Dissertation Title

"Evaluation of the quality of informed consent process for surgical interventions in Max Super speciality hospital"

A Dissertation Proposal for

Post Graduate Diploma in Health and Hospital Management

By

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PG/11/012

International Institute of Health Management Research
New Delhi
01-05-2013

Certificate of Internship Completion

Date: 8th Apr' 2013

TO WHOM IT MAY CONCERN

This is to certify that Dr. Anjana Tomar has successfully completed her 3 months internship in our organization from January 01, 2013 to April 01, 2013. During this intern she has worked on" Evaluation of the quality of the informed consent process for surgical interventions"under the guidance of me and my team at Max superspeciality hospital Mohali. She has performed exceptionall well during her training.

We wish her good luck for her future assignments

For MAX SUPER SPECIALITY HOSPITAL
(A UNIT OF HOMETRAIL ESTATE PVT. LTD.)
AUTHORISED SIGNATORY

(Name)

MANAGER - HR Designation

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FEEDBACK FORM

Name of the Student: DR. ANJANA TOMAR

Dissertation Organisation: MAX SUPER SPECIALITY HOSPITAL, MOHALI

Area of Dissertation: HOSPITAL OPERATIONS & QUALITY

Attendance: 88%

Objectives achieved: The task given to her were handled very efficiently and promptly.

Deliverables: Quality assessment of informed consent process and quality assessment of initial patient assessment.

Strengths: Sincere, Dedicated; Good analytical skill.

Suggestions for Improvement: Work on communication skills.

Dr. AMARPREET SINGH
DEPUTY MEDICAL SUPERINTENDENT
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MAX SUPER SPECIALITY HOSPITAL
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Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date: 08/04/2013
Place: Mohali

Certificate from Dissertation Advisory Committee

This is to certify that **Dr Anjana Tomar** a graduate student of the **Post- Graduate Diploma in Health and Hospital Management**, has worked under our guidance and supervision. She is submitting this dissertation titled" Evaluation of the quality of the informed consent process for surgical interventions "in partial fulfillment of the requirements for the award of the **Post- Graduate Diploma in Health and Hospital Management**.

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book

For MAX SUPER SPECIALITY HOSPITAL
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AUTHORISED SIGNATORY

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DMS
Max Superspeciality hospital
Mohali
Date

Certificate of Approval

The following dissertation titled "**Evaluation of the quality of the informed consent practice for surgical interventions in Max Super Speciality Hospital** " is hereby approved as a certified study in management carried out and presented in a manner satisfactory to warrant its acceptance as a prerequisite for the award of **Post- Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation

Name Signature

DR. BRIJENDER SINGH DHILLON

17/05/2013.

Abstract

Evaluation of the Quality of Informed Consent Process for Surgical Interventions In Max Super Speciality Hospital

by

Anjana Tomar

Background

Pre-operative informed consent is an important legal aspect of surgical interventions. It works as a safeguard of patient's rights and minimizes the chances of legal action against the physician in case of any complication after surgical interventions., Even then the hospitals even large tertiary care set ups ,who has a name in the industry are ignoring the importance of this process. This study was done to assess the preoperative informed consent practice in Max Superspeciality Hospital.

Methods

Audit of the consent forms was done and assessed on the basis of checklist. As well as after taking informed permission, a questionnaire was filled in during an interview with 103 patients, who have undergone elective surgical procedures from Feb to March 2013 and All the patients were asked a set of standard questions which related to the information they were provided before the operation as a part of standard informed consent practice.

Results

The name of the procedure was mentioned in only 70 (67.30%) forms. Details of the procedure were mentioned in very less number of forms i.e. 28 (26.90%). Alternative of the surgery was mentioned in only one form.Assessing the completeness of consent forms only 36 (34.65%) out of total are completely filled rest of them have blanks which are not filled by the hospital staff. Signature of the witness (97) 93.20% was present in most of the forms but signature of the primary consultant was in only 55 (52%) forms.In anaesthetic form the documentation of patient specific risk (24) 23% are below the standard of acceptability. Signature of the attending anaesthetist(83) 80% are in most of the forms. Most i.e. 98 (93 %%) of the patients were informed about their condition and the diagnosis ,but only 70 (67.9%) patients said that knew the details of surgery.64 (64.3%) patient said that they have been told the duration of their stay after the surgery but very few 32 (31%) said they knew about the possible Complications associated with the procedure. Surprisingly only 10(0.9%) have read the consent form and 50(48.5%) patients were aware of the type of anaesthesia but very few i.e. 24(23.3%) were aware of the risk associated with anaesthesia. Sixty seven (67%) patients said that they were provided with the opportunity to ask Questions while giving consent. But even after so much of gap in the information 72.8% patients were satisfied with informed consent process.

Conclusion

This study highlights the quality of informed consent process which is below the quality standards. Patients have poor knowledge of risk and complications of the procedure and anaesthesia. Even the documentation of consent form is again not up to the standards. Half of the forms doesn't have consultants signature. Most of the forms are incompletely filled. Majority of the patients are still satisfied with the process of informed consent .There is a lack of proper understanding by the population and inadequate system of informed consent in our setting.There is a great need to educate the doctors and staff regarding the importance of informed consent process and patient's right to the information about their medical condition and the proposed surgical interventions to ensure their participation in the decision making regarding their treatment.

ACKNOWLEDGMENT

I would like to express my sincere thanks and gratitude to Max Super Speciality Hospital, Mohali, for allowing me to complete my dissertation project in the facility.

This project bears on imprint of many people .I would like to thank Dr Pankaj Dhamija, Deputy Medical Superintendent and Mr. Khokhar, the Head HR department , for giving me the opportunity to do my project at Max Super Speciality Hospital Mohali.

Foremost, I would like to thank Miss Dolly Singh (Quality Manager) who was kind enough to spare her valuable time and provided several important suggestions at every stage of my study.

Sincere thanks to all the staff at all levels, especially the IPD staff, for helping me at each and every step of my work. Heartiest gratitude to them for making my stay and work at this place a memorable one.

I also acknowledge all the help & support provided by in the fulfillment of this project.

Thanks to one and all.

Date: 01.04.2013 **ANJANA TOMAR**

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LIST OF ABBREVIATIONS

1. AHU –air handling unit
2. CCU – critical care unit
3. CT – computed tomography
4. CU – clean utility
5. DU – dirty utility
6. ETO –ethylene tri oxide
7. HDU – High Dependency Unit
8. HVAC – high ventilation air conditioner
9. I.C.U.- intensive care unit
10. IT – information technology
11. IPD - in patient department
12. LiNAc – Linear Accelerator
13. MRI – magnetic resonance imaging
14. MRD- medical record department
15. NICU – neonatal ICU
16. OPD- outpatient department
17. OT- operation theatre
18. PICU – paediatrics ICU
19. PHP – preventive health package
20. SICU – surgical ICU
21. TMT – tread mill test
22. TSSU – theatre sterile supply unit
23. RMO – resident medical officer
24. IC – informed consent

ORGANIZATION PROFILE

Max Super Speciality Hospital, Mohali (MSSH) is a multi-speciality hospital owned and operated by Max Healthcare Institute Limited (MHIL).

