Summer Internship Project Report

Topic – Consent Form Audit

AT

Fortis Memorial Research Institute Gurugram

(April 4th to June 18th 2022)

Submitted by-

Dr.Shruti Tyagi

Post-graduate Diploma in Hospital and Health Management

2021-2023

International Institute of health Management Research,New Delhi

Certification of Approval

The Summer Internship Project Titled "**CONSENT FORM AUDIT**" at **FORTIS MEMORIAL RESEARCH INSTITUTE, GURUGRAM**, 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 there in but approve the report only for the it is submitted

Dr. Nikita Saberwal

Associate Dean (Training)

Associate Professor (Hospital Administration)

IIHMR-Delhi

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RESEARCH INSTITUTE
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June 17, 2022

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Dr. Shruti Tyagi** has undergone an internship in the **"Department of Medical Administration"** from **April 04, 2022 to June 17, 2022** at **Fortis Memorial Research Institute, Gurgaon.**

During this period, she exhibited a high level of professionalism and a tremendous zest for learning.

We wish **Dr. Shruti Tyagi** all the best in her future endeavors.

With Best Wishes,

Shivani Dhir
SBU Head-Learning & Development

Fortis Hospitals Ltd. Gurgaon

Head of Department
Medical Superintendent
Fortis Memorial Research Institute
Sector - 44, Gurgaon - 122002
Haryana (India)

FEEDBACK FORM

(Organization Supervisor)

Name of the Student: Shruti Jydgi

Summer Internship Institution: Fortis Memorial Research Institute, Gurgaon

Area of Summer Internship: Medical Administration

Attendance: Regular

Objectives met: - Assigned Tasks on OT department, IPD's and OPD

Deliverables: - completed Project Work, Administration tasks

Strengths: - Polite, Punctual, Discipline, focused

Suggestions for Improvement: - More Determination towards goals, Aims and Practice

Signature of the Officer-in-Charge (Internship)

Assistant Medical Superintendent
Fortis Memorial Research Institute
Sector-44, Gurugram-122002, Haryana

Date: - 16-06-22

Place: - Gurugram

Acknowledgement

This year during the summer break I worked as an intern at Fortis Memorial Research Institute. I worked for a duration of 10 weeks from 04/4/2022 to 18/6/2022. I was assigned under Medical Administration Department.

Firstly, I would like to express my indebtedness appreciation to Dr Nikita Sabbarwal for her constant guidance and advice played an important role in making the execution of the report. She always gave me her suggestions that were crucial in making this report as flawless as possible.

I would like to thank Dr Nisha Sharma, At Fortis Memorial Research Institute , Gurugram and to allow in her esteemed organization to access the required data.

Finally, I am very lots thankful to my family who constantly gave me regular support and encouragement. I would really like to thank my seniors who helped me substantially to finish this paper. In addition, I want to thank my friends who additionally inspired and helped me to complete my work.

Place:

Gurugram, Haryana

Pin-122001.

Date

17/06/2022

Name:

Dr. Shruti Tyagi

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FORTIS MEMORIAL RESEARCH INSTITUTE

INTRODUCTION

About The Hospital

One of the top hospitals in Gurgaon is the multi-superspecialty, quaternary care Fortis Memorial Research Institute (FMRI). Fortis Hospital, Gurgaon has dedicated to consistently meeting strict international standards and has undertaken a thorough on-site examination of the quality and safety of the care being given. Fortis Hospital, Gurgaon has solidified its position as one of the top hospitals in Gurgaon by using cutting-edge technology and top clinicians to provide the best possible healthcare. Unmatched in the fields of Neurosciences, Oncology, Renal Sciences, Orthopaedics, Cardiac Sciences, and Obstetrics and Gynecology. One of the biggest healthcare organisations in the nation, Fortis Healthcare, operates the main hospital, Fortis Memorial Research Institute. Currently, Fortis hospitals throughout the nation treat more than 3.5 lakh

patients annually, relying on the pulse of the people we serve, ranging from customised preventive health checks to quaternary care from super specialised clinicians conducting rare and complicated operations It was "patient first" back then, and it still is. Because Fortis will always put you first.

Fortis Memorial Research Institute beat out many other top-notch medical facilities worldwide to be ranked No. 2 among the 30 most technologically advanced hospitals in the world by topmastersinhealthcare.com.

Vision

to serve as the "Mecca of Medicine" for healthcare.

Mission

To deliver quaternary care in a caring, honourable, and distinctive way to the community

AFFILIATIONS AND ACCREDIATIONS

The accreditation of hospital programmes and divisions, in FMRI's opinion, is yet another significant accomplishment that strengthens the institute's position in the healthcare industry and will further its exceptional quality medical services.

The National Accreditation Board for Hospitals & Healthcare Providers (NABH) has granted accreditation to Fortis Memorial Research Institute, which abides by its principles in order to meet patients' requirements and establish standards of excellence for the healthcare sector.

On the other hand, the FMRI blood bank has considerable service delivery in the relevant domain, earning it accreditation from NABH. Additionally, the National Accreditation Board for Testing and Calibration Laboratories (NABL), whose goal is to offer the government, regulators, and industry a programme of laboratory accreditation, has granted us accreditation for our laboratory services.

DRIVE TOWARDS CONTINUOUS IMPROVEMENT

The leadership of FORTIS adheres to the quality cycle of planning, designing, checking, and applying the learning to constantly enhance the services, with the collective understanding that the simplest solutions are frequently the most effective. Every important procedure has been given a set of quality indicators, which are tracked to ensure ongoing quality improvement.

More significantly, there are frequent contacts between management and employees, ensuring that everyone in the organisation shares the commitment to ongoing learning and improvement.

Observational learning

1.1. Introduction:

Fortis Memorial Research Institute (FMRI) is a multi-super-speciality, quaternary care hospital with an enviable international faculty, reputed clinicians, including super-sub-specialists and speciality nurses, supported by cutting edge technology. Set on a spacious 11-acre campus with 1000 beds, this Next Generation Hospital is built on the foundation of Trust and rests on four strong pillars: Talent, Technology, Service and Infrastructure.

- ✓ FORTIS Healthcare Limited: Fortis Healthcare Limited is a leading integrated healthcare delivery service provider in India. In a global study of the 30 most technologically advanced hospitals in the world, its flagship, the FMRI', was ranked No.2, by 'topmastersinhealthcare.com, and placed ahead of many other outstanding medical institutions in the world.
- ✓ Vision: To be the ultimate healthcare destination - "Mecca of Medicine"
- ✓ Mission: To provide quaternary care to the community in a compassionate, dignified, and a distinctive manner
- ✓ Affiliations and Accreditations: FMRI Accredited from NABH and NABL and follow their all policies. Standard by ISO
- ✓ Speciality Clinics: Some specialities are:

  1-Paediatric 2-Oncology 3-Dental 4-Nephrology 5-Pulmonology 6-ENT

  7-Neurology 8- Cardiac 10-Gynae 11-Endocrinology 12-Orthopaedic 13-Eye
- ✓ Milestones: 2013-2014- FMRI was established in year 2008, in year 2013-14 so many memorable things was happening like - 1st Bone Marrow Transplant (BMT) was performed, Multiple surgeries for largest head circumference (Hydrophalus), Little Hearts Programme launched, surgery done for Lumber Spine Disc Prolapse, One of the best Fortis Hospital in India to be certified in Water Birth and Kangaroo care, NABH accreditation for Blood Bank

a) March 2014- 1st TCR alpha-beta depleted Haploidentical BMT was performed- 1st centre in India
b) April 2014- inauguration of new Ultrasound Facility- IU22- best features like 3D and 4D imaging

1.2. Method of data collection:

During the summer training worked in Vaccination, MRD, OPD, IPD, OT, PCS etc. Also worked in Medical file auditing and treasure audit. Learn about discharge process.

1.3. General findings on learning:

- ✓ Vaccination – Vaccination drive was started from May 1st, where Covaxin drive was started first but after the shortage of Covaxin, Covishield was stated. It was started in Meditorium which is located in first floor. Meditorium is an Auditorium where hospitals conferences were held.
  - ➢ Vaccination drive started in hospital for healthy or non-covid patients, in which 2 vaccines are given (1) COVAXIN (1250/-), (2) COVISHIED (850/-). Both vaccination centres are separated, which will help the person to find their vaccination centre and both centres are organized in a same way. There are certain steps for the vaccination:
    - Step 1: Patient early scheduled for vaccine in Aarogya Setu app in CoWIN site, once a scheduled will be done the patient will come into the hospital with their reference ID,
    - Step 2: After that they will go for verification in verification counter
    - Step 3: After verification go for billing, once billing will be done patient have to submit their bill in the certificate to next counter
    - Step 4: After billing patient will go for vaccination and they will receive their receipt and certificate
    - Step 5: After vaccination patient will go to in the observation area in which patient's vitals are check and wait for 30 minutes in the observation area
- ✓ MRD- Medical Record Department

- Located at the basement of the hospital.
- MRD co-ordinate with all hospital departments.
- Mainly filing work.
- There are several filing colours – Blue, Pink, and Green etc.
- All death and discharge summaries are saved in digital way.
- Audit

✓ IPD- Inpatient department

- IPD is basically located in 3rd floor, 4th floor, 5th floor and *Nightingale ward which is located in 1st floor*.
- 5th floor is a suite wards.
- Worked alone with nursing department, floor manager, DEOs and summary file entry operator.

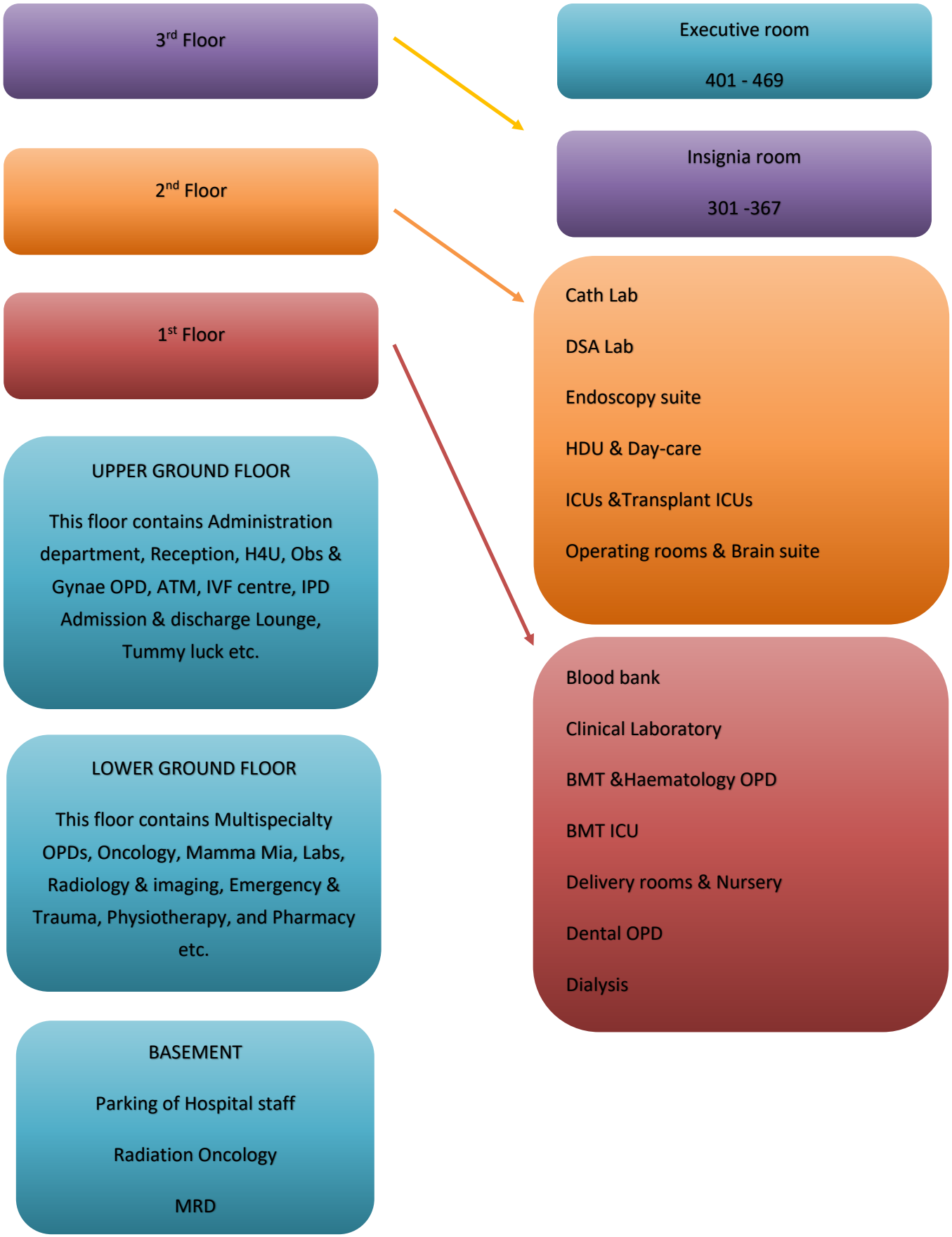
✓ ICU- Intensive Care Unit

- ICU is located in 2nd floor where total 9 ICUs are there.
- During pandemic 3ICUs means 7th, 8th and 9th are Covid ICUs

✓ RRT

- Rapid Responsive Team is very responsive in their work they take action immediately after take any call.
- RRT No. Is 7777
- We call RRT after they receive we say "RRT adult, floor no, Room no and treating Doctor Name" we say it for 3 times. They take immediate action

Floor Structure



Project Report

2.1. Introduction:

Patient consent procedures for medical treatments must be exact and transparent in order to achieve excellence in clinical practice and a high level of healthcare delivery. Patients who are having elective surgery in particular need to be well educated before giving their consent. The importance of the consenting process for doctors is emphasized in the General Medical Council's guidelines, which are titled Consent: Patients and Doctors Making Decisions Together. Almost always, the level of completion of the permission forms has an impact on how well the consenting process works. Additionally, if something goes wrong, physicians and the trust could be held accountable for medical-legal acts due to missing information on consent forms.

