The Awareness of 'Informed Consent', Among Medical Students and the Current Consent Practices at a Tertiary Care Hospital

Objective: Our study aims to document the awareness of 'Informed Consent', among medical students and to evaluate the current consent practices at a hospital setting in Islamabad.

Study Design: Cross-sectional Survey.

Place and Duration: The study was carried out at Islamic International Medical College (IIMC) and IIMC hospital complex at Riphah International University, Islamabad from March 2007 to May 2007.

Materials and Methods: A questionnaire exploring the knowledge about informed consent was offered to the final year students. The post-operative patients at IIMC hospital were interviewed by research assistants, to study the consent practices in the hospital.

Results: Out of the 100 final year students interviewed, 68% were females and 32% were males. The awareness of the process of 'informed consent' was observed in only 12% of the respondents. Out of 100 postoperative patients, data were completed on 86 which included 33 (38%) men and 54 (62%) women. Approximately 41 of the participants (48%) were graduates and 45 (52%) had less than five years of school education. In only about half (52.5%) of the cases the consent form was signed by the patient himself/ herself.

Conclusion: A deficient awareness of informed consent was observed in the final year medical students despite stringent institutional ethical practices. This lack of awareness at undergraduate level is translated into inadequate consent practices which were observed at the clinical scene. To improve awareness, improved training in 'medical ethics' is required at undergraduate as well as postgraduate level.

Key Words: Consent, Medical students, Ethics, Informal consent

Introduction

Patient autonomy and informed consent before medical interventions is a legal and ethical requirement. The medical responsibility has been clearly defined in the Royal Decree No. 78 dated November 11, 1967 concerning the medical practice.\(^1\) With increasing social awareness there is a current need for using informed consent forms for all surgical as well as non-surgical procedures.

Informed consent is the autonomous authorization obtained from the patient after the surgeon explains and describes the nature of the problem, alternative treatments, anticipated benefits of treatments, risks and side effects of treatments and consequences of no treatment. This is a basic human right to be able to participate in one’s own health care decisions. The treating physician's involvement in this process cannot be understated whereas in practice, mostly the “consent signatures” are obtained by a junior doctor or a health worker without any understanding on the part of the vulnerable patient. It is the responsibility of the treating physician to discuss with the patient and obtain consent about the procedure or treatment, how it is carried out, and the risks attached to it. The treating doctor should give a balanced view of the options and explain the need for informed consent and let the patient decide. This is important in the context that the patient himself may have limited awareness of the legal implications of signing or not signing consent forms, and they may not recognize written consent as primarily
serving their interests. Patients may feel scared and stressed by having to give written consent, and may report that they do not read or understand the consent form. In addition there are assumed myths regarding informed consent that have not been explored or documented.

Ethics teaching has been shown to have a profound influence on medical professionals' attitudes. In Pakistan ethics is sometimes not given the due importance at the undergraduate or postgraduate level, though the PMDC guidelines clearly state that medical students must be taught ethics and evaluated. On the other hand, the Pakistani milieu also offers challenges to this process because crucial decision making is often done by family members or is left entirely up to the attending physician. The requirement for an informed consent is well established in all decision making situations in clinical practice. There is a need to train the medical students about this before they enter clinical practice.

This survey was carried out to assess the awareness of undergraduates about informed consent and to evaluate the current status of patient consent and counseling prior to surgery in a private sector hospital and then conclude as to whether the consent met the optimal requirement and which part of information was lacking in the communication.

Ethical issues

Written consent (containing the information sheet) was obtained from the medical students before administration of the questionnaire and their identities were kept confidential. The hospital ethical committee gave permission for the study. The respondents in the hospital survey were informed about the study and their written consent was also acquired.

Sample size: Assuming that 80% of the students will have knowledge about consent, with 10% of required precision and with 95% confidence interval the sample size was calculated to be 97.

Materials and Methods

The study was conducted from Mach 2007 – May 2007, using two pre designed questionnaires. Two separate cross-sectional surveys were conducted using pre-designed questionnaires at Islamic International medical college and Islamic International medical Hospital Complex (IIMHC).

Following a small pilot survey to test the understanding of the questionnaire, 100 final year medical students were interviewed to assess their awareness about consent in medicine. The questionnaire included queries about who should obtain consent and from whom, key components of consent, voluntary decision making, consent in an emergency, consent needs in children, consent capacity age at which consultants consider it appropriate for the patient to sign his/her own written consent and whether written information on the benefits/risks of treatment was needed, etc. Respondents were asked not to consult or discuss the questionnaire with their colleagues during its completion. The questionnaires were collected, the completed questionnaire were computerized and univariate analysis done on SPSS.

In the second part of the study, during 2007, 100 patients admitted for surgery at IIMCH were interviewed, to determine the current consent practices. The sample size calculated to estimate within 10% of the true proportion with 95% confidence interval was 97. The patients were selected on a daily basis through consecutive sampling and consent was taken. A standardized questionnaire was developed which probed 21 questions on informed consent. The questionnaire was in two parts, part 1 included demographic parameters like age, sex, marital status, education along with type of surgery. In the next section questions about the key elements of informed consent (voluntary participation, confidentiality, the main risks and benefits) were listed. The questionnaire included questions pertaining to surrogate consent, information about the type of surgery, alternate treatment options, side effects, and choice as well as complications of anesthesia. Complete confidentiality of names, addresses and any other information that the patient wanted to remain discrete was assured.

