EVERCARE GROUP
Dissertation
At
Care Hospitals

"A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery"

By
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PG/20/045

Under the guidance of
Dr. Pankaj Talreja

Post Graduate Diploma in Health and Hospital Management
2020-2022

International Institute of Health Management Research
New Delhi

CARE HOSPITALS

Dissertation Certificate

This is to certify that **Dr. Nidhi Khatri**, a graduate student of the PGDM (Hospital & Health Management, International Institute of Health Management & Research, New Delhi) has successfully completed her dissertation in the department of quality. The candidate has successfully carried out the study designated to her titled **"A retorspective assesment of compliance of appropriateness, timliness, legibility, of informed consents taken during surgery at Care Hospitals (BANJARA IP)"**, during the period 14.03.2022 to 15.06.2022

She comes across as a committed sincere and dilegent person who has a strong drive and zeal for learning.

We wish her all the best for future endevors.

Mr. Rajeev Chourey
VP Quality & Operations

Mr. Rajendar Prasaad
AGM HR

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. Nidhi Khatri student of PGDM (Hospital & Health Management) from International Institute of Health Management Research, New Delhi has undergone internship training at Care Hospitals from 14.3.2022 to 15.06.2022

The Candidate has successfully carried out the study designated to him during dissertation 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 him all success in all his/her future endeavors.

Dr. Sumesh Kumar
Associate Dean, Academic and Student Affairs
IIHMR, New Delhi

Mentor
DR. PANKAJ TALREJA
IIHMR, New Delhi

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CERTIFICATE ON PLAGIARISM CHECK

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Title of the Dissertation/ Summer Assignment	"A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery at Care Hospitals"		
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The following dissertation titled "A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery " at "Care Hospitals" 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 PGDM (Hospital & Health 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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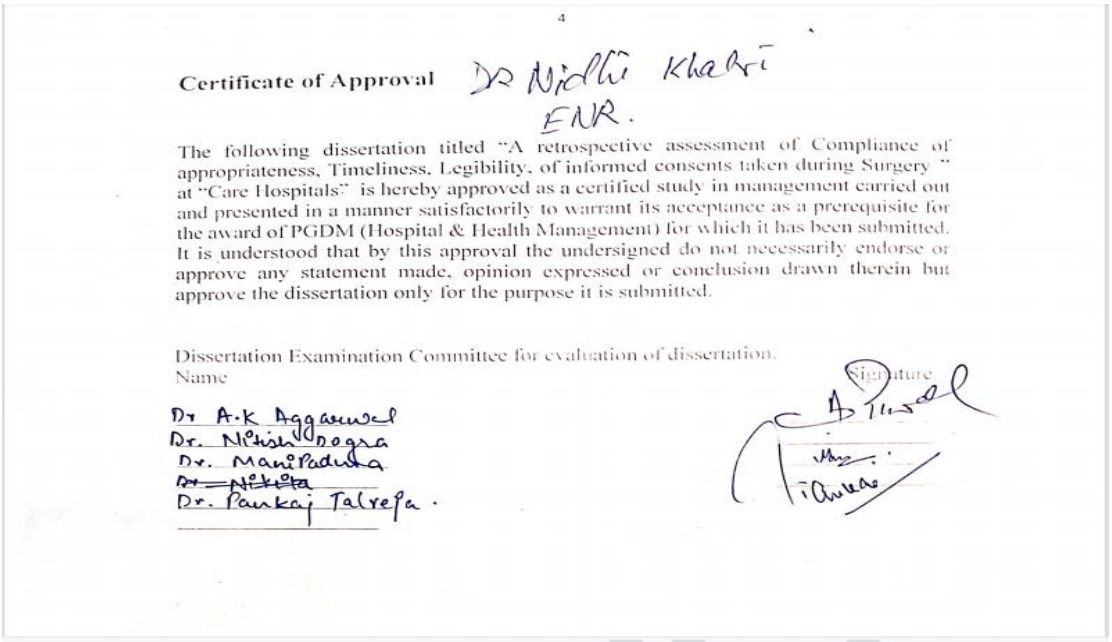
Dr. Nitish Dogra	



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Certificate of Approval Dr Nidhi Khatri ENT.

The following dissertation titled "A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery " at "Care Hospitals" 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 PGDM (Hospital & Health 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.

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FEEDBACK FORM

Name of the Student: Dr. Nidhi Khatri

Name of the Organization in Which Dissertation Has Been Completed:
Care Hospitals

Area of Dissertation: OT (operation Theatres)
@ Care hospitals Banjara hills. (IP)

Attendance: 100%

Objectives achieved: She has done the required audits prospectively and has achieved objective of Shadow Audit.

Deliverable s: Sample Size achieved, Methodology of Audit Achieved.

Strengths: Good understanding of Hospital processes & is dedicated in working.

Suggestions for Improvement: Need to improve on techniques of Analysis of data

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

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

Dr. Saket Bansal.

Date: 30/6/2022
Place Hyderabad.

ACKNOWLEDGEMENT

I bow before almighty, most gracious, and most merciful for enabling me to complete this dissertation.
I owe a great debt of gratitude to the professionals listed below who have distinguished themselves in the field of healthcare and hospital management studies , for having so generously giving knowledge ,time and expertise for successful completion of dissertation.

I am deeply privileged to work under the guidance of **Dr. PANKAJ TALREJA of IIHMR DELHI.**

I would like to express my deep gratitude to **Mr. Rajeev Chourey Vice President of Quality &Operations at Care Hospitals,** for his support and motivation.

My heartfelt thanks to **Dr. SAKET BANDAL ANKUSH Sr. Manager Quality Dept. at Care Hospitals,** for his support, encouragement and who stood as guide for my dissertation work.

My Hearty thanks to Administrative officer **Md. Zeeshan Ahmed ESG officer**

I would like to thank all the **MRD staff Mrs. Jhansi, Mrs Shirisha, Satsya at Care Hospitals of Hyderabad** who supported me in collecting passive files samples and helped me in completing dissertation.

Dr. Nidhi Khatri

Table of Contents:-

Chapter 1
Abstract

"A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery at Care Hospitals"

Background

Consent is an ethical and legal requirement that must be obtained before any procedure is carried out in clinical practice. Informed consent is an essential step in helping patients be aware of consequences of their treatment decisions. When obtained based on balanced information, it practically improves patients' satisfaction in virtually all outcomes, it is vitally important for patients to understand the risks and benefits of the procedure and decide accordingly.. In our ever increasingly litigious world of medicine, informed consent has become more sophisticated and involves much more than completing a form.

Method

Audit of informed consent was done and assessed on the basis of checklist and sample collection was done from the passive files in medical record department who have undergone elective surgical procedure. The checklist created was on the basis of information provided on consent formats and with under the guidance of Dr. Saket Bandal Ankush. All files were audited on the basis of checklist questionnaire. The Sample size is 72

Results

UHID/IP/OP number in the consent was mentioned in 31(43.05%) forms. Date on which consent taken was mentioned on 48 (82.76%), signature taken by the patient was on 59 (81.9%), signature taken by the witness was 61(84.7%), address of the witness was mentioned in 28 (38.9%), proposed procedure was mentioned in 62(86.1%), date of procedure was mentioned 58(80.6%). Assessing the availability of consents forms in passive files, in 68 file consents was available and res 4 missing consents are missing in file. Timing of the consents was available in 17(24%) which is not the acceptable standard. Relation with the witness was written in 34(47%) consents. Alternative treatment was written in 27(35.7%), expected risk was mentioned in 59(81.9%), benefits of the procedure was written in 62(86%) consents. Appropriate language used by the patient English 15(20.8%), Hindi 3(4.15), Telugu 19 (26%), no language 31(43%). Surgeries performed under general anaesthesia are11(15.2%), spinal anaesthesia 7(6.9%), local anesthesia 5(6.9%), regional anesthesia 14(19.4%), no anesthesia was mentioned in 33 (46%). Signature taken by the staff (doctor) are 63 (86%), no of extra incomplete consent signed by the staff are 9 (12.5%). In 6(8.3%) consent was signed by surrogate because the reason was child, illiteracy, dementia, patients with illiteracy their thumb impression are been taken on the consents form. Name of the staff mentioned in 53 (73%), address of the patient was mentioned in 19(26%), 59(82%) consents are signed by patient himself.