Max Healthcare extends its dedicated care & personalised service with customized healthcare solutions, cutting edge technology combined with state of the art healthcare services and expertise.

200 bedded facility Infrastructure offers

- OP & IP Departments
- PHPs (Preventive Healthcare Programmes)
- OTs (Operation Theatres), Cath Lab, ICUs, HDU, Ambulatory Care
- Blood Bank
- Endoscopy
- Oncology Day Care
- LINAC (Radiation Oncology)
- Dialysis
- 24 hour Pharmacy
- 24 hours Lab services

Hospital has state-of-the-art medical equipments along with emergency & intensive care infrastructure including Cath Labs, ICUs, and HDU backed by 24-hour supervision of highly experienced anaesthetists, technicians and nurses and is also supported by high dependency units & state-of-the-art diagnostics.

Max Super Speciality Hospital, Mohali is a state of the art hospital, LINAC for Cancer care, Cath lab, ICUs and OT. The hospital is designed to provide highest level of professional expertise and world class care in Comprehensive Cancer Care, Orthopedics, Cardiac Sciences, Neurosciences, Nephrology and Urology, Medical and Surgical gastroenterology, Laparoscopic surgery, Bariatric surgery, Minimal access surgery, General surgery , Mother & Child Care, Internal Medicine and allied branches, Critical Care, Emergency & Trauma, ENT and Ophthalmology.

Key services includes:-

Key Specialities	Diagnostics
Cancer Care	Radiology & Imaging
Trauma & Orthopaedics	Nuclear Medicine Lab
Cardiac Sciences	MRI
Neurosciences	CT Scan
Surgical Services	X-Ray
Mother & Child	Fluoroscopy
Critical Care	Mammography
Emergency & Trauma	Bone Densitometry
Dentistry	Ultrasound

LOCATION : Near Civil Hospital , Phase 6 Mohali , Punjab

PASSION

To deliver International Class healthcare with a total service focus, by creating an institution committed to the highest standards of medical & service excellence, patient care, scientific knowledge and medical education.

VISION

Deliver international class healthcare with the total service focus by creating an institution committed to the highest standards of medical and service excellence , patient care, scientific knowledge , research and medical education.

MISSION

- Create exceptional standards of medical & service excellence
- Care provider of FIRST CHOICE
- Principal Choice for physicians
- Ethical Practices
- Create International Centre of excellence for select Super Specialities
- Safety – Patient , customer, staff

INTERNSHIP REPORT

Introduction:

Internship is a part of second year programme where we have to observe and learn the working and culture of the organisation. It is necessary during this process to participate in various activities so that we can orient ourselves with different field that gives us initial exposure. Internship is the process through which first we understand the functioning of an organisation and there after we are involved in the decision making. Being a trainee in max hospital gave me an opportunity to get experience of quality administration in private setting and gave me practical experience in handling managerial issues which are likely to come up in day to day administration.

Objectives of Internship

- To complete my internship with full efficacy and efficiency
- To understand working of whole hospital and seek opportunity that provides me real experience to groom myself as a professional.
- Become familiar with the roles and responsibilities associated with the day-to-day work of a health care administrator.
- Become involved in various activities and administrative projects at the internship site that achieves the specified goals of the learning contract.
- Implement, complete, and report on administrative project as specified in the learning contract

It requires significant involvement in management activities. The various responsibilities require the ability to work effectively with co-workers and to meet the demands of the patient as well.

I was introduce to the hospital as management trainee in the department of hospital operations and quality to collect the data on indicators developed by the quality department and to identify the problem areas and to suggest the corrective measures..

TASK GIVEN

1) Initial patient assessment:

- To assess the time gap in Nursing assessment
- To assess the time gap in Medical assessment
- To assess the time gap in Nutritional assessment

2) Quality of assessment by nurse, doctor and nutritionist.

3) Completeness of consent forms and quality of informed consent procedure

4) Setting up of the roaster of RMO's

To identify the problem areas and bottlenecks and suggested corrective and preventive action for this problem areas my attempt would be successful if my project and project report serves the need and requirement of the organisation in future.

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PART II

Evaluation of Quality of Informed Consent Process In Surgical Interventions

Introduction

Informed consent (IC) is a legal term that is supported by jurisdiction and international laws and is described as "voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and for medical and surgical treatment" (year introduced: 1973 (1971)[1.] There is also a legal angle to this concept. No one has the right to even touch, let alone treat another person. Any such act, done without permission, is classified as "battery" - physical assault and is punishable. Hence, obtaining consent is a must for anything other than a routine physical examination.[2]

Physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known.
- The nature and purpose of a proposed treatment or procedure.
- The risks and benefits of a proposed treatment or procedure.
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance).
- The risks and benefits of the alternative treatment or procedure.
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, patient should have an opportunity to ask questions to make a better understanding of the intervention and its consequences.[3]
Increasing medico-legal litigation–and the desire to provide patients with more information concerning their own treatment, has highlighted the issue of informed consent and how it is obtained. An appropriate information is required for the patient to make the sensible decision. This exchange of information may occur via discussions with medical/nursing staff, via the media/internet, or from speaking with friends who have undergone a similar procedure. However, it chiefly occurs during the acquisition of informed consent, during which the risks and benefits of any surgical procedure are explained.[4]So informed consent plays a greater role in patient physician relationship also.

