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Informed Consent in Clinical Practice and Research and Its Awareness among Under Graduate Medical Students

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Abstract

Consent denotes voluntary agreement, permission or compliance. Informed consent in medical practice is the grant of permission by a patient for an act to be carried out by a doctor, such as a diagnostic, surgical or therapeutic procedure. Informed Consent in research is the voluntary agreement to participate in the study.

The study was undertaken with the objective to assess the level of knowledge regarding informed consent among Second MBBS undergraduate medical students at the beginning of the class by a pretest and to demonstrate measurable gain in knowledge at the end of the class by a posttest using the same questionnaire.

This quasi-experimental study conducted in the Department of Forensic Medicine, Govt.T.D Medical College, Alappuzha, among 118 students using a structured and close ended, pretested questionnaire containing 13 multiple choice questions.

Statistical analysis done on average pre and posttest score and on difference in pre and posttest responses to individual questions; revealed measurable gain in knowledge at the end of the class, since p value was < 0.05.

Key words: *informed consent, clinical practice, research, pre and posttest, gain in knowledge.*

Introduction and Background

Consent denotes voluntary agreement, permission or compliance. It should be free, voluntary, informed, clear and direct. According to Indian Contract Act, 1872 two or more persons are said to consent when they agree upon the same thing in the same sense[1]. As per Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 that a physician, performing an operation without written informed consent, shall constitute professional misconduct rendering him/her liable for disciplinary action by MCI[2].

Informed Consent must be obtained for all types of human subjects research including; diagnostic, therapeutic, interventional, social and behavioral studies, and for research conducted domestically or abroad[3]. A doctor must give a patient adequate information to understand the various aspects of the proposed treatment such as: The nature and procedure of the treatment, purpose and benefits, likely effects and complications, alternatives if available, substantial risks and adverse consequences of refusing treatment[2].

Types of Consent[4,5].

Implied consent: Seen in routine medical practice. Here the consent is implied in the mere fact that the patient comes to the physician with a problem or when a patient holds out his arm for an injection.

Expressed consent: May be written or oral. Any procedure beyond the routine physical examination, like operation, collection of blood, blood transfusion etc. needs expressed consent. Consent should be taken before the proposed act and not at the time of admission to the hospital.

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Informed consent: In medical practice anything beyond routine would require informed written consent.

Blanket consent: It is a consent taken on a printed form that covers (like a blanket) almost everything a doctor or a hospital might do to a patient, without mentioning anything specifically. Blanket consent is legally inadequate for any procedure that has risks or alternatives.

The concept of informed consent is embedded in the principles of Nuremberg Code, The Declaration of Helsinki and The Belmont Report[6,7]. Consent to participate in a research should be understood as a *process* rather than an event. In order for participants to give meaningful consent, they should be able to understand the intent of the research, be clear about what they are being asked to do and if any risks are involved, and know how their information will be used[8].

Informed Consent Document (ICD)[6]

Before requesting an individual's consent to participate in research, the researcher must provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. ICD has two parts –

- Patient/participant information sheet (PIS)
- Informed consent form (ICF).

Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research. Adequate time should be given to the participant to read the consent form.

Special situations[6]

1. *Waiver of consent*: The researcher can apply to the Ethics committee (EC) for a waiver of consent if the research involves less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants.

2. *Re-consent or fresh consent*: Re-consent is required in situations where new information pertaining to the study becomes available, a research participant who is unconscious regains consciousness, a child becomes an adult during the course of the study, research requires a long-term follow-up or requires extension, there is a change in treatment modality, procedures, site visits, data collection methods or tenure, and when there is possibility of disclosure of identity.

3. *Assent*: Assent is defined as a child's affirmative agreement to participate in research. The assent process should take into account the children's developmental level and capability of understanding and should be obtained from children of 7to18 years of age. [6,9].

4. *Electronic consent*: Electronic media can be used to provide information as in the written informed consent. Hon'ble Supreme Court has issued direction that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process also should be done. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials[6,10]

5. Gatekeepers: Permission of the gatekeepers, that is, the head/leader of the group or culturally appropriate authorities, may be obtained in writing or audio/video recorded on behalf of the group and should be witnessed.

6. Community consent: There may be situations when individual consent cannot be obtained as it will change the behaviour of the individual. In such situations community consent is required. When permission is obtained from an organization that represents the community, the quorum required for such a committee must be met. Individual consent is required even if the community gives permission.

