EVALUATION OF THE NEED AND PREPARATION OF SPECIFIED INFORMED CONSENT FORMS OF MAJOR SURGERIES IN 3 DEPARTMENTS – GASTRO, URO, AND ORTHO IN A SUPER SPECIALTY TERTIARY CARE HOSPITAL

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of Master of

Business Administration (MBA)

in

Hospital and Health Management

By

Dr. Gandhi Drashti Atulbhai

Under the Supervision and Guidance of

Dr. Susmit Jain

2022

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Evaluation of the need and Preparation of specified informed consent forms of major surgeries in 3 departments – gastro, uro, and ortho in a super specialty tertiary care hospital** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Dr. Gandhi Drashti Atulbhai

Date: - 1st July,2022

KD Hospital

Certificate of Completion of Projects

This is to certify that **Dr. Gandhi Drashti Atulbhai** in partial fulfillment of the requirements for the award of the degree of MBA Hospital and Health from the IIHMR University, Jaipur has successfully completed her internship at **KD Hospital, Ahmedabad** during 28th March 22, 2022 to 28th June, 2022.

Ms. Nisha Joshy

Head of the Department
Quality Department

Place:
Ahmedabad

Date:
28th June,2022

Name of the organization
KD Hospital, Ahmedabad, Gujarat

CERTIFICATE

This is to certify that dissertation titled **evaluation of the need and preparation of specified informed consent forms of major surgeries in 3 departments – gastro, uro, and ortho in a super specialty tertiary care hospital** is a

record of the research work undertaken by Dr Gandhi Drashti Atulbhai in partial fulfillment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Dr. Susmit Jain
Faculty Guide
IIHMR University, Jaipur

Date 1st July,2022

Dr (col) Mahender Kumar
School Dean
IIHMR University, Jaipur

Date 1st July,2022

ABSTRACT

Study Objectives:

- To assess the importance and need of the specified informed consent form.
- To increase legal safety for both patients and doctors through specific consent forms for surgery.
- To make patients easily understand the purpose, benefits, procedure, complications, risks, and alternatives of surgery that they need as treatment.
- To make the explanation process easy and less time-consuming for consultants/doctors/health care providers.

Methodology:

- Study Design: Descriptive Study.
- Setting: KD Hospital, Ahmedabad (Gujarat)
- Sample Size: 61 – Consultant/Doctors, Nursing staff, Quality department staff and medical admin staff
- Sampling Technique: Convenience sampling
- Data Collection Procedure: Data collected through a structured questionnaire. Google form and printed papers are created and circulated through email, social media, and manually to the consultants/Doctors and Quality, Medical Admin and Nursing Staff. Questionnaires include a total of 10 questions. The quantitative approach was used for data collection by using YES/NO attributes and the Likert Scale for the questions.
- Data Analysis Plan:
- MS Excel used for data analysis of collected data from the questionnaire.

Key Results:

More or less every department staff think that there is need of specified informed consent form for improved quality of care and in aspect of medico legal safety, highest positive response came from the doctors which is 95%, medical admin 100% and quality department staff also 100% agrees to it and only few of nursing staff which are 3.3% response negatively to it.

Conclusion:

This study revealed the results that present that Specified informed consent form has a great importance in Medical Practices according to the majority of the doctors, and

Quality, Medical admin and nursing staff of the KD Hospital at Ahmedabad and there are need of the Specified Informed Consent form for different surgeries of different departments. So according to the need of the informed consent, Specified Informed Consent prepared for 3 Departments Gastro, Uro and Ortho.

Key Words:

Specific Informed Consent Form, Medico legal, Major surgeries

ACKNOWLEDGEMENTS

Internship form KD Hospital at Ahmedabad was a great learning experience for me. I would like to thank my industry Mentor Nisha Joshy who give me opportunity to work and polish and increase my skills through the internship and also I would like to express my gratitude toward consultants/Doctors of the Gastroenterology Department, Urology Department and Orthopedic Department their insights and suggestions helped me to improve my project work efficiency.