The practice of surgery entails many things, from the mastery of good clinical judgment to the cultivation of advanced technical and operative skills. Equally paramount to the practice of surgery is the ability to develop relationships with patients that instil trust and facilitate communication. During the past 50 years, the nature of the patient-surgeon relationship has undergone a significant transformation. Although certain central ethical tenets of medicine have remained unchanged, the emphasis on patient autonomy, transparency, and shared decision-making has increasingly come to the forefront of medical practice.[5] For example, although the Hippocratic tenet of premium non nocere and the principle of beneficence continue to be central to the ethical practice of surgery, more paternalistic conceptions of the surgeon have largely been abandoned. Rather, over the past 50 years, patient autonomy and the right to individual self-determination have replaced the previous belief that "doctor knows best."[5].This has increased the importance of informed consent not only ethically but

legally also. Physicians and surgeons could no longer hide behind therapeutic privilege to excuse a lack of adequate disclosure to patients. Information sharing to the patient has become a matter of paramount importance. Today, patients tend to be well- or ill-informed about the disease and health.With the hype created in the print and visual media regarding 'beauty', 'shape, size and appearance of body parts', 'quality and quantity of hair', etc., patients tend to come to dermatologists with unreasonable demands and unrealistic expectations. Therefore, providing adequate information and educating the patient about realities and obtaining informed consent before subjecting a patient to any test/procedure/surgery is very essential.[2]

Rationale of the study

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention. This communication process or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. Patient autonomy is the overarching ethical consideration that forms the core of informed consent.[2] In contrast to a past era largely characterized by a minimal exchange of information and unilateral decision-making, informed consent was held up as the legal and ethical solution to avoid previous paternalistic pitfalls. Armed with the tool of informed consent, surgeons now were expected to have a formal mechanism both to recognize patient autonomy and to address patients as self-determining moral agents. In the routine use of informed consent, therapeutic privilege and other more paternalistic tendencies would hopefully bereplaced.[5] but still there is a lack of proper understanding by the population and inadequate system of informed consent in our setting. However, majority of the people still feel satisfied with the information provided[6]. Reason may be the illiteracy or the paternalistic thinking that doctor is god and he knows everything..Patient understanding in clinical informed consent is often poor. They have a little knowledge of the importance of the intervention and the consequences of such interventions. So they largely depend on the surgeon. Here comes the role of surgeons in the picture.Unfortunatly we are still lacking here. However providing information is also an important aspect of doctor-patient relationship. But the scenario is changing, the need to provide relevant and comprehensible information to patients before invasive procedures is continuously increasing.[7]Now a days, informed consent has replaced the old paternalistic notion of ''the doctor knows best'', with a more mutual patient physician relationship. Successful surgery depends on a relationship of trust between the patient and the doctor. Establish this; the patient's right to autonomy must be respected, even if their decision results in harm or death. Surgery is technically an assault, unless the patient has given permission for this to occur[5]. However, despite these requirements; instances still arise in which patients claim to have been inadequately provided with the information necessary to make informed decisions[8] A paradigm shift has been observed in the west whereby increasing number of patients want to be extensively informed about procedural alternatives, risks and benefits before electing to undergo a surgical procedure. Unfortunately, in hospital practice in our setup, patients and their families are mostly given very little or inadequate information[9].This study will be able to evaluate the current practice of taking informed consent in elective surgical intervention in a tertiary care hospital in Mohali

Problem statement :- As the hospital is undergoing NABH assessment so they had to work upon the non conformities identified .One of the non –conformities was improper maintenances of consent forms form both side the doctors and the nursing staff. This study was done to assess the existing deficiencies in informed consent practice and take corrective measures for proper maintenance of record and informed consent practice. and to hasten these process immediate and simultaneous corrective actions can be taken for sustainable improvement. This study will help in adequate

management of the department working in reviewing the performance of the department and in providing better patient care.

Review of literature

Today in India every hospital has a aim to get an NABH accreditation and in NABH policies the importance of consent form is given very clearly in patient rights and education the 3rd standard is "A documented process for obtaining patient and / or families consent exists for informed decision making about their care"

Objective elements

a) General consent for treatment is obtained when the patient enters the organization

b) Patient and/or his family members are informed of the scope of such general consent

c) The organization has listed those procedures and treatment where informed consent is required

d) Informed consent includes information on risks , benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand

e) The policy describes who can give consent when patient is incapable of independents decision making.

A. Mohammed (2009) A cross sectional survey was carried out at a tertiary care teaching hospital Islamabad and 200 patients were included who responded to the questionnaire. The survey concluded that is a lack of proper understanding by the population and inadequate system of informed consent in our setting. A total of 98% of patients admitted that informed consent was taken, however, only 81 (40.5%) patients understood the information provided. Patients reporting that their decision to proceed with surgery was actually influenced by other people including the treating doctor numbered 112 (56%). Only 58 (29%) signed their own consent form, the rest of them were signed by relatives. Only 96 (48%) patients admitted having been informed about possible complications of surgery as against 156 (78%) who were informed of sequelae of not having the surgery done. Signatures taken by the paramedics were 138 (69%). Despite a poor understanding of the process of informed consent, 187 (93.5%) still felt satisfied with the process of informed consent.[6]In this matter the opinion of K H Satyanarayana Rao (2008) is interesting according to him the level of Obtaining consent is not only an ethical obligation, but also a legal compulsion. The level of disclosure has to be case-specific. There cannot be anything called a standard consent form. No doctor can sit in comfort with the belief that the "consent" can certainly avoid legal liability. This is highlighted by the note of The California Supreme Court:*"One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved."*One can only take adequate precaution and act with care and diligence. Maintaining good relationship with patient often works better than the best informed consent.[2]

M Jawaid (2012) a study done in Pakistan has also highlighted the poor quality of patient knowledge about surgical procedures and the inadequate information provided as well the issue of formal training for informed consent. In this study 307 (87.7%) patients were informed about their condition but very few 12 (3.4%) were briefed regarding complications. Only 17 (4.9%) patients said they knew about the risks and complications of proposed anesthesia.The consent form was signed by the patients themselves in only 204 (58.3%) cases and by their relatives in the rest. About half the number of patients 171 (48.9%) interviewed were satisfied from the information they received as informed consent process.[7] In a study done by Dr Raab(2004) important parameters of the informed consent process were discussed that are often neglected or overlooked by the busy clinician and can be used against the physician in a medical malpractice case. Some of these components include disclosure of risks and possible alternatives, the experience of the physician, risks from anaesthesia, and off-label uses of a device or medication. He emphasizes that malpractice and informed consent issues are distinct causes of action and that a claim of inadequate or improper informed consent is a convenient fallback position when the malpractice component of the claim is weak[10].

Ryan Childers and Pamela A Lipsett in a study have given the four models of informed consent there definition and problems.The four models are Professional model, reasonable model, subjective model and balanced model and not only that but issues and consideration related to informed consent such as patient refusal, diminished capacity, cultural and family issues and ways to handle these issues[5]. Schenker Y, Fernandez A, has done a study on Interventions to improve patient comprehension in informed consent for medical and surgical procedures. They have given a wide range of communication interventions improve comprehension in clinical informed consent. They said that the decisions to enhance informed consent should consider the importance of different elements of understanding, beyond procedural risks, as well as feasibility and acceptability of the intervention to clinicians and patients. Conceptual clarity regarding the key elements of informed consent knowledge will help to focus improvements and standardize evaluations[11].

Objectives

General objective: - To assess the quality of preoperative informed consent practice max.