Conclusion

Study highlights that the patient have poor knowledge of complications of risk and procedures and anaesthesia. Documentation of the consents was not up-to standard mark, 4 consents were missing in passive files, consents are incompletely filled, blank consents were signed by the patient was attached in the files. Their is lack of understanding by the doctors about the informed consents. There is need to educate the staff and the patients regarding the importance of informed consents and patient has a right to get the information about the surgical intervention.

Chapter-2
About the organization
Care Hospitals (EVERCARE GROUP)

CARE Hospitals Group is the regional leader in South and Central India and is amongst the top-four Pan-Indian hospital chains. It delivers comprehensive care in over 30 clinical specialties such as Cardiac Sciences, Oncology, Neurosciences, Renal Sciences, Gastroenterology & Hepatology, Orthopaedics & Joint Replacement, ENT, Vascular Surgery, Emergency & Trauma and Integrated Organ Transplants to name a few. With its state-of-the-art infrastructure, internationally-certified team of eminent doctors and a caring environment, CARE Hospitals Group is the preferred healthcare destination for people living in India and abroad.

CARE Hospitals Group is a multi-Speciality healthcare provider with 14 healthcare facilities serving 6 cities across 5 states in India. A regional leader in South and Central India and counted among the top 5 pan-Indian hospital chains, CARE Hospitals delivers comprehensive care in over 30 medical specialties. CARE Hospitals is part of the Ever care Group, the leading impact-driven healthcare group in South Asia and Africa.

Achievements

- 1st Hospital to develop India's First Indigenous Coronary Stent "KALAM-RAJU" stent
- 1st Hospital in South India to perform SWAP Kidney Transplantation
- Performed more than 500+ Kidney Transplants
- Pioneered in Bone Marrow Transplantation with high success rate
- Performed South India's first Split Liver Transplantation
- The first hospital in Eastern India to perform Awake Open Heart Surgery
- One of the first hospitals to use minimally invasive techniques for weight loss surgery
- 1st Hospital to perform Fetal Heart Procedure in India
- 1st Atrial Fibrillation Clinic in India
- One of the first hospitals in India to set up a 53-nation Pan African Network through tele medicine.
- One of the first hospitals in India with the highest number of patients treated through the Afghan Red Cross Society

Chapter -3
Introduction

The term "informed" refers to having knowledge or information about a topic. In detail, it comes out to be the required information to the person who requires it; there should be a comprehensive understanding of the facts and information without ambiguity.
Informed consent is the process by which a patient is made aware of the details of a medical or surgical intervention, which includes everything like clinical trials, and is then able to weigh the risks and advantages of the proposed course of action. Giving patients all the information they need to make an informed decision is a standard and important first step. In essence, this is done so that the patients or the person in charge, whoever that may be, would strive to understand all the implications of the treatment. By keeping the safety feature in view, this is accomplished.
In order to obtain the patient's informed consent, clinicians must takes responsibility and first make ensure that the patient has all the necessary information. This information must also be given in plain language without using complicated words. Since patients typically lack a background in medicine, it is best if the information is communicated verbally to them. But written informed consent is also acceptable.

Information included in the consents:-

- Patient’s medical condition.
- Procedure for treatment as advised by the healthcare providers
- Treatment benefits and expected risks and consequences of the procedure to be performed.

Responsibility of the patient:-

The consent signed by the patients states that the patients has read all the treatment procedure and he/she agreeing to all the circumstances. He/she can asks questions from the healthcare providers and clear all the doubts before the procedure. Healthcare provider must ensure that the patient has got the satisfaction and chooses the whole treatment procedure or the on portion. When two or ore person agree upon the same thing in the same sense, the y are said to have consent as per section 13 of Indian Contract Act, 1872. Person equal to or above 18 years of age can give a legally valid consent for any procedure that include risk to his/her life as per the implications of Indian Penal Code Section 87.
Another section of the IPC, Section 89, gives the guardian of a child under the age of 12 or a person who is mentally ill of any age the authority to consent to doing injury to the child or person as long as it is done in good faith and for that person's benefit.

According to Section 88 of the IPC, adults over the age of 12 are regarded to be able to give permission. This provision is different from Section 87 in two ways:
(1) Any harm other than death may be inflicted under it, and
(2) No mention is made of the consenting party's age (but under Section 90, the age of the consenting party must be at least being 12 years).
Even when the case for any negligence is weak, the patient may nonetheless prevail in legal actions due to a lack of informed consent. Therefore, having a greater grasp of the informed consent procedure serves the interests of both the patient and the doctor

in addition to protecting them. Therefore, it is crucial that the consents obtained be complete and include all of the elements of an informed consent.

If consent is not obtained, there will be grounds for pursuing both a criminal defence under Section 350 IPC for performing any invasive procedure without the patient's consent, which is equivalent to assault using criminal force, and a civil claim for damages for the harm the patient suffered under the law of torts. The patient has the right to sue the doctor for violating his personal or private rights even if no harm results from the doctor's failure to get a legally acceptable permission.

According to the NCDRC, the idea of "informed consent" stipulates that all information must be disclosed to the patient and/or guardian in plainly understandable non-medical terms, preferably in the patient's native tongue, regarding:- Diagnosis, Nature of treatment, prospectus of success, prognosis if procedure not performed, alternative methods of treatment.

According to NCDRC, such consent forms cannot be regarded as "informed consents" because they include no particular mention of the name of the surgery, the type of anaesthetic, and signatures are obtained mechanically many weeks before the intended surgery date.

Type of informed consents:-

There are 5 types of consents:-

Parental Permission:- Properly signed by the child's parents or legal guardians. Parental consent is required since a youngster cannot choose what is good and wrong for

Assent:- It is the child's affirmative permission when the informed consent form's content is stated in straightforward language that the child can easily read.The reading level of the content should be written in such a way that the child of age 7 to 17 years can understand it easily.

Verbal:- Patients verbally reads the consents and verbally gives the consents.

Consent :- An adult participant who is of legal age may grant permission or consent on their own, but only if they are at least 18 years old.

Short Form:- Approved consent is translated in to patients native language.

Why consent is necessary?

Consent protects the doctor from the unwanted accusation. Consent is now clearly required for the disposal of human tissue as well as the handling of personal data. Consent being regarded as the cornerstone of a doctor–patient relationship, no patient can be forced, directly or indirectly, to accept treatment which it may refuse, even if it is painless, beneficial, without any risk, or even life threatening.

The Nuremberg Code report discusses the requirement for voluntary, informed consent as a fundamental ethical precept. The participant must grant their autonomy, which suggests that it is their obligation to decide what to do and obtain consents relating to their medical circumstances. It is crucial not only for the patient's security and protection, but also for the patient's integrity and respect.

The form is a legal document that demonstrates the patient's acceptance of and consent to the medical procedure recommended by the healthcare professionals. When the consent form is signed, it indicates that the patient has read and understood all pertinent information concerning the operation and has freely consented.This means that the medical professional can continue with the treatment. Participants are not allowed to sign the form if they object to the medical advice given to them. If they

are able to make their own decisions, everyone has the freedom to refuse treatment. The moral and legal right to refuse any treatment belongs to the legal competent who is able to make medical decisions.

Informed consents Legal Scenario:-

Doctors have a responsibility to fully disclose to patients any potential hazards associated with their diseases. However, the doctor will be held accountable for medical negligence if they are unable to discharge their duty. In medical negligence cases, the doctors carelessly or improperly treat the patient it can be either without adequate technical skills or knowledge. In one instance, the doctor found the woman's torn womb while executing the procedure. Without getting her permission, he sterilized her. Medical malpractice has led to the doctor's liability. In this event the information was not disclosed, the doctor was held to be responsible for the consequences as a result of medical negligence.

In the instances listed below, consent must be obtained; else, legal action will be taken:-

Minor's Consent:- In India, the age of majority is 18 years old according to Section 3 of the Indian Majority Act, 1875. As a result, the person is a minor and is unable to grant permission. The parental approval will be regarded as legitimate.

Right to Refusal:- Doctors cannot treat patients who have not provided their consent for therapy, and if they do so, they will face consequences. A. In India, it is the doctor's responsibility to provide evidence to support activities that, absent agreement, would be against the law. Up to a certain point, Indian courts may assume that consent was given implausibly. Beyond that, the court must be given the precise evidence.