7. Consent from vulnerable groups: Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent.

Informed consent is probably the most important concept flowing from the doctrine of autonomy. In the Indian context, informed consent was practically nonexistent till the Consumer Protection Act was made applicable to the medical profession. Now, both doctors and patients are becoming more aware about this concept, and patients are better informed of their rights[11].

This study was undertaken with the objective to assess the level of awareness regarding informed consent among Second MBBS undergraduate medical students at the beginning of the class by giving a pretest and to

demonstrate measurable gain in knowledge at the end of the class by a posttest using the same questionnaire.

Materials and Method

This quasi-experimental study was conducted in the Dept. of Forensic Medicine, Govt. T D Medical College, Alappuzha for one month period. One Hundred and Eighteen (118) Second professional MBBS students willing to participate in the study were included. Students who were absent on the day of assessment, did not participate both in pre and posttest and have given partly filled questionnaire were excluded. Domains included definition, types and components of consent, informed consent in medical and medicolegal practice, informed consent in research and special situations.

Study tool was structured and close ended, pilot tested questionnaire based on informed consent in clinical practice and research containing 13 multiple choice questions with five options and single correct response, covering key points. After obtaining informed consent, pretest questionnaire was given, then a lecture pertaining to the topic was delivered for about 40 minutes and the same questionnaire was given as posttest. For pre and posttest 10 minutes each was given.

Data entered in Microsoft Excel worksheet and analysis done using SPSS version 18.0. Correct answer was given score 1 and wrong answers were given score 0. Maximum achievable score was 13. Average score and standard deviation (SD) for pre and posttest were calculated and analysis done using Wilcoxon signed rank test for paired data. Responses to individual questions were also expressed as number and percentage and difference in responses were subjected to statistical analysis using McNemar's test for paired samples. Gender wise distribution of students and its relation with score obtained was also studied.

Findings

Gender wise distribution of the students and score gained:

Among the students participated, 39 (33.1%) were males and 79 (66.9%) were females. Pre and posttest scores were categorised into two groups, those who scored ≤ 6 and who scored ≥7. These groups were cross tabulated with gender. Majority of male students scored less than or equal to 6 (19.5%) for pretest and more than or equal to 7 in posttest (28.0%). Majority of female students scored more than or equal to 7 in both (38.1% and 64.4% respectively). Only posttest values showed significant association with gender (p=0.026 i.e. <0.05) (Table 1).

Table 1. Showing association of gender of students and test score.

Gender	Pretest group Number (%)		Posttest group Number (%)		Total Number (%)
	Score ≤6	Score ≥7	Score ≤6	Score ≥7	
Male	23(19.5%)	16(13.6%)	6(5.1%)	33(28.0%)	39(33.1%)
Female	34(28.8%)	45(38.1%)	3(2.5%)	76(64.4%)	79(66.9%)
Total	57(48.3%)	61(51.7%)	9(7.6%)	109(92.4%)	118(100%)
Significance(Chi-square)	P=0.103 (p>0.05)		P=0.026 (p<0.05)		-

Analysis for paired data:

Mean and standard deviation (SD) calculated for pre and posttest samples for all questions (1 to13). Mean pretest score was 6.32 with SD 1.871 and mean posttest score was 9.57 with SD 2.154. Wilcoxon signed rank test for paired data revealed highly significant p value i.e. p=0.000 (p<0.05), so there is statistically significant difference between pre and posttest score (Table 2).

Domains were classified into informed consent in clinical practice including its essential elements, application in medical and medicolegal practices (questions 1 to 6) and informed consent in research

including informed consent document and special situations (questions 7 to 13). Mean and SD calculated for these sub groups also. For questions 1to 6, mean pretest score was 3.60 with SD 1.269 and mean posttest score was 4.74 with SD 0.910 and for questions 7 to 13, mean pretest score was 2.72 with SD 1.161 and mean posttest score was 4.83 with SD 1.635. Wilcoxon signed rank test revealed statistically significant difference between pre and posttest sub group values (for questions 1to6, p=0.000 and for 7 to 13, p=0.000) (Table 2).