Specific objectives:-

- To assess the consent forms for quality of information filled.
- To find out the gaps in information sharing in informed consent process
- To assess the level of knowledge of the patient regarding surgical interventions.

Data and methods

Study design: Prospective observational study

Study population: Patients who had undergone elective surgery at Max Super Speciality hospital of Mohali

Sample size:-103

Sampling method –Convenient sampling

Study setting- Max Super speciality Hospital Mohali

Methodology:-

The study was designed as an observational study. Study was carried out by using structured questionnaire-based interview technique and the audit of the consent forms filled by the healthcare personal and signed by the patient during the consent form . After taking informed consent, patients who had undergone elective surgery at Max Super Speciality hospital of Mohali was interviewed from Feb. 2013 to March 31 2013 .Audit of the consent form was done during this period only. Patients aged under 18 or above 80 were excluded. The selection criteria of the patients for interview were done on the basis of convenience sampling and the consent form of the same patient was selected for the audit.All the patients were asked a set of standard questions which related to the information they were provided before the operation as a part of standard Informed consent practice. No interference was done in the informed consent process to the patient. Bed side interviews were taken without the presence of the treating staff of the hospital. Privacy and confidentiality was ensured throughout the interview and response to individual questions was only marked after reconfirming from the patient that the question had been clearly understood. The questions were asked in the local languages as per the convenience of the patient mostly Hindi Punjabi and English languages were used for the interview as per the choice of the patient and his attendant. The questionnaire sought information in yes/no format regarding the patient's knowledge prior to surgery, operative details with risks, type of anaesthesia to be given with its risks, alternate treatment options, outcome in case of no treatment. Timing of consent, designation of consent taker and who gave the consent were also enquired. All the interviews were conducted by interviewer who had no involvement in the delivery of health care, between one to three days postoperatively at the earliest time the patient is comfortable to do so.

The data collected was analysed in excel. The question asked are shown in table

Table 1

Question asked in interview
Are you aware of your problem and diagnosis?
Have you told about details of surgery? If yes
Did you Sought information on internet?
Did you Consulted outside physician?
Consent form read carefully if yes Consent form easy to understand?
Have you told about the type of anesthesia to be given?
Have you told about the complications of anesthesia?
Have you told about alternate treatment options?
What was the timing of consent?
Consent was taken by whom?
Consent was signed/given by?
Were you informed about the duration of your hospital stay?
Were post-operative issues (such as complications) discussed?
Were you informed about the duration of your treatment?
Were you informed about the significance of the consent form at the time of signing the consent form?
Did you get sufficient opportunity to ask questions?
Are you satisfied with informed consent process?

Results

Results Of The Audit:

A total of 103 patients of surgery were taken for the audit and then the interview of the same patient was taken.

Table 2: Demography of patients

Age group	Number of patients
18-25	10
25-35	9
35-45	7
45-55	19
55-65	28
65-75	26
75-80	4
Age mean	54.19
Gender M:F	53:50

Table 2 is representing the age group and the number of patient in that age group. Maximum number of patients belongs to the age group of 55 to 75.This helps in understanding the relationship between age and diseases. After 55 years of age people are most susceptible to diseases which may require surgical interventions also. As per the ratio of gender the males are more susceptible to diseases as compare to females. This has been proved in many other researches also.

Table 3: Surgical Department

Specialities	Number of surgeries
Orthosurgery	51
Urology	10
Gen.surgery	20
Oncosurgery	14
Neurosurgery	5
Plastic surgery	2
Gynae	3

Table 3: The pattern of surgeries in Max during the period of research. The highest number of surgeries is in orthopaedic department rest of the specilaities are less than 20 in number.

Table 4: Post-operative audit of the consent forms and results. (n=103)

Parameters	Percentage
Patient demographics in procedure form	(95) 91.30%
Name of Procedure	(70) 67.30%
Details of the procedure	(28) 26.90%
Benefit of Surgery	(0) 0.00%
Risks and complications during the surgery.	(68) 65.30%
Alternative of Surgery	(1) 0.90%
Patient's Signature	(57) 54.80%
Name of the person signing/relationship	(96) 92.30%
Form completely filled	(36) 34.65%
Signature of Witness	(97) 93.20%
Consultant Signature	(55) 52%
Name of the Doctor signing	(87) 83.60%
Whether signed by operative surgeon/Surgical Team member/ Primary Consultant/ Jr. Consultant	(66) 63.40%
Patient demographics in anaesthetic form	(97) 93.20%
Patient specific risk in anaesthesia	(24) 23%
Signature of the attending consultant in anaesthesia	(83) 80%

(Table 4) In most of the consent form patient demographics 95 (91.3%) are mentioned but on the other side the name of the procedure was mentioned in only 70 (67.30%) forms. Details of the procedure were mentioned in very less number of forms i.e. 28 (26.90%). These are mostly TKR and Hysterectomy consent forms in which the details are already incorporated. Otherwise mostly even after the availability of different forms for different procedures the staff were using the generic consent forms. Benefits of the surgery were not mentioned in any of the forms. Alternative of the surgery was mentioned in only one form.54.8 % (57) number of forms were signed by the patient

