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

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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.

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The majority of published data and opinions on informed consent in India relate to research study settings.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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)

<table>
<thead>
<tr>
<th>Q. No.</th>
<th>Question</th>
<th>Correct response</th>
<th>No. of responder with correct response</th>
<th>Incorrect response given by &gt; 25% respondents</th>
<th>Variables associated with responses in univariate analysis (p&lt;0.05)*</th>
<th>Variables associated with responses in multivariate analysis (OR, 95% confidence interval)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>What is the legal age at which a the valid consent can be taken</td>
<td>18 years</td>
<td>387 (93.7%)</td>
<td>No</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q2</td>
<td>When does the consent need to be taken in Pre-planned(elective) procedures?</td>
<td>Before starting the procedure</td>
<td>341 (82.6%)</td>
<td>No</td>
<td>Specialization-Surgery (84.9%) (p=0.027)</td>
<td>NS Specialization-Anaesthesia (0.41, 0.19-0.87)</td>
</tr>
<tr>
<td>Q3</td>
<td>When does the consent need to be taken in Emergency procedures?</td>
<td>Before stating the procedure</td>
<td>308 (74.6%)</td>
<td>Yes</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q4</td>
<td>When can the surrogate consent be taken?</td>
<td>When the patient is 385 (93.2%) minor, unconscious or of unsound mind?</td>
<td>No</td>
<td>Rank- Consultant (96%) (p=0.006)</td>
<td>NS Rank-Resident (0.22, 0.62-0.79)</td>
<td>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)</td>
</tr>
<tr>
<td>Q5</td>
<td>Whether the consent taken for major procedure can be used for minor procedure?</td>
<td>No</td>
<td>282 (68.3%)</td>
<td>Yes</td>
<td>Specialization-Surgery (73%) (p=0.011)</td>
<td>p=0.0008 Rank-Resident (0.14, 0.05-0.42)</td>
</tr>
<tr>
<td>Q6</td>
<td>Does a consent taken for a diagnostic procedure hold good for a therapeutic procedure (either conservative or radical) as well?</td>
<td>No</td>
<td>364 (88.1%)</td>
<td>No</td>
<td>Rank-Consultant (93.1%) (p=0.0001)</td>
<td>p=0.0001 Rank-Resident (0.32, 0.17-0.58) Specialization-Surgery (2.19, 1.39-3.43)</td>
</tr>
<tr>
<td>Q7</td>
<td>Who is required to take a valid consent for intervention/surgery?</td>
<td>Consultant</td>
<td>205 (49.6%)</td>
<td>Yes</td>
<td>Gender-Male (63.5%) (p=0.035)</td>
<td>p=0.025 Age (0.97, 0.95-1.0) Gender-Male (1.79, 1.16-2.78)</td>
</tr>
<tr>
<td>Q8</td>
<td>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?</td>
<td>3 consents-for each procedure</td>
<td>246 (59.6%)</td>
<td>Yes</td>
<td>Rank-Consultant (60.9%) (p=0.0001), Specialization-Surgery (59.1%) (p=0.008)</td>
<td>p=0.0001 Rank-Resident (0.32, 0.17-0.58) Specialization-Surgery (2.19, 1.39-3.43)</td>
</tr>
<tr>
<td>Q9</td>
<td>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?</td>
<td>Both husband and wife</td>
<td>270 (65.4%)</td>
<td>Yes</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q10</td>
<td>A 20 year old female presenting with Fibroid opts for surgery. Consent for elective surgery is required from?</td>
<td>Patient herself</td>
<td>272 (65.9%)</td>
<td>Yes</td>
<td>Rank-Resident (72.1%) (p=0.029), Specialization-Anaesthesia (83.3%) (p=0.023)</td>
<td>p=0.007 Age (0.98, 0.95-1.0) Specialization-Anaesthesia (2.42, 1.04-5.56)</td>
</tr>
<tr>
<td>Q11</td>
<td>A 17 year old female requires dental extraction. Consent is required from?</td>
<td>Legal guardian</td>
<td>244 (59.1%)</td>
<td>Yes</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
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<td>Q12</td>
<td>When can the diagnostic/therapeutic procedure be carried out without consent?</td>
<td>In case of emergency when no relatives of patients is available for consent</td>
<td>385 (93.2%)</td>
<td>No</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q13</td>
<td>What to do in case of refusal by the attendants for CPR?</td>
<td>Start CPR as the refusal by relatives has no value</td>
<td>237 (57.4%)</td>
<td>Yes</td>
<td>Rank-Consultant (64.5%) (p=0.0001)</td>
<td>p= 0.0004 Gender-Male (0.55, 0.35-0.85)</td>
</tr>
<tr>
<td>Q14</td>
<td>What are the consequences of invalid consent/ no consent?</td>
<td>It is to be treated as misconduct under MCI ethics regulations, Amount to negligence in rendering the treatment and Liable for Punishment</td>
<td>328 (79.4%)</td>
<td>No</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q15</td>
<td>Under what circumstances, additional surgery is permitted without consent of the patient?</td>
<td>It is necessary to save the life or preserve the health of the patient</td>
<td>351 (85%)</td>
<td>No</td>
<td>Nil</td>
<td>p= 0.026 Specialization-Anaesthesia(6.26, 1.41-27.79)</td>
</tr>
<tr>
<td>Q16</td>
<td>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?</td>
<td>No</td>
<td>306 (74.1%)</td>
<td>Yes</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Q17</td>
<td>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?</td>
<td>No</td>
<td>319 (77.2%)</td>
<td>No</td>
<td>Rank-Consultant (83.1%) (p=0.001)</td>
<td>p= 0.004 Rank-Resident (0.27, 0.13-0.57)</td>
</tr>
<tr>
<td>Q18</td>
<td>Whether a valid consent excludes doctors’ responsibility from negligence?</td>
<td>No</td>
<td>359 (86.9%)</td>
<td>No</td>
<td>Nil</td>
<td>NS</td>
</tr>
</tbody>
</table>

*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.
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). 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 6). 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 a particular mode is taken from the surgery where express consent for these questions being that in a planned surgery were extended to additional procedures but there are certain gaps well-sensitized to informed consent knowledge gaps, respondents were uncertain about informed consent when and under what circumstances additional surgery is permitted without further consent. The physician’s knowledge of consent regarding these surgical issues needs supplementation.

The deficiencies in providing 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. 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. 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 relatives. 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 anesthetists 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 of consent regarding these surgical issues needs supplementation.

The deficiencies in providing correct consent.
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 faired significantly worse than consultants. So, knowledge regarding, how to take an informed consent properly, needs to be incorporated in the medical curriculum.

References

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