Medical Termination Pregnancy:- No pregnancy may be ended without the women's agreement, according to the Medical Termination of Pregnancy Act, 1971. Only acts in good faith and for the sake of a person's life may be terminated.

There are some standards that must be met by a person in the event that they are somehow unable of giving informed consent in order to prevent any confusion:

- A suitable justification must be provided.
- An individual's assent is necessary.
- It is in the best interest of the person to take into account their preferences.
- If a substitute consent exists, it must be confirmed that it satisfies all necessary conditions. In a same vein, if doctors follow suit, they too should have a thorough justification for everything. Furthermore, it is not expected of the doctors, but even so, they should carefully present any issues.
- The major significance of this agreement is that it assures you of treatment and ensures that any risks to your health should have been previously discussed with you.

As a human body's most fundamental need, health and life, there should be no risk relating to that body's state of health. In India, doctors are revered as being on par with gods as they save our lives and provide us with a glimmer of hope during our darkest hours. Since it is believed that doctors are the ones who always serve their patients in whatever circumstance, there shouldn't be any ignorance on their part. The recent example of the corona virus in society makes this point very evident.

Sometimes medical professionals, whether for lack of time, a failure to perform their duties, or for any other cause, forget to sign the informed consent form. Therefore, it is crucial that doctors carry out their duties flawlessly, without any gaps that can cast doubt on their profession. A normal person values their health above all else, so any negligence on the part of a doctor would be completely unacceptable. A doctor should exercise responsibility and complete dedication during the entire course of treatment.

CHAPTER-4
Literature Review

1. **A Journal Length of time a signed informed consent is valid by Byron Burlin game RN,BSN,MS,CNOR (AORN JOURNAL 2007-2017)** answer to the question by the patient who was admitted to ambulatory surgery for a tubal litigation and patients consent had been signed 2 months approximately earlier in a doctor's office and patient asked for the new informed consent and the hospital supervisor said it was not necessary.The amount of time a signed informed consent is valid should be determined by the health care organization's policy, according to this publication, because otherwise there are no national criteria that are specified for how long a signed informed consent is valid. While creating the informed consent policies, first consultation should be taken from state department of health and health care organization's risk management, medical record departments and quality improvement. If any healthcare organization does not have these department, then consultation will be taken from state department of health and facility legal representatives.

While other facilities believe the consent is valid indefinitely, some consider it valid for only 30 days or the length of admission. For the current method, informed consents must be incorporated into the admission-related documents. Having a patient undergo a series of procedures, such as chemotherapy infusions and blood transfusions, should be covered under policy. For such series of procedures, whether the patient signs a fresh consent form for each admission or signs a single informed consent form for a course of treatment, a copy of the consent is then recorded on the patient's document for each hospitalization.
Every organization of healthcare should determine the length of time that a consent is valid. This decision is based on state rules, especially pertaining to Medicaid recipients. An exception must be made for the patient receiving Medicaid who desires to have a voluntary sterilization. According to the rules of Medicaid consent form for the voluntary sterilization must be signed at least 30 days but not more than 180 days before the surgical procedure is completed, if the healthcare organization and state determine the time frame as equal to 30 days or less than 30 days.
Prior to a vaginal or preterm Caesarean delivery, prior to an urgent abdominal surgery that results in sterilization, this period is extended to at least 72 hours (three days). The doctor and the business won't get paid by Medicaid if the treatment is done before this window of time. This rule solely applies to reimbursement and shouldn't be taken to mean that if the time period hasn't passed, the required permission hasn't been obtained.

2. **Junior-doctor Experience and challenge in Obtaining Surgical informed Consent: A qualitative systematic review and meta-ethnography by Josephine DE Costa BA, LLB, MD, M Med, Mandy Shircore BSc, LLB, LLM and Alan de Costa FRACS 2021** has used a meta-ethnography approach

along with a thorough, standardized search of the 34 literature, compared with traditional quantitative systematic reviews of the literature, and found that only 13 studies out of 34 recommend the implementation of additional educational interventions for all staff, including junior doctors, to enhance skills and knowledge surrounding surgical informed consents. Junior doctors in all of the polls have a poor comprehension of the surgical informed consents legal criteria, particularly when it comes to assessing competence and defining material risk. The majority of research on capacity revealed that contestant know of the need for capability, but had difficulty gauging it in practise. However increasing experience of junior doctors is linked to better confidence in gaining surgical informed consent, which is fairly unsurprising. The inclusion of required lectures as part of pre-internship training may be beneficial for all medical schools, including vocational surgical programmes, even though this was not the primary method of instruction outlined in the literature. Specific intervention programme, like as case studies or simulation or videos, are also beneficial and easier to integrate into structured student of medical profession and education of junior doctors. This proof/ evidence based, on the other hand, supports strongly an clinical approach to a teaching consent, which would necessitate motivating clinical teams to promote surgical informed consents learning in the same way they teach clinical skills, with a combination of practical as well as theoretical, observing the opportunities. Repositioning surgical informed consents as a fundamental clinical skill, instead of administrative activity, likely to be crucial to make ensure that junior doctors must feel comfortable seeking help in acquiring surgical informed consents. This includes by training medical schools, colleges also as well as hospitals. Educators in medical profession and policy creators should have the knowledge of the issues faced by junior doctors who are Post graduate students and lacking in adequate training and education about the legal aspects while making policies impacting surgical informed consents, and while designing surgical education programs because the junior doctors are likely to obtain a significant portion of surgical informed consent; however, they have difficulties when determining capacity, making sure surgical procedures are appropriately disclosed, and properly documenting consent, all of which could undermine the reliability of whatever surgical informed consent they get.[(2)]

3. **Are patients truly informed ? A retrospective chart review the documentation of informed consent sin laparoscopy cholecystectomy 2021** say that

- **Context--** Examination is done on whether the documents are complete or not in favor all the aspects of informed consents for Laparoscopic Cholecystectomy (LC):- it's alternatives to laparoscopic cholecystectomy, details of the procedure and potential complications. Variances in the documentation of informed consents for emergent and for elective LC were been examined.

- **Objective--** To assess the success rate of obtaining informed consents for laparoscopic cholecystectomy in both elective and emergency situations.

- **Design--** All patients who underwent laparoscopic cholecystectomy at one of the Kingston Health Sciences Centre's two academic hospitals between 2015 and 2017 had their records retrospectively reviewed.

- **Sample size --** 270 patients visited the Kingston Health Sciences Center. The Kingston Health Sciences Center's Health Sciences Research Ethics Board granted its permission for the project during the period 2015 to 2017

- **Study population--** Patient undergone Laparoscopic Cholecystectomy

- **Results :-** Sample Size of 270 patients and their analysis was done. Result are as follows

  - 5 (2%) with complete documentation.
  - 232 (86%) potential complications was noted in documentation.
  - 58(25%) - Elective
  - 174(75%) - Emergent
  - 28 cases details noted (10%)
    - 21(75%) - Elective
    - 7(25%) - Emergent
  - Surgical procedure alternatives (documented least frequently) in 23 cases (9%)
    - 20 (87%)- Elective
    - 3(13%)- Emergent

- **Discussion :-**Data revealed that residents produced better documentation on consent forms and clinic notes, whereas attending offered better documentation in OR notes, despite the fact that teaching of informed consents is primarily centred on trainees. Highlight are the reality that attending surgeons are similarly unreliable documenters, and that lack of experience and understanding among trainees are not the only factors leading to it.

- **Conclusion:-** The documentation of informed consents for Laparoscopic Cholecystectomy was poor; informed consents elements was missing in maximum cases. The aspect of informed consent that was most frequently documented was problems; the discussion of Laparoscopic Cholecystectomy alternatives and the specifics of the procedure were generally not included. Although it is crucial to address problems in research aimed at enhancing IC documentation, it is also necessary to discuss options to surgical care, process specifics, and efforts to guarantee patient understanding. [3]

Chapter -5

Objective:-

a) To measure compliance with standards in available guidelines for informed consent for during surgery.
b) To make recommendations to improve the timeliness, and Legibility of process of consenting in surgery.

Methodology :-

◆ Research Design:- Retrospective Study

◆ Data Type:- Secondary Data

◆ Data collection Method:- Purposive sampling from MRD at CARE HOSPITALS.