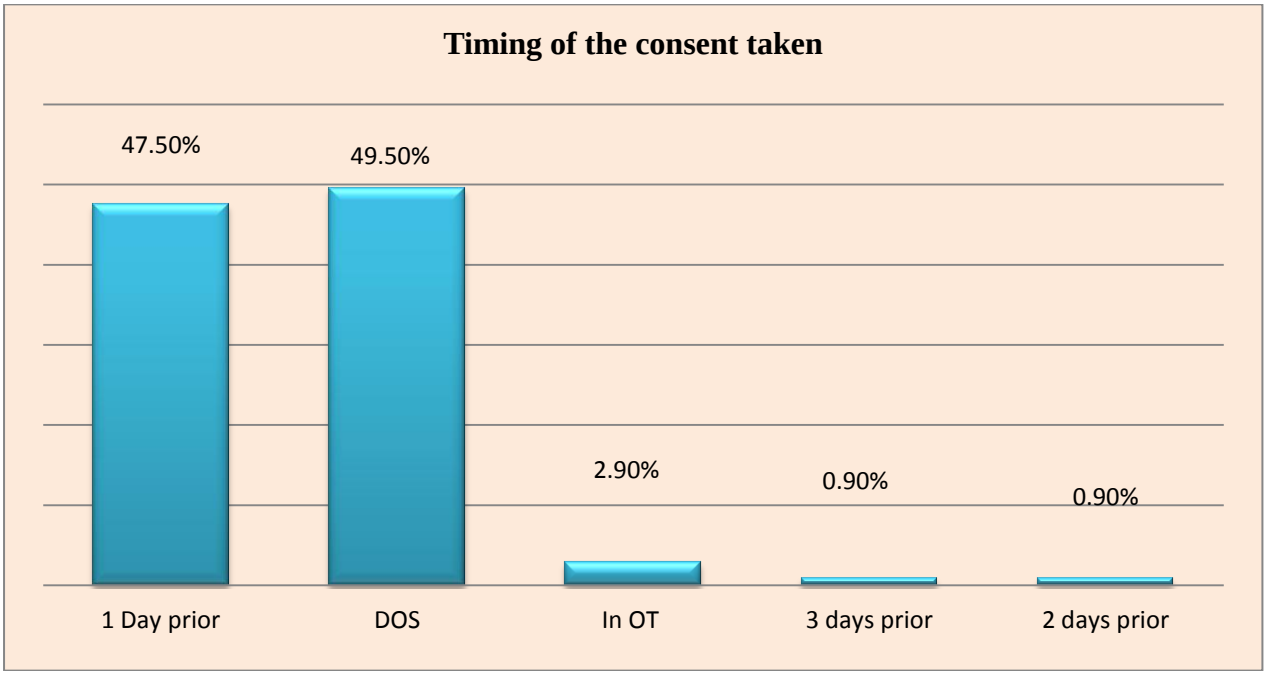
rest of the forms were signed by the relatives. Most of the forms (92.30%) 97 had the relationship mentioned. Assessing the completeness of consent forms only 36 (34.65%) out of total are completely filled rest of them have blanks which are not filled by the hospital staff. Signature of the witness (97) 93.20% was present in most of the forms but signature of the primary consultant was in only 55 (52%) forms. The doctor's name was present in many of the forms (87)83.60%.Signature of any doctor from the operative team was present in (66)63.40% the consultant's signature are included in this 63.40%. In anaesthetic form the demographics (97) 93.20% are up to the mark however it should be hundred percent but documentation of patient specific risk (24) 23% are below the standard of acceptability. Signature of the attending anaesthetist(83) 80% are in most of the forms.

Table 5: **Based on responses of patients at Post-operative Interview (n=103)**

Questions asked	**Percentage of Patient informed**
Awarness regarding Problem/diagnosis	93%(98)
Details of surgery	67.9%(70)
Information on internet	0.8%(9)
Consulted outside physician	61%(64)
Form read	0.9%(10)
Type of anaesthesia	48.5%(50)
Complications of anaesthesia	23.3%(24)
Alternate treatment	17%(18)
Duration of stay	64.3% (64)
Complications discussed	31% (32)
Duration of treatment	45%(47)
Significance of the consent	22.3%(23)
Opportunity to ask questions	67% (67)
Satisfied	72.8%(75)

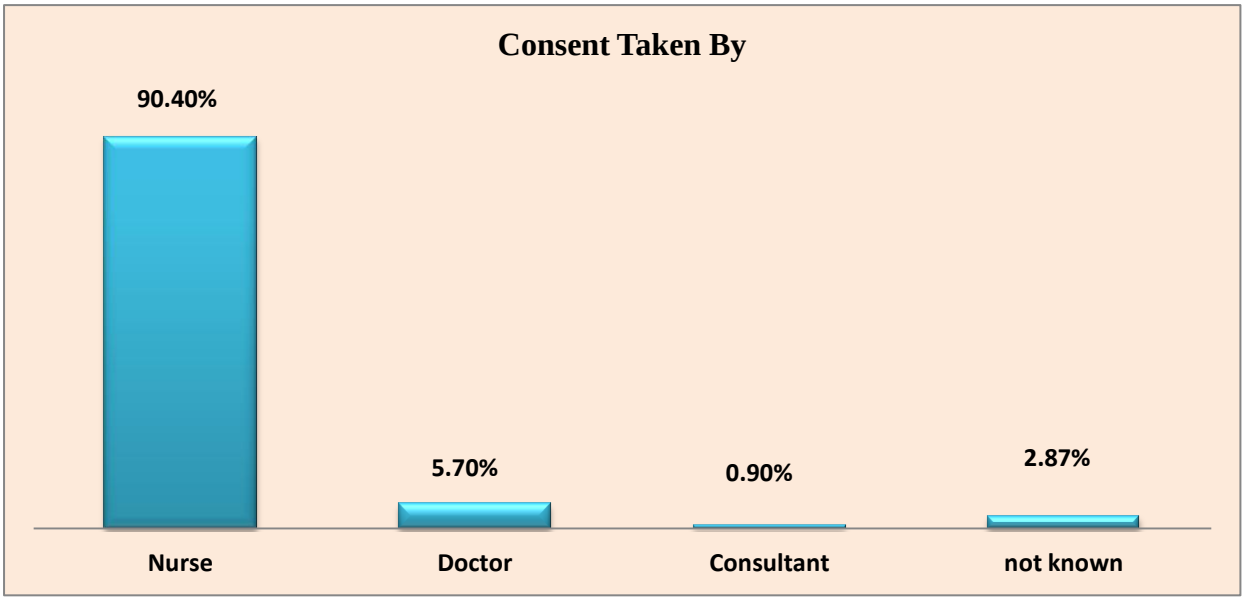
(Table 5)Most i.e. 98 (93 %%) of the patients were informed about their condition and the diagnosis, but only 70 (67.9%) patients said that knew the details of surgery. Very few patients 9(0.8%) said that they sought the information about the surgery on internet. And Many of them i.e. 61 %(64) said that they have some or other way consulted other doctors also to collect the information about the diseases and the treatment.64 (64.3%) patient said that they have been told the duration of their stay after the surgery but very few 32 (31%) said they knew about the possible Complications associated with the procedure. Surprisingly only 10(0.9%) have read the consent form and 50(48.5%) patients were aware of the type of anaesthesia but very few i.e. 24(23.3%) were aware of the risk associated with anaesthesia. Sixty seven (67%) patients said that they were provided with the opportunity to ask Questions while giving consent. But even after so much of gap in the information 72.8% patients were satisfied with informed consent process.

Graph 1: Timing of the consent taken



Maximum numbers of consents were taken on the day of surgery i.e. 51.Most of the consents i.e. 49(47.5%) were taken a day before surgery. Very few 3(2.9%) were taken in OT.Timing of consent plays a greater role in the quality of informed consent. Consent should be not be taken in a hurry this will lead to the information gap. Sufficient time should be given to the patient to take decision. Healthcare personnel should not rush in taking the consents from the patient.

