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Evaluating the Informed Consent Process: Insights from Post-Operative Experiences in Pharmaceutical Care

Muhammad Ajmal[1], Dr. Arslan Wajid[2], Dr. Zahra Rafique, Ahsan Sikandar Khan[4], Abdul Rehman Saddiq[5], Muhammad Sulaiman[6*], Muhammad Aqeel Sultan[7], Dr. Usman Wajid[8*].

[1]Department of Surgical Technology, Faculty of Allied Health Sciences, Gomal University D.I. Khan, Pakistan.

[2]Department of Critical Care Medicine, Pakistan Institute of Medical Sciences Islamabad, Pakistan.

[3]Department of Medicine, Islamabad Medical Complex, Islamabad, Pakistan.

[4]Faculty of Pharmacy, Hamdard university Islamabad Campus, Pakistan.

[5]Surgical Tower Mayo Hospital, King Edward Medical University Lahore.

[6*]Department of Surgical Technology, Faculty of Allied Health Sciences, Khyber Medical University, Peshawar.

[7]National Centre of industrial Biotechnology, Pir Mehr Ali Shah Arid Agriculture University Rawalpindi, Pakistan.

[8*]University Institute of Biochemistry and Biotechnology, Pir Mehr Ali Shah Arid Agriculture University Rawalpindi, Pakistan.

Correspondence Author: msulaiman.ipms@kmu.edu.pk. wajidusman323@gmail.com.

ABSTRACT:

Background: An informed consent must be obtained legally and ethically before invasive or high-risk therapeutic procedures are performed. It is defined as the "process of communication between a patients and healthcare professionals that leads in the patient's permission or agreement to undergo any specific medical procedure.

Aim: To investigate informed consent's practices and determine whether the persons who have signed for surgical treatments have a sufficient understanding about the process of informed consent.

Methodology: It was a descriptive cross-sectional study that was conducted at the Rehman Medical Institute (RMI) Peshawar. Using Simple Random Probability Sampling Technique; a sample of 108 surgical patients was recruited. Data was collected using closed ended interview schedule. The validity of the redesigned instrument was evaluated by a panel of specialists, including a research supervisor and surgical practitioners. To analyze data a descriptive statistic will be used. The computer's software, Statistical Package for Social Science (SPSS version 20) will be used for data analysis and interpretation.

Result: The sample size was 108 patients, with a 100% response rate. A total of 108 patients (89 male and 19 female) were randomly selected for post-operative interviews. Out of 108 patients, all the patients gave and signed the pre-operative informed consent process form on their own. Only 21 (19.44%) patients already knew about the informed consent process because they had almost a bachelor's degree

education. Only 31 patients (28.70%) read and fully understood the surgical informed consent process form. And 106 (98.14%) had their consent taken by a young doctor rather than the surgeon who would be doing the surgery.

Conclusion: Our study revealed that quality of informed consent process is limited at RMI Hayatabad Peshawar, due to surgeons making little or no attempt to educate their patients on this subject and the informed consent form is only available in English, with no verified translation into the patient's mother tongue.

INTRODUCTION

Informed consent is a valid contract between a patient and his or her physician.[2] The term "consent by law" refers to a person's voluntary authorization of an intervention suggested by another person.[1] Informed consent is defined as, "The exchange of information between a patient and a physician that results in the patient's consent or authorization to conduct a specific medical procedure."[2] It is more than just a form to be signed as a health facility formality; it ensures respect for people by providing thoughtful consent for the option to choose the best possible treatment in disease processes. [3,10] It is the basic method by which a physician tells a patient about the many possibilities for diagnosing and treating the patient's disease. [3] Successful surgery relies on the patient-to-doctor relationship of trust. [4,16] Informed consent for medical care must be presented, understood, and documented well to ensure a healthy doctor-patient relationship. [5,11]

In non-emergency cases, the process of informed consent will involve discussion of several aspects, including the type of the medical procedure proposed, hospital stay duration, alternate treatment possibilities, hazards, advantages, disadvantages, and process more complicated. [6] Information may be given orally, in writing, or both about the procedure for which consent is given. In effective informed consent, patients fully understand the procedure, their rights and duties. [6,15] An ideal consent form for surgery should start with a brief description of the procedure, including the type of anesthesia to be used. Informed consent is controlled by a set of criteria that assumes the person giving the consent is well- informed. [17] When a person rejects the information and refuses to give consent, however, he is considered to have made an informed refusal. [7,13].

