Dissertation

at

Aakash Healthcare Super Speciality Hospital, Dwarka

Evaluation of Quality Of Complete Documentation of Informed Consent

by

DR MANSI BHOLA

PG/18/036

Post Graduate Diploma in Hospital and Health Management

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International Institute of Health Management & Research

New Delhi

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr Mansi Bhola student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at Aakash Healthcare Super Specialty Hospital, Dwarka from 01-02-2020 to 31-03-2020.

The Candidate has successfully carried out the study designated to him during internship training and his/her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all his/her future endeavors.

Dr Pradeep K Panda

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Certificate of Approval

The following dissertation titled **"Evaluation of Quality of Complete Documentation of Informed Consent"** at **"Aakash Healthcare Super Specialty Hospital, Dwarka"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily 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.

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FEEDBACK FORM

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Dissertation Organisation: Aakash Healthcare Super specialty Hospital, Dwarka, New Delhi

Area of Dissertation: Quality Department

Attendance: Sincere & Punctual

Objectives achieved: She has completed the task very efficiently and with full enthusiasm.

Deliverables: Recommendations given by her can be very useful for improving the various processes in organization.

Strengths: Hardworking, Passionate and proactive. Committed towards assigned work.

Suggestions for Improvement:

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

Vaishali

Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date: 02-06-2020
Place: DWARKA

Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Mansi Bhola** a graduate student of the **Post- Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. He/ She is submitting this dissertation titled Evaluation of Quality of Complete Documentation of Informed Consent at Aakash Healthcare Super Specialty Hospital, Dwarka 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.

Institute Mentor Name,
Designation,

Organization

Organization Mentor Name
Designation, SENIOR EXECUTIVE

Organization AAKASH HEALTHCARE SUPER SPECIALTY HOSPITAL, DWARKA

ABSTARCT

Evaluation of the Quality of Complete Documentation of Informed Consent At Aakash Healthcare Super Speciality Hospital

By

Dr Mansi Bhola

Background

Informed consent taken pre-operatively is an important legal criteria of surgical interventions. It works for rights of patients and minimizes the chances of legal action against the physician in case of any complication. Even then the hospitals, even, large tertiary care set ups, who has a name in the industry are ignoring the importance of this process. The study was done to see the complete documentation of informed consent at Aakash healthcare Super Specialty Hospital.

Methods

Audit of the consent forms and patient information literature forms was done and assessed on the basis of checklist. A total of 219 patient's forms were audited who underwent surgical interventions during Feb 2020 to March 2020.

Results

Comparison of various parameters of consent form was made with four main specialties (Orthopedics, Obstetrics & Gynecology, Opthalmology, Cardiology). Suprisingly, In the consent form process the compliance for the following parameters-the name of procedure, patient/substitute decision maker (name, relationship, sign, date & time), witness (name, relationship, sign, date & time), interpreter (name, translator, sign, date & time) was found to be 100% for ophthalmology. For doctor's name, 95% compliance was for orthopedics. In PIL Forms, compliance for patient details was 100% for ophthalmology & Obstetrics & Gynecology. Compliance for risk specific to patient condition was 76% for orthopedics & obstetrics & gynecology; for rest 2 specialties it didn't crossed 50%. Patient/Substitute decision maker (name, relationship, sign, date & time) compliance was almost 100% for cardiology compared to the rest of the specialties. Compliance for interpreter (name,

translator, sign, date & time) is almost 100% for obstetrics & gyanecology compared to the rest of the specialties.

Conclusion

This study highlights the quality of informed consent process. Documentation of informed consent and PIL forms are still not up to the standards. Most of the forms are incompletely filled. Population does not have proper understanding of informed consent in our setting. Doctors and staff should be given more education related to the importance of informed consent process and patients should be rightly informed related to their medical condition and surgeries so that they can make their own decisions accordingly.

ACKNOWLEDGMENT

Completion of this work would not have been above all without the blessings from the Almighty God. I sincerely express my gratitude to all those who, in one way or another, supported this endeavor. I would like to thank my project guide, **Ms Vaishali Sharma (Senior Executive)** for her skillful and dedicated guidance, valuable criticism and accessibility during the entire course of this study. I wish to extend my heartfelt thanks to **Dr. Tushar PalChoudhry (GM-Quality at Aakash Super Specialty Hospital)** for their valuable guidance during the entire period of my study. I also show my gratitude towards all the Nursing Staff who helped me to collect data for the study.

I wish to express my sincere thanks to my mentor **Dr. Preetha G. S (IIHMR, DELHI)** for her advice and encouragement including assistance she accorded me during the program. In the end, I am thankful from the core of my heart to my beloved parents who supported

me throughout the course of study

Last but not the least; I am thankful to all the colleagues for their cooperation.