Graph 2 :Consent taken by



Most of the consents (90.4%) were taken by nurse and paramedic staff .Very few were taken by doctor i.e. 5.70% these doctors are the duty doctors of the hospital and consultant has taken only 0.9% consents which should be ideally done by consultant only. In few instances patient do not remember that who has taken the consent from them it means whoever staff has taken the consent has not introduced himself/herself. So policy should be made that every staff who is interacting with the patient should introduce him first to the patient

Graph 3 : Decision making in informed consent process

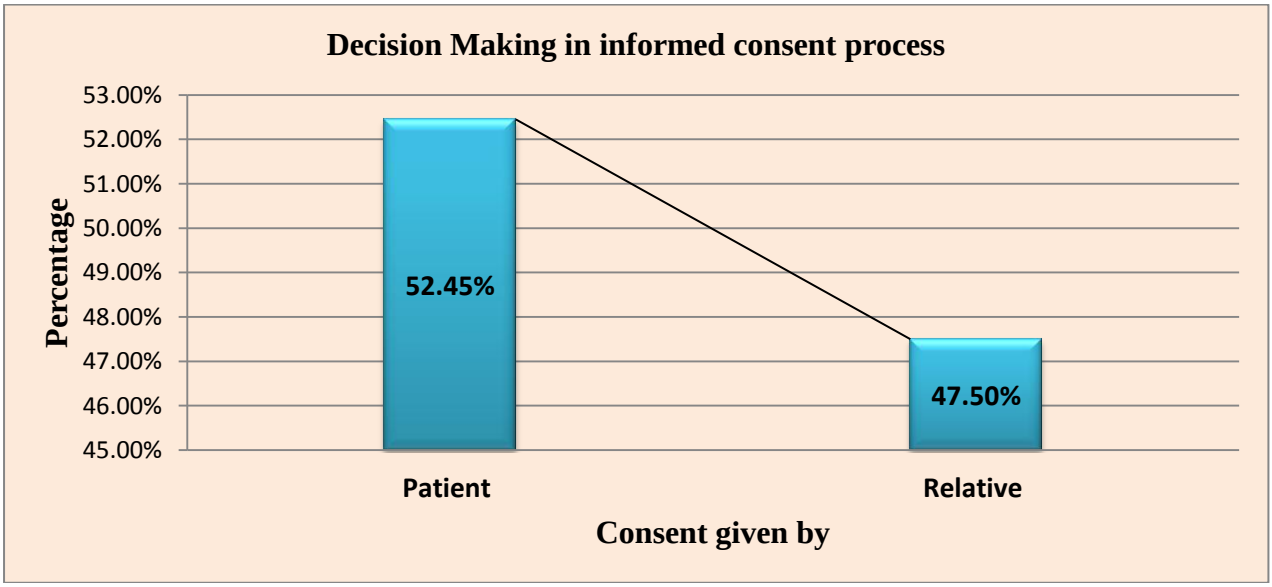


Table 6: Involvement of patient in decision making

Signed	(54) 52.4%
Capable not signed	(31) 30%
Not capable	(18) 17.4%

Table 6 and Graph 3: During the audit of the consent forms people involve in decision making also came into picture which is represented by the above graph3 also.Only 54 (52.4%) number of forms were signed by the patient himself rest of the forms are signed by the relatives i.e 49(47.50%).31(30%) patients were capable of singing but did not signed the consent form. And 18 (17.4%) consent form was not signed by the patient because of incapability.

Table 7:-Distribution of decision makers in relatives

Husband	13.5% (14)
Son	12.6%(13)
Wife	4.8% (5)
Daughter	4.8% (5)
Brother	2.9% (3)
Father	1.94% (2)
Nephew	2.9% (3)
Brother in law	0.9%(1)
Daughter in law	0.9% (1)
Sister	0.9% (1)
Sister in law	0.9% (1)

(Table 7) There is a wide distribution among relatives in decision making. The highest number of consents in behalf of the patient is signed by the husband i.e. 14(13.5%).Then the son which is 13(12.6%).in comparison to this number of consent forms signed by daughter and wife is very less i.e. 5(4.8%).It is clearly depicting the involvement of males in decision making is more than the females. As further statistical analysis is done the difference in self decision making among male and females also came into light.In 52 % cases females has taken the decision of treatment and in case of

males it is 55.7 % .India has definitely improved in male dominance in decision making but still there is a scope of improvement.

Hypothesis Testing

1. Variation in completeness of consent forms and surgical departments

Null hypothesis: - There is no significant difference between completeness of consent forms and surgical departments.

Alternate hypothesis: - There is a significant difference between completeness of consent forms and surgical departments.

Chi square test is applied for hypothesis testing -

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	8.010[a]	5	.156
Likelihood Ratio	7.977	5	.157
Linear-by-Linear Association	.847	1	.357
N of Valid Cases	103		

a. 6 cells (50.0%) have expected count less than 5. The minimum expected count is 1.05.

The value of significance is less great than .05 so the null is accepted. So it suggests that there is no significant difference between completeness of consent forms and surgical departments.

2. Variation between the surgical departments and consultant signature

Null hypothesis - There is no significant variation between the surgical departments and consultant signature.

Alternate hypothesis – There is no significant variation between the surgical departments and consultant signature

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.169[a]	5	.015
Likelihood Ratio	15.276	5	.009
Linear-by-Linear Association	2.071	1	.150
N of Valid Cases	103		

a. 4 cells (33.3%) have expected count less than 5. The minimum expected count is 1.43.

The value of significance is less than .05 so the alternate hypothesis is accepted that there is significant relationship between the surgical departments and consultant signature

Name of the procedure / consultant signature Cross tabulation

			consultant signature		
			0	1	Total
Name of the procedure	ortho	Count	21	30	51
		Expected Count	24.3	26.7	51.0
	uro	Count	4	7	11
		Expected Count	5.2	5.8	11.0
	neuro	Count	1	5	6
		Expected Count	2.9	3.1	6.0
	general	Count	16	3	19
		Expected Count	9.0	10.0	19.0
	gynae	Count	1	2	3
		Expected Count	1.4	1.6	3.0
	onco	Count	6	7	13
		Expected Count	6.2	6.8	13.0
Total		Count	49	54	103
		Expected Count	49.0	54.0	103.0

4. Variation between risks mentioned in the forms and surgical speciality.

Hypothesis

Null – There is a no significant variation between risks mentioned in the forms and surgical s speciality

Alternate hypothesis - There is a no significant variation between risks mentioned in the forms and surgical speciality.

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	18.974[a]	5	.002
Likelihood Ratio	19.221	5	.002
Linear-by-Linear Association	2.080	1	.149
N of Valid Cases	103		

a. 6 cells (50.0%) have expected count less than 5.

The minimum expected count is 1.02.