◆ Data Sources:- Published articles, New Articles, Journals.

A retrospective study was conducted from for 3 months. The data was collected by using MRD records of passive patients who had under gone surgeries. Administered structured questionnaire will be created based on the standard criteria and will be analyzed in Excel.

◆ The Check list that was created is mentioned in below table 1

TABLE 1

Department
PATIENT UHID
NAME OF CONSENT
IP/OP NO/UHID
DATE OF CONSENT TAKEN BY PATIENT /WITNESS
Signature done by Patient
Signature of witness
Relation with witness
Address of witness
Signature Taken by staff
Proposed Procedure
Date of procedure
Benefits of procedure
Alternative treatment

Disposal of any tissue or part to be removed during the procedure
Expected Risk
Appropriate language used for patient understanding(English/Telugu)
Type of anaesthesia given
General
L/A
Spinal
Epidural
Caudal
Bronchial plexus
Regional block
Timing of consent
Signed by staff
Missing Consent
No. of extra consent signed by patient or staff
Demographics
Witness
Thumb impression/ Not capable to sign
General risk procedure marked (yes /no)
Specific risk procedure marked
Name of Staff mentioned
Address of patient
Consent signed by
Surgery Name

Name of the consents included during the Audit:-
Table 2:-

NAME OF CONSENTS
INFORMED CONSENT

HIGH RISK CONSENT
LAPROSCOPIC UTERINE MYOMECTOMY
CONSENT FOR C SECTION

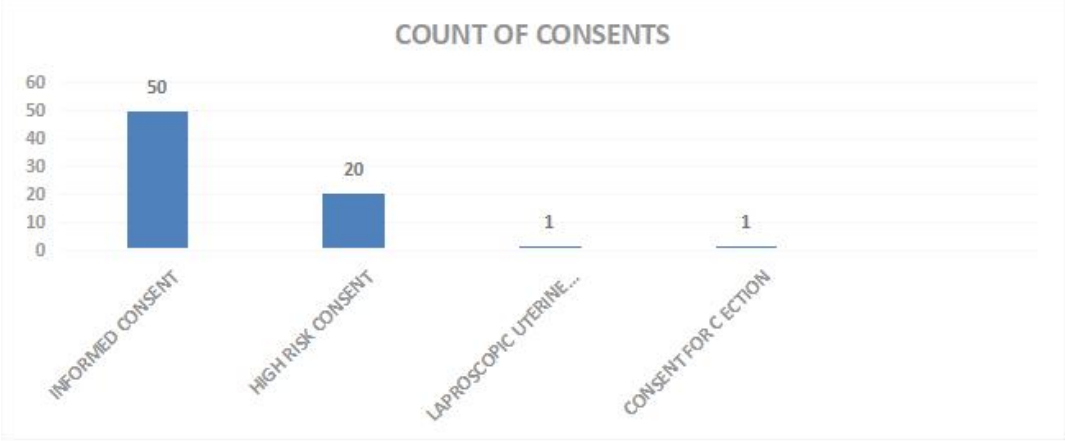

Figure 1 - Showing the type and number of consents taken during the study. Maximum consents taken are the informed consents from all the department.

Chapter -6

Result of the Audit:-

A total of 72 passive files were audited as per the mentioned above checklist in Table 1

No. Of Samples Collected from each department:-

Table 2:- Representing the no. Of samples collected from each department

DEPARTMENT	COUNT
BARIATRIC SURGRY	7
CARDIOTHORACIC	7
ENT HEAD AND NECK	1
GASTROENTEROLOGY	4
HAEMATOLOGY	1
NEUROSURGERY	10
OBSTRETICS & GYNAEC	5

SURGICAL ONCOLOGY	2
ORTHOPAEDICS	19
PAEDIATRICS	1
PLASTIC SURGERY	2
POST CATH	2
UROLOGY	11
TOTAL	72

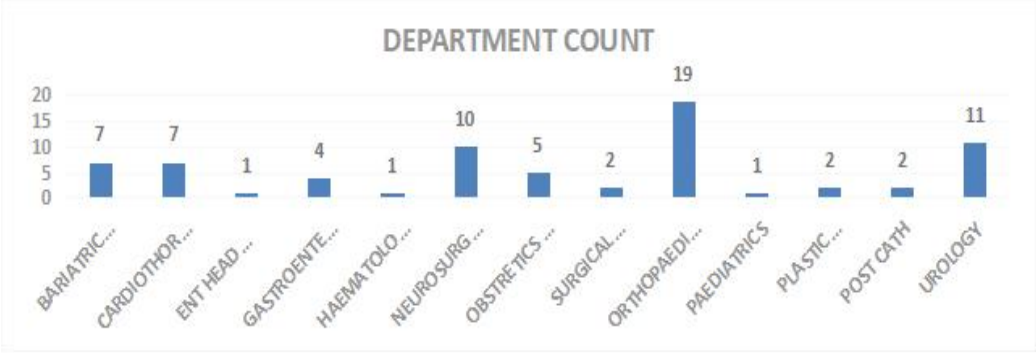

Figure 2- Showing the Departments of which the consent was taken. Maximum number of consents was taken from orthopaedics departments that is 19

Table :- 3

Post-operative audit of the consent forms and Result (n=72)

PARAMETERS	COUNT	PERCENTAGE
UHID/IP/OP NO. Mentioned in the consents (Yes/No)	31	43%
Date on which consents taken(Yes/No)	58	80%

Date of consent taken and date of surgery performed was same in all the files.

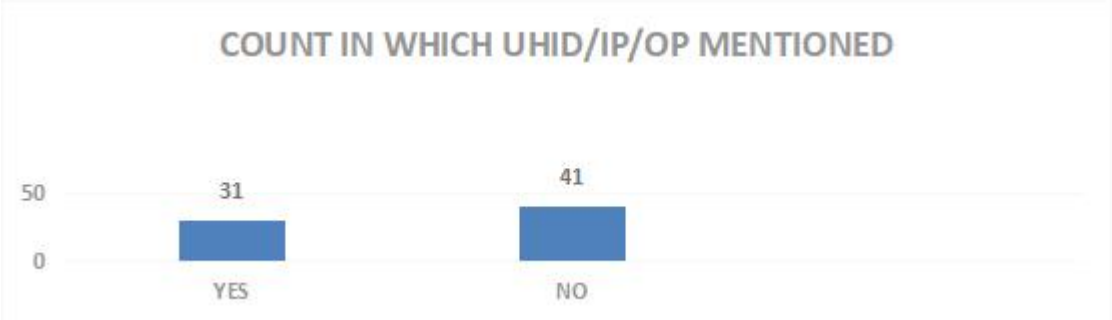

Figure 3 Showing count in which patients UHID/IP/OP no. was mentioned is 31(43%) only.

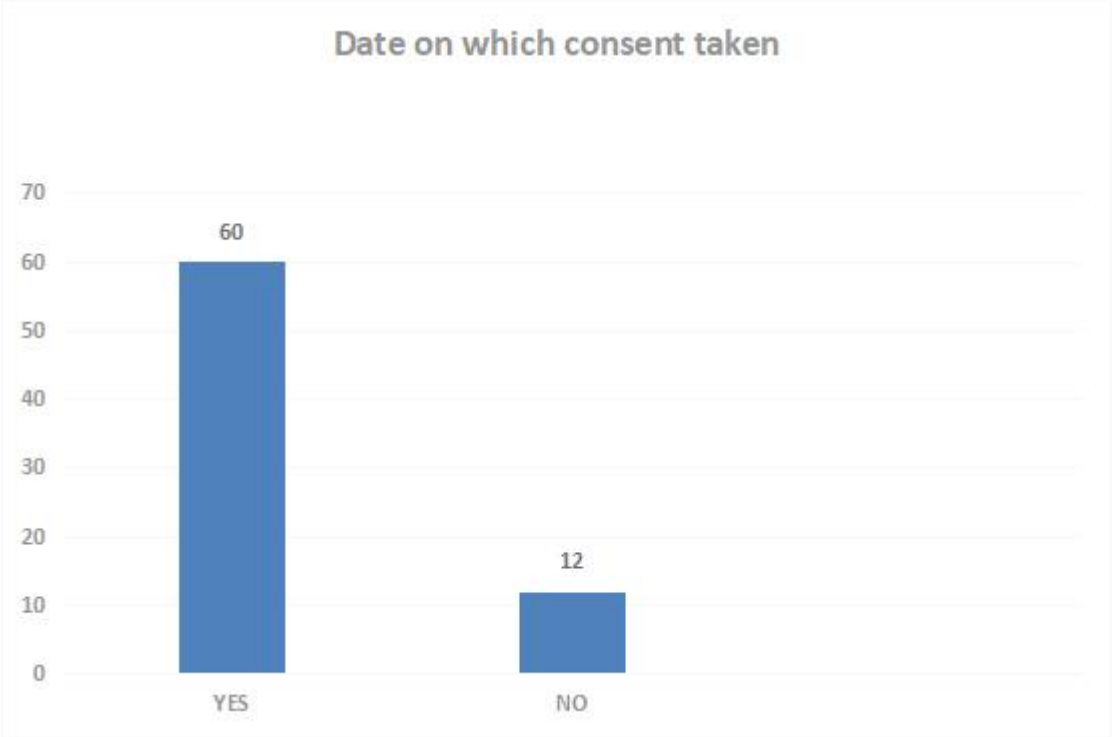

Figure 4 showing date on which the consent taken was mentioned is 60 (83%)