Informed consent for surgical operations is a newer trend in the field of surgery. For thousands of years, doctors believed that lying was a necessary element of medical practice. [2,12] At the beginning of the 18th century, the United States of America was regarded as the birthplace of informed consent, whose original goal was

to ensure that the correct dignity of the patient's independence was preserved during decision-making and medical option selection. [8,14]

In 1767, informed consent was obtained in a leg fracture case. Since then, informed consent has been amended and finished in accordance with various types of anesthesia procedures.[9] In 1957, the term "informed consent" was developed in the health care setting in the United States. In 1964, it was further improved by the Declaration of Helsinki, which set international ethical standards for medical research involving human subjects. [8,11]

OBJECTIVES:

To investigate informed consent's practices and determine whether the persons who have signed for surgical treatments have a sufficient understanding about the process of informed consent.

METHOD AND MATERIAL

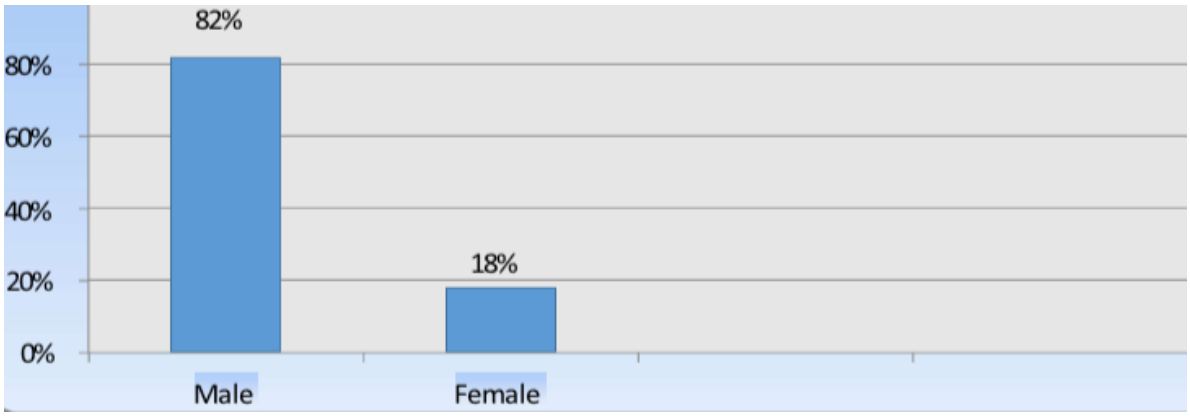
This is a descriptive cross-sectional study, conducted in Surgical Ward at Rehman Medical Institute Peshawar. Duration of research study was 1 year from April 2023-march 2024. The study population included post-operative patients admitted at Rehman Medical Institute Peshawar done elective surgery in various disciplines (n=108), namely Obstetrics and gynaecology, orthopaedics, and general surgery. Patients aged 18 and above who underwent elective (planned) surgery in the departments of general surgery, orthopaedics, obstetrics, and gynaecology, and consented to participate in the study were included in the inclusion criteria. Patients underwent emergency surgery, which could result in patient death or health damage if operation was postponed; patients less than 18 years of age, painful patients, and patients with postoperative complications were included in the exclusion criteria. Probability stratified sampling technique was used for this research. According to WHO formula sample size is 108. Statistical Package for Social Science (SPSS version 20), was used. Graphs and tables were generated using Microsoft Office Excel sheets.

RESULTS

Patient's gender wise distribution:

To analyse Demographic data, descriptive statistics was used in the form of graphs and tables. A total of 108 patients were recruited to participate in the study. Eighty-nine (82%) of the sample population was male and 19 (18%) were female.