I would like to express my heartfelt gratitude to my IIHMR University, Mentor, Dr Susmit Jain for his great support, his guidance and supervision helps me to complete my dissertation report, without his encouragement and guidance it may not be possible.

I am also grateful to our IIHMR University placement committee in charge Mr. N Satheesh Kanna for providing me the platform where I can learn more and gain experience and improve my skills.

I would like to thank my co-interns and colleagues for their Constant Support.

My sincere gratitude towards the participants of the survey without their involvement this research project could not be completed.

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ABBREVIATIONS

PCNL – Percutaneous Nephrolithotomy

VIU – Visual Internal Urethrotomy (DVIU – Direct Vison Internal Urethrotomy

TURP – Transurethral Resection of the Prostate

URS – Ureteroscopy

RIRS – Retrograde Intrarenal Surgery

TKR – Total Knee Replacement

THR – Total Hip Replacement

DISSERTATION

Submitted by – **Dr. Gandhi Drashti Atulbhai**
Guided by: Dr. Susmit Jain
Roll no. – 1096

Evaluation of the need and Preparation of Specified Informed Consent Forms of Major Surgeries in 3 departments – Gastro, Uro, and Ortho in a Super Specialty Tertiary Care Hospital

Chapter 1: Introduction

Informed Consent Form for surgery is a document with important information about a medical procedure/surgery or treatment with the information on possible risks and benefits.

Consent form has to be signed by a patient/ Patient relative prior to a medical procedure to confirm that he or she agrees to the procedure and is aware of any risks and complications that might be involved. The primary purpose of the consent form is to provide evidence that the patient or his/her relative gave consent to the procedure in question.

An informed consent form is a process of communication between patient/patient relative and their health care provider that often leads to agreement or permission for care, treatment, or services. Every patient has the right to be informed and to ask questions if there is any kind of doubts, they have regarding the treatment.

Information may include the informed following:

- Purpose of the surgery/treatment
- Benefits of the surgery
- Procedure of the surgery
- Risk and complications may be included in the surgery

- Alternatives of surgery
- The section where patients sign the form once he/she fully informed and cleared their every doubt and after that if they are fully agreed to receive the treatment and one space of witness signature.

Once the patient signs the consent form it means,

• The patient/patient relative understands the information and has had an opportunity to ask any questions.

• The patient/patient relative has received all the information from their healthcare practitioner regarding his/her treatment options.

• With the help of this information, the patient and/or patient's family members can decide if they want to proceed with the indicated course of therapy or surgery. The patient or a patient's relative may occasionally decide to take only a portion of the prescribed care. They can discuss alternative choices with their healthcare professional.

• The patient/patient may sign a consent document to indicate their agreement to receive all or some of the treatment options. The paperwork must be filled out and signed in order for the doctor to proceed with the treatment plan.

The main intention of the informed consent process is to protect the patient as well as doctors from any questions or legal procedures after surgery. A consent form is a legal document that ensures an ongoing communication process between patient/patient relative and their health care provider. It implies that the health care provider/doctor has given all the information about the patient's condition and treatment options and that information can be used by the patient and their relative to choose the option that feels right for them.

It is very common to use general consent form for every surgery but with changing medicolegal scenario, there is need to create informed consent forms specific to the procedure/surgery. Every surgery has a different purpose, benefits, procedure and risks, and complications and alternatives to that surgery. So, if there is only one general consent form used for every surgery

then it might get difficult to explain to the patient every aspect of the surgery through the one general consent form and might get a time-consuming procedure both for the patient as well as doctors.