DR MANSI BHOLA

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LIST OF ABBREVIATIONS

1. ORTHO-Orthopedics
2. CARDIO-Cardiology
3. OBGY-Obstetrics & Gynecology
4. PIL-Patient Information Literature
5. ICU-Intensive Care Unit
6. ENT-Ear, Nose, Throat
7. OT-Operation Theatre
8. ID- Identity Document
9. IP- In Patient
10. CPR- Cardio Pulmonary Resuscitation
11. EMO- Emergency Medical Officer
12. ER- Emergency Room
13. MAR- Medication Administration Record
14. TAT- Turn Around Time
15. OP- Out patient
16. NABH- National Accreditation Board of Hospitals & Healthcare Providers
17. Mesh-Medical Subject Headings
18. URO- Urology
19. NEPHRO- Nephrology
20. NEURO-Neurology
21. CTVS- Cardiothoracic & Vascular Surgery
22. UHID- Unique Health Identification
23. MED-Medical

24. LAB- Laboratory

25. F:M- Female:Male

ORGANIZATION PROFILE

Aakash Healthcare Super Specialty Hospital is a 230 bedded tertiary care facility, with 15 Dialysis, and 70 Critical care beds for treating the most complex cases in the National Capital Region (NCR) of Delhi, Dwarka. The hospital is equipped with state of the art infrastructure, latest technology, competent clinicians and compassionate staff.

Aakash Healthcare Super Specialty Hospital is known for its leading care in the Orthopaedic and Joint replacement surgery. To complement high quality and comprehensive services, Aakash has several 'Centers of Excellence'; namely Cardiology and Cardiac Surgery, Orthopedics & Joint Replacement, Mother & Child, General & Minimal Access Surgery, Ophthalmology & Refractive Error Surgery, Neurology & Neuro Surgery and Renal Services.

The hospital also has a 24×7 ‘Trauma & Emergency Center’, blood bank, with state of art Neonatal and Pediatric ICU. The Super Specialty Hospital is being managed by highly qualified and trained experts from their respective fields and a unified team of healthcare experts ensure 24×7 comprehensive patient care. The Hospital has deployed high-end technologies and smart digital systems along with robust Hospital Information Systems to address complex medical needs and convenience of patients.

Mr. J C Chaudhary is the chairman of Hospital and Dr. Aashish Chaudhary is Managing Director, who is also a renowned Orthopedic Surgeon in this region.

KEY SPECIALITIES

- Orthopedics & Joint Replacement
- Cardiology & Cardiac Surgery
- Urology & Kidney Transplant
- Ophthalmology & Refractive Surgery
- Oncology
- Obstetrics & Gynecology
- Pulmonology
- Pediatrics & Neonatology
- Internal Medicine
- Family Medicine
- Dermatology
- Neurology & Neuro Surgery
- Hearing & Speech
- Anesthesiology & Pain Management

- Blood Bank & Transfusion Medicine
- Gastroenterology Surgery
- Rheumatology
- ENT
- Dentistry
- Emergency (24x7)
- Diet & Nutrition
- Physiotherapy & Rehabilitation
- Critical Care Medicine
- Diabetes & Endocrinology
- Lab Medicine
- Vascular & Endovascular Surgery
- Radiology
- General & Minimal Access Surgery
- Nephrology

VISION

To become the most desired healthcare brand by providing compassionate, caring and world class healthcare services with the help of talented team of doctors, professionals and latest technology.

MISSION

To achieve the highest patient satisfaction index by delivering patient centric best healthcare services among the local and extended community.

CORE VALUES


I
C
A
R
E
Integrity
Compassion
Accountability
Respect
Excellence

INTERNSHIP REPORT

Introduction:

Internship is a part of second year programme where we have to observe and learn the working and culture of the organization. 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 organization and there after we are involved in the decision making. Being a trainee in aakash hospital gave me 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 professional

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 introduced to the hospital as management trainee in the department of Quality to collect data as indicators developed by the quality department and to identify the problem areas and to suggest the corrective measures.

