unsound mind, the consent of the guardian is sufficient (1). As per doctrine of *in loco parentis*, consent for treatment of children is to be carried out under the consent of parent or guardian (5).

(b) Who should obtain consent?

(i) The duty to obtain a patient’s consent for treatment rest on the patient’s treating physician (8).

(ii) Hospitals, nurses, surgical assistants, and referring physicians do not owe this duty to their patients (9)

(iii) The treating physician’s duty to obtain a patient’s informed consent cannot be delegated (3)

(iv) The duty is not eliminated, lessened , or spread by having the hospital nurse secure the patient’s consent before surgery (3).

(c) When is consent not required? In Emergency cases, the Supreme Court has observed that “ every injured citizen brought for medical treatment should instantaneously be given medical aid to preserve life” and that “ every doctor whether in Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life” (3-5).

(d) What information should be provided to patient? The law has identified certain minimum amount of information that needs to be communicated to the patient, to enable him to make an “informed decision”. These are

(i) The ‘adequate information’ to be furnished by the doctor (or a member of his team) who treats the patients, should enable the patient to make a balanced judgment as to whether he should submit himself to particular treatment or not. This means that the doctor should disclose nature and procedure of treatment and its purpose, benefits and effect; alternatives if any available; an outline of the substantial risks; and adverse consequences of refusing treatment. (3)

(ii) There is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for necessary treatment. (3)

(iii) There is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. (3)

Objective 3: Assessment of the impact of demographic factors on the responses of doctors and patients.

1. Analysis on Impact of age seniority of Doctors on awareness regarding Informed Consent: Age-wise percentage of correct responses by Doctors is calculated and CHI square test was applied as shown below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Age Group | Correct Responses | Incorrect Responses | Total | % of correct responses |
| 25- 35 yrs. | 366 | 19 | 385 | 95.06 % |
| > 35 yrs. | 104 | 06 | 110 | 94.50 % |
| Total | 470 | 25 | 495 | - |

Table 3 : Age-wise percentage of correct responses

(a) Test the ‘null hypothesis’:

(i) Null Hypothesis: *There is no significant difference between the awareness level of two Age groups*

(ii)Alternate Hypothesis: *There is a significant difference between the awareness level of two Age groups*

(b) Result: p value is = .821, therefore the result is *not* significant as p < .05. Hence null hypothesis is accepted i.e. *There is no significant difference between the awareness level regarding Informed Consent between Senior Doctors and Junior Doctors*

(c) Inference: Even though percentage of correct responses is more for juniors doctors, statistically there is no significant difference in awareness level regarding Informed Consent between Senior Doctors and Junior Doctors

2. Analysis on Impact of Gender of Patients on awareness regarding Informed Consent: Gender -wise percentage of correct responses by patients are calculated and CHI square test was applied as shown below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Gender | Correct Responses | Incorrect Responses | Total | % of correct responses |
| Male | 364 | 117 | 481 | 75.68 % |
| Female | 205 | 123 | 328 | 62.5 % |
| Total | 569 | 240 | 809 | - |

Table 4 : Gender-wise percentage of correct responses by Patients

(a) Test the ‘null hypothesis’:

(i) Null Hypothesis: *There is no significant difference between the awareness level of Male and Female patients*

(ii)Alternate Hypothesis: *There is a significant difference between the awareness level of Male and Female patients*

(b) Result : The P-Value is .000058. The result is significant at p < .05. Hence null hypothesis is *Rejected* which means *There is difference between the awareness level regarding Informed Consent of Male and Female patients*

(c) Inference: The Awareness regarding Informed Consent is higher in Male patients as compared to female patients

3. Analysis on Impact of Age of Patients on awareness regarding Informed Consent: Age-wise percentage of correct responses by patients is calculated and CHI square test is applied as shown below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Age Group (yrs.) | Correct Responses | Incorrect Responses | Total | % of correct responses |
| 18-25 | 163 | 77 | 240 | 67.9% |
| 26-35 | 133 | 53 | 186 | 71.5 % |
| 36-45 | 146 | 52 | 198 | 73.7% |
| 46-55 | 74 | 14 | 88 | 84.1% |
| Above 55 | 64 | 33 | 97 | 65.9% |
| Total | 580 | 229 | 809 |  |

Table 5 : Age-wise percentage of correct responses by Patients

(a) Test the ‘null hypothesis’:

(i) Null Hypothesis: *There is no significant difference between the awareness level regarding Informed Consent amongst patients of different age groups*

(ii)Alternate Hypothesis: *There is a significant difference between the awareness level regarding Informed Consent amongst patients of different age groups*

(b) Result : The P-Value is < .014866. The result is significant at p < .05. Hence null hypothesis is *Rejected* which means *There is a significant difference between the awareness level of patients under different age groups.*

(c) Inference: *Patients between the age of 46 to 55 yrs. have higher awareness level regarding Informed Consent than other age groups.*