Hence, the project was carried out to evaluate the importance and need of the specific informed consent form in medical practices by taking survey of the doctors/consultants and staff of Quality department, Medical Admin department and Nursing department of KD Hospital, Ahmedabad, and to prepare specific informed consent forms for major surgeries of 3 departments of KD Hospital which include Gastroenterology, Urology, and Orthopedic with the help and continuous guidance and approval of consultants of respective departments. The major surgeries which included are following,
In Gastroenterology - Whipple's Procedure, Frey's Procedure, Ventral Hernia Repair, Laparoscopic Fundoplication, and Ileostomy Closure are included.
In Urology – PCNL, VIU, TURP, URS, RIRS, Cystoscopy, DJ Stenting, and Stent Removal are included.
In Orthopedic – TKR, THR, and Shoulder Replacement are included.

The aim of the study was to evaluate specific informed consent forms need and importance in medical practices and to create informed consent forms for 3 departments gastro, uro and ortho.

The study was carried out with the following objectives:

- To assess the importance and need of the specified informed consent form.
- To increase legal safety for both patients and doctors through specific consent forms for surgery.
- To make patients easily understand the purpose, benefits, procedure, complications, risks, and alternatives of surgery that they need as treatment.
- To make the explanation process easy and less time-consuming for consultants/doctors/health care providers.

Chapter 2: Review of Literature

Sr No.	Title	Author and year	Research Design	Salient Features
1.	"Perceptions and practices regarding the process of obtaining informed consent from surgical patients at a tertiary care hospital" (1)	• Muhammad Asharib Arshad • Naureen Omar • Zaid Amjad • Khalid Bashir • Muhammad Irfan • Irfan Ullah (2022)	Cross sectional study	"According to results patients had enough knowledge about the process of the informed consent and considered it important in developing countries. Language, higher educational status and position, and not being asked by relatives were all recognized as hurdles to patients signing informed consent forms. A higher percentage of

				patient are satisfied with the informed consent process."
2.	"The patient and clinician experience of informed consent for surgery: a systematic review of the qualitative evidence"**(2)**	• L. J. Convie, • E. Carson, • D. McCusker, • R. S. McCain, • N. McKinley, • W. J. Campbell, • S. J. Kirk & • M. Clarke (2020)	Descriptive study	"A total of 94 findings were taken from the main publications and categorised into 17 categories, resulting in six synthesised findings on patient characteristics, knowledge, communicatio n, the model patient, trust, and decision making. Which are following, The first one , The manner in which the informed consent procedure is carried out is heavily

				influenced by the patient's inherent features. The second one is, The sharing of knowledge was described as a crucial feature of the consent procedure by patients and professionals involved in the process. Third one, Patients and clinicians alike saw consent as a test of communicatio n abilities. Next one, Patients' desire to be seen as a "model patient" makes it difficult for them to participate fully in the informed

				consent process. On the fifth, the consent procedure has the potential to increase or decrease trust. The patient's decision to consent or not consent was influenced by this trust. And the last one is, Important other people, their physical condition, and whether they saw a choice of therapeutic choices all influenced patients' decision-making during the consent process.”
3.	“Does content of informed consent forms make surgeons vulnerable	• Perihan Elif Ekmekci	Observational Study	“126 Informed Consent forms were randomly selected and

	to lawsuits?" (3)	• Müberra Devrim Güner • İlayda • Nurelif Toman • Gülce Karaca • Berkem Karakoyunlu • Rabia Çatal • Merve Erdem • Emre Ömeroğlu (2020)		analyzed for 22 criteria, 80% of the 126 ICFs contained Risks, diagnosis, procedure explanation, prioritization of the willingness of the patient, and a blank space for doctor and patient signature, Other 20% of the ICFs contained duration of patient admitted period, alternatives treatment – benefits and complications and severity of the diagnosed disease. According to conclusion all ICFs are insufficient for

				defending the healthcare professional or doctors/surgeons during lawsuit."
4.	"Medico-legal issues in consent and medical practice" (4)	• Asim Sheikh (2018)	Descriptive Study	"Do's and Don'ts in Consent Form according to discussion in the article some **do's** are, Consider the consent as a process, Consider consent as a continuous process, Talk to your patient and engage in communication, Make sure you reserve enough time for talking and communicating with your patient,

