

ORIGINAL ARTICLE

Knowledge about Informed Consent among Doctors of Various Specialities: A Pilot Survey

Gayatri Gupta¹, Amol Nanak Singh², Namita Bansal³, Gurpreet S Wander^{4*}

Abstract

Background: Informed consent is an integral part of clinical practice. Improper informed consent can lead to mistrust between doctors and patients as well as medico-legal issues. Awareness and knowledge of various aspects of consent is essential in present day medical practice.

Methods: A paper and web-based survey was undertaken to evaluate knowledge about informed consent among doctors. A law and a medical student generated a list of questions based upon available case laws and legislations which were further validated by experts. 500 doctors undertook the survey and of these 457 completed the survey of 18 questions. Both univariate and multivariate models were used to analyze responses.

Results: 413 complete questionnaires were included in the analysis. The proportion of respondents furnishing correct responses varied between 49.6% and 93.7%. There were 9 questions for which, over 25% respondents provided inappropriate responses. The questions included those enquiring whether initial consent for diagnostic or therapeutic procedures could apply to extended procedures or surgery and who was capable of giving consent for different procedures. There were significant differences of knowledge between residents and consultants for few questions. The physicians fared worse than surgeons and anesthetists although the difference was not statistically significant.

Conclusion: Significant knowledge gaps were identified. There were deficiencies in providing correct response particularly in practical scenarios. There is a need to include knowledge about different aspects of informed consent in the medical curriculum.

Introduction

Informed consent refers to "an individual's autonomous authorization of a medical intervention or of participation in research."¹ The origin of consent stems from ethical issues of respect for autonomy, individual integrity and self-determination. Consent is considered real and valid when it is voluntarily signed by the patient who has the capacity to understand information provided in relation to the proposed intervention or treatment.

Although principles of informed consent have been established since 1914,² medical professionals are not fully conversant with its elements and nuances, thus leading to variations in its application and practice. Most

of the developments in the practice of informed consent in India have taken place only very recently after a landmark judgement in 2008³ in which, the principles related to real and valid consent were laid down. Shortcomings in knowledge and awareness of the stipulations of this judgment are probably widespread and sadly are often the premise for lawsuits related to medical negligence. Indeed in certain cases, doctors have been held guilty of medical negligence as the only deficiency in services established pertained to consent.⁴ Most of the studies carried out to determine the practices of doctors regarding consent

have been conducted outside India.⁵⁻⁷ The few that have been conducted in India are on a small scale.^{8,9} A PubMed search on the terms 'informed consent' and 'India' in the title/abstract field yielded 30 articles from 1991 onwards.

This study was carried out in order to determine the prevailing levels of knowledge and attitude regarding medical-legal consent across a spectrum of doctors. This is important in order to identify the knowledge gaps among the postgraduate residents and consultant doctors before we initiate formal teaching on informed consent in the medical curriculum. We undertook a survey of knowledge and awareness of practices regarding selected medico-legal issues faced by doctors in daily practice. Here, we report an analysis of the survey results.

Material and Methods

This, part 'paper-pencil' and part 'web-based' survey, was undertaken in December 2017.

Sampling frame: Doctors were invited to complete the survey administered in English language mostly during medical conferences of different specialities. A convenience sampling strategy was employed but efforts were undertaken to ensure a range of participation across age groups, gender, level of qualifications and specialities (medicine, surgery, anaesthesia).

Design of questionnaire: A law student and a medical student generated a list of 40 questions, which were then reviewed by 5 experienced senior specialist doctors at a medical college, who independently rated the questions on a Likert scale of 0 to 5. The ratings were averaged and 18 of those with the highest ratings were included

¹Student, NALSAR University of Law, Justice City, Shameerpet, Hyderabad, Telangana; ²Student, ³Statistician, ⁴Professor and Head of Cardiology, Dayanand Medical College and Hospital, Ludhiana, Punjab; *Corresponding Author
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Table 1: Demographic features of the doctors who participated in the part 'paper-pencil' and part 'web-based' survey (n=413)

Age	
Mean	38.79 ± 11.74
Range	61
IQR	28-48
Gender	
Male	260 (63%)
Female	153 (37%)
Rank	
Consultant	248 (60%)
Resident	165 (40%)
Broad specialization	
Medicine	206 (49.9%)
Surgery	159 (38.5%)
Anaesthesia	48 (11.6%)

*IQR= Interquartile range

in the final survey. Another set of 5 senior consultants provided the most appropriate answers for the chosen questions based on available case laws and legislative acts supported by literatures and legal survey provided by the student authors.^{3,10} Those questions with consistent answers across the respondents were included straight-away and those for which answers were incongruous, a consensus was reached through discussion.