Timing of the Consents (Yes/No)

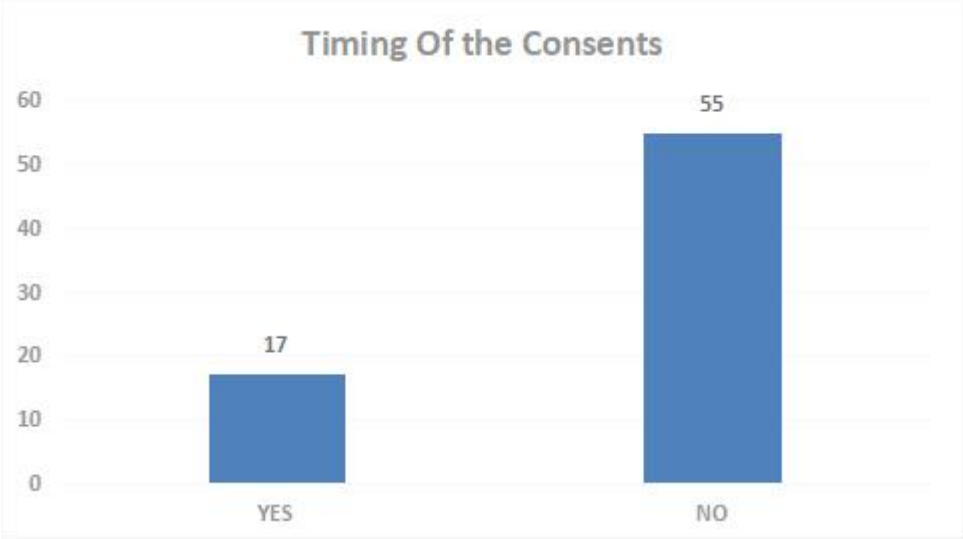

Figure 5:- Showing the timing of the consent was mentioned in 17(23%) of consents.

Signature Taken The Patients

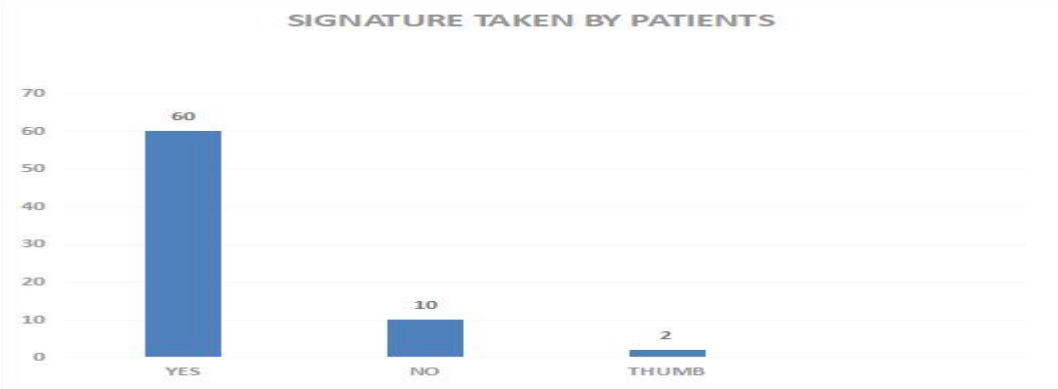

Figure 6:- Showing the decision makers the patients are 60(83%)

Signature taken by the Witnesses(Yes/No)

There was only 1 witness option was mentioned in the consent form.

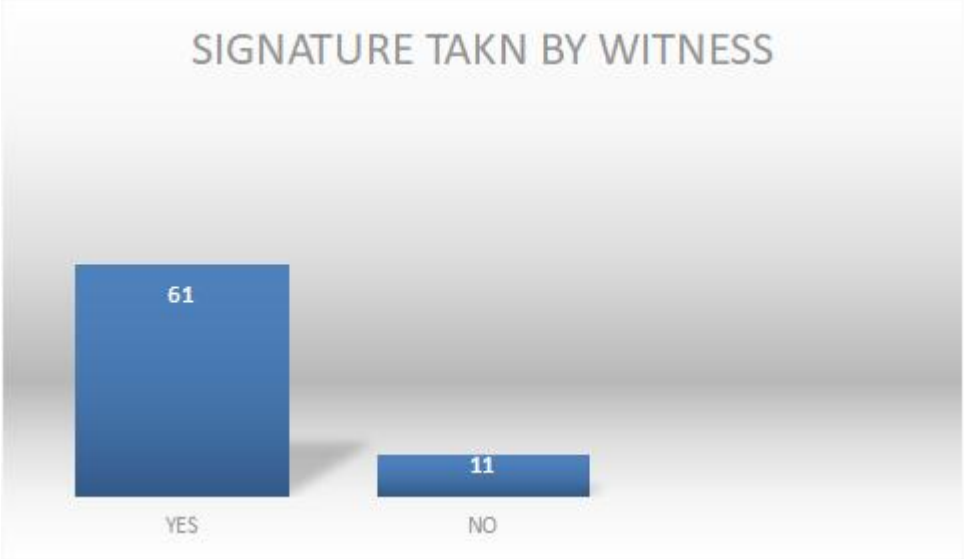

Figure 7:- Showing the decision making witnesses signed the consents are 61(84%)

Decision making witness and their relation with patient:-

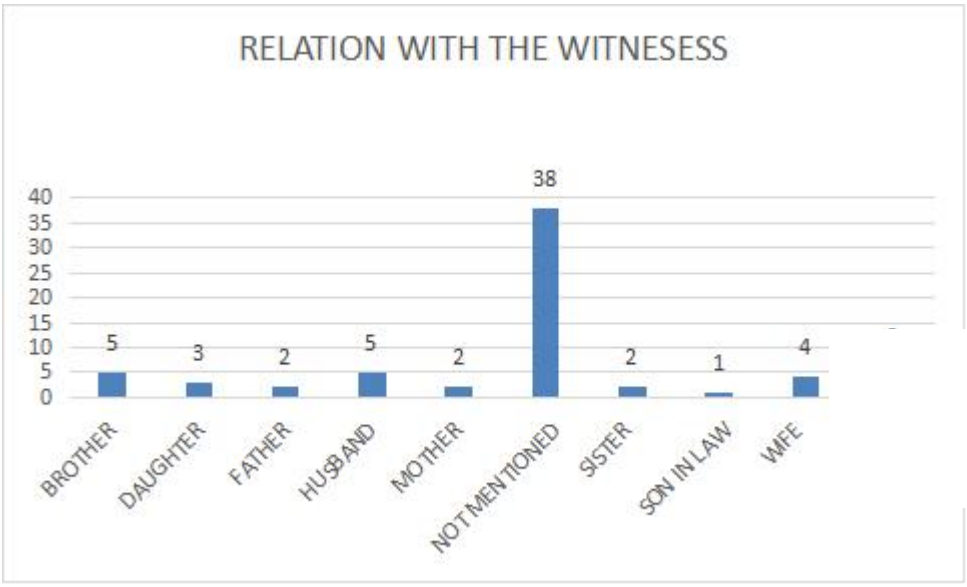

Figure 8:- Showing the more than 35 (48%) people has not mentioned the their relation with the patients and has signed as the witnesses.