				Recognize that a patient who is an adult is presumed to have ability, Recognize that the functional test is the one that determines capacity, When a capacity problem emerges, take the required actions to get it resolved, with the help of the court, if necessary, Give the patient a clear explanation of any significant complications related to the treatment, Accept that it is okay for a patient to make "an unreasonable judgement." However, a

				patient's "irrationality" could raise questions about capacity and some **don’ts** are, Consider obtaining consent to be a formality, Delegating the process of obtaining consent in an inappropriate manner to someone who don’t has sufficient knowledge of the proposed inquiry or course of treatment, is unaware of the risks involved, and is unable to explain and discuss these issues, Hasten the discussion of

				complications with patients, Assume that an adult patient lacks capacity and treat them accordingly, Ignore or eliminate family members' opinions regarding a patient who has no capacity since this information can be used to determine the patient's desires, Disregard children's viewpoints, Don't explain important risks in a way that the patient will understand, Get consent just before the procedure, or at the

				"eleventh hour." , Ask the patient's permission if they are anxious, sedated, or in pain. Disregard an advance directive."
5.	"The Importance of Informed Consent in Medicine"	• Kusa Kumar Shaha, • Ambika Prasad Patra • Siddhartha Das (2013)	Review Article	"In the larger interest of the patient-doctor relationship, all clinicians and medical researchers should take Informed Consent seriously, and there should be no compromise in disclosing information that is not "reasonable" in the eyes of the court. Written recordings of

				such exchanges can be the doctor's greatest defense in the event of a negative medical outcome, as the court can demand relevant documents/X-ray pictures of the patient. There are eight strategies to improve the informed consent process. 1. Improve your rapport. 2. Discuss all therapy choices with them, regardless of whether or not they are covered by insurance 3.Use these feature; Alternative

				Benefits Common risks Devastating risks Patient Specific risks Facial expressions, body language, and questions 4. Determine the amount of medicine information the patient requires. 5. Keep records 6. Documentation 7. Avoid making guarantees 8. Discuss about results"
6.	"Informed consent for clinical treatment."(5)	• Daniel E. Hall, • Allan V. Prochazka, • Aaron S. Fink (2012)	Descriptive study	"Purposes of informed consents: Legal, Ethical and Administrative compliance Factors affect obtaining informed consent: Patient

				Comprehension, Patients' use of information which are disclosed, Informed Consent demands maturity and self-awareness from the providers, meeting minimal standards by physician. Informed consent is a complicated procedure that necessitates flexibility in order to achieve its numerous objectives. The legal goal is to preserve patients' rights; the ethical goal is to encourage autonomous decision-making; the

				administrative goal is to provide efficient health care; and the interpersonal goal is to create the trust necessary to proceed with therapeutic procedures."
7.	"Patient-Centered Informed Consent in Surgical Practice"	• James L. Bernat, • Lynn M. Peterson (2006)	Literature Review	"Surgical consent is an ongoing process of communicatio n that continues during preoperative, perioperative, and postoperative care rather than being an event or a signature on a document. Consent is best understood in the context of patient-centered

				medicine as joint decision-making with patients or their proxy."
8.	"Current practices and medico-legal aspects of pre-operative consent" **(6)**	• C Osime • Okojie, • F Osadolor, • S Mohammed (2004)	Cross-sectional study	"139 respondents, 118 among them were noted for documentation regarding consent,74.6% felt that they had enough time to reflect on consent obtained, 48 respondents were meeting first time the person who obtained their consent. 100 above respondents were not informed about risk of the procedure, overall, 50% above of the respondents felt satisfied

				with the information supplied.”

Chapter 3: Methodology

The key research question was “Is specific informed consent form important for medical practices and why?”

STUDY DESIGN: Descriptive Study.