Administration of questionnaires: Respondents were given 25 to 30 minutes to complete the forms. No explanations were provided by the study volunteers for any of the questions. All responses were anonymized.

Analysis of responses: Responses were scored as either correct or incorrect, compared against the expert group appraisals. The primary outcome variables were the proportion of correct responses to each question in the questionnaire and percentage of correct response. These were analyzed in relation to several explanatory variables including age, gender, rank (consultant vs resident) and type of specialization (medical, surgical and anaesthesia). First, an association between explanatory variables and the proportion of the correct responses were explored for each of the questions in the questionnaire. Measures of association were considered significant at $p < 0.05$. Next, explanatory variables for those questions for which an association was established with $p < 0.1$ were entered in to logistic regression models to determine their significance. Linear regression model also were

used to determine the significance of explanatory variables for percentage of correct response. Stata ver. 12 (Statacorp, USA) was used for analysis.

Results

In all, 500 medical graduates working at various levels and in different specialities were invited to undertake the survey and of these, 457 provided responses. Forty-four were excluded because of incomplete demographic information, leaving 413 questionnaires to be analyzed. Demographic features of the subject population are presented in Table 1. Table comprising the questionnaire and the proportion of correct responses provided by the subjects for each of the questions is shown in Table 2. There were nine questions for which over one quarter of the respondents provided incorrect responses (Q's 3, 5, 7, 8, 9, 10, 11, 13, 16). These comprised largely of questions; probing whether the scope of initial consent taken for a diagnostic or therapeutic procedure or surgery could be extended to further interventions or surgery, who is legally competent to give a valid consent and questions on the timing of consent in emergency procedures.

Significant associations between the proportions of correct responses and age, gender, rank and specialization were noted for 9 of the 18 questions analyzed in the univariate analysis (Q's 2,4,5,6,7,8,10,13,17; column five of Table 2). A number of questions bore an association with rank (Consultant vs Resident) both in the univariate and multivariate analysis (Q's 4, 6, 7, 17). The questions also included those that referred to situations in which initial consent could apply to follow-up procedures or surgery (Q's 5 and 17). Knowledge about the course adopted in event of refusal for cardiopulmonary resuscitation (CPR) by the patient or the family of the patient appeared to be significantly deficient among residents (Q 13; $p = 0.0001$). Residents were also significantly less-knowledgeable about surrogate consent (Q 4; $p = 0.006$). On comparing the percentage of correct response, consultants showed significantly more knowledge than residents (Figure 1). In linear regression, the residents were found to be significantly less knowledgeable than the consultants. There was no difference regarding

correct response to the questions by gender or by the specialization (Table 3). The correct and incorrect responses (percentage) for each question for the consultants (lower panel 0-100%) and for the residents (upper panel 101-200%) are shown in a pictorial form in Figure 2.

Specialities differed from each other significantly in terms of who could take consent (Q 7) (poor among medical specialists; $p = 0.008$) and the individual from whom consent should be taken (poor among surgeons; $p = 0.023$) (Q 10). In addition, anaesthetists appeared to be significantly less-knowledgeable about the timing of consent in elective procedure ($p = 0.027$) and whether consent for major procedures can be applied to minor procedures ($p = 0.011$) (Q's 2 and 5). On comparing the three specialities overall no significant difference were found between them (Figure 1).

Discussion

The majority of published data and opinions on informed consent in India relate to research study settings.¹¹⁻¹³ Scientific journals and meetings devote little time and space to informed consent in routine clinical (both medical and surgical) practice. A small number of surveys have captured patient and community views regarding informed consent and still fewer have studied it from the medical professionals perspective.^{8,14,15} A study compared the attitudes towards informed consent among doctors in Malaysia and Kashmir but covered only small samples and limited domains.¹⁶ None, however, have addressed the variety of contexts in medical and surgical practice encompassed by informed consent. The questionnaire was designed rather carefully in order to test knowledge relating to a range of situations in clinical practice. Moreover, the questionnaire was pilot tested across a sample comprising a range of respondents in order to accrue data on factors associated with knowledge and awareness of informed consent practices. Among the variables for which we collected information we looked at differences in knowledge and responses amongst the variables of different age, rank (consultant vs resident) and speciality (medical, surgical and anaesthesia).