TASK GIVEN

- ✓ Hand Hygiene Observation Audit (5 Moments of Hand Hygiene)
- ✓ OT Surgical Safety Checklist Audit
- ✓ In Patient Initial Assessment Form Audit
- ✓ In Patient transfer Summary Audit
- ✓ Medication Reconciliation Audit
- ✓ Patient Identification & Verification Audit
- ✓ Compliance to Endorsement by Primary Consultant of Initial Medical Assessment
- ✓ Compliance to Purple Color ID Band to Vulnerable Patient by Nursing Staff
- ✓ Compliance to Completeness of Informed Consent
- ✓ Compliance to Completeness of IP Nutritional Assessment Form
- ✓ Compliance to Completeness of Code Blue Record & Analysis Sheet in Patient who Underwent CPR
- ✓ Compliance to Completeness of Fall Risk Assessment Form by Nursing Staff for all the 3 Shifts
- ✓ Compliance to Pre-Operative Checklist by Nursing Staff
- ✓ Compliance to Refilling of Fire Extinguisher Within Due Date
- ✓ Awareness of Hospital Staff on Fire Safety
- ✓ Compliance to Completeness of Nursing Care Plan
- ✓ Compliance to Temperature Monitoring of Refrigerator for Medication Storage
- ✓ Compliance to Completeness of Braden Scale for Pressure Score Risk Assessment
- ✓ Compliance to Signature of EMO on ER Initial Medical Assessment
- ✓ Compliance to Completeness of Documentation of ER Initial Nursing Assessment Within 1 Hour of Patient Admission

- ✓ Compliance to Name of Medications Written in Capital Letters in MAR Sheet by Doctors
- ✓ Awareness of Hospital Staff on Management of Needle Stick Injury
- ✓ Compliance to Counter Sign by Consultant Within 24 Hours in General Surgery
- ✓ Awareness of Hospital Staff on Emergency Alert Codes
- ✓ Compliance to Final Report Generation and Uploading Within Defined TAT for Routine Test
- ✓ Compliance to Documentation of Pain Score of OP & IP Initial Physiotherapy Screening & Assessment Form
- ✓ Compliance to Advice of Diabetic Diet for Diabetic Patients by Dietician
- ✓ Compliance to Patient Visit by Primary Consultant Within 24 Hours
- ✓ Awareness of Nursing Staff on 5 Moments for Hand Hygiene
- ✓ Compliance to Documentation of OP/IP Physiotherapy Reassessment Form

PART II

EVALUATION OF QUALITY OF COMPLETE DOCUMENTATION OF INFORMED CONSENT

Introduction

Informed consent is a legal term which 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". According to this act, doctors cannot treat the patient alone or touch them anyway. Doing any of the above things without permission is classified as "battery"-physical assault which is punishable. Obtaining informed consent apart from routine physical examination is very important.

Physician should discuss the following things with the patient before performing any procedure/treatment:

- Diagnosis of patient, if known
- The purpose of treatment or procedure
- Any risks and benefits of treatment or procedure
- Any other alternatives
- Any risks and benefits of the alternative treatment or procedure

. Information can be shared or discussed with medical/nursing staff in various ways like

- Media
- Internet
- Talking to friends who had already undergone with similar procedure.

So the informed consent plays a greater role in patient physician relationship also.

Rationale of the study

Informed consent means getting written approval from the patient. It helps in better interaction between patient and the physician regarding their medical condition & treatment. In our setting the patients don't have adequate knowledge regarding informed consent. Reason may be the illiteracy or the paternalistic thinking that the doctor is god and he knows everything. They have little knowledge of the importance of intervention and the consequences of such intervention. So they largely depend on the surgeons. Here comes the role of surgeons in the picture. Unfortunately we are still lacking here. A paradigm shift has been observed in the west whereby increasing number of patients want to be extensively informed about procedural alternatives, risk and benefits before electing to undergo a surgical procedure. Unfortunately, in hospital practice in our setup, patient and their families are mostly given very little or inadequate information. This study will be able to evaluate the current practice of taking informed consent in elective surgical intervention in a super specialty hospital in Delhi, Dwarka.

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 maintenance of consent forms, from both side of the doctors and the nursing staff. This study was done to know the existing deficiencies in the practice of informed consent and take corrective measures for proper maintenance of record and informed consent practice, and to hasten these process immediately and simultaneous corrective actions can be taken for sustainable improvement. This study will help in reviewing the performance of the department and in providing better patient care.

Review of Literature

Today in India every hospital has an aim to get an NABH accreditation and in NABH policies the importance of informed consent form is given very clearly in patients' rights and education.

Sherlock A, et al. ANZ J Surg. 2014. The objective was to explore patient's recollection and understanding of the proposed medical procedures for which they have consented. Six databases were searched from January 1995 to March 2013 for articles using the Mesh terms 'informed consent', 'patients' and 'comprehension', and the free text search term 'patient understanding'. This search identified 354 articles. Once duplicates (n=213) were removed, the remaining 141 articles were screened, resulting in 13 high-quality studies that met the inclusion criteria. The result was, when asked to reflect on the consenting process, between 21% and 86% of patients were able to recall the potential risk and complications of their medical procedure. The degree of understanding of the consenting process decreased with age. Some patients were of the opinion that the primary purpose of the consent procedure was to protect hospitals and doctors.