The value of significance is less than .05 so null is rejected. There is a significant variation between these two variables. The variation can be seen in the table given below

Name of the procedure * Risks during the surgery. Cross tabulation

			Risks during the surgery.		
			0	1	Total
Name of the procedure	ortho	Count	12	39	51
		Expected Count	17.3	33.7	51.0
	uro	Count	3	8	11
		Expected Count	3.7	7.3	11.0
	neuro	Count	3	3	6
		Expected Count	2.0	4.0	6.0
	general	Count	14	5	19
		Expected Count	6.5	12.5	19.0
	gynae	Count	0	3	3
		Expected Count	1.0	2.0	3.0
	onco	Count	3	10	13
		Expected Count	4.4	8.6	

Total	Count	35	68	
	Expected Count	35.0	68.0	103.0

5. Variation between awareness of type of anaesthesia and age

Null hypothesis there is no significant variation between awareness of type of anaesthesia and age

Alternate hypothesis there is a significant variation between awareness of type of anaesthesia and age

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.927[a]	2	.085
Likelihood Ratio	5.154	2	.076
Linear-by-Linear Association	.313	1	.576
N of Valid Cases	57		

a. 1 cells (16.7%) have expected count less than 5. The minimum expected count is 4.56.

The value of significance is greater than 0.05 so the null is accepted

6. Variation between Awareness of complications/risks of surgical interventions and age

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.315[a]	2	.518
Likelihood Ratio	1.479	2	.477
Linear-by-Linear Association	.302	1	.583
N of Valid Cases	57		

a. 1 cells (16.7%) have expected count less than 5. The minimum expected count is 2.28.

The value of significance is greater than .05 so the null i.e. there is no significant variation between Awareness of complications/risks of surgical interventions and age

7. Variation between decision making and gender

Null - There is a significant no variation between decision making and gender

Alternate hypothesis- There is a significant variation between decision making and gender

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.929[a]	4	.295
Likelihood Ratio	6.480	4	.166
N of Valid Cases	103		

a. 4 cells (40.0%) have expected count less than 5. The minimum expected count is .49.

As the value of significance is greater than 0.05 so the null is accepted

8. Variation between awareness of risks and Gender.

Null hypothesis –There is no significant variation between awareness of risks and Gender

Alternate hypothesis - There is no significant variation between awareness of risks and Gender .

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.052[a]	1	.820		
Continuity Correction[b]	.000	1	.988		
Likelihood Ratio	.052	1	.820		
Fisher's Exact Test				.835	.495
Linear-by-Linear Association	.051	1	.821		
N of Valid Cases[b]	103				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 15.53.

b. Computed only for a 2x2 table

As the value is greater than .05 so the null is accepted

Disscussions

This study showed that the quality of preoperative informed consent practice in Max Super speciality Hospital which is itself a large chain of tertiary care set ups is less than ideal. The hospital like Max are the hospital which is been look up to when we talk about quality healthcare. People believe that such hospitals provide the best healthcare treatment possible and they maintain each and every quality standard which is necessary for patient care. But it is sad to say that the quality of such an important ethical and medical process is not up to the mark. Informed consent is not simply the signing of a consent form by the patient but more importantly, it is a process of a detailed discussion between the doctor and the patient. This process takes time. However, in the hospitals there is often a trend to hand over the consent form to the patient for signing it or delegate the responsibility to paramedics.It is important to realize that signing a consent form does not constitute informed consent (12). Very few patients in this study said that the details of surgery were explained to them. 32 (31%) said they knew about the possible Complications associated with the procedure. Most patients in this study gave pre-operative consent in less than perfect circumstances, as they had already been through the admission process and were within 24 hours of surgery and even in few instances on the operating table. In these circumstances, it is difficult to imagine how a patient would feel free to ask questions, risks and refuse the proposed surgical treatment? Surprisingly only 10(0.9%) have read the consent form . In a study about patient's perceptions, one third of the patients did not realize that they can change their mind after they had signed the consent form[9].We can't wait for patient to ask questions and then we will start doing our duty..Osuna et al. demonstrated in their study that patients were not satisfied with the information they were provided. They did sign the consent form but felt that they have not fully understood the risks involved in the surgery and anaesthesia. On the other hand giving too much information has a grave potential of making the patient refuse surgery, even when told with the best of intentions [7].

A similar trend was observed in our study where although information provided was not adequate but more than half of the patients were satisfied with the information received. In a study done by Saw et al. concluded that 41% of their patients did not mind what happened to them provided they were made better; 54% trusted their doctor to do the right thing and did not think detailed explanation was important (20).An increasing number of patients are now being involved in the decision making regarding health care provision, especially in the west. This change has come about mainly due to the increased patient knowledge about their rights, generated by the mass media and better education.[9] Leclercq W K et al demonstrated that informed consent should be integrated into our surgical practice. Unfortunately, a big gap exists between the theoretical/legal best practice and the daily practice of informed consent. An optimally informed patient will have more realistic expectations regarding a surgical procedure and its associated risks. Well-informed patients will be more satisfied and file fewer legal claims.[1]This has been supported by another study done by Tay CSK .Tay has said that better communication between the doctor and his patient and with a proper informed consent taking as reviewed above, will avoid claims based on perceived rather than actual negligence on the part of the doctor.[8]Not only legal actions but patient physician relationship also improves with the detailed discussion of disease. This has seen during this research also that the doctors who had explained the details of the interventions and consequences of such interventions their patient has been more relaxed before surgery and their trust and satisfaction level is much higher than the other patients who had little knowledge of their treatment. Sahai A et al in study of informed consent and its impact on patients satisfaction has clearly demonstrated that the patient who were provide with video of the laparoscopic urology rather than the leaflet of information has understood it in a better way and The mean patient satisfaction (CSQ-8) score was 29.8 of a possible maximum score of 32. The importance of better communication with patient is given importance by

one more author.Schenker Y et al clearly said that a wide range of communication interventions improve comprehension in clinical informed consent. Decisions to enhance informed consent should consider the importance of different elements of understanding, beyond procedural risks, as well as feasibility and acceptability of the intervention to clinicians and patients. Conceptual clarity regarding the key elements of informed consent knowledge will help to focus improvements and standardize evaluations.[11]In this study 50(48.5%) patients were aware of the type of anaesthesia but very few i.e. 24(23.3%) were aware of the risk associated with anaesthesia. In current medical practice, patients once have given the consent for procedure is considered to have given the consent for anaesthesia also. But undergoing anaesthesia its self is a major process which has its own risk and complications and the complications of anaesthesia cannot be explained by a surgeon or a junior doctor its a separate speciality which cannot be explained by any other doctor .Anaesthetists, therefore, should understand their duty to explain to the patient the type of anaesthesia to be given and the risk associated with anaesthesia,.In this study 36 (34.65%) out of total forms which has undergone the audit are completely filled rest of them were incompletely filled by the hospital staff. So the documentation of informed consent is considered an integral element in the informed consent process which should also be taken seriously by the policy makers. It is beneficial for the protection of both the patient and the surgeon . In this study (90.4%) consents were taken by nurse and paramedic staff .Very few were taken by doctor i.e. 5.70% these doctors are the duty doctors of the hospital and consultant has taken only 0.9% consents which should be ideally done by surgeons who is going to perform the procedure, as they are usually the best person to answer the queries. However, this task is usually left to the nurses and the resident doctors. There is a dire need for designing specific guidelines for the process of taking consent and not only that there should be a formal training also to understand the process. Education should be given not only to the doctors and the staff but patient should also be educate about their rights.