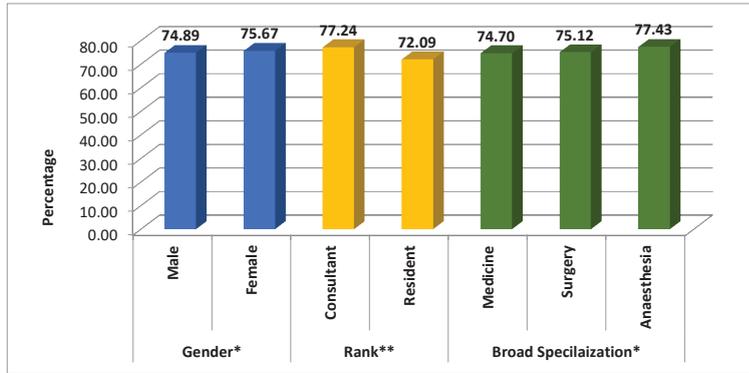
Table 2: Detailed questions (1-18) that were part of the questionnaire, the correct answers, the percentage of respondents giving correct and incorrect responses to each of these questions and univariate and multivariate analysis of the variables evaluated (gender, rank and specialties)

Q. No.	Question	Correct response	No. of responder with correct response	Incorrect response given by > 25% respondents	Variables associated with responses in univariate analysis (p<0.05)*	Variables associated with responses in multivariate analysis (OR, 95% confidence interval)**
Q1	What is the legal age at which a the valid consent can be taken	18 years	387 (93.7%)	No	Nil	Nil
Q2	When does the consent need to be taken in Pre-planned(elective) procedures?	Before starting the procedure	341 (82.6%)	No	Specialization-Surgery(84.9%) (p=0.027)	NS Specialization-Anaesthesia(0.41, 0.19 - 0.87)
Q3	When does the consent need to be taken in Emergency procedures?	Before stating the procedure	308 (74.6%)	Yes	Nil	Nil
Q4	When can the surrogate consent be taken?	When the patient is minor, unconscious or of unsound mind?	385 (93.2%)	No	Rank- Consultant (96%) (p=0.006)	NS Rank-Resident (0.22,0.62 - 0.79)
Q5	Whether the consent taken for major procedure can be used for minor procedure?	No	282 (68.3%)	Yes	Specialization-Surgery (73%) (p=0.011)	p= 0.009 Age (0.97, 0.94-0.99) Rank- Resident (0.46, 0.24-0.88) Specialization-Anaesthesia(0.43, 0.22-0.84)
Q6	Does a consent taken for a diagnostic procedure hold good for a therapeutic procedure (either conservative or radical) as well?	No	364 (88.1%)	No	Rank- Consultant (93.1%) (p=0.0001)	p=0.0008 Rank-Resident (0.14, 0.05-0.42)
Q7	Who is required to take a valid consent for intervention/surgery?	Consultant	205 (49.6%)	Yes	Rank- Consultant (60.9%) (p=0.0001), Specialization-Surgery (59.1%) (p=0.008)	p= 0.0001 Rank-Resident (0.32, 0.17-0.58) Specialization-Surgery(2.19, 1.39- 3.43)
Q8	A patient with shock comes to the emergency room and is required to get a central venous catheter, C.T. angiography, urinary catheterization. What would be the number of consents required?	3 consents-for each procedure	246(59.6%)	Yes	Gender- Male (63.5%) (p=0.035)	p= 0.025 Age (0.97, 0.95-1.0) Gender- Male (1.79, 1.16-2.78)
Q9	A couple-male=42 years old, Female= 39 years old, having a child (19 years old). The wife wants to get herself sterilized. The consent needs to be taken from?	Both husband and wife	270(65.4%)	Yes	Nil	Nil
Q10	A 20 year old female presenting with Fibroid opts for surgery. Consent for elective surgery is required from?	Patient herself	272 (65.9%)	Yes	Rank- Resident (72.1%) (p=0.029), Specialization-Anaesthesia (83.3%) (p=0.023)	p= 0.007 Age (0.98, 0.95-1.0) Specialization-Anaesthesia (2.42, 1.04-5.56)
Q11	A 17 year old female requires dental extraction. Consent is required from?	Legal guardian	244 (59.1%)	Yes	Nil	Nil