4. Analysis on Impact of Education of Patients on awareness regarding Informed Consent: Education -wise percentage of correct responses by patients is calculated and CHI square test is applied as shown below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Education Level | Correct Responses | Incorrect Responses | Total | % of correct responses |
| 10th/12th pass | 320 | 140 | 460 | 69.6 % |
| Graduate | 104 | 28 | 132 | 78.8 % |
| Postgraduate | 56 | 10 | 66 | 84.8 % |
| < 10th grade | 104 | 47 | 151 | 68.9 % |
| Total | 584 | 225 | 809 |  |

Table 6 : Education-wise percentage of correct responses by Patients

(a) Test the ‘null hypothesis’:

(i) Null Hypothesis: *There is no significant difference between the awareness level of patients with different education level*

(ii)Alternate Hypothesis: *There is a significant difference between the awareness level of patients with different education level*

(b) Result : p value = .014829. The result is significant at p < .05. Hence null hypothesis is *Rejected* which means *There is a significant difference between the awareness regarding Informed Consent amongst patients with different education level.*

(c) Inference: Patients who are educated up to post graduate level have the highest awareness regarding Informed Consent amongst patients of other education level

Objective 4: To study the differences in responses of doctors and patients

1. Application of Independent samples/ Unpaired t- test was done to compare the mean awareness score between Doctors (Group 1) and Patients (Group 2) in the following manner:

(a) Null Hypothesis: There is no significant difference in the awareness level regarding Informed Consent between Doctor and Patients.

(b) Alternate hypothesis: There is a significant difference in the awareness level regarding informed consent between Doctors and Patients.

(c) Testing the hypothesis by applying Independent Samples T- test

(d) Result: The result is significant at p < .05. Hence null hypothesis is *Rejected* and alternate hypothesis is *Accepted* i.e. *There is a significant difference in the awareness level regarding Informed Consent between Doctors and Patients.*

(e) Inference: *The Surgeons are significantly more aware regarding Informed Consent than Patients.*

2. Analysis of the responses by Doctor Vs Patients to semi-structured question :

(a) Response of Doctors: Following are the main concerns of Doctors while obtaining consent from patients:

(i) Language Barrier: It is difficult to explain the patient in Marathi.

(ii) Psychological Barrier: It is difficult to explain and make patient understand the procedure when he is apprehensive

(iii) Understanding Ability of Patient: The understanding ability of each patient also varies. Even after explaining everything in the language understood by the patient, they still don’t understand.

(b) Response of Patients: The concerns of the patients are grouped into the following themes:

(i) Shared Decision Making: Majority of patients wished for the Involvement of near relatives in decision making.

(ii) Soft skill of doctors: Doctor should take care of mental state of the patient while explaining the disease and treatment course to the patient and relative.

(iii) Continuity of process: Doctors are either posted out of hospital or goes on Temporary Deputation. Same treating doctor should explain and take consent for the treatment as ‘Trust building’ is a very essential part of Doctor-Patient relation.

(iv) Time: Doctor should take time to explain the procedure in the language which is understood by patient and should also listen to what patient is saying.

RECOMMENDATIONS;

**1. High Priority Recommendations:**

1.1 Interpreter: The hospital should employ an Interpreter who can speak Marathi (local language), Hindi and English to bridge the gap between doctor who is English and Hindi speaking and patient who is mainly Marathi speaking.

1.2 Counselling sessions by Doctor: For inpatients, a dedicated time may be allotted for counselling of patients and/ or relatives by the treating doctors in order to keep them well informed about planned procedures.

1.3 Involvement of Relatives in Decision Making: Doctor must ask the relative if he/she wishes to be explained about the procedure in presence of a near relative.

1.4 A informed consent must be obtained afresh in following situations:

(a) The operating surgeon changes

(b) New risk factor is identified in patient

(c) The surgeon plans to perform the surgery with new procedure than new technique than previously explained.

**2. Desirable Recommendations:**

2.1 Medical Counsellor: In OPDs with high workload doctors are busy and may not be available to the patients for repeated queries and doubts related to surgery. Appointment of counsellors can provide assistance to doctors and provide relevant information to patients whose surgery is being planned. The counsellors can be stationed in a quiet room next to waiting areas in OPDs and PA check-up rooms

2.2 Informative Material: In OPDs, fliers and educational movie clips can be provided on most common surgeries in Marathi, Hindi and English language containing:-

(a) Relevant information regarding procedures,

(b) Instructions for patients,

(c) Answers to frequently asked questions (FAQs) and

(d) Illustrative before and after procedure diagrams for patients review must be provided.

2.3 Training:

(a) Communication skill development: The findings of this study prove that there is a significant difference in the level of awareness regarding Informed Consent between the cohorts of varied demographics. Therefore, doctors should be trained on how to communicate with people of different age, gender and education level, so that the information is understood by them. Doctor must ask the patient to repeat the information provided to them to assess their level of understanding

(b) Knowledge: Seminars on Legal Implications of not taking Informed Consent with examples of land mark cases should be planned for Doctors.