A Mohammed (2009) a cross sectional survey was carried out at a tertiary care teaching hospital Islamabad and 200 patients were included in who responded to the questionnaire. The survey concluded that there 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 sequeale of not having the surgery done. Signatures taken by the paramedics were 138 (69%). Despite the poor understanding of the process of informed consent, 187 (93.5%) still felt satisfied with the process of informed consent. 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 law suit 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.

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 as 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 that they knew about the risk 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 (49%) interviewed were satisfied from the information they received as informed consent process. In a study done by Dr Raab (2004) important parameters of informed consent process were discussed that are often neglected or overlooked by the busy clinicians 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 physician, risk from anesthesia, and off-label use of 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

Objectives

General Objective: - To assess the quality of preoperative informed literature process

Specific Objective:-

- To assess the consent forms for quality of information filled
- To find out the gaps in information sharing in informed consent process
- To see the compliance according to the given guideline

Data & Methods

Study Design: Observational Cross-Sectional Study

Study Area: The study was conducted in Aakash Healthcare Super Specialty Hospital Delhi, Dwarka

Sampling Method: Convenience Sampling

Sample Size: 219

Duration of the Study: 1 Month (20-02-2020 to 20-03-2020)

Tool: Observation & Checklist

Methodology: The study was designed as an observational study. The study was carried out by doing audit of consent forms and patient information literature by the healthcare personal and signed by patient during the consent form. The study was conducted for a period of 1 month i.e. from 20 Feb 2020 to 20 March 2020. The sample size is 219. Various things were observed like whether doctors name was filled/not, Procedure was filled/not, patient/substitute decision maker (name, relationship, sign, date & time) filled/not, witness (name, relationship, sign, date & time) filled/not, interpreter (name, relationship, sign, date & time) filled/not, patient information literature form was completely filled/not. The data collected was analyzed in excel.

Results

A total of 219 patients of surgery (informed consent) were taken for audit

Table 1: Demography of Patients

AGE GROUP	NUMBER OF PATIENTS
1-11	3
12-22	3
23-33	43
34-44	27
45-55	36
56-66	69
67-77	27
78-88	11
Gender F:M	126:93

Table 1 is representing the age group and the number of patient in that age group. Maximum number of patients belongs to the age group of 56-66. 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

Table 2: Surgical Department

SPECIALITIES	NUMBER OF SURGERIES
Uro/Renal Transplant	11
General & Minimal Access	21
Cardio	34
Respiratory & Sleep Medicine	5
OBGY	37
ORTHO	33
Gastroenterology	3
Brain & Spine	2
Ophthalmology	40
Internal Medicine	8
NEPHRO	3
Plastic & Cosmetic Surgery	1
NEURO	3
CTVS	3
ENT	3
Med Oncology	6
Pediatrics	3
Surgical Oncology	2

Table 2 shows the pattern of surgeries in Aakash during the period of research. The highest number of surgeries is in Ophthalmology.

Table 3: Overall Compliance of Post-Operative Audit of the Consent Forms and the Results (n=219)

PARAMETERS	PERCENTAGE
Name of Doctor Filled	78%
Name of Procedure Filled	93%
Patient/Substitute Decision Maker (Name, Relationship, Sign, Date & Time) Filled	95%, 91%, 96%, 93% respectively
Witness (Name, Relationship, Sign, Date & Time) Filled	86%, 86%, 86%, 85% respectively
Interpreter (Name, Translator, Sign, Date & Time) Filled	65%, 55%, 60%, 50%
Department Filled by Doctor	92%
Signature Done by Doctor	89%
Date & Time Filled by Doctor	91%

Table 3 shows that compliance of name of the doctor filled was only 78% & on the other hand compliance of name of the procedure filled was up to 93%. Patient/Substitute decision maker criteria compliance was also above 90%. Witness criteria compliance was above 85%. Interpreter criteria compliance was above 50% which is not up to the mark. Department filled by doctor compliance was 92%. Signature done by doctor compliance

was 89%. Date & Time filled by doctor compliance was 91%. In all of the above none of the parameters met 100% compliance.