SETTING: KD Hospital, Ahmedabad (Gujarat)

STUDY POPULATION

- **Inclusion criteria:** Doctors, Nursing Staff, Quality Department Staff and Medical Admin staff of KD Hospital
- **Exclusion criteria:** The other departments of Hospital
- **Study tools:** structured questionnaire

DURATION OF STUDY: 3 months (Arpil,2022 to June 2022)

SAMPLE SIZE: 61 – Consultant/Doctors, Nursing staff, Quality department staff and medical admin staff

SAMPLING TECHNIQUE: Convenience sampling

DATA COLLECTION PROCEDURE: Data collected through a structured questionnaire. Google form and printed papers are created and circulated through email, social media, and manually to the consultants/Doctors and Quality, Medical Admin and

Nursing Staff. Questionnaires include a total of 10 questions. The quantitative approach was used for data collection by using YES/NO attributes and the Likert Scale for the questions.

OPERATIONAL DEFINITIONS:

Gastroenterology – The branch of the medicine which deals with disorders of the stomach and intestines.

Urology – The branch of medicine and physiology concerned with the function and disorders of the urinary systems

Orthopaedic – relating to the branch of medicine dealing with the correction of deformities of bones or muscles.

DATA ANALYSIS PLAN:

MS Excel used for data analysis of collected data from the questionnaire.

ETHICAL CONSIDERATIONS:

Neither the employee ID or names of the participants were noted down to preserve their identity, prevent anxiety and social desirability bias. It was completely voluntary to respond to the questionnaire or refuse to participate in the study.

Chapter 4: Data Compilation - Analysis and Results

A total of 61 staff members of the KD Hospital, Ahmedabad responded to the survey were studied and they are doctors and staff members from Quality, Medical Admin, and Nursing Department.

1. **Respondents according to the Department:**

Respondents	Frequency
Doctors	20
Quality Department	3
Medical Admin Department	8
Nursing staff	30