CONCLUSION

1. This study was taken up to assess the awareness level regarding Informed Consent amongst doctors and patients in a Tertiary Care Teaching Hospital of Pune. Demographic data was collected to study differences in the response of the study population.

2. A semi-structured questionnaire was devised consisting of 11 closed ended questions and 01 open ended question. The summary of analysis of closed ended questions is as follows:

(a) Descriptive Analysis: The mean awareness score for doctors (n= 45) is 95.37 % which amounts to Very Good Awareness and that for patients (n= 75) is 71.23 % which amounts to Average Awareness.

(b) Statistical Analysis: The findings of statistical analysis are :-

(i) No significant difference in awareness level of Junior doctors (< 35 yrs.) Vs Senior doctors (> 35 yrs.)

(ii) Awareness in Male patients is significantly higher than female patients

(iii) Awareness in Post Graduate level patients is significantly higher than other level patients.

(iv) Awareness amongst doctors is significantly higher than patients.

3. Upon analysis of the open ended question it was found that main cause of communication gap between doctors and patients is language barrier and non-involvement of “near relatives” to participate in the decision making. Low literacy and high apprehension level of patient necessitates presence of an emotionally stable relative who can understand the procedure.

4. It is essential for healthcare provider to understand that social demographics does have an impact on comprehension of the patient. Hence, communication with patients and policy regarding it must address and bridge these communication barriers.

Assessment Of Awareness Regarding Informed Consent Amongst Doctors

Appendix ‘A’

I, Dr Shruti Samyal, Department of Hospital Administration, am doing a research project on assessment of awareness regarding Informed Consent amongst doctors. The study cohort includes the doctors of Surgery department. The responder will remain anonymous. Response to all the questions is required.

\* Required

Top of Form

Gender \*

*Mark only one oval.*

* + - Male
    - Female

Age Group \*

*Mark only one oval.*

* + - 25-35 yrs
    - 36-45 yrs
    - 46-55 yrs
    - > 55 yrs

Patient's consent is required before procedure. \*

*Mark only one oval.*

* + - Always
    - Sometimes
    - Never

When is consent not required? \*

*Mark only one oval.*

* + - In Emergency
    - For Children
    - For very old patients

Who should obtain consent? \*

*Mark only one oval.*

* + - Doctor
    - Nurse
    - Nursing assistant
    - Anyone from the hospital

Who should give consent? \*

Appendix ‘A’

*Mark only one oval.*

* + - Patient
    - Nearest relative
    - Husband or wife of patient

Who should give consent for children? \*

*Mark only one oval.*

* + - Mother
    - Father
    - Guardian
    - Any of the above

Who should give consent for comatose patient? \*

*Mark only one oval.*

* + - Nearest relative
    - Clinician
    - Administrator
    - Judge

Should type of illness be told to patient before taking consent? \*

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should type of procedure be told to patient before taking consent? \*

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should benefits of procedure be told to patient before taking consent? \*

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should risks of procedure be told to patient before taking consent? \*

Appendix ‘A’

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

What is most important in consent in hospital setting? \*

*Mark only one oval.*

* + - Signature of patient
    - Explaining to patient
    - Understanding of patient

Describe how you obtained consent recently (issues & challenges). \*

Bottom of Form

# Assessment Of Awareness Regarding Informed Consent Amongst Patients

Appendix ‘B’

I, Dr Shruti Samyal, Department of Hospital Administration, am doing a research project on awareness assessment on Informed Consent amongst patients. The study will be conducted in the Male and Female Surgical Ward of a Tertiary care teaching hospital. The identity of the responder is not required. Response to all the questions is necessary.

Top of Form

Gender

*Mark only one oval.*

* + - Male
    - Female
    - Other

Age (years)

*Mark only one oval.*

* + - 18-25
    - 26-35
    - 36-45
    - 46-55
    - >55

Education

*Mark only one oval.*

* + - 10th / 12th
    - Graduate
    - Post Graduate
    - None

Patient's consent is required before procedure

*Mark only one oval.*

* + - Always
    - Sometimes
    - Never

When is consent not required?

*Mark only one oval.*

* + - In Emergency
    - For Children
    - For very old patients

Who should obtain consent?

Appdx ‘B’

*Mark only one oval.*

* + - Doctor
    - Nurse
    - Nursing Assistant
    - Any one from the hospital

Who should give consent?

*Mark only one oval.*

* + - Patient
    - Nearest Relative
    - Husband or Wife of Patient

Who should give consent for children?

*Mark only one oval.*

* + - Mother
    - Father
    - Guardian
    - Any of the above

Who should give consent for comatose patient?

*Mark only one oval.*

* + - Nearest relative
    - Clinician
    - Administrator
    - Judge

Should type of illness be told to patient before taking consent?

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should type of procedure planned be told to patient before taking consent?

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should benefits of procedure be told to patients before taking consent?

Appdx ‘B’

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should risk of procedure be told to patient before taking consent?

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Should alternative treatment be told to patient before taking consent?

*Mark only one oval.*

* + - Yes
    - No
    - Sometimes

Describe how you gave consent recently.

Bottom of Form

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