**Adequacy, efficiency and patients’ perceptions regarding the informed consent in surgical department of Dr. Ruth K.M. Pfau Civil Hospital Karachi (DRKMP-CHK).**

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**Abstract**

Objective: The aim of this study was to find adequacy and perception of patients regarding informed consent for elective and emergency surgical procedures in a tertiary-care hospital in Karachi.

Methodology: This was a questionnaire based cross-sectional study. This study was done for a duration of two months at Dr. Ruth K.M. Pfau Civil Hospital Karachi (DRKMP-CHK). About 270 adult patients undergoing emergency or elective surgery in Surgical Department of DRKMPCUH and being able to give consent themselves were included in the study. The questionnaire included questions regarding patients’ knowledge about their disease, its treatment options, risk of procedure; whether the patient had been informed about the procedure, risk, benefit, complication and other treatment plan before the surgery. The patients with psychiatric illness history or pre-operative cases were excluded from this study.

Results: A total of 270 patients were included in the study after obtaining informed consent. Majority of the patients (25.5%) were aged between 36 and 45 years. A substantial number wanted to know about the details of their procedure (90.37%), potential risks (88.5%) and benefits (251; 93%) of their surgical procedure. A considerable number of patients (86.3%) wanted to give consent themselves. Several of the patients (70%) reported that they were given sufficient time to think before taking decision to go for surgery.

Conclusion: The patients were found to be less aware of their underlying disease and were unaware of alternate treatment options available for their illness. The informed consent process was poorly practiced in the hospital. Education of staff and patients are required in this regard.

Keywords: informed consent, patient perception, surgical procedure

**Introduction**

The inform consent is one of the most important parts of preoperative surgical care, both from ethical and legal point of views. Informed consent is defined as “the process whereby someone competent and having capacity can agree to proposed procedure or detail, having had sufficient information without being pressured in making decision” (1). This process requires the provision of associative and relatable information to patients about the intervention and its consequences to help them make a conscious decision. The availability of information, patients free will and medicolegal consideration are part of informed consent (2). From a surgical perspective, the treatment options, necessity, consequences and risks associated with the surgical procedure must be provided to patients pre-operatively along with complete explanation of procedure. Only then the patient is enabled to make his/her decision with free will. However, Akkad et. al. observed that a number of patients consider informed consent as a formality, paper work and a hurdle or delay in procedure (3). It was further noted that some patients do not read or understand the informed consent prior to agreeing to it (4,5).

The situation in Pakistan may not be much different from what Akkad and colleagues (3) have described. This assumption can be attributed to a low literacy rate (6), multi-lingual population, non-availability of interpreters in hospitals (7) and lack of national guidelines on informed consent in the country. However, there is no evidence in existing local literature.

Hence, the aim of this study was to find adequacy of current informed consent process and the perception of patients regarding informed consent for surgical procedures in a tertiary-care hospital in Karachi. The findings from this research will identify the intensity of problem and provide guidance for taking corrective measures.

**Methods**

This was a questionnaire based cross-sectional study that was carried out at Dr. Ruth K.M. Pfau Civil Hospital Karachi (DRKMP-CHK), between May and June 2018. A sample size of 267 was calculated using formula for quantitative cross-sectional study. Ethical approval was taken from the Hospital Ethics Committee. All adult patients undergoing emergency or elective surgery in Surgical Department of DRKMPCUH and being able to give consent themselves were included in the study. To ensure reliability, study participants were asked questions by trained data-collectors. Where needed, the questions were translated into responder’s relative understandable language before filling the questionnaire. The patients younger than 18 years, guardian or parents as consent giver, patients with psychiatric illness history or pre-operative cases were excluded from this study.

The questionnaire was designed to obtain demographic information including age, gender, educational level and marital status of patients. The questionnaire also inquired regarding patients’ choice on whether h/she wanted to know about their disease, its treatment options, risk of procedure; whether the patient had been informed about the procedure, risk, benefit, complication and other treatment plan before the surgery; whether the patient was given enough time to decide and rethink his/her decision regarding the procedure.

Collected data was recorded and analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0 by IBM, New York, USA. Continuous variable like age reported as frequencies and percentile, and categorical variables reported as the number or percentage of subjects with a particular characteristic. Frequencies of the answer to the dichotomous questions made. A p-value of less than 0.05 was accepted as significant. Results presented as prose, tables and figures as appropriate.

**Results**

A total of 270 patients were included in the study after obtaining informed consent. Female to male ratio was 1:1.06 (136 female and 139 male). Majority of the patients (69; 25.5%) were aged between 36 and45 years, followed by 66 patients (24.4%) aged between 18 and25 years (Table 1).

Majority of patients (157; 58%) did not receive primary education, while 54 (20%) had completed their secondary education (Table 2). Most of the participants (232; 86%) were married (Table 3).

A large number of patients in this study (254; 94%) wanted to know about their disease, and most of them (240; 89%) also wanted someone from their family to know about their illness. Similarly, a significant number wanted to know the details of their procedure (244; 90.37%), potential risks (239; 88.5%) and benefits (251; 93%) of their surgical procedure. A significant majority (233; 86.3%) wanted to give consent themselves (Figure 1).

However, out of the 270 patients, 209 (77.4%) did not know details of proposed procedure, 209 (76%) did not know about possible risks, 200 (74.1%) were not aware of benefits and majority patients (252; 93%) were not informed about alternate treatment options for their disease (Figure 2).