Address of the witnesses :-

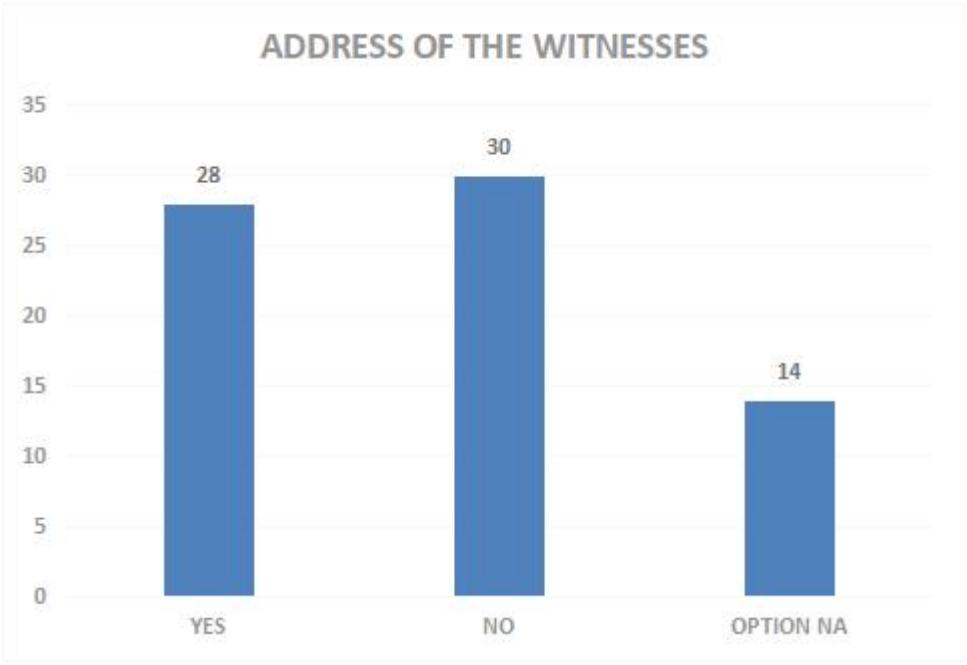

Figure 9 :- Showing address of the witnesses was either incomplete or not mention in the consents is 30(41%)

Proposed Procedure:-

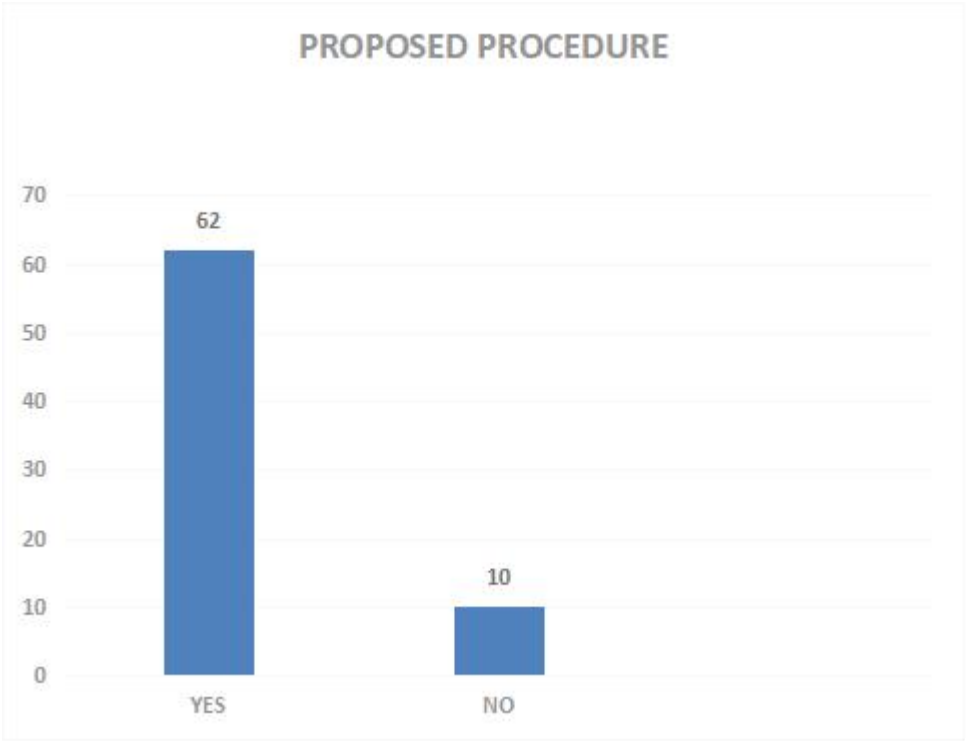

Figure 10:- Showing in 62(86%) of the consents the proposed procedure was mentioned.

Alternative treatment:-

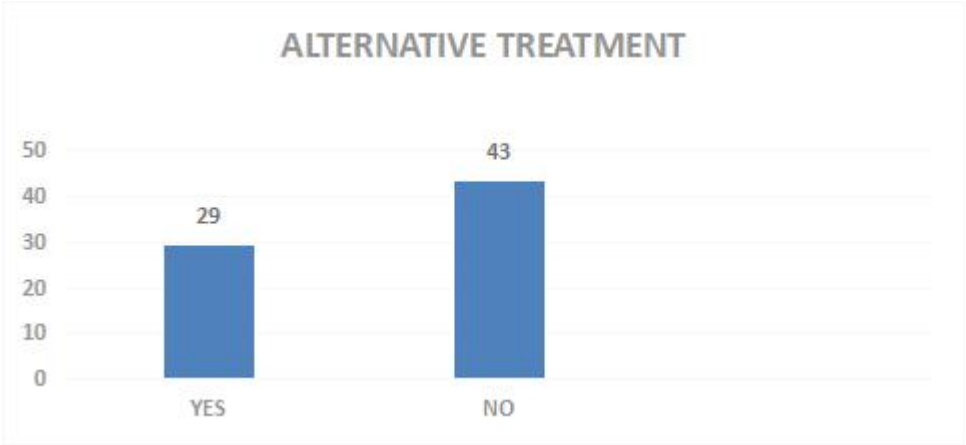

Figure 11:- Showing the alternative treatment was mentioned in the 29(40%) .

Benefits of the Procedure:-

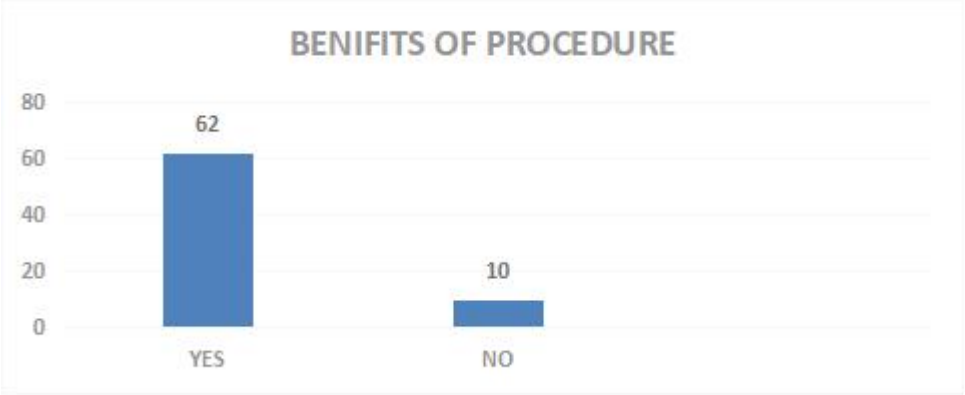

Figure 12:-Showing the benefits of the procedure was mentioned in 62 (86%) consents.