Purpose of consent forms

Informed consent has become the standard prototype for safeguarding patient's legal rights and directing the medical practice in an ethical direction. It may be used for different purposes in different contexts: legal, ethical or administrative. Although these purposes overlap, they are not identical, thus leading to different standards and criteria for what constitutes "adequate" informed consent.

Legal: Legally, Consent protects patients against assault in the form of unwanted medical interventions. The higher standard of informed consent further safeguards patients' rights to autonomy, self-determination and inviolability. It is important for the decision maker to understand the relevant information, he or she should also be able to appreciate the information's importance and use it to weigh treatment options in light of their values.

Ethical: It is morally correct to uphold patients' autonomy and their stated objectives. The ethical purpose of informed consent is somewhat more abstract and ideological, seeking to respect patient autonomy by ensuring that treatment is directed toward the ends desired and is chosen by the patient. In this context, informed consent is intended to shift the ethical prototype for decision-making away from physician-centered models to more patient-centered approaches. The ethics literature regarding informed consent also emphasizes that it is not an event, but a process that precedes the "signing" of the document and continues for as long as the choice remains relevant. Thus, the consent to undergo dialysis or continue with chemotherapy is continually re-evaluated (and may change). The consent form should not be confused with the consent process; the form merely documents that the process has occurred. Importantly, other parts of the patient record (e.g., clinic and/or operative notes) should corroborate details of the process.

Administrative: For the sake of compliance, the informed consent document serves the administrative purpose of a systems-level check to ensure that a consent process has occurred.

Patients simply do not advance to the operating room, for example, without a signed consent form. Unfortunately, pressures for efficient workflow may shift the focus of the informed consent process from robust conversation to the mere requirement of getting a signature.

Stakeholders in the informed consent process agree on at least four basic elements for discussions of informed consent: decision makers must have the capacity to make decisions; the doctor must disclose enough details for the decision maker to make an informed choice; decision makers must demonstrate understanding of the information disclosed; and the decision maker must freely authorize the treatment plan.

In present clinical practice, these four factors translate into five components that must be included in the discussion in order to reach agreement: diagnosis, suggested treatment, and risks and benefits associated with the treatment. alternative treatments, their risks and benefits, and the risks and benefits of refusing treatment.

2.2 Aim and objectives: -

2.2.1 Aim: -

The aim of this prospective study was to audit the quality of consent forms in a multidisciplinary 1000 bedded hospital and to suggest measures for improvement of practice.

2.2.2. Objective: -

- This project's goal was to evaluate our consenting procedures and identify the area of improvement.
- To suggest relevant measures for optimal consent taking procedure in order to maintain best practices.

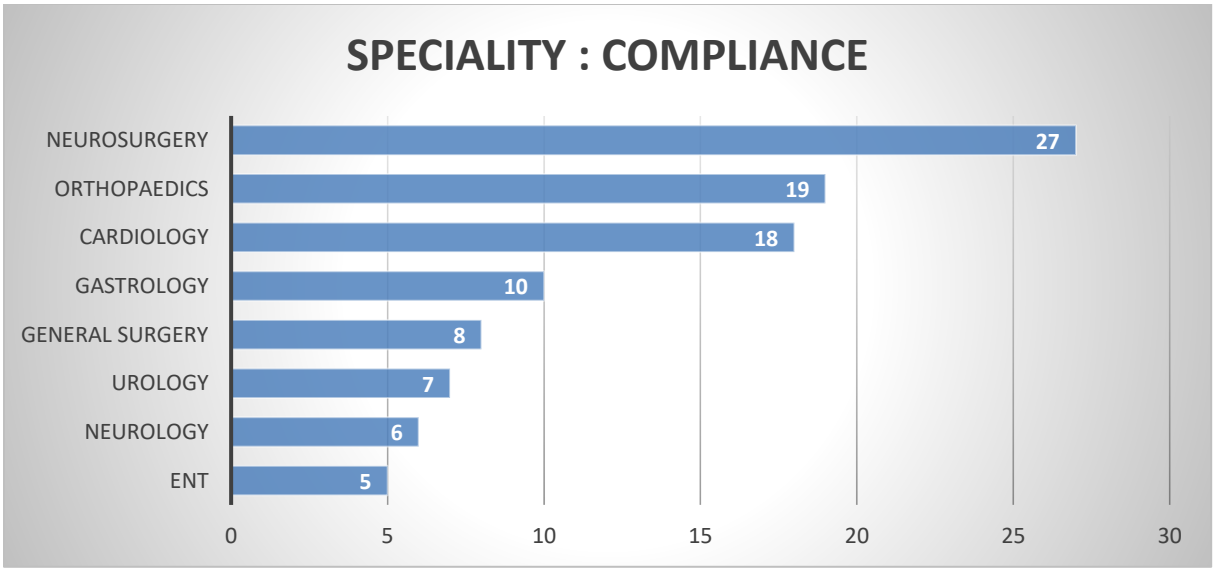
2.3 Methodology: -

- **Type of Study:** Qualitative Study.
- **Study Area:** Main OPD Area
- **Duration of Study: 6 weeks**
- **Type of Data**: Qualitative Data
- **Technique**: Direct observation
- **Sample size**: 200(N=200)
- **Sampling Technique**: Stratified Randomized selection was done.

- **Data Collection:** Primary and secondary.
  Primary data collection was done by auditing the patients' files in various IPDs to look for the completion of different types of consent forms.
  Secondary data was collected through internet by various data sources like PubMed, google scholar for review of literature.
- **The Methods of Ratings**: Here we give ratings to the findings,
  '0' Means the listed parameter is not documented in the form.
  '1' Means the listed parameter is documented in the form.
  '3' Means not applicable.
- **Data Analysis**: Using bar charts in Microsoft Excel

2.4 Data Analysis: -

SPECIALITY	COUNT	%
CARDIOLOGY	247	24
ENT	42	4
GASTROLOGY	121	12
GENERAL SURGERY	46	4
NEUROLOGY	155	15
NEUROSURGERY	220	21
ORTHOPAEDICS	139	13
UROLOGY	70	7

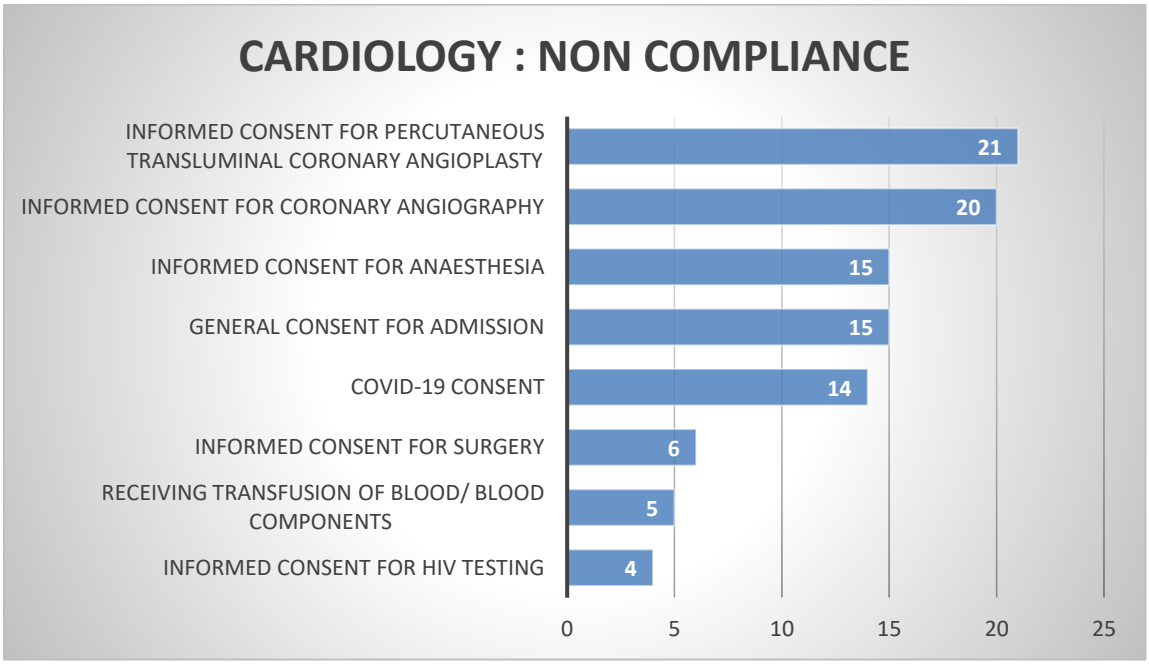


SPECIALITY	COUNT	%
CARDIOLOGY	396	18
ENT	103	5
GASTROLOGY	234	10
GENERAL SURGERY	188	8
NEUROLOGY	130	6
NEUROSURGERY	616	27
ORTHOPAEDICS	420	19
UROLOGY	162	7

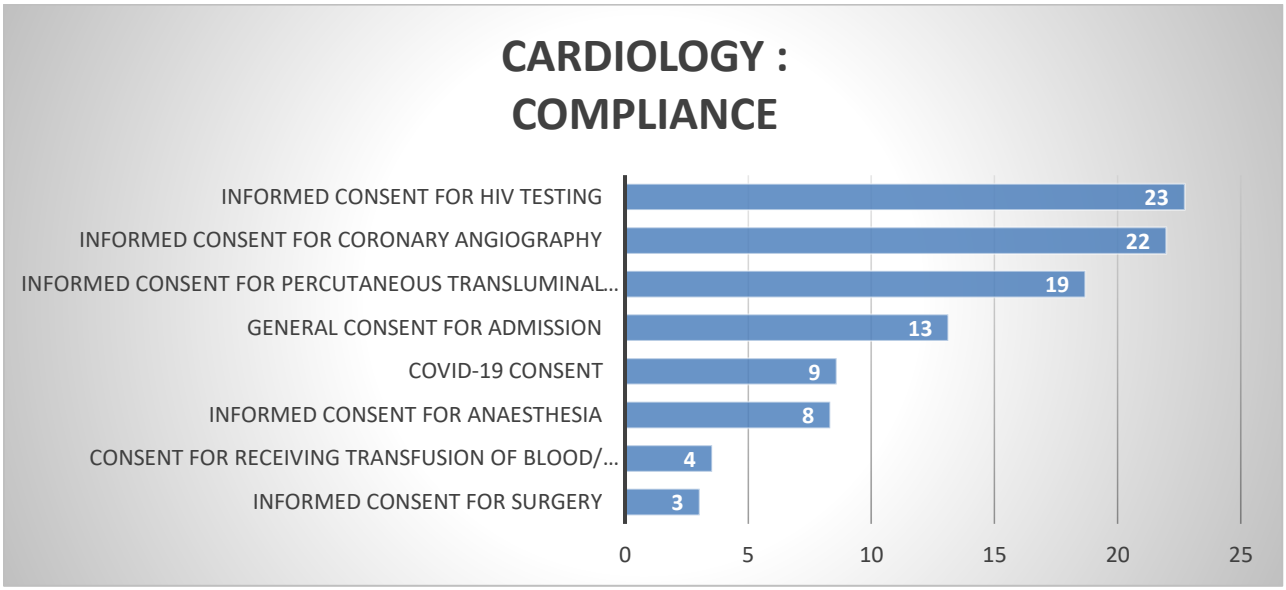
CARDIOLOGY

GRADE	COUNT OF GRADE
0	247
1	396

CARDIOLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Receiving Transfusion of Blood/ Blood Components	12	5
Covid-19 consent	35	14
General Consent for Admission	38	15
Informed Consent for Anaesthesia	36	15
Informed Consent for Coronary Angiography	49	20
Informed consent for HIV Testing	11	4
Informed Consent for Percutaneous Transluminal Coronary Angioplasty	52	21
Informed consent for surgery	14	6