Table 4: Overall Compliance of Post Operative Audit of Patient Information Literature Forms and Results (n=219)

PARAMETERS	PERCENTAGE
Patient Name, Age/Sex, UHID, Department, Consultant Filled	98%
Risk Specific to Patients Condition Filled	54%
Patient/Substitute Decision Maker (Name, Relationship, Sign, Date & Time) Filled	92%, 87%, 93%, 89% respectively
Interpreter (Name, Translator, Sign, Date & Time) Filled	55%, 27%, 50%, 41% respectively

Table 4 shows that the compliance of patient name, age/sex, UHID, department, consultant name filled was 98%. Compliance of risk specific to patient's condition filled was only 54% which is not up to the mark. Compliance of the patient/substitute decision maker criteria was above 85%. Compliance of interpreter criteria was above 25% which is also not up to the mark. It is observed, in all of the above, none of the parameters met 100% compliance.

Table 5: Patient's Involvement in Decision Making

Capable (Signed)	(185) 97%
Capable (Not signed)	(6) 3.1%
Not Capable	(28) 13%

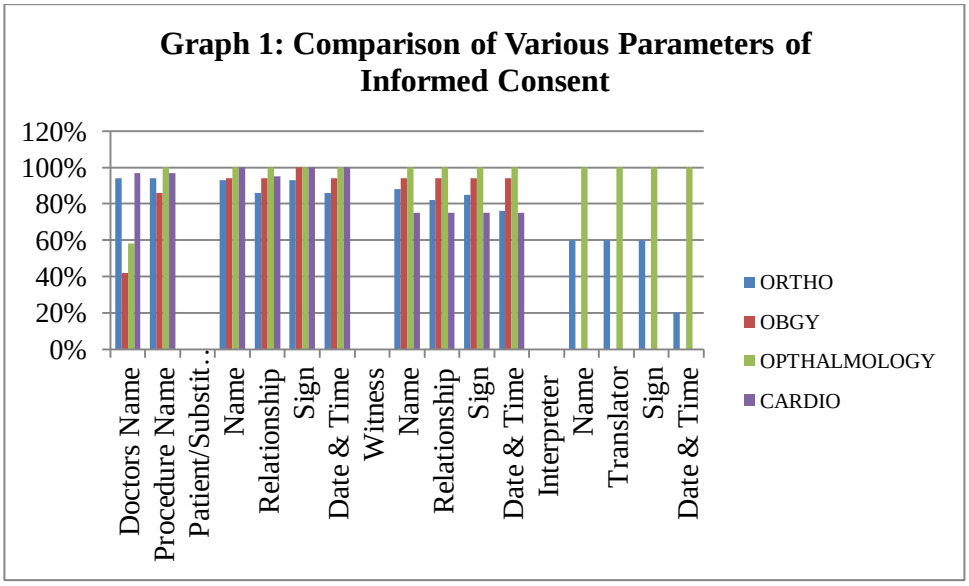
Table 5 shows that 97% of the patients were capable and they signed the consent form whereas in 3.1% of cases were the patient was capable himself of signing but on his behalf it was signed by his relative. In 13% of cases the patient was not capable of signing.

- As in Table 2 we have seen list of surgeries for various specialties. For comparison, 4 top specialties are taken to compare the results of complete documentation of various parameters of consent form & patient information literature form.

Table 6: Comparing Different Specialties with Various Parameters of Consent Form

	ORTHO	OBGY	OPTHALMOLOGY	CARDIO
Doctors Name	94%	42%	58%	97%
Procedure Name	94%	86%	100%	97%
Patient/Substitute Decision Maker				
Name	93%	94%	100%	100%
Relationship	86%	94%	100%	95%
Sign	93%	100%	100%	100%
Date & Time	86%	94%	100%	100%
Witness				
Name	88%	94%	100%	75%
Relationship	82%	94%	100%	75%
Sign	85%	94%	100%	75%
Date & Time	76%	94%	100%	75%
Interpreter				

Name	60%	NA	100%	NA
Translator	60%	NA	100%	NA
Sign	60%	NA	100%	NA
Date & Time	20%	NA	100%	NA