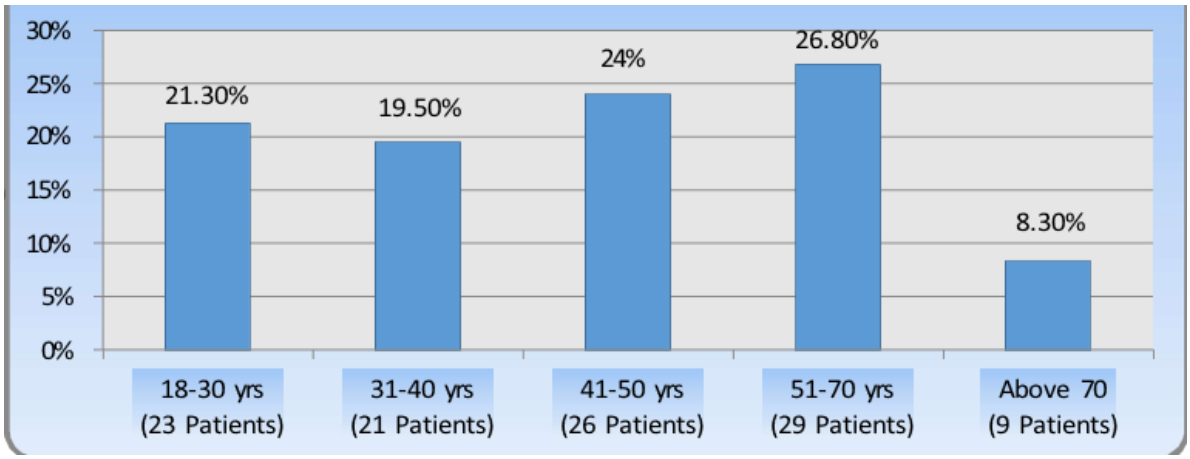
Figure 1 reveals the Patient's Distribution per Gender



Patients' age categories:

In terms of age, 29 (26.8%) of the sample population were between 51 and 70 years old, 26 (24%) were between 41 and 50 years old, 23 (21.3%) were between 18 and 30 years old, 21 (19.5%) were between 31 and 40 years old, and 9 (8.3%) were above 70 years old. Figure 1.2 shows the Patient's Distribution per Age group.

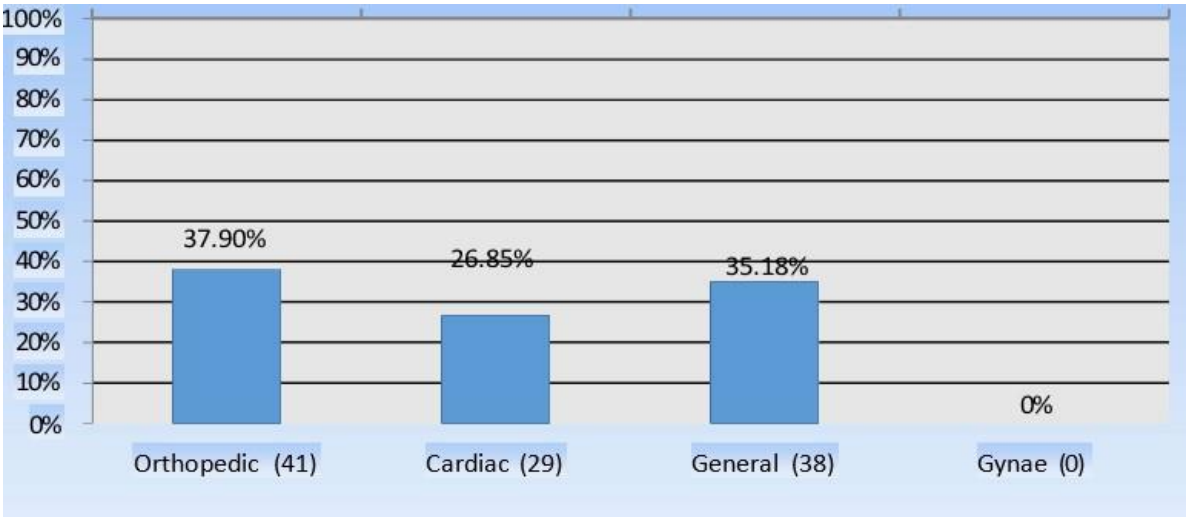
Figure 2 shows the Patient's Categories per Age group