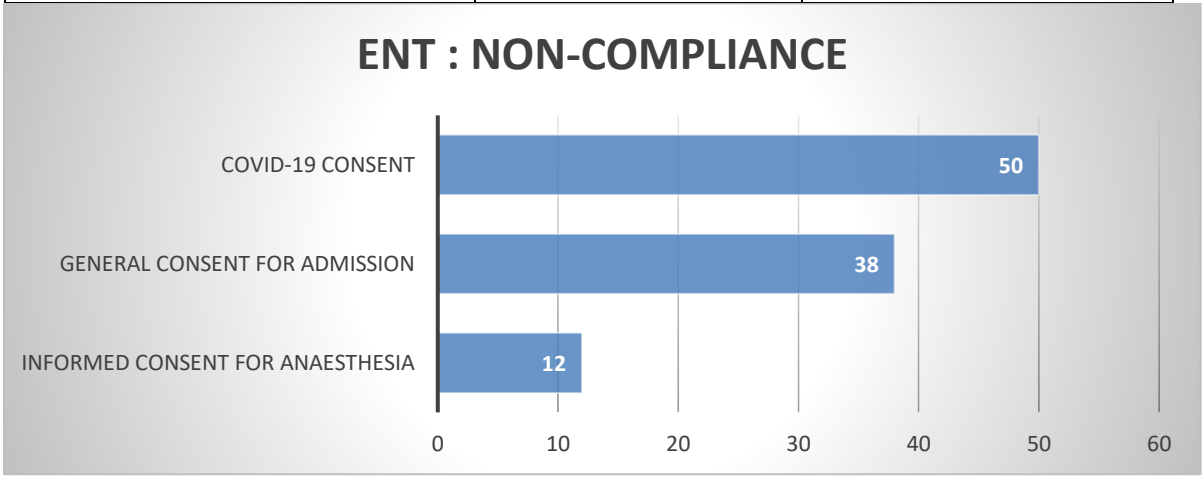
CARDIOLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Informed consent for surgery	12	3
Consent For Receiving Transfusion of Blood/ Blood Components	14	4
Informed Consent for Anaesthesia	33	8
Covid-19 consent	34	9
General Consent for Admission	52	13
Informed Consent for Percutaneous Transluminal Coronary Angioplasty	74	19
Informed Consent for Coronary Angiography	87	22
Informed consent for HIV Testing	90	23



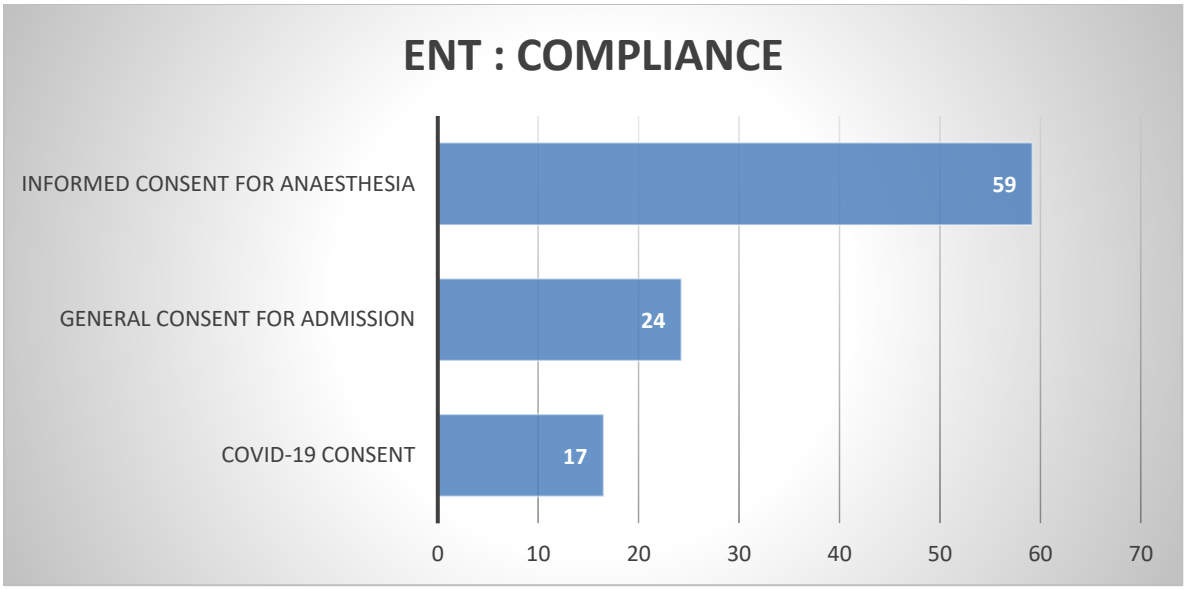
ENT

GRADE	COUNT OF GRADE
0	**42**
1	**103**

ENT CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Covid-19 consent	21	50
General Consent for Admission	16	38
Informed Consent for Anaesthesia	5	12



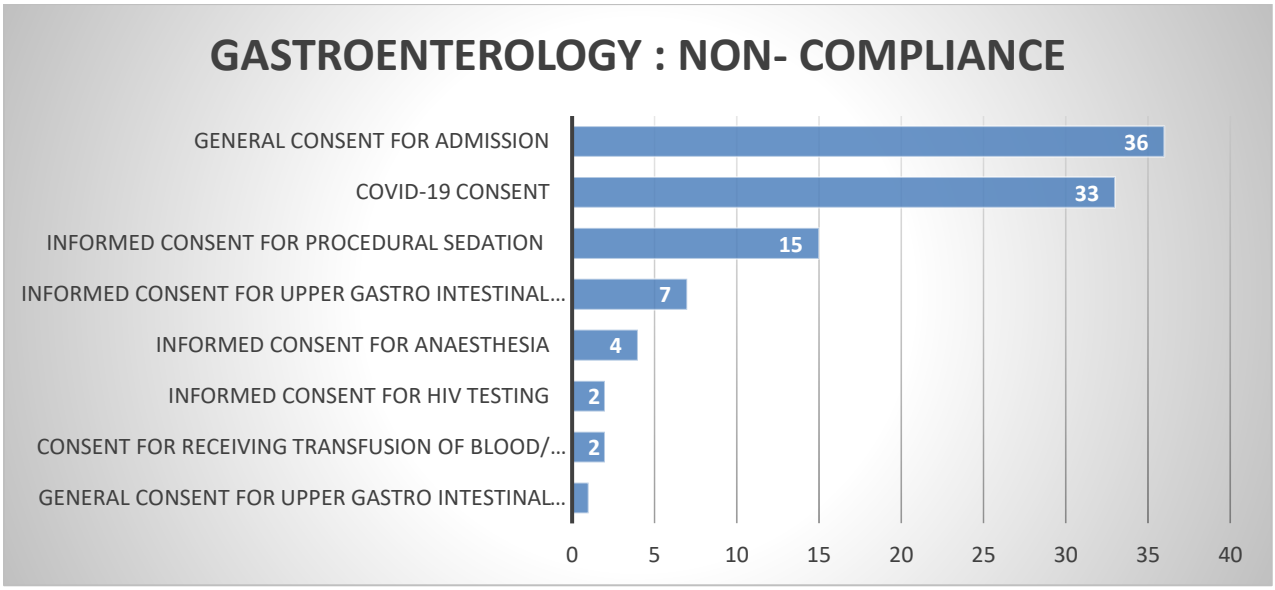
ENT CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Covid-19 consent	17	17
General Consent for Admission	25	24
Informed Consent for Anaesthesia	61	59



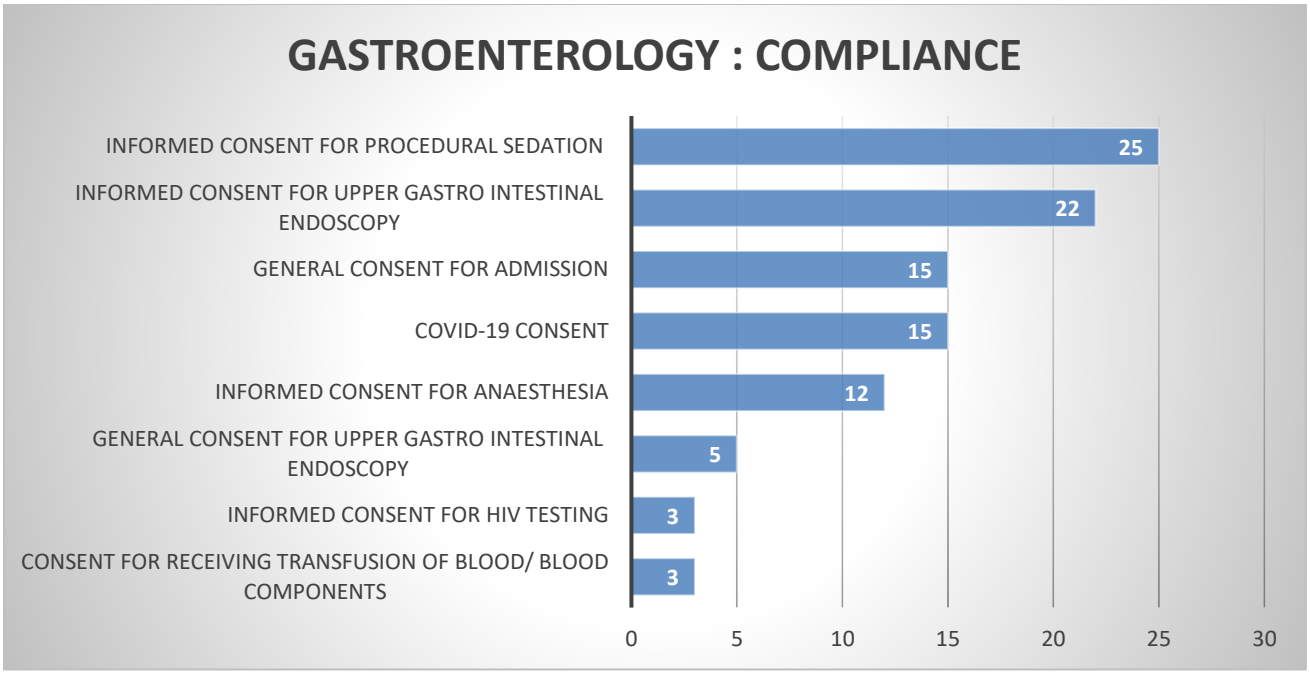
GASTROENTEROLOGY

GRADE	COUNT OF GRADE
0	121
1	234

GASTROENTEROLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	3	2
Covid-19 consent	40	33
General Consent for Admission	43	36
General Consent for Upper Gastro Intestinal Endoscopy	1	1
Informed Consent for Anaesthesia	5	4
Informed consent for HIV Testing	2	2
Informed Consent for Procedural Sedation	18	15
Informed Consent for Upper Gastro Intestinal Endoscopy	9	7



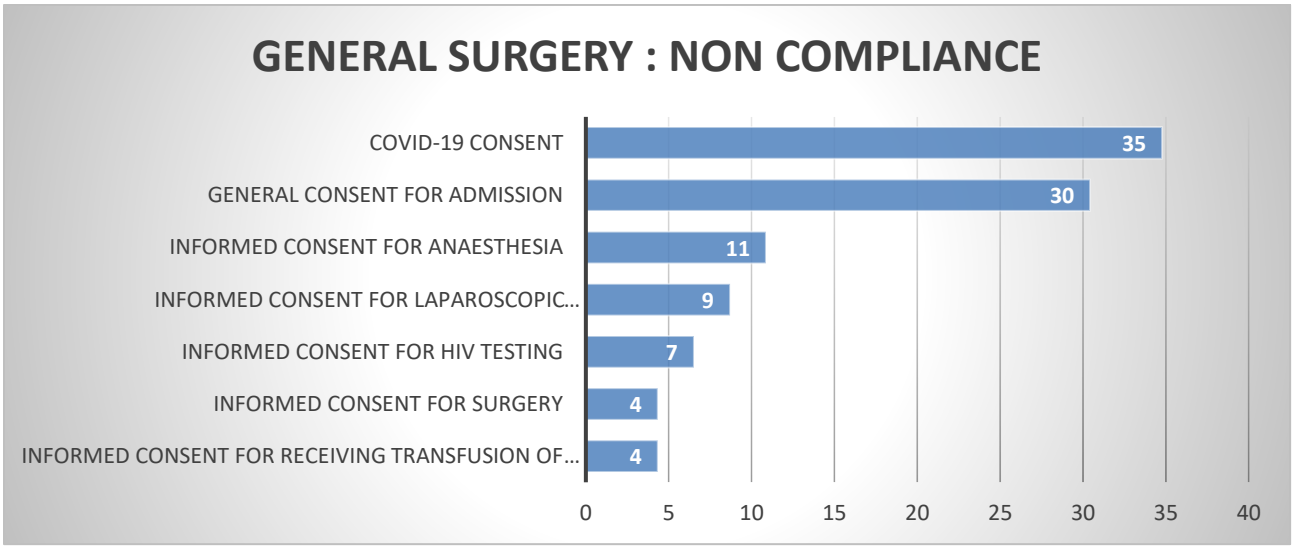
GASTROENTEROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	8	3
Covid-19 consent	36	15
General Consent for Admission	35	15
General Consent for Upper Gastro Intestinal Endoscopy	12	5
Informed Consent for Anaesthesia	28	12
Informed consent for HIV Testing	7	3
Informed Consent for Procedural Sedation	58	25
Informed Consent for Upper Gastro Intestinal Endoscopy	51	22