Conclusion

This study has highlighted deficiencies in a number of areas; hence improvements are needed to upgrade the quality of pre-operative informed consent practice. Patients have poor knowledge of risk and complications of the procedure and anaesthesia. Even the documentation of consent form is again not up to the standards. Half of the forms doesn't have consultants signature. Most of the forms are incompletely filled. But majority of the patients are still satisfied with the process of informed consent. So there is a lack of proper understanding by the population and inadequate system of informed consent in our setting. Informed consent not only works as a safeguard of patient's rights but also minimizes the chances of legal action against the treating physician. And it can also dispel any unrealistic expectations of the patient from the surgeon and the intervention done which can help if operative complications arise. So it works best to improve the patient physician relationship of openness and trust. Senior doctors should play a major role and provide specific information before or just after admission to hospital. The information should be simple and concise, and should highlight possible complications to enable the patient to determine whether to undergo or decline a procedure. It is equally important to confirm that the patient understands and is fully satisfied with the information provided. Yet, the quality of existing informed consent process is less than ideal There is a great need to educate the doctors and staff regarding the importance of informed consent process and patient's right to the information about their medical condition and the proposed surgical interventions to ensure their participation in the decision making regarding their treatment. There is a need for formulating standard guidelines about informed consent in our country and to train health care providers in this aspect.

Recommendations

1. To increase the quality of informed consent practice small group workshops for the staff and awareness seminars for doctors can be conducted.

2. Regular audit at 3 months interval should be done to assess the documentation of the consent forms and regular feedback should be given to the stakeholders.

3. Only qualified person should take the consent form ideally it should be done by the surgeon if not then senior house surgeon should take the responsibility.

4. Consent form should be easily understandable and should be in local language so that one who cannot understand English can also read it

5. Consent should be taken a day before the surgery.

6. Healthcare personnel should not rush in taking signature of the patient sufficient time should be given to take the decision

Limitations of the Study

Interviews were conducted in the postoperative period, so there is a possibility that some of the information might have been forgotten by the patients which was given preoperatively.

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APPENDICES

Checklist To Assess the Timeliness of the Initial Patient Assessment

1	UHID & IP No.
2	Time of Admission
3	Time of Arrival in the ward
4	Time of Completion of Initial Nursing Assessment
5	Time of Completion of Initial Medical Assessment
6	Time of Completion of Initial Nutritional Assessment
7	Time of countersignature by Primary Consultant
8	Whether Care plan with desired outcome is documnted and countersigned by the clinician or not? (Check after 24 hrs stay)
9	Whether screening for nutritional needs has been done or not? (Check after 24 hrs stay)
10	Whether nursing Care plan is documented or not? (Check after 24 hrs stay)

Checklists To Assess The Quality Of Patient Assessment

Chesklist To Assess The Quality Of Nursing Assessment

1	UHID
2	Identification of the patient
3	Self Introduction
4	Date & Time of Arrival of Ward
5	Information to Duty Doctor
6	Time of Information
7	Patient Accompanied by
8	Vitals
9	Presenting Complaints
10	Source of Information
11	Language known
12	Orientation to Patient Environment
13	Histor of Allergy
14	Whether Allergy Band applied?
15	List of valuables with the patient
16	Medication Reconciliation
17	Investigations Advised
18	Whether patient is with any invasive lines/devices
19	Whether patient is vulnerable?
20	Physical Assessment
21	Plan of Care (COP 5d and CQI 3a iv)
22	Signature of the Staff nurse
23	name of the Staff nurse
24	Date
25	Time
26	Whether completed within 3n minutes?

Checklist For The Assessment Of Quality Of Medical Assessment

1	UHID & .
2	Demographic Information (If manual)
3	Source of Information
4	Presenting Complaints
5	History of Allergy
6	Past Medical History
7	Personal History
8	Family History
9	Occupational History
10	Socio-economic History
11	Review of Systems- Positive Findings
12	Review of Systems- negative Findings
13	Provisional Diagnosis
14	Plan of Care
15	Preventive Aspects of Care
16	Medication Prescribed
17	Investigations Advised
18	Signature of the doctor
19	name of the Doctor
20	Date
21	Time
22	Whether Initial Assessment was done within 1 hr from arrival in the ward?
23	Whether countersignature by the Primary Consultant ?
24	Whether countersignature by the Primary Consultant within 24 hrs from admission?

Checklist For The Assessment Of Quality Of Nutritional Assessment

1	UHID
2	Diagnosis
3	Presenting Complaints
4	Additional Problems
5	Present Diet
6	Height
7	Weight
8	BMI
9	Biochemical Parameters
10	Food Drug Interaction
11	Energy Requirements
12	Protien Requirements
13	nutritional Status
14	Follow up date
15	Diet Plan
16	Signature of the Dietician
17	name of the Dietician
18	Date
19	Time
20	Whether completed within 24 hrs?

Checklist For The Assessment Of Compliance Of The Consent Forms

1	UHID
2	Name
3	Age
4	Sex
5	Demographics on surgical consent form mentioned
6	Name of Procedure/Surgery mentioned
7	risk during anesthsia
8	Benefit of Surgery/Procedure mentioned
9	Risks during the surgery/procedure mentioned
10	Possible complication after the surgery/procedure
11	Alternative of Surgery/Procedure mentioned
12	Patient Signature; whether Signature Done
13	Name of the person signing mentioned
14	Whether Patient has signed if he is capable or not
15	Signature of legal representative(if paediatric)
16	Signature of Witness mentioned
17	Consultant Signature; whether signature done
18	Name of the Doctor signing mentioned
19	Whether signed by operative surgeon/Surgical Team member/ Primary Consultant/ Jr. Consultant
20	Form filled completely or not
21	Patient demographics on anaesthesia consent form mentioned
22	Patient specific risks of anesthesia
23	Signature of attending consultant in anesthesia