Results

Fifty In the student knowledge survey, 53% of the students reported that the consent should be obtained from patient whereas the rest thought that the consent should be given by male attendants like father or husband. Only 6% of the students could themselves identify the various components of the informed consent. When asked about individual parameters following responses were received. Though 90% of the students agreed that written consent is necessary before surgery, only a little more than half of the students thought that discussion about the other options of treatment/ risks of the surgery were appropriate during consent. Consent for examination or treatment was considered important by 37% only. The knowledge about the voluntary nature of consent was deficient. Confidentiality was acknowledged as a priority by majority. According to the students perceptions a patient can sign the consent form himself/ herself only if the age is 18 or above (Figure.1).

For the hospital survey 100 participants were approached out of which a total of 86 subjects were included in this study. A total of 14 questionnaires were excluded, as the information provided was either incomplete or incomprehensible. The study population included 37% male participants and 63% female
subjects. With regards to the educational status 32% were illiterate, 38% had secondary education and 30% were graduates. The subjects were in between the age groups 2 years to 70 years with the mean age being 37 yrs. (SD =8.7). A wide range of surgeries were performed on the patients ranging from, thyroidectomy to appendectomy. Majority of the surgeries performed (83%) were elective.

A written consent form was signed by either the patient or the relative in most of the instances. In about half of the cases the consent form was signed by the patient, and in the remaining instances a relative/caretaker signed the consent form. Out of the 48% who did not sign the consent themselves, 16.3% were physically unable, 8% were not of age and husbands were asked to give consent instead of the women themselves in 12 cases. The consultant in charge discussed the disease with the patients in majority of the cases. Most of the patients were told about the surgical procedure before the surgery. Very few patients undergoing surgery were aware of the choice of anesthesia. About half of the patients were not counseled about the side effects/possible complications of the procedure. In one third the patients did not know of other treatment options (Table. I).

### Table I: Consent practices observed at a private hospital in 2007

<table>
<thead>
<tr>
<th>Consent practices</th>
<th>No. of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written consent obtained</td>
<td>84</td>
<td>97.7%</td>
</tr>
<tr>
<td>Consent signed by Patient</td>
<td>44</td>
<td>52.4%</td>
</tr>
<tr>
<td>Relative</td>
<td>40</td>
<td>47.6%</td>
</tr>
<tr>
<td>Disease discussed by consultant</td>
<td>81</td>
<td>94.2%</td>
</tr>
<tr>
<td>Surgical procedure explained</td>
<td>55</td>
<td>91.9%</td>
</tr>
<tr>
<td>Choice of anesthesia discussed</td>
<td>39</td>
<td>45.3%</td>
</tr>
<tr>
<td>Complications discussed</td>
<td>44</td>
<td>51.2%</td>
</tr>
<tr>
<td>Other treatment options</td>
<td>60</td>
<td>70%</td>
</tr>
</tbody>
</table>

### Discussion

In clinical situations it is important to have informed consent to make important decisions, however the consent practices vary in different institutions and countries. There is a lack of awareness about consent even in educated patients in Pakistan. Previous studies have also looked at the consent practices in surgical patients. We have documented the knowledge about informed consent in final year medical students of a private medical college, as well. The holistic knowledge about obtaining consent was very deficient, which is unacceptable but correlates with another study in UK where correct answers on capacity to consent to or refuse medical treatment were given by 15% of the medical students only. Majority of the students in our study think that taking consent before any kind of treatment is not important as the patients do not know what is best for them. Their lack of knowledge about who should give consent, what information has to be shared and the appropriate age for consent needs specific training in this area.

### Figure I: Knowledge of students regarding consent

Age at which written consent is given for surgical treatment was thought to be 18 by majority of the students. Very few thought that consent could be obtained from patients of a younger age. Weithorn studied subjects aged 9, 14, 18 and 21 using hypothetical treatment dilemmas and concluded that 14-year-olds did not differ from adults in their competency to make treatment decisions. At age 16 a young person can be treated as an adult and can be presumed to have capacity to decide; under age 16 children may have capacity to decide, depending on their ability to understand what is involved.

The practices in the hospitals are no different from the student views. Though written information on the benefits/risks of treatment should be provided to the patient for a shared decision making, none of the doctors were practicing this in our study. It is very difficult for the patient and relatives to remember all the information and advice provided at a single consultation. No Information leaflets were available in reinforcing this information.

Written consent was routinely obtained for surgical treatment usually by the para medical staff who found themselves inefficient in providing related information. This practice has previously been pointed out in another study in Pakistan. A signature on a
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consent form does not indicate a valid consent if insufficient information has been provided to enable a considered choice to be made. Nevertheless, a signed consent form following an informed discussion of the benefits and risks with an individual patient can be a useful written record of that consent process. A little less than half of the patients did not sign the consent themselves. The results are a little better than the results of another study in a tertiary care hospital in Pakistan where only 29% signed their own consent form, the rest were done by the relatives. It was considered appropriate to obtain consent from the husband for women undergoing surgery, reiterating the student's views. This gender bias is unacceptable.

Previous researchers have suggested bioethics education at all levels, encouraging the involvement of families in decision making, using improvisation in procurement of consent are suggested solutions and our study indorses this view. The medical students should be assessed on performance based key ethics skills as early as in the first year of training to improve their skill and knowledge about informed consent.

Another matter that was discussed rarely with the patients was the choice of anesthesia as well as the complications of surgery. There are examples of providing information leaflets for anesthesia, which can be modified locally and used.

This study has certain limitations including small sample size, and convenience sampling from only one medical college students. Hence this cannot be generalized to the rest of the colleges in Pakistan. Similarly the hospital findings though depict a general trend should not be considered generalized. We suggest future multicenter studies to explore this issue.

Conclusion

The knowledge about informed consent in medical students is deficient specifically about the age of consent and who should give consent. The practices of the surgeons are also far from perfect, hence the need for an objective training in this area.

References