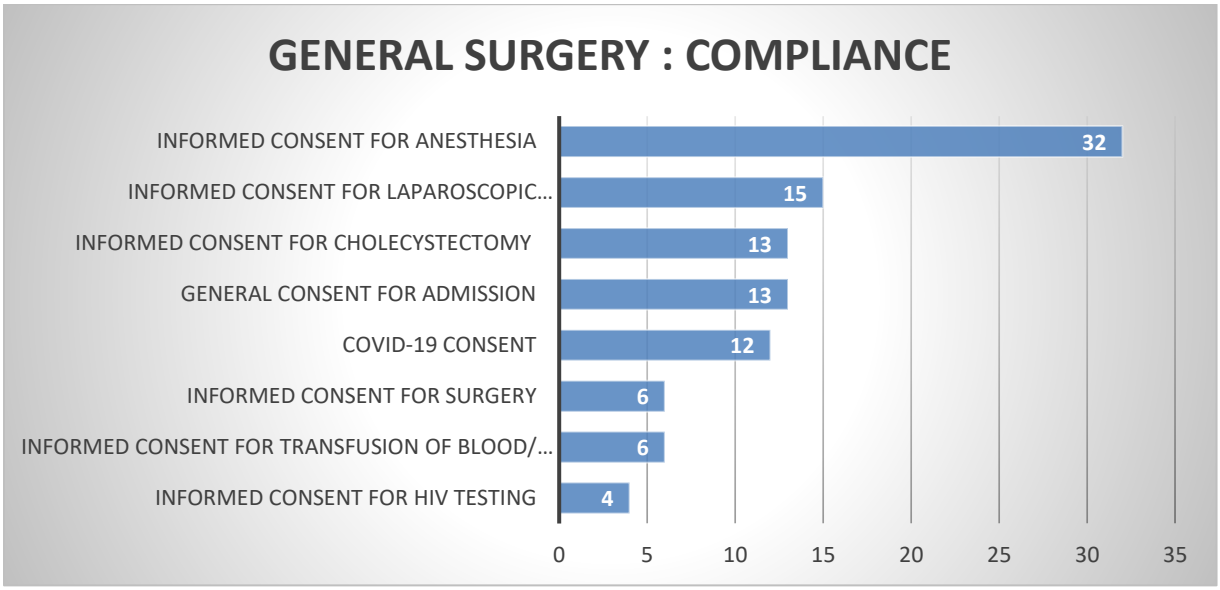
GENERAL SURGERY

GRADE	COUNT OF GRADE
0	46
1	188

GENERAL SURGERY CONSENT FORMS	0	1
Covid-19 consent	16	22
General Consent for Admission	14	24
Informed Consent for Anaesthesia	5	60
Informed Consent for Cholecystectomy	0	24
Informed consent for HIV Testing	3	7
Informed Consent for Laparoscopic Cholecystectomy	4	29
Informed Consent for Receiving Transfusion Of Blood/ Blood Components	2	11
Informed consent for surgery	2	11



GENERAL SURGERY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Covid-19 consent	22	12
General Consent for Admission	24	13
Informed Consent for Anesthesia	60	32
Informed Consent For Cholecystectomy	24	13
Informed consent for HIV Testing	7	4
Informed Consent For Laparoscopic Cholecystectomy	29	15
Informed Consent For Transfusion Of Blood/ Blood Components	11	6
Informed consent for surgery	11	6

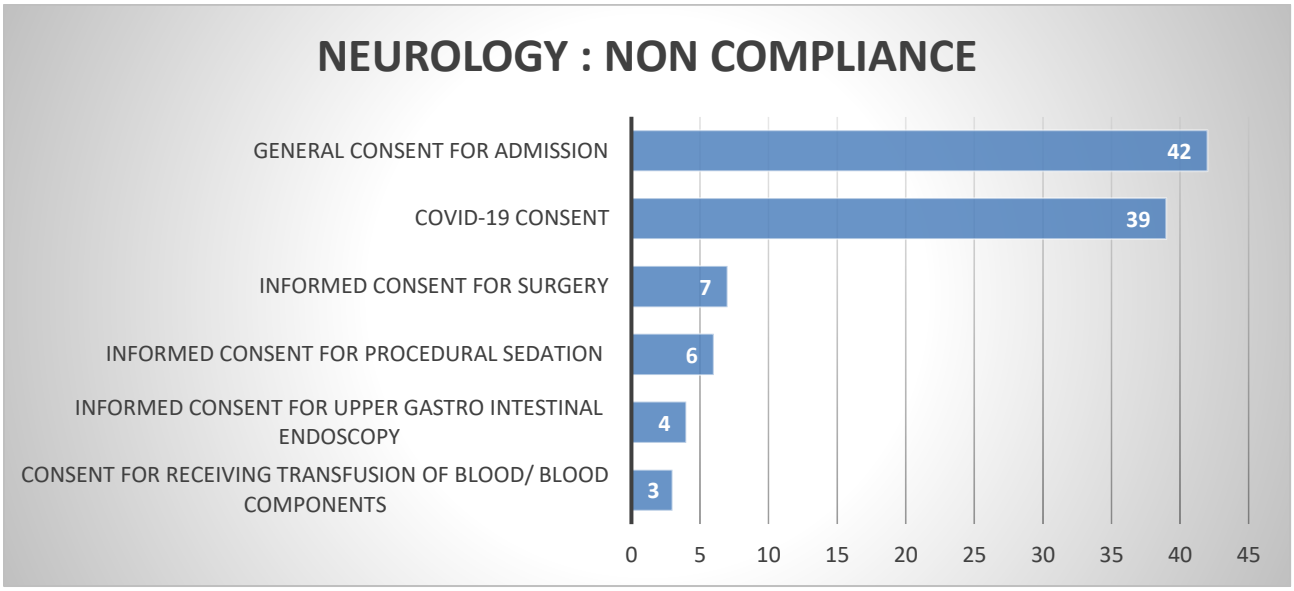


NEUROLOGY

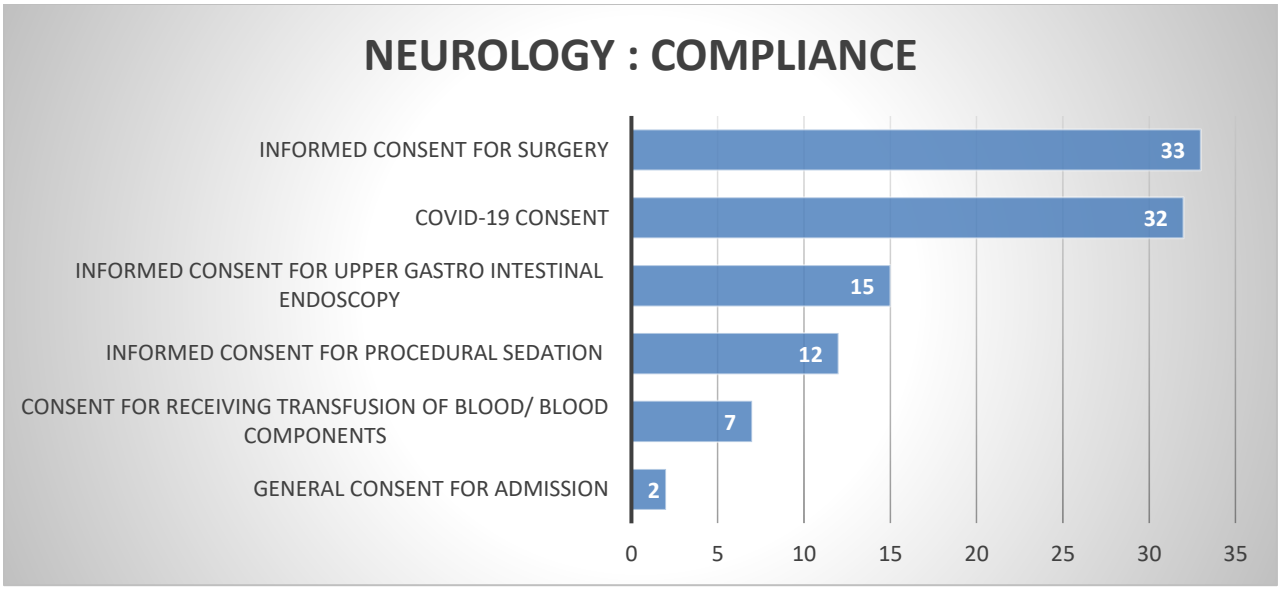
GRADE	COUNT OF GRADE
0	155
1	130

NEUROLOGY CONSENT FORMS	NON COMPLAINCE	NON COMPLAINCE%
Consent For Receiving Transfusion of Blood/ Blood Components	4	3
Covid-19 consent	60	39

General Consent for Admission	65	42
Informed Consent for Procedural Sedation	9	6
Informed consent for surgery	11	7
Informed Consent for Upper Gastro Intestinal Endoscopy	6	4



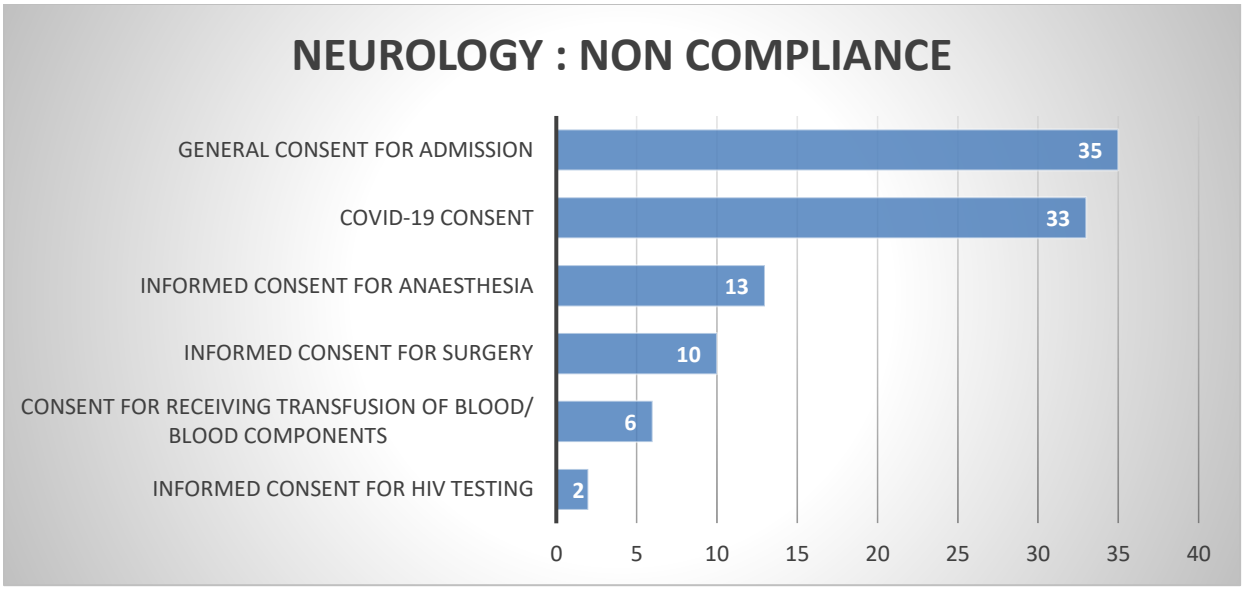
NEUROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	9	7
Covid-19 consent	41	32
Informed Consent for Surgery	43	33
Informed Consent for Procedural Sedation	15	12
General consent for Admission	3	2
Informed Consent for Upper Gastro Intestinal Endoscopy	19	15