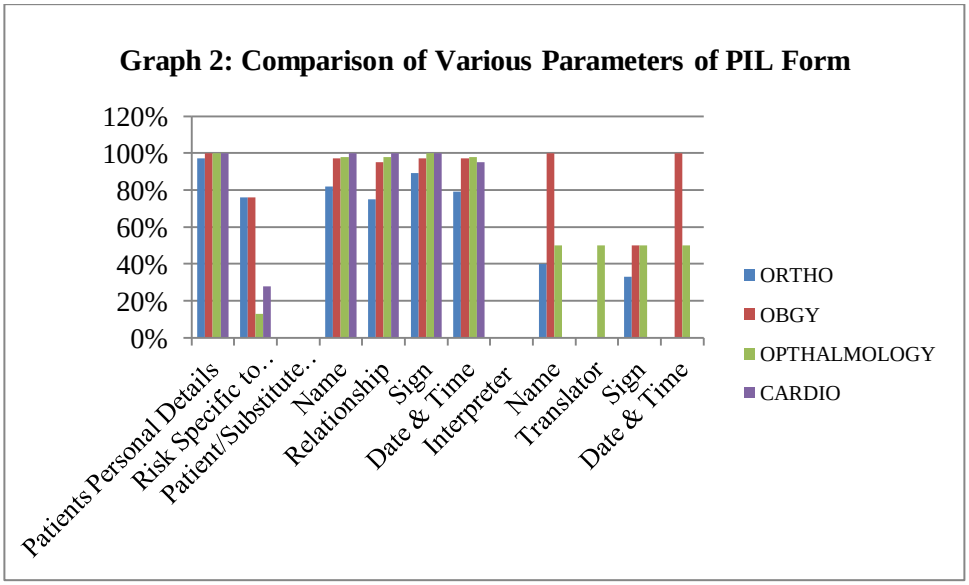


- Table 6 & Graph 1 shows that the compliance of doctors name filled was 97% in cardiology as compared to ortho, ophthalmology & obgy which are 94%, 58%, 42% respectively.
- Compliance of procedure name filled was 100% in ophthalmology as compared to cardiology, ortho, obgy which are 97%, 94%, 86% respectively.
- Compliance of patient/substitute decision maker (Name) is 100% in both ophthalmology & cardiology whereas in obgy & ortho it is 94% & 93% respectively.
- Compliance of patient/substitute decision maker (Relationship) is 100% in ophthalmology as compared to cardiology, obgy, ortho which are 95%, 94%, 86% respectively.

- Compliance of patient/substitute decision maker (Sign) is 100% in obgy, ophthalmology, cardiology whereas in ortho it is 93%.
- Compliance of patient/substitute decision maker (date & time) is 100% in ophthalmology & cardiology whereas in obgy & ortho it is 94% & 86% respectively.
- Compliance of witness (Name) is 100% in ophthalmology whereas in obgy, ortho, cardio it is 94%, 88%, 75% respectively.
- Compliance of witness (Relationship) is 100% in ophthalmology whereas in obgy, ortho, cardio it is 94%, 82%, 75%.
- Compliance of witness (Sign) is 100% in ophthalmology whereas in obgy, ortho & cardio it is 94%, 85%, 75%.
- Compliance of witness (Date & time) is 100% in ophthalmology whereas in obgy, ortho & cardio it is 94%, 76%, 75%.
- Compliance of interpreter (Name) is 100% in ophthalmology & 60% in ortho whereas in obgy & cardio it is not applicable.
- Compliance of interpreter (Translator) is 100% in ophthalmology & 60% in ortho whereas in obgy & cardio it is not applicable.
- Compliance of interpreter (Sign) is 100% in ophthalmology & 60% in ortho whereas in obgy & cardio it is not applicable.
- Compliance of interpreter (Date & Time) is 100% in ophthalmology & 20% in ortho whereas in obgy & cardio it is not applicable
    - ❖ Not applicable indicates that interpreter part should only be filled in case of foreign patients or patients who do not understand local language.

Table 7: Comparing Different Specialties with Various Parameters of Patient Information Literature Form

	ORTHO	OBGY	OPTHALMOLOGY	CARDIO
Patients Personal Details	97%	100%	100%	100%
Risk Specific to Patients Condition	76%	76%	13%	28%
Patient/Substitute Decision Maker				
Name	82%	97%	98%	100%
Relationship	75%	95%	98%	100%
Sign	89%	97%	100%	100%
Date & Time	79%	97%	98%	95%
Interpreter				
Name	40%	100%	50%	NA
Translator	0%	0%	50%	NA
Sign	33%	50%	50%	NA
Date & Time	0%	100%	50%	NA



- Table 7 & Graph 2 shows that compliance of obgy, ophthalmology, cardiology were 100% whereas for ortho it was 97%.

- Compliance to risk specific to patient condition was 76% for both ortho & obgy whereas for cardiology & ophthalmology it was 28% & 13% respectively.
- Compliance to patient/substitute decision maker (Name) is 100% for cardiology whereas for ophthalmology, obgy & ortho it is 98%, 97%, 82% respectively.
- Compliance to patient/substitute decision maker (Relationship) is 100% for cardiology whereas for ophthalmology, obgy & ortho it is 98%, 95%, 75% respectively.
- Compliance to patient/substitute decision maker (Sign) is 100% for cardiology & ophthalmology whereas for obgy & ortho it is 97%, 89% respectively.
- Compliance to patient/substitute decision maker (Date & Time) is 98% for ophthalmology whereas for obgy, cardio & ortho it is 97%, 95%, 79% respectively.
- Compliance to interpreter (Name) is 100% for obgy whereas for ophthalmology & ortho it is 50% & 40% respectively. For Cardiology it was not applicable.
- Compliance to interpreter (Translator) is 50% for ophthalmology whereas for ortho & obgy it is 0%. For Cardiology it was not applicable.
- Compliance to interpreter (Sign) is 50% for ophthalmology & obgy whereas for ortho it is 33%. For Cardiology it was not applicable.
- Compliance to interpreter (Date & Time) is 100% for obgy whereas for ophthalmology it is 50% & for ortho it is 0%. For Cardiology it was not applicable.