Table 2: Detailed questions (1-18) that were part of the questionnaire, the correct answers, the percentage of respondents giving correct and incorrect responses to each of these questions and univariate and multivariate analysis of the variables evaluated (gender, rank and specialties) (Contd...)

Q. No.	Question	Correct response	No. of responder with correct response	Incorrect response given by > 25% respondents	Variables associated with responses in univariate analysis (p<0.05)*	Variables associated with responses in multivariate analysis (OR, 95% confidence interval)**
Q12	When can the diagnostic/therapeutic procedure be carried out without consent?	In case of emergency when no relatives of patients is available for consent	385 (93.2%)	No	Nil	Nil
Q13	What to do in case of refusal by the attendants for CPR?	Start CPR as the refusal by relatives has no value	237 (57.4%)	Yes	Rank-Consultant (64.5%) (p=0.0001)	p= 0.0004 Gender-Male (0.55, 0.35-0.85)
Q14	What are the consequences of invalid consent/ no consent?	It is to be treated as misconduct under MCI ethics regulations, Amount to negligence in rendering the treatment and Liable for Punishment	328 (79.4%)	No	Nil	Nil
Q15	Under what circumstances, additional surgery is permitted without consent of the patient?	It is necessary to save the life or preserve the health of the patient	351 (85%)	No	Nil	p= 0.026 Specialization-Anaesthesia(6.26, 1.41-27.79)
Q16	A 30 year old patient consented for an elective laparoscopic cholecystectomy only. Due to the discovery of adhesion and swollen, inflamed gall bladder during the procedure, the said procedure could not be performed. The surgeon proceeded to perform open Cholecystectomy (conventional Procedure). Whether the consent taken for laparoscopic cholecystectomy can be used for open cholecystectomy?	No	306 (74.1%)	Yes	Nil	Nil
Q17	A patient consented for a caesarean section. During the course of the procedure, the doctor found fibroid tumors in the patient's uterus. The doctor performed a sterilization procedure considering that the tumor would be a danger in case of future pregnancy. Whether there was implied consent for the sterilization procedure?	No	319 (77.2%)	No	Rank-Consultant (83.1%) (p=0.001)	p= 0.004 Rank-Resident (0.27, 0.13-0.57)
Q18	Whether a valid consent excludes doctors' responsibility from negligence?	No	359 (86.9%)	No	Nil	NS

*Shows percentage of the variable which is significantly higher/highest as compared to other; **Odd ratio is calculated for the rank in relation to consultant and for specialization in relation to medicine; Nil: indicates no significant difference in response between various variables on univariate and multivariate analysis.



*p-value =Non-significant

**p-value =Significant (<0.0001)

Fig. 1: Percentage of correct responses amongst the three variables (gender, rank and specialties)

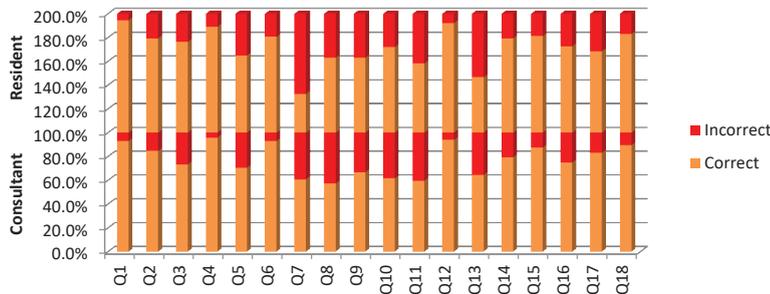


Fig. 2: The correct and incorrect responses (percentage) for each of the eighteen questions among the consultants (lower panel 0-100%) and for the residents (upper panel 101-200%)