Department wise Distribution:

Out of 108 patients, 41 (37.9%) of the sample were orthopedics patients, 38 (35.1%) were general surgery patients, and 29 (27%) were cardiac surgery patients. And no patients from obstetrics and gynecology were chosen because males are not permitted in the ward, and our researcher group had no female mates.

Figure 3 shows the Department wise Distribution



Elements of informed consent process covered with patients:

Figure 1.4 reveals the element (1-5) of informed consent process covered with patients. A total of 108 patients (89 male and 19 female) were randomly selected for post-operative interviews. Out of 108 patients, all the patients gave and signed the pre-operative informed consent process form on their own. Only 21 (19.44%) patients already knew about the informed consent process because they had almost a bachelor's degree education. Only 31 patients (28.70%) read and fully understood the surgical informed consent process form. And 106 (98.14%) had their consent taken by a young doctor rather than the surgeon who would be doing the surgery.

Figure 1.5 reveals the element (2-10) of informed consent process covered with patients. And most of the 96 (89%) were patients to whom anesthetists told about complications, risks, and type of anesthesia, but only 26 (24.07%) patients knew about complications or risks that may arise in intra or post-op. And 89 (82.40%) patients to whom the consent taker told about approximated intraoperative time but only 23 (21.29%) participants informed about when they returned to their daily activities. And 98 (90.74%) patients were informed about the nature and purpose of the proposed surgery, and 69 (63.88%) patients whom the surgeons told about expected benefits after surgery.

Figure 4: element (1-5) of informed consent process covered with patients.