Conclusions

There were various deficiencies found after the completion of the study and improvements has to be done in the practice of informed consent process. The documentation of the consent form is not up to the standard. Half of the forms don't have consultant's signature. Most of the forms are incompletely filled. But majority of the patients are still satisfied with the process of informed consent. Informed consent plays major role in right to patient information but also reduces the chance of legal action against the physician. And it can also dispel any unrealistic expectations of the patients from the surgeon and the intervention done which can help if operative complications arise. So it works best to improve patient physician relationship of openness and trust. To provide specific information to the patients before or just after the admission to the hospital, the senior doctors play a major role in this. The information provided should be simple & easy language, and should tell the complications the patient so that they can make their decision accordingly. It is equally important to confirm that the patient understands and is fully satisfied the information provided. Yet, the quality of existing informed consent process is less than ideal. Staff and doctors should be made well educated regarding patients right to know about their medical condition. Standard guidelines should be formulated about informed consent in our country. Training of the healthcare providers should also be given.

Recommendations

1. Quality of informed consent practice can be increased by small group workshops for the staff and awareness seminars for doctors can be conducted.
2. Regular audit at the interval of 3 months 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 surgeons 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.

Limitations of the study

1. Time constraint was one of the major factors.
2. Doctors who have initiated the consent form process could not give their valuable time for discussing the gaps that has been found in the audit.

References

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APPENDICES

Checklist for Assessment of Compliance for Consent Form

1	Patient Name
2	Age/Sex
3	UHID
4	Consultant
5	Department
6	Doctors Name
7	Procedure
8	Patient/Substitute Decision Maker (Name, Relationship, Sign, Date & Time)
9	Witness (Name, Relationship, Sign, Date & Time)
10	Interpreter (Name, Translator, Sign, Date & Time)

Checklist for Assessment of Compliance for PIL Forms

1	Patient name, Age/Sex, UHID, Consultant, Department
2	Risk Specific to Patient's Condition
3	Patient/Substitute Decision Maker (Name, Relationship, Sign, Date & Time)
4	Interpreter (Name, Translator, Sign, Date & Time)

Checklist for Documentation of OP/IP Physiotherapy Reassessment Form

1	Patient Name
2	UHID
3	Age/Sex
4	Date
5	OP/IP Physiotherapy Reassessment Partially Filled
6	OP/IP Physiotherapy Reassessment Fully Filled

Checklist for Compliance to Patient Visit by Primary Consultant Within 24 Hours

1	Patient Name
2	UHID
3	IP No
4	Date of Admission
5	Department
6	Visit Notes-Total No of Days Admitted, No of Days Consultant Visited

Checklist for Compliance to Advice of Diabetic Diet for Diabetic Patient by Dietician

1	Patient Name
2	UHID
3	IP No
4	Date of Assessment
5	Whether Patient is Diabetic-Yes/No
6	Whether Diabetic Diet was Prescribed-Yes/No

Checklist for Compliance to Documentation of Pain Score of OP & IP Initial Physiotherapy Screening & Assessment Form

1	Patient Name
2	UHID
3	Saved By
4	Date
5	Pain Score Filled-Yes/No

Checklist for Compliance to Completeness of Surgical Safety Checklist

(Date, Start Time, End Time, Duration of Surgery)

1	Patient Name
2	UHID
3	Department
4	Doctor Name
5	Date Filled-Yes/No
6	Start Time Filled-Yes/No
7	End Time Filled- Yes/No
8	Duration of Surgery Filled-Yes/No

Checklist for Compliance to Final Report Generation and Uploading within Defined TAT for Routine Test

1	Priority Name
2	UHID
3	Patient Name
4	Test Name
5	Ward Name
6	Collection Date & Time (T2)
7	Sample Acknowledge Date & Time (T3)
8	Report Provisional Date & Time (T5)
9	Report Verify Date & Time (T6)
10	Average Defined TAT for Test to Complete
11	Test was Done within Defined TAT-Yes/No