Overall, the analysis revealed that the respondents were reasonably well-sensitized to informed consent practices but there are certain gaps identified by selecting arbitrarily those questions with over 25% incorrect responses. For instance, there was some ambiguity of responses in relation to the questions relating to whether consent for major procedures would be applicable if the procedure/surgery were extended to additional minor procedure/surgery (Table 2; Q 5).¹⁷ Consistent with the identified knowledge gaps, respondents were unclear about informed consent when the elements were illustrated by specific examples, of the decision of conversion of a laparoscopic cholecystectomy to open cholecystectomy (Table 2; Q 16).¹⁸ The underlying principle behind these questions being that in a planned surgery where express consent for a particular mode is taken from the patient, there can be no deviation in mode of surgery, particularly, when there is no emergency.

A major lacuna identified was concerned with the question relating to the personnel in the treating unit

who are authorized to obtain consent from the patient (Table 2; Q 7). Only 49.6% of the respondents provided the correct response. It is desirable that the operating physician or a member of his/her team who has clear knowledge of the procedure and the potential risks and complications should obtain the consent.

The second least correct answer overall was Q 13 / question no. 13 regarding what to do when attendants refuse CPR. The correct answer is start CPR as the refusal by relatives has no value. Ordinarily for a physician the life of the patient is supreme and hence to be saved. However, we have to accept the patient's choice and in case of a valid living will, respect it. If the patient has expressed his desire to the contrary in the living will, the physician should act accordingly.¹⁹

The majority of the respondents (93.7%) were knowledgeable of the minimum age (18 years) required to provide consent (Q 1). However, when administered indirect questions (Q's 10 and 11) in relation to the minimal age for providing consent,

Table 3: Linear regression analysis of the correct answers amongst variables of gender, rank and specialties

	Coefficient	p-value (95% confidence interval)
Age	-0.027	0.095 (-0.06-0.01)
Gender (Male)	-0.202	0.472 (-0.75-0.35)
Rank (Resident)	-1.500	0.0001 (-2.25- -0.75)
Specialization		
Surgery	0.781	0.778 (-0.47-0.62)
Anaesthesia	0.643	0.138 (-0.21-1.49)

only 59–66% of the respondents gave the correct answers. This suggests that there is need for reinforcing the practical application of the existing statutes regarding informed consent. In particular relation to the minimum age to provide informed consent, there appears to be controversy in the existing laws. For instance, Section 88, 89 and 90 of the Indian Penal Code advocates that the minimum age of consent for medical procedures and examination is 12 years if the procedure is done in good faith for the person's benefit.²⁰ Whereas, according to Section 11 of the Indian Contracts Act, a person of 18 years or above is of the age of majority and is competent to contract.²¹ Hence, the legal validity of consent given by patients between ages of 12 and 18 years needs to be clarified.

The consultants fared statistically better than the residents for three questions (numbers 4,6 and 7) regarding when and who can take valid consent and for Q no 13 regarding what to do if CPR is refused by attendants. Also, for the practical question regarding need for separate consent during change of extent of surgery in a caesarean section (Q 17).

The surgeons fared better than physicians regarding when the consent is to be taken for elective and emergency procedures and who is required to a take valid consent. Thus, physician needs to be trained regarding timing and person taking consent since their knowledge was significantly weaker.

The anaesthetists were better than physicians in Q 10 and 15 which address whether for a 20 year female undergoing surgery for fibroid who can give consent and under what circumstances additional surgery is permitted without further consent. The physician's knowledge for consent regarding these surgical issues needs supplementation.

The deficiencies in providing correct

responses to other questions in which practical but some what complicated situations were presented (Q's 8 and 9) suggest that doctors need to be trained in the finer nuances of the practical applications of the law in relation to informed consent.

A limitation of this survey was that it was restricted to only three major specialization fields (medicine, surgery and anaesthesia) and excluded non-clinical fields. Another limitation was its limited scope across respondents. Clearly, a large-scale survey across different geographic regions, stratified by different age groups, ranks and specializations is warranted. Meanwhile, this survey underscores the need for incorporating continued scholarship in relation to evolving informed consent practices.

Apparently, doctors are learning by experiencing the issues regarding consent since resident fared significantly worse than consultants. So, knowledge regarding, how to take an informed consent properly, needs to be incorporated in the medical

curriculum.

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