Expected risk:-

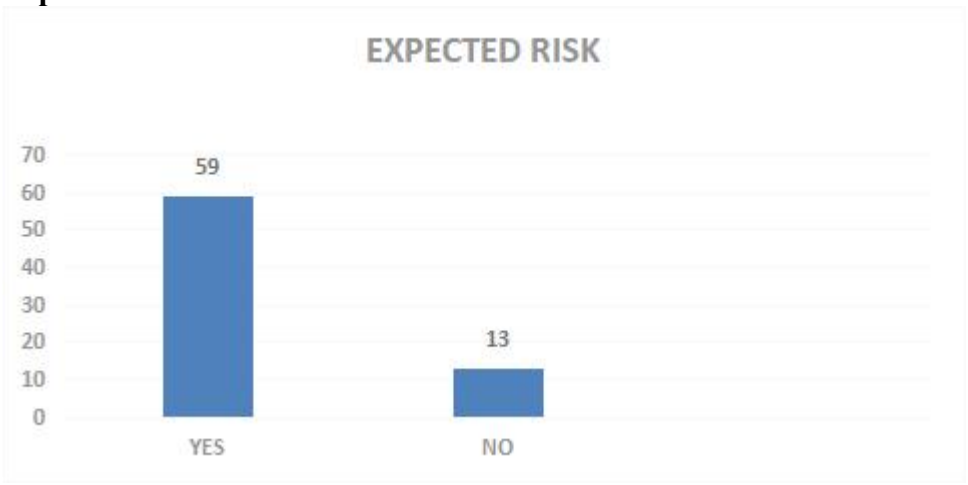

Figure 13:- showing the expected risk was mentioned in 59 (82%) of consents.

Anaesthesia mentioned in the consent

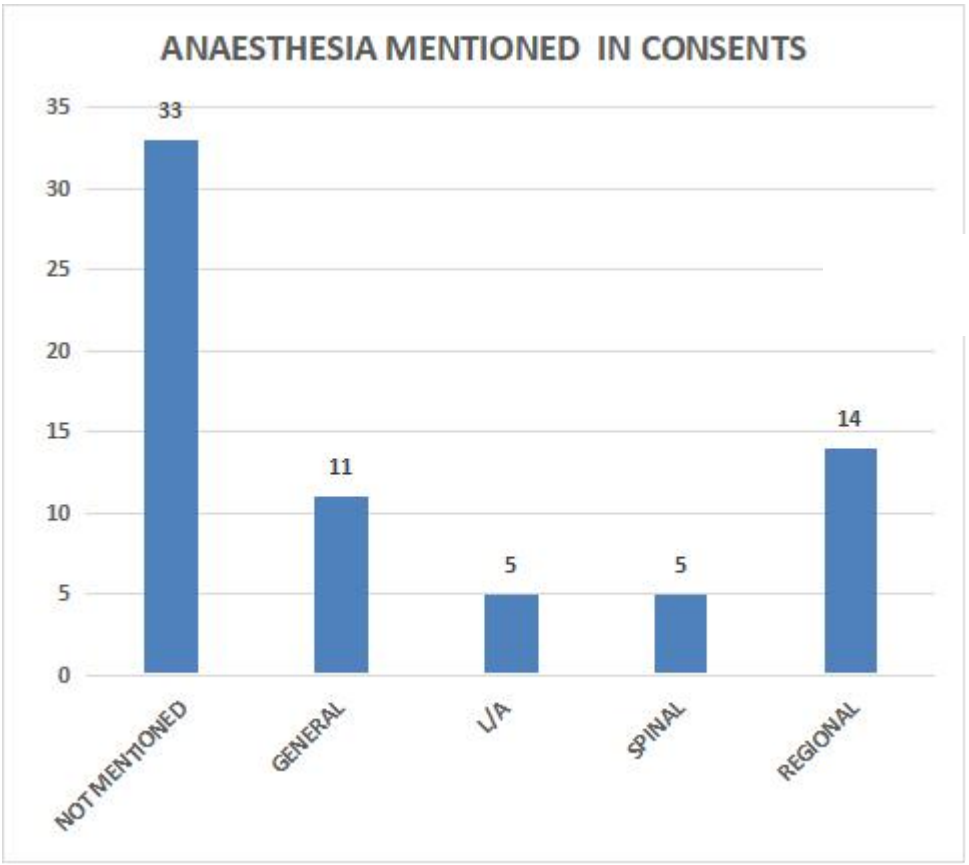

Figure 14:- Showing 14 (19%) was given regional anaesthesia, followed by general anaesthesia 11(15%).

Extra/blank consents signed by staff /Patient found in passive files:-

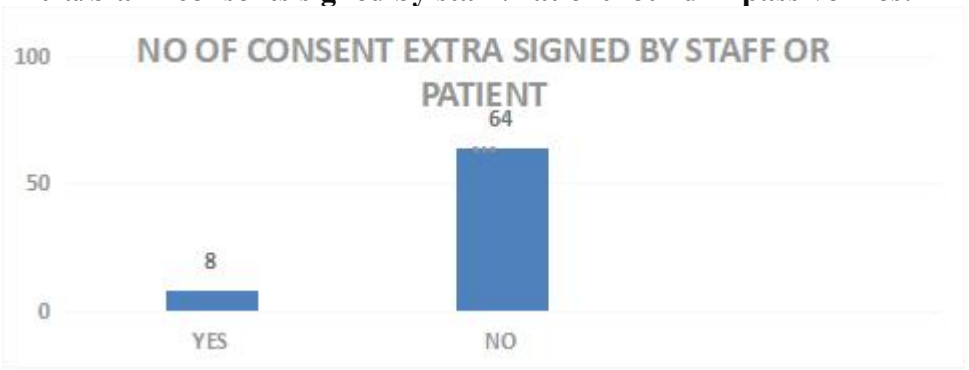

Figure 15:- Showing total 8 consents was extra/blank signed by the patients/ doctors.

Demographics pasted on consent label box:-

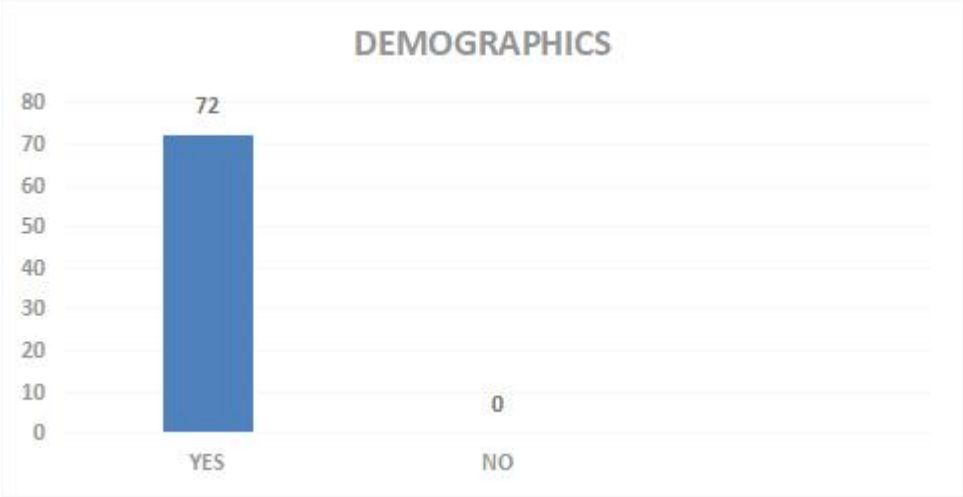

Figure 16:- Demographics was mentioned in all the consents.

General/Specific risk procedure marked in consent 0f gynaecology.

Figure 17:- Showing the general and specific procedure was not marked in the gynaecology and obstetrics consents.

Address of patients:-

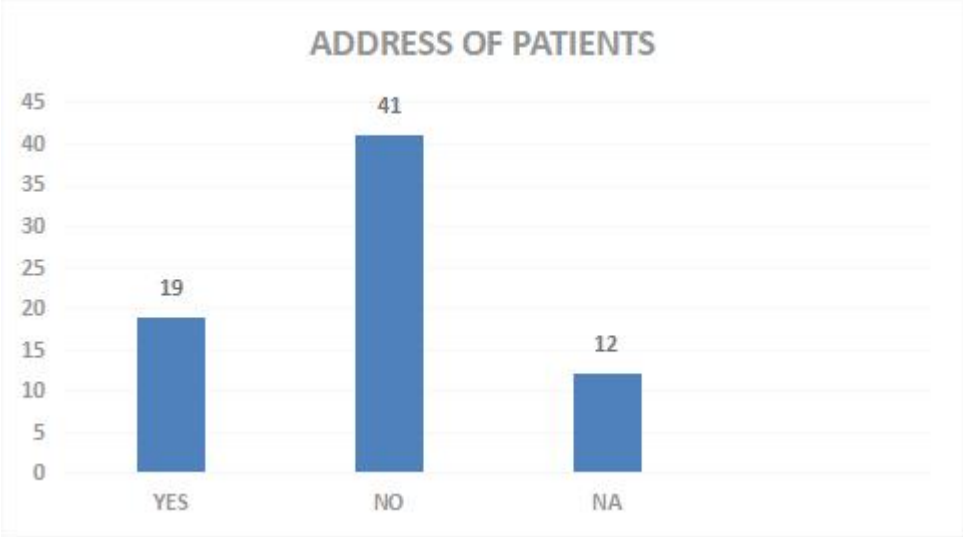

Figure 18:- 41(56%) consents address of the patients was mentioned incomplete or not mentioned. In high risk procedure consents their was no option for address of the patients.