Checklist for Compliance to Name of Medications written in Capital Letters in MAR Sheet by Doctors

1	Patient Name
2	UHID
3	Location
4	Drugs Written in Capital Letters-Yes/No

Checklist for Compliance to Counter Sign by Consultant within 24 Hours for General Surgery

1	Patient Name
2	UHID
3	Age/Sex
4	Date
5	Consultant Name
6	Signed By Done-Yes/No
7	Signed On Done-Yes/No

Checklist for Compliance to Completeness of Documentation of ER-Initial Nursing Assessment within 1 Hour of Patient Admission

1	Patient Name
2	UHID
3	Age/Sex
4	Date & Time of Arrival
5	Signed By Done-Yes/No
6	Signed On Done-Yes/No

Checklist for Compliance to Signature of EMO on ER Initial Medical Assessment

1	Patient Name
2	UHID
3	Age/Sex
5	Signed By Filled-Yes/No
6	Signed Date Filled-Yes/No

Checklist for Compliance to Endorsement by Primary Consultant of Initial Medical Assessment

1	Patient Name
2	UHID
3	Gender
4	Admission Date & Time
5	Bed No
6	Admitting Doctor
7	Endorsement by Primary Consultant (Signature, Name, DMC No, Date & Time)

Checklist for Compliance to Temperature Monitoring of Refrigerator for Medication Storage

1	Location
2	Temperature Recorded-Yes/No
3	PM Maintained-Yes/No

Checklist for Compliance to Completeness of Nursing Care Plan by Nursing Staff

1	UHID
2	Patient Name
3	Age/Sex
4	Admission Date & Time
5	Ward No
6	Nursing Assessment Filled-Yes/No
7	Problem Identified Filled-Yes/No
8	Goal Filled-Yes/No
9	Intervention Filled-Yes/No
10	Implementation Filled-Yes/No
11	Outcome Filled-Yes/No
12	Added By Added On Filled-yes/No
13	Verified By Verified On Filled-Yes/No
14	Nursing Care Plan Partially Filled-Yes/No
15	Nursing Care Plan Fully Filled-Yes/No

Checklist for Compliance to Refilling of Fire Extinguisher within Due Date

1	Location
2	Refilling Date
3	Due Date
4	Whether Fire Extinguisher Filling Criteria Met-Yes/No

Checklist for Compliance to Completeness of Pre-Operative Checklist by Nursing Staff

1	UHID
2	Patient Name
3	Admitting Doctor
4	Name of Ward Nurse
5	Name of OT Nurse
6	Whether Pre-Operative Checklist Filled-Yes/No

Checklist for Compliance to Completeness of Fall Risk Assessment Format by Nursing Staff for all the 3 Shifts

1	UHID
2	Patient Name
3	Age/Sex
4	Admission Date & Time
5	Fall Risk Assessment Format Filled-Yes/No
6	Fall Risk Assessment Format Done for all the 3 Shifts-Yes/No

Checklist for Compliance to Completeness of Code Blue Record & Analysis Sheet who Underwent CPR

1	UHID
2	Patient Name
3	Location
4	Date & Time of Event Recognized
5	Code Blue Record Sheet Present-Yes/No
6	Code Blue Analysis Sheet Present-Yes/No

Checklist for Compliance to Completeness of IP Nutritional Assessment Form within 24 Hours

1	UHID
2	Patient Name
3	Admission Date & Time
4	Bed No
5	Ward No
6	Saved By
7	Saved Date & Time
8	Admitting Doctor
9	IP Nutritional Assessment Form Completely Filled-Yes/No
10	Whether Nutritional Assessment Form was Filled within 24 Hours-Yes/No

Checklist for Medication Reconciliation Audit

1	UHID
2	Patient Name
3	Date
4	Medication/Dose/route Filled-Yes/No
5	Frequency/Last Dose Filled-Yes/No
6	Remarks Filled-Yes/No
7	Partially Filled-Yes/No
8	Completely Filled-Yes/No

Checklist for In Patient Transfer Summary Audit

1	UHID
2	Patient Name
3	Age/Sex
4	Date of Transfer
5	Time of Transfer
6	Shifting From (Ward, Bed)
7	Shifting To (Ward, Bed)
8	Partially Filled-Yes/No
9	Fully Filled-Yes/No

Checklist for In Patient Medical Assessment Audit

1	UHID
2	Patient Name
3	Age/Sex
4	Admission Date & Time
5	Bed Occupied Date & Time
6	Ward No
7	Saved By
8	Saved Date & Time
9	Admitting Doctor
10	In Patient Initial Medical Assessment Criteria Met-Yes/No
11	Signed By On Duty Doctor-Yes/No