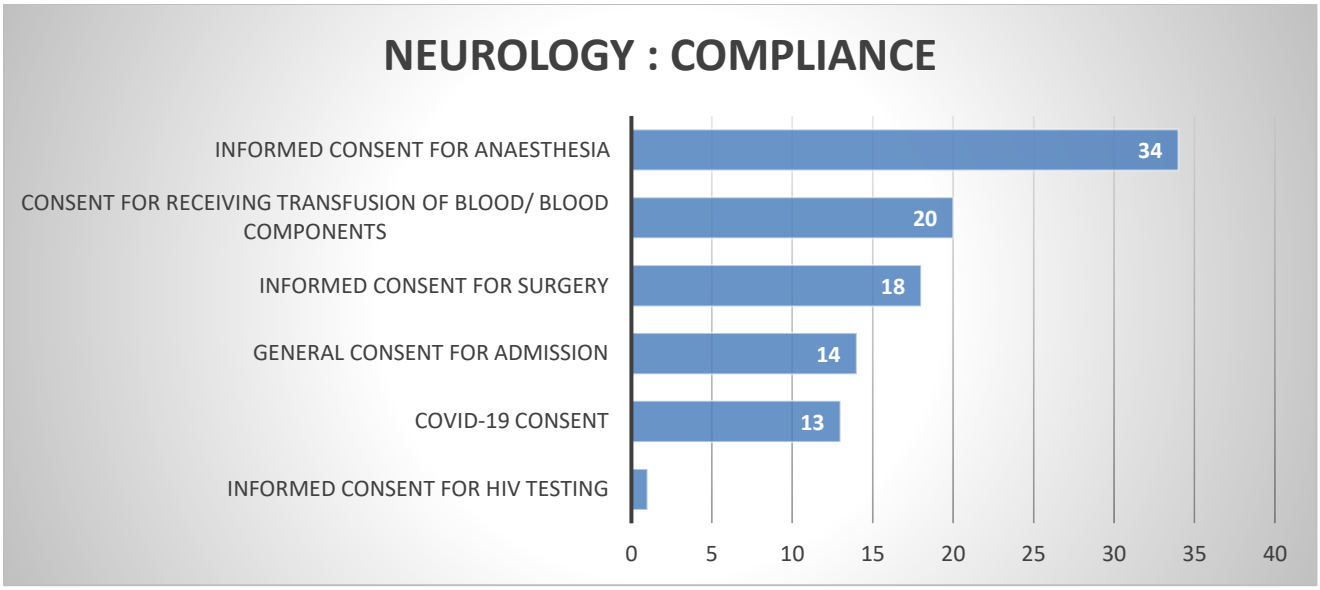
NEUROSURGERY

GRADE	COUNT OF GRADE
0	220
1	616

NEUROLOGY CONSENT FORMS	NON COMPLIANCE	NON COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	14	6
Covid-19 consent	72	33
General Consent for Admission	78	35
Informed Consent for Anaesthesia	29	13
Informed consent for HIV Testing	4	2
Informed consent for surgery	23	10



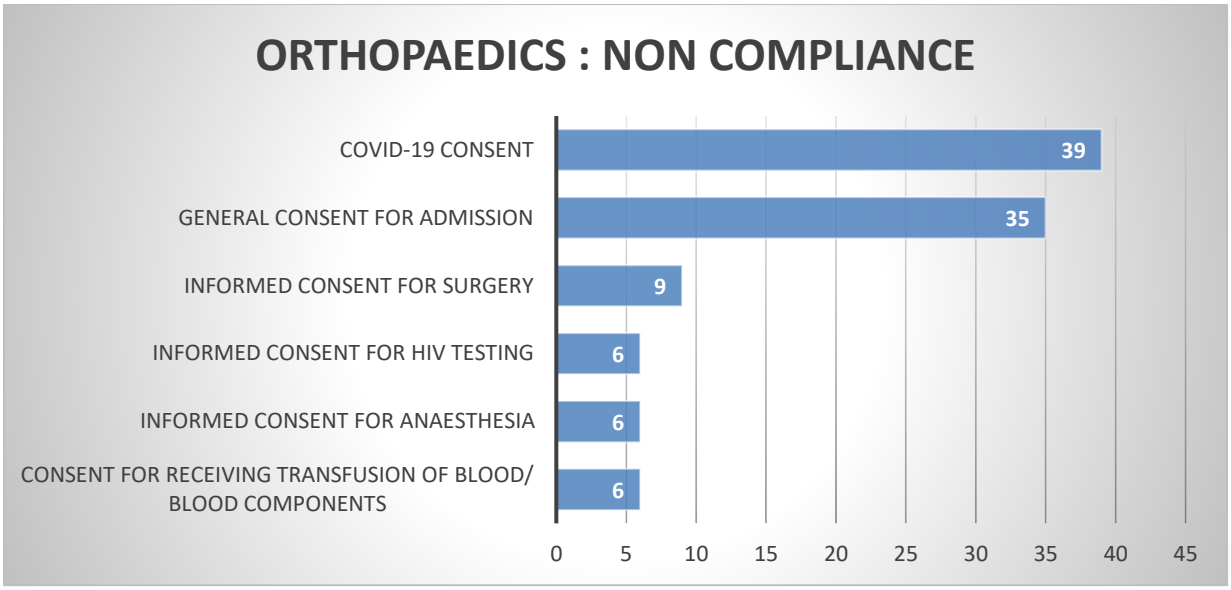
NEUROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	122	20
Covid-19 consent	79	13
General Consent for Admission	88	14
Informed Consent for Anaesthesia	209	34
Informed consent for HIV Testing	5	1
Informed consent for surgery	113	18



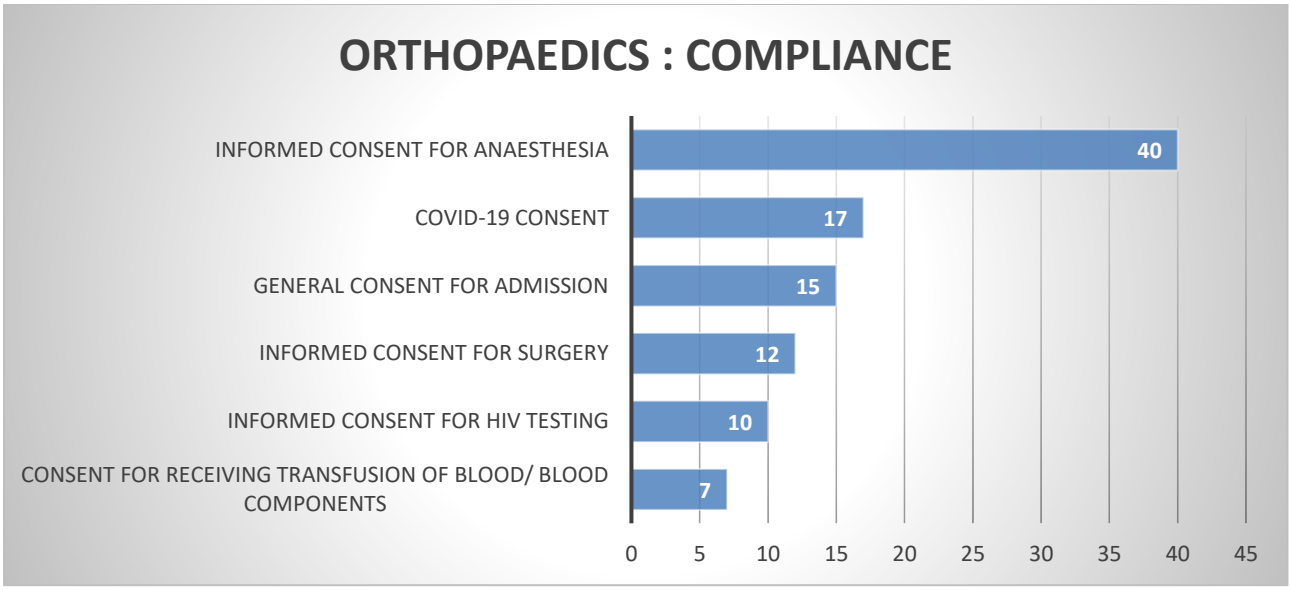
ORTHOPAEDICS

GRADE	COUNT OF GRADE
0	139
1	420

ORTHO CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	8	6
Covid-19 consent	54	39
General Consent for Admission	48	35
Informed Consent for Anaesthesia	8	6
Informed consent for HIV Testing	9	6
Informed consent for surgery	12	9



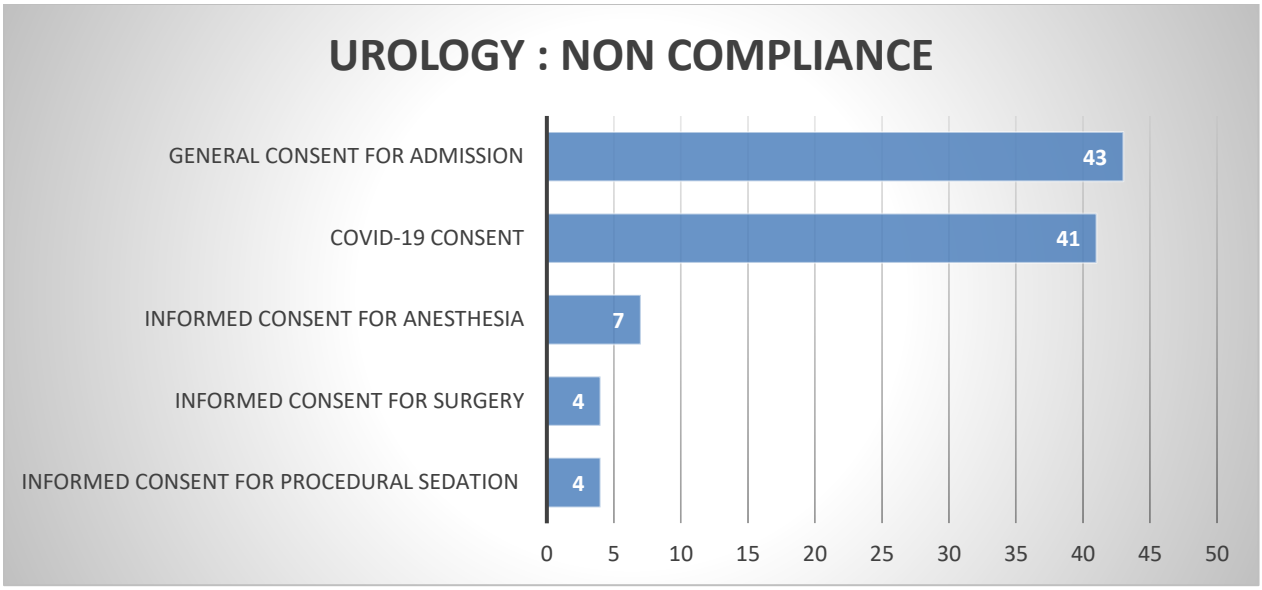
ORTHO CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	29	7
Covid-19 consent	70	17
General Consent for Admission	61	15
Informed Consent for Anaesthesia	168	40
Informed consent for HIV Testing	42	10
Informed consent for surgery	50	12



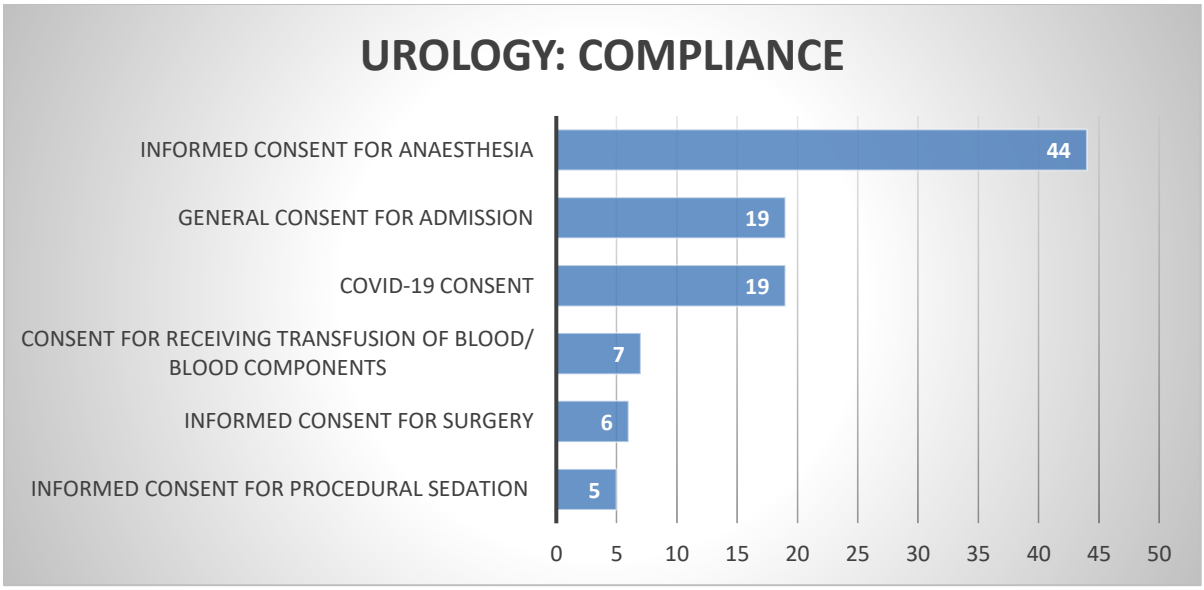
UROLOGY

GRADE	COUNT OF GRADE
0	70
1	162

UROLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Covid-19 consent	29	41
General Consent for Admission	30	43
Informed Consent for Anaesthesia	5	7
Informed Consent for Procedural Sedation	3	4
Informed consent for surgery	3	4



UROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	12	7
Covid-19 consent	30	19
General Consent for Admission	31	19
Informed Consent for Anaesthesia	72	44
Informed Consent For Procedural Sedation	8	5
Informed consent for surgery	9	6



2.4 Data Interpretation: -

Out of 200 files studied, maximum parameters listed in the form i.e., Compliance was seen in Neurosurgery specialty followed by orthopedics and cardiology.