Appropriate language used by the Patients

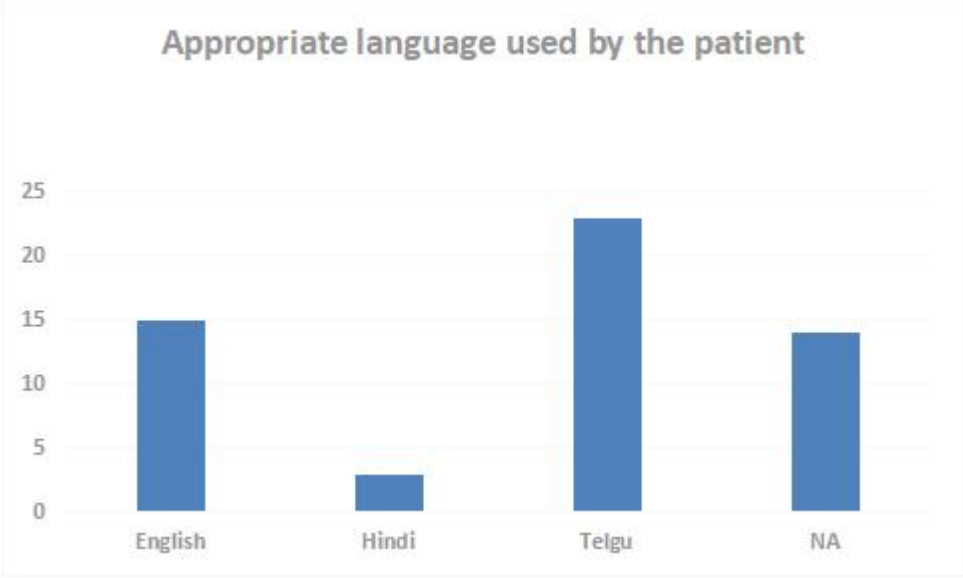

Figure 19:- Language used by the patients to understand all the complication , procedure all the aspects of the consents was Telugu that is more than 20 patients has used the Telugu.

Chapter 7

Observation:-

1. In obstetrics and gynaecology consent it is been observed that in one consent in place of name of attending physician the patient name was written.
2. Name of the procedure was not written in illegible handwriting which is not clearly understood.
3. It was observed that in few passive files more than 1 no. Of incomplete consents were their. For example in few only signature of patient mentioned but not the witness, or procedure , name and other credentials which are necessary was not mentioned only signature of patient was mentioned which goes in to the non compliance. Taking signature by the patient and witness on blank consent is an illegal activity.
4. In English consent the patient name was written in Telugu language which is inappropriate and in place of name thumb impression of patients was taken.
5. If relative of the patient is giving the consent then it is not marked in the consents (self/father/mother etc).
6. In few of the informed consent option for time is not mentioned in some consent it was mentioned which indicates that the old format is been used in the organization.
7. Consent is taken by the patient on the day of surgery this is observed by the day of surgery performed and the day of the consent taken. However the gap between the time of the consent taken and the time of surgery performed can not be clearly mentioned because their is no such proof.
8. Type of anaesthesia given to the patient not mentioned in few of the consents.
9. Demographics not clearly printed.
10. It is been observed that the demographic of the patient was different and name of the patient written in the consent was different.
11. UHID/IP /OP option was not filled in consents
12. Although the language used in the consent was English, Hindi, Telugu. But in High Risk consents for surgery their was no option for mentioning language in the consent. So their was no Telugu language signed by the patient in consent so we can consider in place of NA as English.
13. Incomplete address in the consent is a non compliance so in this study it is mentioned as NO

Points to note in consents.

1. In c-section consents the procedure was clearly explained. But general and special risk procedure is not been marked in any of the consent of gynecology and obstetrics consent.
2. The nature and the procedure purpose, possible alternative methods or treatment risk involved and possible complication was explained to patient was mentioned in few consents only.
3. General risk and specific risk procedure are mentioned in consents of c section but not filled.
4. Their is no option for signature of translator.
5. In informed consents type of anaesthesia mentioned but not in c section consent.

Recommendation to organization:-

1. Kindly write the type of anesthesia in c section consents.
2. Timing of the consent taken must been mention in the consents

3. Patient informed about the surgery date and time should be mentioned.
4. Consent Location should be mentioned in the consent so it will help in analyzing the time between transfer of the patient,
5. Translator option should be mentioned in all the consents.
6. Whether the patient was informed about the duration of procedure should be mentioned.
7. Experience of the procedure performing consultant can be mentioned it will help in branding of the hospital.
8. Thumb impression box should be different for illiterate patients.
9. If the signature or name of the patient is written in local language then it should be written on local language consent.
10. In the column of age, gender should also be mentioned.

Chapter- 8

Results:-

UHID/IP/OP number in the consent was mentioned in 31(43.05%) forms. Date on which consent taken was mentioned on 48 (82.76%), signature taken by the patient was on 59 (81.9%), signature taken by the witness was 61(84.7%), address of the witness was mentioned in 28 (38.9%), proposed procedure was mentioned in 62(86.1%), date of procedure was mentioned 58(80.6%). Assessing the availability of consents forms in passive files, in 68 file consents was available and res 4 missing consents are missing in file. Timing of the consents was available in 17(24%) which is not the acceptable standard. Relation wt h the witness was written in 34(47%) consents. Alternative treatment was written in 27(35.7%), expected risk was mentioned in 59(81.9%), benefits of the procedure was written in 62(86%) consents. Appropriate language used by the patient English 15(20.8%), Hindi 3(4.15), Telugu 19 (26%), no language 31(43%). Surgeries performed under general anaesthesia are11(15.2%), spinal anaesthesia 7(6.9%), local anaesthesia 5(6.9%), regional anesthesia 14(19.4%), no anesthesia was mentioned in 33 (46%). Signature taken by the staff (doctor) are 63 (86%), no of extra incomplete consent signed by the staff are 9 (12.5%). In 6(8.3%) consent was signed by surrogate because the reason was patient was 5 year old children, illiteracy, dementia, patients with illiteracy their thumb impression are been taken on the consents form. Name of the staff mentioned in 53 (73%), address of the patient was mentioned in 19(26%), 59(82%) consents are signed by patient himself.

Limitations of the study:-

1. Patient under gone Foley's cauterization, Ryles tube has given the informed consent is not been consider.
2. Patient gone under transplants surgery are not included in the study.

Discussion :-

The study showed that the quality of post operative consents is not up-to the mark at Care Hospitals. A thorough discussion between the patient and the doctor constitutes informed consent, which goes beyond the patient's simple signature on a consent form. This procedure requires time. However, it's common practise in hospitals to either provide the consent form to the patient for their signature or to give junior doctors this duty. In very few consents time of consents was mentioned, relation of the witnesses was not mentioned in more than 35 consents, anaesthesia was not mentioned in most of the consents. In a research study Saw et al. 54% of patients trust doctors to do the right thing they do not go for the detailed explanation. In this study 10(14%) consent was not signed by the patients. 11(15%) of the consent was not signed by the patients. 30(41%) has incomplete address, 43 (59%) patients no alternative treatment for their surgery. In 14(19%) language used by the patient was not mentioned.

Conclusion:-

The human status of a person determines their rights. In clinical trials, the informed consent is a crucial instrument. The obligations and significance of this assent must be morally righteous and sincere for the benefit of the participant.

In the age of patient autonomy, it is equally crucial to explain the treatment and offer nonsurgical care options as it is to transmit any potential risks. This conclusion might be explained by the fact that surgeons and medical students do not believe patients desire to be informed of their options or specifics when discussing a course of therapy.

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