This study showed that even though many were not aware of the details regarding the procedure, majority believed that they had agreed to the procedure by their own will (244; 90 %) and were not forced or pressurized to take the procedure. Several of the patients (188; 70%) reported that they were given sufficient time to think before taking decision to go for surgery. Majority of the participants (232; 86%) were aware of their right to refuse the treatment However, they believed that they cannot change their mind on procedure once consent was signed (Figure 3).

**Discussion**

Like most third world countries, Pakistan does not have in-place guidelines for the informed consent process. However, the code of ethics of Pakistan Medical & Dental Council (PMDC) informs about its importance and necessity in clinical work of professionals. Hence, in this scenario, it becomes the moral and ethical responsibility of the healthcare professionals to ensure appropriate methods for taking informed consent. The process of informed consent thus depends on individual physicians, community requirement and institutional/ hospital policy.

This study looked at the current practices of informed consent and perceptions of patients undergoing surgical procedure in our community. Our results showed an alarmingly high percentage of patients with inadequate disclosure of information given before they consented for the surgical procedures. Similar findings have been reported from developing (8,9,10) and developed (11,12) countries. The authors from different countries have described multifactorial reasons for this shortfall. Limited resources, lack of community education and awareness, and inadequate training of physicians are considered the main reasons.

The reasons for poor informed consent process can also be seen in our study. Education and awareness of patients were on the forefront. Level of education of patients was quite low in our study group. There is evidence to suggest that educated patients are more aware of their rights regarding informed consent (13) This can be one of the main reasons for our study participants being clearly less informed in many aspects of information regarding surgical procedure.

Contrary to general belief of healthcare providers, patients, weather educated or illiterate, want to get information regarding their illness and treatment. In a survey held in Japanese population on how much information a healthy person expected to be delivered to him/her from their doctor in event of cancer development, majority responders (84.5%) wanted full disclosure from their doctor (14). This is similar to attitude of patients in our study where majority wanted to know about their disease. Our study shows that majority patients were aware of their right to refuse the treatment and had voluntarily agreed to undergo proposed surgical procedure, fulfilling the definition of informed consent. The patients seemed to have understood the benefits of surgical procedure regarding their illness and had consented without being pressurized and took their desired time to make decisions. This high level of awareness was seen in spite of lower education level in our participants. Similar findings have been reported from Nigeria where literacy rate is low as in Pakistan (15).

There were negative findings from our research that show the poor state of current situation. It was found that many of the patients did not have any idea that they can change their decision regarding surgical procedure after giving informed consent. The patients were found to be less aware of their underlying disease and were unaware of alternate treatment options available for their illness. These findings have also been reported from other developing countries and reflect the authoritarian approach of surgical fraternity where surgeons would give the “final verdict” for treatment (11,16).

A unique secondary finding in our study was the language barrier in communication. Karachi is a metropolitan city. The patient population of DRKMP-CHK belongs from different regions of the country and speak varied languages. This was observed while collecting the data. The data collection could not have been possible without the use of translators for multiple regional languages. These translators are generally not available in hospitals for the process of informed consent. Hence, the challenges that the doctors must face while completing the formalities of an adequate informed consent process.

**Limitation**

The study was conducted in a single state-run hospital of Karachi city which primarily caters to a low socio-economic population group. Therefore, the findings may not be generalizable to the rest of the city.

**Conclusion**

The informed consent process was poorly practiced in the hospital. Patients were not aware of their rights. Education of staff and patients are required in this regard.

**Conflict of Interest**

There is no conflict of interest between authors or by institute in which this study is conducted.

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Table 1. **Gender and Age of patients**

Table 2. **Educational Level of patients**

Table 3. **Marital Status of patients**

Figure 1. **Information seeking behavior of the patients about their disease**

Figure 2. **Has sufficient information been provided to the patient**

Figure 3. **Enough time given to consent voluntarily**

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Table 1. **Gender and Age of patients**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Range | | Gender | | |
| Male | Female | Total |
| AGE |  |  |  |  |
| 18-25 | 33 | 33 | 66 |
| 26-35 | 37 | 23 | 60 |
| 36-45 | 34 | 35 | 69 |
| 46-55 | 29 | 32 | 61 |
| 55< | 6 | 8 | 14 |
| Total | 139 | 131 | 270 |

Table 2. **Educational Level of patients**

|  |  |  |  |
| --- | --- | --- | --- |
| Level of Education | | Frequency | Percent |
|  | None | 157 | 58.1 |
| Primary | 43 | 15.9 |
| Secondary | 54 | 20.0 |
| Vocational | 6 | 2.2 |
| Training | 4 | 1.5 |
| University | 6 | 2.2 |
| Total | 270 | 100.0 |

Table 3. **Marital Status of patients**

|  |  |  |  |
| --- | --- | --- | --- |
| Marital Status | | Frequency | Percent |
|  | Single | 30 | 11.1 |
| Married | 232 | 85.9 |
| Divorced/widowed | 8 | 3.0 |
| Total | 270 | 100.0 |

Figure 1. **Information seeking behavior of the patients about their disease**

Figure 2. **Has sufficient information been provided to the patient**

Figure 3. **Enough time given to consent voluntarily**

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