- Out of 14 samples in cardiology, non-compliance was seen in 247 parameters of consent form and compliance was seen in 396 parameters of consent forms. Noncompliance was highest seen in Informed Consent for Percutaneous Transluminal Coronary Angioplasty and compliance was seen highest in Informed consent for HIV Testing.
- Out of 7 samples in ENT, noncompliance was seen in 42 parameters of consent forms and compliance was seen in 103 parameters of consent forms. Noncompliance was seen highest in Covid 19 Consent and compliance was seen highest in Informed consent for Anesthesia
- Out of 12 samples of Gastro-enterology, non-compliance was seen in121 parameters of consent forms and compliance was seen in 234 parameters of consent forms. Noncompliance was seen highest in General consent for Admission whereas compliance was seen highest in Informed consent for Procedural Sedation.
- Out of 6 samples of General surgery, non-compliance was seen in 46 parameters of consent forms and compliance was seen in 188 parameters. Noncompliance was seen highest in Covid 19 consent and compliance was seen highest in Informed Consent for Anesthesia
- Out of 16 samples in Neurology, non-compliance was seen in 155 parameters of consent forms and compliance was seen in 130 parameters. Noncompliance was seen highest in General consent for Admission whereas compliance was seen highest in Informed consent for Surgery.

- Out of 23 samples of Neurosurgery, non-compliance was seen in 220 parameters of consent forms whereas compliance was seen in 616 parameters. Noncompliance was highest seen in General Consent for Admission and compliance was seen highest in Informed consent for Anesthesia
- Out of 18 samples of Orthopedics, non-compliance was seen in139 parameters of consent forms and compliance was seen in 420 parameters. Noncompliance was seen highest in Covid 19 Consent and compliance was seen highest in Informed consent for anesthesia
- Out of 9 samples of Urology, noncompliance was realized in 70 parameters of consent forms and compliance was seen in 162 parameters. Noncompliance was seen highest in General consent for admission and compliance was seen highest in Informed Consent for anesthesia.

2.5 Discussion & Conclusion: -

Although the historical evidence is somewhat ambiguous, informed consent in the sense in which it is understood and practiced today appears to be a relatively recent arrival in medical ethics. Consent has been an important area of clinical surgery since the early 20th century, with shift in attitude of clinical practice from an authoritative role of the physician or surgeon to a patient centred approach.

The "reference guide to consent" published by the department of health, stated that although not a legal requirement, the completion of consent forms is good practice where an intervention is to be undertaken.

The NABH guidance regarding consent states that the task of seeking consent is the responsibility of the doctor providing treatment. This responsibility may be delegated to someone else, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved.

Audiotape analysis showed that consent information provided to patients through verbal discussion is often deficient. It has been reported that patient recall of the information at the consent interview is generally poor. The NABH guidance also states that information discussed with the patient and any written information given as well as details of any decisions must be recorded in the patient's medical records or a consent form.

However, there remain concerns regarding the quality of documentation of the consent process.

The aim of this study was to assess the documentation of the consent process FMRI, Gurugram undertaking a wide range of invasive procedures in different surgical specialities. In our study,

we assumed that patients had a copy of the consent form if the "patient's copy" was not found in the medical records. Although the medical records were randomly selected, we believe that this study represents the current practice.

Initially only 20-25% of consent forms completely met NABH guidelines. This demonstrates an alarmingly poor adherence to such guidance that plays a vital role in patient safety, patient ethics autonomy, not to mention potential medico-legal and clinical governance implications for surgical practice.

Our intervention has improved the quality of consenting within our hospital according to these guidelines. With these interventions set to continue and further develop, we expect that the quality of the consenting process will continue to provide patients with all that it is designed to.

The results of this study led to several changes being made within the trust. We have developed a presentation to be given to all new doctors starting at the trust with the intention of giving appropriate training on the process of consenting of patients and how related documentation should be completed. We have also increased the availability of patient information leaflets on common procedures, by placing them in clinics and wards. Staff awareness regarding importance of securely filing consent forms and the process of confirming consent in those patients consented in advance was increased.

To determine whether these interventions improved our adherence to consenting guidelines we completed a re-audit exercise. This involved the random selection of adult patient medical records who were undergoing procedures at our hospital. We examined the notes in the same way making note of whether the NABH guidelines for consenting were adhered to.

2.6 Recommendation: -

- **PROCEDURE SPECIFIC STICKERS:** Using procedure-specific stickers in surgical and medical departments that employ consent forms that require handwritten inputs is straightforward and may be easily generalised. This implementation ought to be long-lasting given how simple and satisfying it is to use.
- Printed leaflets and fact sheets: Additionally educating patients about the clinical trial may also help them grasp it better.
- Audio-visual presentation: It has been shown that audio-visual methods are effective at communicating informed consent information. With the use of this instrument, textual knowledge can be immediately spoken reinforced, facilitating efficient comprehension and retention.
- Extended discussions about informed consent: Encouraging extended discussions between the patient, attendant, and medical team for greater understanding and information retention is another strategic method to improving the informed consent process. These protracted conversations can

2.7 References: -

1. Panos A Dimitriadis, Stavros Constantinou: Audit of the quality of consent form completion and improvement of practice September 2012,
2. https://www.researchgate.net/publication/267423443_Audit_of_the_quality_of_consent_form_completion_and_improvement_of_practice
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5. Jones MA. Medical Negligence. 4th ed. Sweet & Maxwell, London: Indian Reprint 2010; 2008. p. 548.
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2.8 Annexure

Sr.No	Name of department	Page no.
Annexure 1	**Detail of reasons for cancellations of surgeries in OT (Additional learning)**	**36**
Annnexure 2	**Consent Form Layouts**	**51**

REASONS FOR CANCELLATION AND DELAY FOR SURGERY IN OT

2.2.Aim :

The aim of this prospective study was to analyse the causes of cancellation and delays of elective procedures in a multidisciplinary 1000 bedded hospital and to suggest measures for optimal utilization of OR time.

2.3.Rationale :

The report is designed to deliberate the delays and cancellation of scheduled elective operations in Fortis Memorial Research Institute, Gurugram as main the goal is to provide best patient satisfaction. Elective operations on scheduled time can lead to significant utilization of OR time and would lead to efficient of resources for both hospital and patient

2.4.Objective :

- General Objective –Reasons for delay and cancellation of scheduled surgeries in Fortis Memorial Research Institute, Gurugram
- Specific Objective –

1. To find the number of OT cancellations and reasons attributing to it.
2. To suggest relevant measures for optimal utilization of preoperative room, operation theatre time, and reducing surgery cancellation rates.

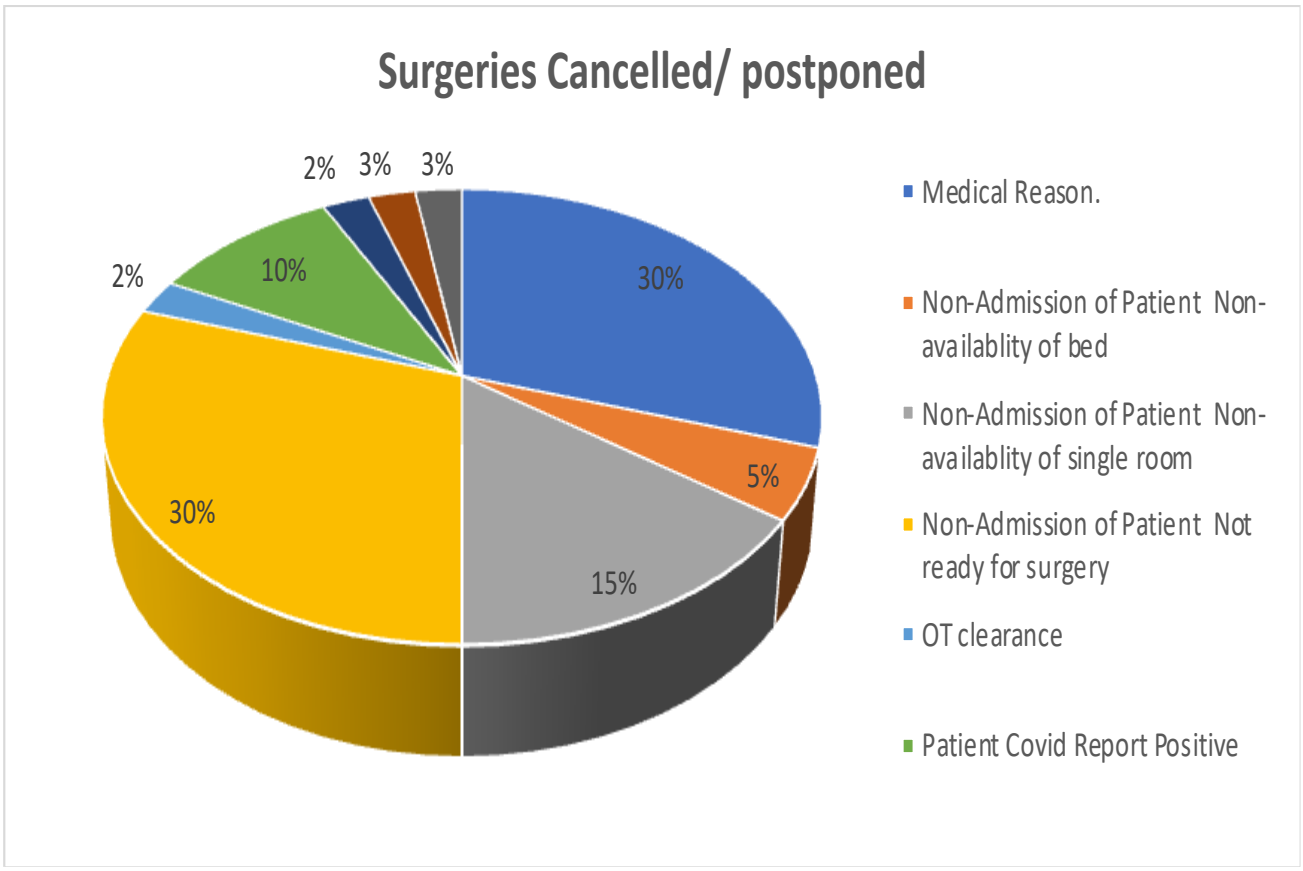
2.5. Research Methodology :

- Type of study : A Quantitative, observational study
- Study area : Main Operation Theatre with significant Operation Rooms

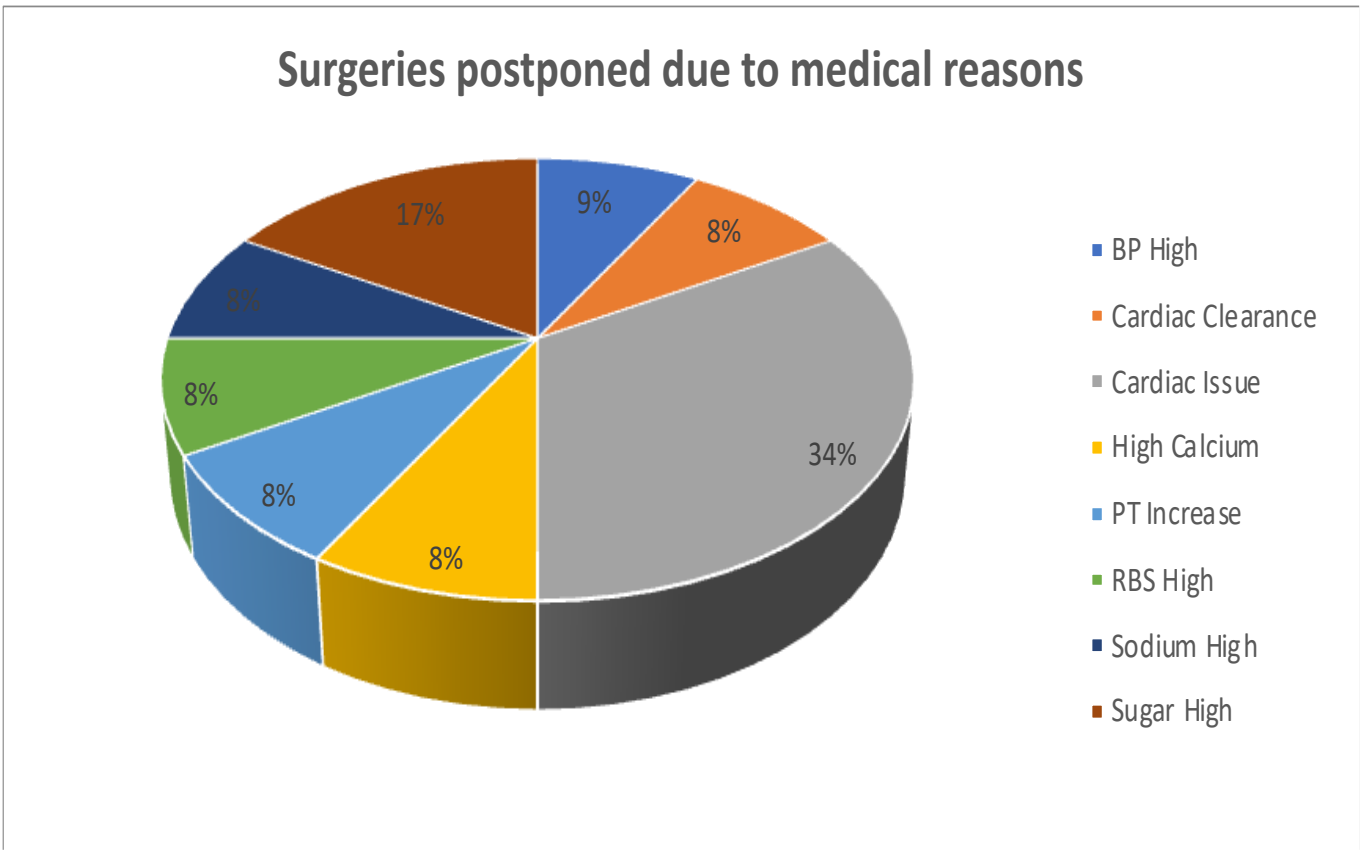
- Duration of study : 2 Weeks (1st May 2022- 15th May 2022)
- Type of data : Quantitative
- Technique : Direct Observation
- Sample Size : 432
- Sampling technique : Simple Random Sampling
- Data collection : Primary and quantitative data collected through the handover registers and data maintained by the nursing staff in the Preoperative room and by the OT reception staff. Informal discussions with patients, doctors, and staff were also carried out to explore their experiences.
- Data analysis : Using bar charts and pie charts in Microsoft Excel