Table 2. Showing Mean, Standard Deviation (SD), Median and Wilcoxon Signed Rank Test

Score	Question numbers 1 to6		Question numbers 7to13		Total (1to13)	
	Pretest	Posttest	Pretest	Posttest	Pretest	Posttest
Mean	3.6	4.74	2.72	4.83	6.32	9.57
SD	1.269	0.910	1.161	1.635	1.871	2.162
Median	4.0	5.0	3.0	5.0	7.0	10.0
Wilcoxon Signed Rank Test						
Z value	-6.900[a]		-7.875[a]		-8.493[a]	
P value	0.000		0.000		0.000	
a. Based on negative ranks.						

Analysis based on response to individual questions:

Individual questions were analysed and difference in pre and posttest responses were expressed as number and percentage. Statistical analysis was also done using McNemar's test, for comparison of responses in paired samples. All questions except 2 and 10 showed increase in frequency of correct response and statistically significant p value (Table 3).

Table 3. Distribution of correct response for individual questions and p value of McNemar's test for paired samples.

Question No.	Questions	Correct response (Pretest)		Correct response (Posttest)		McNemar's test
		Number	Percent	Number	Percent	P value
1	Informed consent in medical practice refers to	89	75.4%	109	92.4%	0.000
2	The type of consent required for medicolegal examination is	75	63.6%	62	52.5%	0.098
3	Minimum age for giving valid consent for surgery is	93	78.8%	110	93.2%	0.002
4	Consent is not required as per law in the following situations, EXCEPT.	44	37.3%	60	50.8%	0.014
5	A person can give consent for physical examination if he is above	24	20.3%	100	84.7%	0.000
6	Essential component/s of consent includes	99	83.9%	118	100%	Cannot be done (100% in posttest)

Cont... **Table 3. Distribution of correct response for individual questions and p value of McNemar's test for paired samples.**

7	Parts of informed consent documents are	67	56.8%	94	79.7%	0.000
8	Audio-visual recording of consent process has been made mandatory in	64	54.2%	93	78.8%	0.000
9	Waiver of consent may be granted by the ethics committee in following situations, EXCEPT	15	12.7%	46	39.0%	0.000
10	Reconsent or fresh consent is required in situation/s	65	55.1%	54	45.8%	0.161
11	In some situations, consent has to be obtained from organisations that represents the community. This type of consent is termed as	38	32.2%	82	69.5%	0.000
12	Fundamental ethical principles of autonomy is ensured through the practice of	55	46.6%	101	85.6%	0.000
13	Assent is obtained from	18	15.3%	100	84.7%	0.000

Discussion

Didactic lecture is one of the most widely accepted methods among teaching and learning methodology. Because of time restriction and vast syllabus to be covered through lectures, feedback knowledge before and after the lectures to assess the extent of knowledge of learners gained provides the platform for feedback[12,13].

The pretest can be used as a feasible tool to get useful information about the knowledge of students, to shape group specific education programs, to use as a diagnostic tool for obtaining early feedback on the need for assistance and also to provide a benchmark for assessing teaching effectiveness[14].

Pre-post testing is valuable to teachers because it allows for real-time progress monitoring. Multiple posttest can be administered throughout a student's enrollment, and thus educational gains can be monitored and instruction can be adjusted appropriately[15]. In pre and posttest based learning method, the student will be actively involved in education. [12]. Pre and posttest can also be used as a powerful diagnostic tool to identify; weak students, strongest students, topics students already know, topics students don't know and the topics students have not leaned[16].

Disadvantages of pre and posttest includes, students may absorb knowledge just from taking the test and may attend more readily to the content and there may be a tendency to teach to the posttest[17].

A pre and posttest study conducted to evaluate whether formal communications skills training on informed consent improves the quality of written informed consent among untrained Post-Graduate Residents in the Department of Obstetrics and Gynaecology at a Medical College Hospital, Maharashtra revealed that the intervention had increased the mean scores in post-test (5.17 to 9.33) and the paired t test was highly significant with t = -13.61, < 0.0001[18]. In the present study also statistical analysis done on average pre and posttest score and on difference in pre and posttest responses to individual questions; revealed measurable gain in knowledge at the end of the class, since $p < 0.05$.

Conclusion

Knowledge regarding informed consent is indispensable in medical practice and research and it is an integral part of medical curriculum. Measuring academic progress through appropriately administered pre-post tests can be a powerful tool in providing teachers feedback about how to better meet students' academic needs.

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