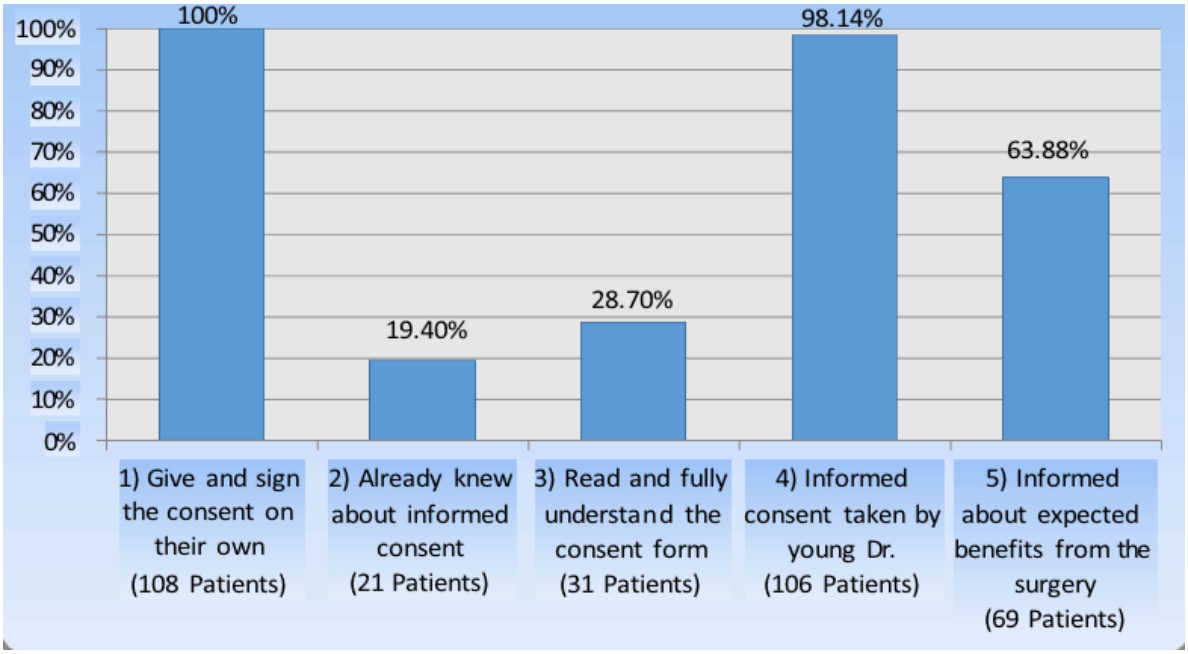
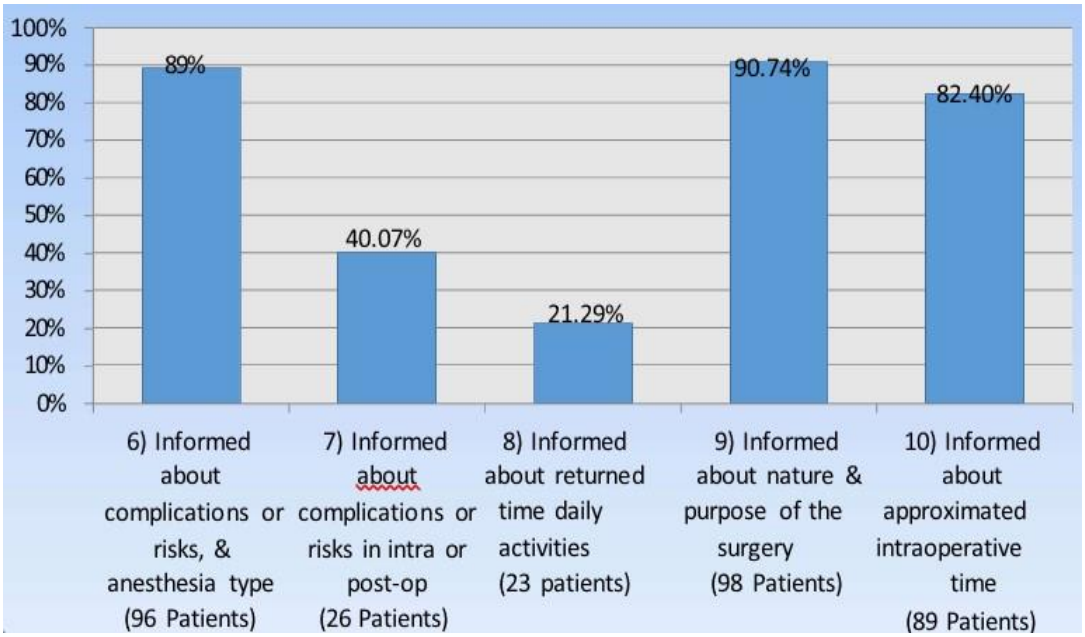


Figure 5: Element (2-10) of informed consent process covered with patients.



CONCLUSION

There is no relationship between patient age, gender, surgical discipline, and knowledge of the informed consent process. However, there is a relationship between a patient's degree of education, career, and awareness of surgical procedures and their ability to give informed consent. But it is also concluded that even patients who have a higher

level of education did not prove to have a proper understanding of informed consent. This was thought to be related to surgeons making little or no attempt to educate their patients on this subject.

DISCUSSION

Fisher's (1998) and Mugenda M (2003) formulas were used to calculate the sample size of 106 patients. In a study on informed consent in surgical patients conducted at a university hospital, nearly the same number of participants (106) was recruited. As a result, the sample size is sufficient to reflect the practice of providing informed consent for surgical procedures.

The study enrolled about the same number of participants aged 31 to 40 years (19.5%) and 18 to 30 years (21.3%). In terms of age, the findings of this study are similar to those of Agu et al (2014), who found that more than 70% of the study participants were over the age of 40. Eighty-nine (82%) of participants were men, while 19 (18%) were women. Females were less than males because most of the females were admitted to the gynae and obstetrics wards and there was no permission for males and, unfortunately, no female mate in our research group.

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