2.6.Data Analysis :

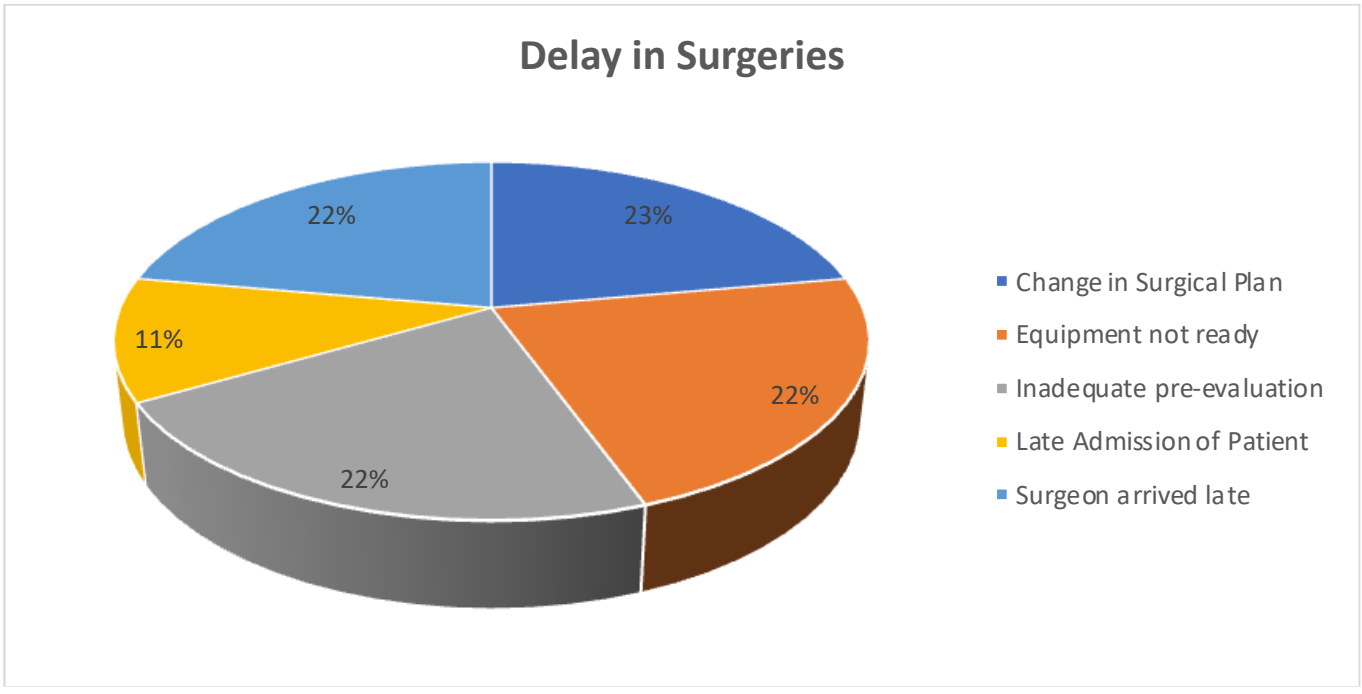
Surgeries Cancelled/Postponed	Count of patients
⊞ Medical Reason.	12
⊟ Non-Admission of Patient	20
Non-availablity of bed	2
Non-availablity of single room	6
Not ready for surgery	12
⊞ OT clearance	1
⊞ Patient Covid Report Positive	4
⊞ Patient ERCP report pending	1
⊞ Patient On High Risk	1
⊞ Patient Refused The Surgery.	1
Grand Total	40


Surgeries Cancelled/ postponed
30%
5%
15%
30%
2%
10%
2%
3%
3%
Medical Reason.
Non-Admission of Patient Non-availablity of bed
Non-Admission of Patient Non-availablity of single room
Non-Admission of Patient Not ready for surgery
OT clearance
Patient Covid Report Positive

Surgeries postponed due to medical reasons	Count of patients
BP High	1
Cardiac Clearance	1
Cardiac Issue	4
High Calcium	1
PT Increase	1
RBS High	1
Sodium High	1
Sugar High	2
Grand Total	**12**


Surgeries postponed due to medical reasons
9%
8%
34%
8%
8%
8%
8%
17%
BP High
Cardiac Clearance
Cardiac Issue
High Calcium
PT Increase
RBS High
Sodium High
Sugar High

Delay in Surgeries	Count of Patients
Change in Surgical Plan	2
Equipment not ready	2
Inadequate pre-evaluation	2
Late Admission of Patient	1
Surgeon arrived late	2
Grand Total	**9**



2.7.Results :

2.7.1.Overall results:-

A total of 432 cases were scheduled during the study period of which 378 cases were operated and 40 (9.26%) were cancelled and postponed and 12 (2.78%) were delayed due to various reasons.

2.7.2.Cancellation :

During the study of 2 weeks, a total of 432 surgeries were performed were scheduled in different operation rooms under observation. 50% of the cancellations are patient based which occurred due to non-admission of patients due to various reasons such as non-readiness for surgery, non-availability of single rooms and bed. Cancellation due to unfavourable medical reasons of the patient was responsible for 30% cancellations. Another major unavoidable reason for cancellation of surgeries is Patient report covid positive which contributed to 10% cancellations of elective surgeries. The rest of the delay types were 3 or fewer such as OT clearance, pending ERCP report, Patient's refusal for surgery and Patient under High Risk (Blood Thinner).

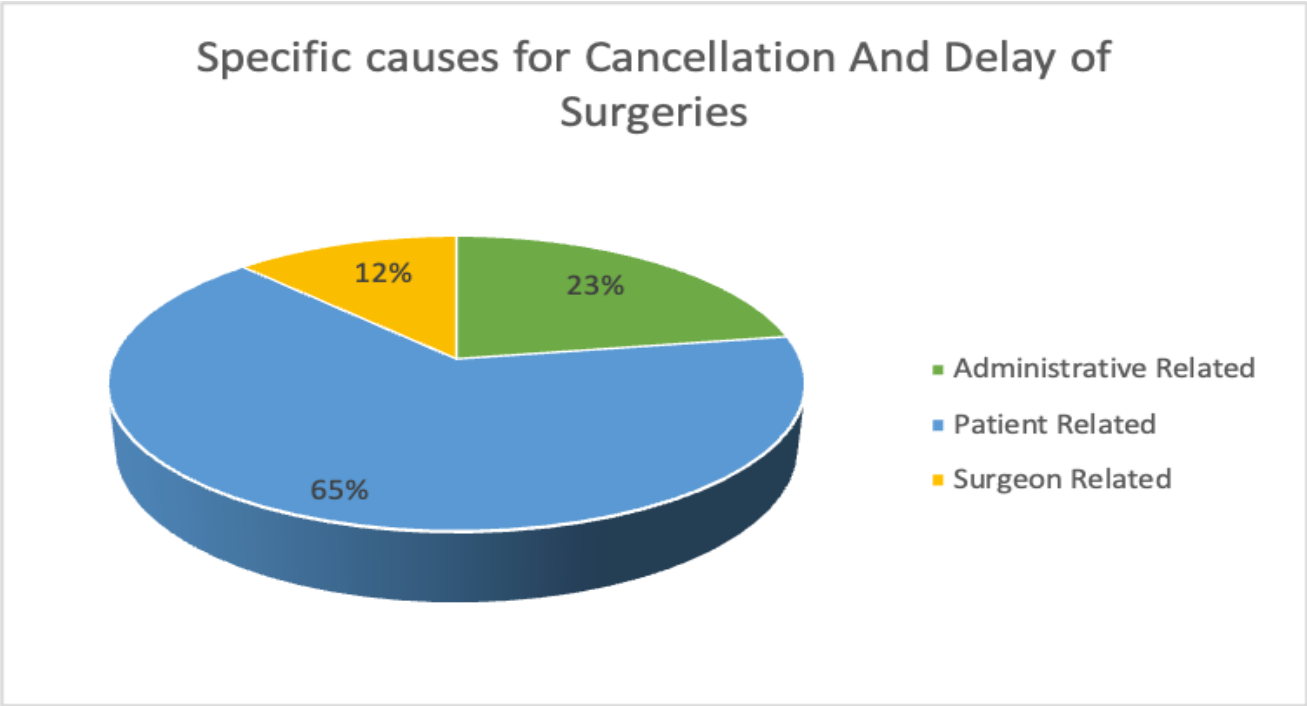
2.7.3. Delay :

There was a total of 9 Delays from the observed surgeries or 2.7%. Thus, only few of the surgeries observed were delayed. The maximum delay was due to change in surgical plan which contributed to 23% of the delay. The surgeons arriving late in the Operation Theatre for their surgeries led to 22% of the total delays. The OT staff failed to prepare the equipment or shortage of surgical equipment resulted in 22% of delays. Another Hospital based reason for delay is inadequate pre-evaluation which occurs due to lack of proper coordination and communication among hospital staff, the number of delays due to this type was 22%. Another patient-based cause for delay is late admission and late reporting of patient to operation theatre which further delays

the admission formalities, financial clearance of their procedure and then wait for pre-op formalities to finish. This contributed to 11% of delays.

2.8. Discussion :

Discussion Cancellation of elective surgical operations in hospitals is a significant problem with many undesirable consequences. Cancellations are a major drain on health resources, increases theatre costs, decrease patient satisfaction, wasted operating room time and decrease efficiency. An efficient surgical service should have a low rate of cancellation.



Specific Causes	Count of Patients
Administrative Related	**11**
Delayed because equipment not ready	2
Non-availablity of bed	2
Non-availablity of single room	6
Postponed Because of TPA approval	1
Patient Related	**32**
Cancelled Because Patient Covid Report Positive.	2
Cancelled Because Patient Refused The Surgery.	1
Cancelled due to Non- Admission of Patient	12
Delayed due to late Admission	1
Postponed Because Patient On High Risk	1
Postponed due to Medical Reason	12
Surgery Postponed Because Patient Covid Report Positive.	2
Surgery Postponed Because Patient ERCP Pending	1
Surgeon Related	**6**
Delayed because Surgeon arrived late	2
Delayed due to Change in surgical plan	3
Postponed due to Inadequate pre-evaluation	1
Grand Total	**49**

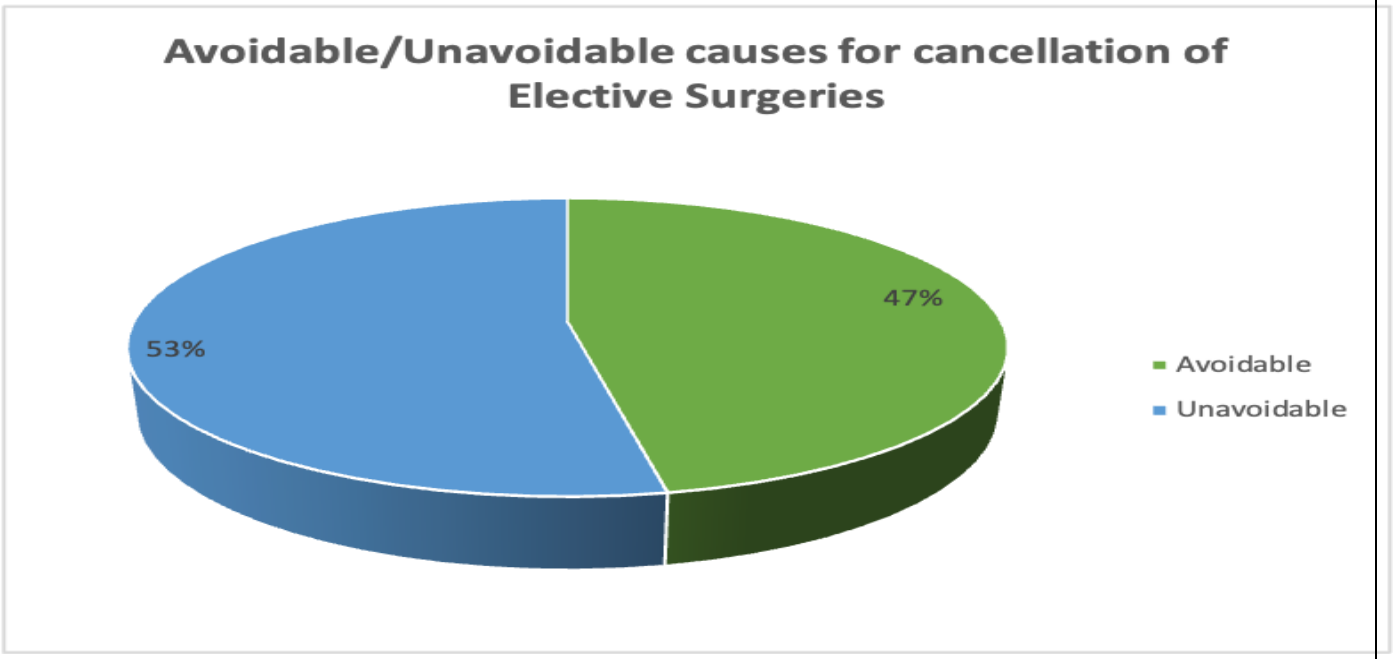
The study revealed that about 11.34% of the elective surgical case were cancelled, indicates preoperative system was inefficient.

This study revealed that patient-related factors were the most common reason for the cancellation of elective surgical cases accounted (65%) of cancelled cases. Cancellation of the case caused by Patient related factor was mainly due to acute and chronic medical illness, being on medication. Non-admission of patient due to non-willingness for surgery. Patient related delays were mainly due to late admission and reporting to operation theatre.

Administration related factors were another most common cause for cancellation and delays of elective surgical cases in the hospital, which accounted for 11 (23%) of cases. The commonest reason of Administration non availability of single ward room (36.3%), another factor which

contributed to cancellation due to non-availability of bed (18.18%), due to lack of equipment (36.3%) and Due to TPA approval (9.09%)

Surgeon-related factors were another most common cause for cancellation and delays of elective surgical cases in the hospital, which accounted for 6 (12.24%) of cases. The commonest reason of surgeon related factor was change of surgical plan due to changed diagnosis or sudden medical issues (50%) another most common delay is caused due to inadequate pre- evaluation (16.67%), late arrival of surgeon (33.3%)



Causes	Count of patients
Avoidable	**23**
Cancelled Because Patient Refused The Surgery.	1
Cancelled due to Non- Admission of Patient	6
Delayed because equipment not ready	2
Delayed because Surgeon arrived late	2
Delayed due to Change in surgical plan	3
Delayed due to late Admission	1
Non-availablity of bed	2
Non-availablity of single room	4
Postponed Because of TPA approval	1
Postponed due to Inadequate pre-evaluation	1
Unavoidable	**26**
Cancelled Because Patient Covid Report Positive.	2
Cancelled due to Non- Admission of Patient	8
Postponed Because Patient On High Risk	1
Postponed due to Medical Reason	12
Surgery Postponed Because Patient Covid Report Positive.	2
Surgery Postponed Because Patient ERCP Pending	1
Grand Total	**49**

In this study cancellations and delay can be classified as the potentially avoidable(Late arrival of surgeon, sudden change in surgical plan, late admission of patient etc.) and non-avoidable acute or chronic medical reasons, pending reports.

Potentially Avoidable causes are the causes that are Hospital based and can be prevented by cumulative effort and coordination among hospital staff. It comprises of surgeon based and administrative based factors. The most common Avoidable Hospital Based factor is Cancelled due to non-admission of patient due to un-availability of bed, this is major administrative issue which is contributing in maximum cancellation by (26.09%), another most significant cause for

delay in OT is change in surgical plan which could be due to sudden medical issue which causes maximum surgeon related delays (13.04%) other causes for delay are Inadequate pre-evaluation this could occur due to inefficiency of hospital staff or communication gap between different units responsible for surgery, this cause contributes (4.35%), another significant factor is late arrival of surgeon (8.7%) and shortage of equipment (8.7%)

Unavoidable factors are generally based on Acute or Chronic medical conditions. The most common causes for cancellation or postponement of surgery are Medical reasons which contributes about (46.15%). Another most common factor is Non-Admission of patient for surgery which contributes to (30.77%). Other unavoidable reasons responsible for Delay and cancellation includes positive covid reports (15.38%) ,high risk medication such as blood thinner(3.84%) and Pending reports (3.84%)

This study has established that a number of factors come into play for cancellation, postponement and delay of a planned surgical procedure. Additionally, delayed elective surgery negatively impacts the patient, the hospital, and the community at large. Therefore, we advise that all concerned stakeholders should advocate for spending resources on a detailed study of the socioeconomic implications of delayed surgery and come up with timely and acceptable remedial strategies.

2.9.Recommendation:

- Patients who are scheduled for day care and OPD surgeries should be asked to report 2 hours before the schedule time of Surgery to facilitate their smooth pre-op process.
- They should be educated about the pre operation formalities by the hospital staff when they are scheduled for surgeries. They can be alerted via emails, text messages by the hospital 2-3 days prior to the date of surgery.
- Emphasis on prior financial clearance
- Patient’s involvement in deciding date of planned surgery
- Surgeons should be urged to report on time to the OT. They should be sensitised of the inconvenience caused to the patient their families as well as hospital staff.

- Junior Consultant / Clinical associates can begin with the preparation phase in the OT till the surgeon washes up.
- Patient non admission can be reduced by improving communication between patient and surgeon (so that the patient knows the details of surgery properly.
- Administration should focus on fulfilling the need of necessary operating room equipment's
- Delay in elective surgeries can also be prevented by earlier and adequate pre-evaluation and listing of only adequately prepared patients for surgeries.

Fortis MEMORIAL RESEARCH INSTITUTE

Patient's
UID :
Age :
D.O.A.
Female

INFORMED CONSENT FOR CHEMOTHERAPY

I, _____, ☐ (the Patient) or ☐ representative of patient
of the patient (_____), have (please tick the correct option above and below)

1. read
2. been explained this consent form in _____ (name of language) which I fully understand,

and understood the information provided about CHEMOTHERAPY in this consent form.

I am aware that Chemotherapy is a treatment procedure wherein strong medicines are administered orally (by mouth) or by injection / infusion to treat difficult diseases (like cancer etc.). The intent of chemotherapy can be for curing (curative), for improving survival, for control of symptoms, for maintenance/palliation (keeping disease under control) for adjuvant/neo-adjuvant purpose (after or before definitive treatment to minimize risk of recurrence or shrink the disease) or a combination of one or more of these.

I am now aware of the intended benefits, possible risks & complications, and available alternatives to Chemotherapy given below. I am also aware that results of Chemotherapy can vary from patient to patient; and declare that no guarantees have been made to me regarding success of this procedure. I am aware that while majority of patients usually have an uneventful Chemotherapy session, some cases may sometimes develop complications. I also understand that sometimes a Chemotherapy session may need to be stopped, delayed and/or abandoned midway if the patient's clinical condition worsens, or if the patient cannot tolerate. I understand that if medical exigencies demand, further or alternative treatment measures may need to be carried out. I am aware that I may require administration of blood and/or blood products during or after the Chemotherapy session if found necessary by the doctor (for which a separate consent shall be obtained). I am also aware that sometimes admission to an Intensive Care Unit and/or extension of duration of hospitalization may be required.

Intended benefits: (TICK AS APPROPRIATE)

- ○ Improved survival
- ○ Control of symptoms
- ○ Induction – therapy given in the acute state of the ailment aiming to shrink the disease/tumor
- ○ Curative – to give the best possible chance of being cured
- ○ Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms
- ○ Disease control / palliative – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival

Fortis MEMORIAL RESEARCH INSTITUTE

Patient's Name
UID
Age
D.O.A. : Insurance
Female
Unit :

INFORMED CONSENT FOR HIV TESTING

CONSENT FOR HIV ANTIBODY BLOOD TEST

Please read this consent form with care so that you can make an informed decision about getting the blood test done. You are welcome to ask your doctor or counselor any queries that you may have regarding this test.

1. INTRODUCTION: Acquired Immunodeficiency Syndrome (AIDS) is a serious disease caused by infection with Human Immunodeficiency Virus (HIV). Not all persons with HIV infection develop AIDS provided preventive treatment and other measures are started in time. However, anyone with HIV can spread it to others. HIV is spread through unsafe sex, sharing of needles, or receiving blood or blood products or other tissues infected with HIV. Infected mothers can spread HIV to their babies through their breast milk. The test for HIV detects the body's reaction to the antibody) and not the virus itself.

IAT THE TEST MEANS : If the test is NEGATIVE it means that antibodies (body's immune response to the ion) were not detected in the blood sample. This usually means that the person is not infected with HIV. However, in some cases the infection may have happened too recently for the antibodies to have been generated and the test to be positive. It may take up to six months for the antibody test to be positive after HIV infection.

If you test POSITIVE it means that antibodies (body's immune response to the infection) were found present in the blood sample this implies infection with HIV and you can pass it on to others. **It does not necessarily mean that you have AIDS,** which is the most advanced stage of HIV infection.

False results (negative test in someone who is infected with HIV or positive test in someone not infected with HIV) may occur. Indeterminate results (when it is unclear whether the test is positive or negative) may occur. When the test result is indeterminate, repeat test or special confirmatory test may help determine the person's true status.

3.BENEFITS OF BEING TESTED : There are substantial benefits of being tested for HIV. Knowing one's HIV status helps people make personal and lifestyle choices including those related to sex, contraception and pregnancy. Infected sons benefit as they can start appropriate treatment to delay or prevent AIDS and other serious infections.

SKS OF BEING TESTED : You may feel anxious till the test result is available. Repeat or further testing required in of an unclear result may cause further stress. A positive test result may cause severe stress, anxiety and depression. You would be asked to consider declaring the result to your partner. Persons with negative test results may be tempted to indulge in risky behavior which may further increase the chances of contracting HIV infection.

5. CONFIDENTIALITY :

The law requires that health care providers (hospitals) and laboratories report the details of persons infected with HIV to the local health department. This helps the government in knowing the disease burden in the society and take appropriate action. Hospitals or laboratories do not maintain a separate list of persons with positive HIV testing.

In case the hospital bill is being directly settled by my insurance company, the hospital is bound to provide all treatment papers & test reports to the TPA / Insurance Company and patient privacy shall be disclosed, as the same is under exception & exemption. For such disclosure(s) I hereby give my consent to the hospital.

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Patient's
UID :
Age :
D.O.A. :

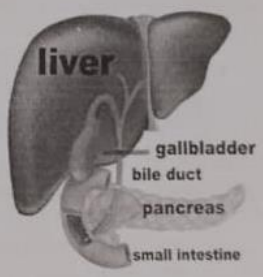
INFORMED CONSENT FOR LAPAROSCOPIC CHOLECYSTECTOMY

A. All fields must be completed by the person explaining the consent. Mark NA if a field is not relevant.
B. For information regarding Anesthesia type and its risks and complications, please see Anesthesia Consent Form.
*C. For further information, please see the **PATIENT INFORMATION LITERATURE** (if provided) or speak with your Doctor.*

PART A

1. Full Name of the Operation/procedure: **LAPAROSCOPIC CHOLECYSTECTOMY**

2. Details of operation/procedure: Laparoscopic Cholecystectomy means removal of the Gall Bladder with the help of a telescopic camera (laparoscope). In this operation, the abdomen is inflated with carbon dioxide gas and the laparoscope is inserted through a small cut near the umbilicus. Other smaller cuts may be made to insert other instruments required during the operation. The Cystic (bile) duct and blood supply to Gall Bladder is clipped and the Gall Bladder removed through one of the cuts. A suction tube may be left in the operated area to drain any secretions.



3. Intended benefits:

- ✓ Removal of the diseased Gall Bladder (e.g. Gall stones)
- ✓ Relief from the diagnosed illness (e.g. pain due to Gall stones)
- _____
- _____
- _____