Table 1 Respondents distributions according to Departments

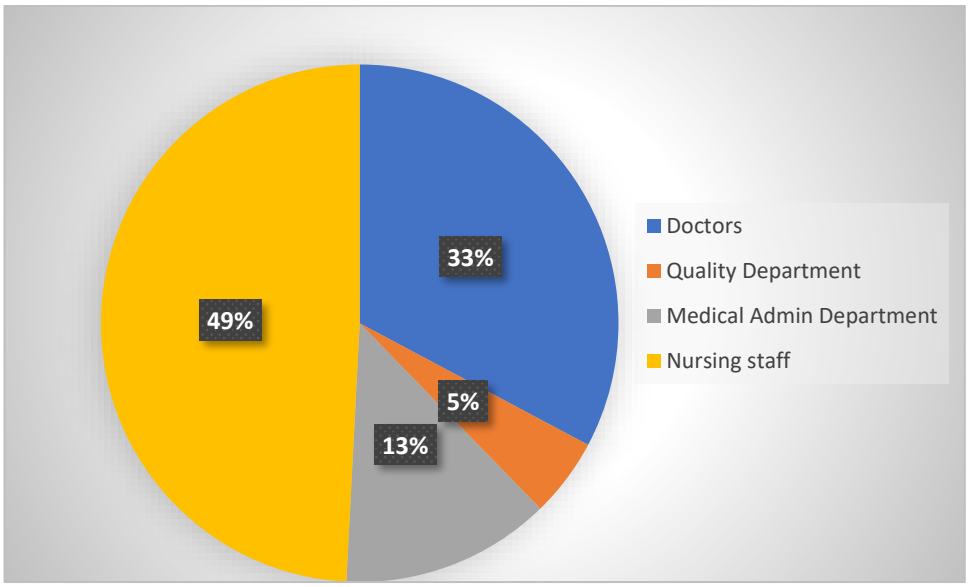


Fig. 1 Respondents distribution according to the Department

2. **Participants Experience in Healthcare Sector**

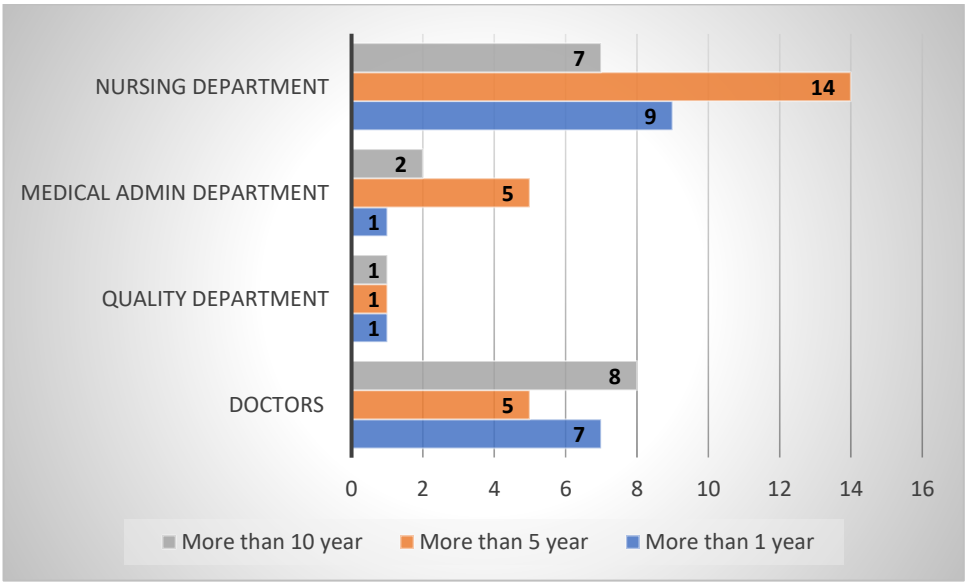


Fig. 2 Respondents experience

3. **Did you experience or know about any Medico-legal issues that happened due to problems of consent form?**

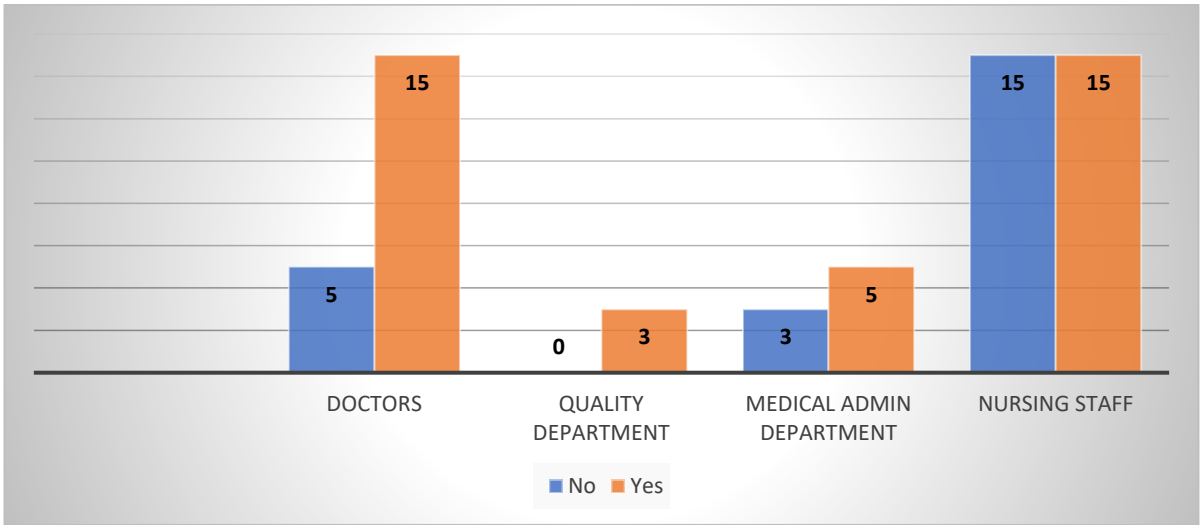
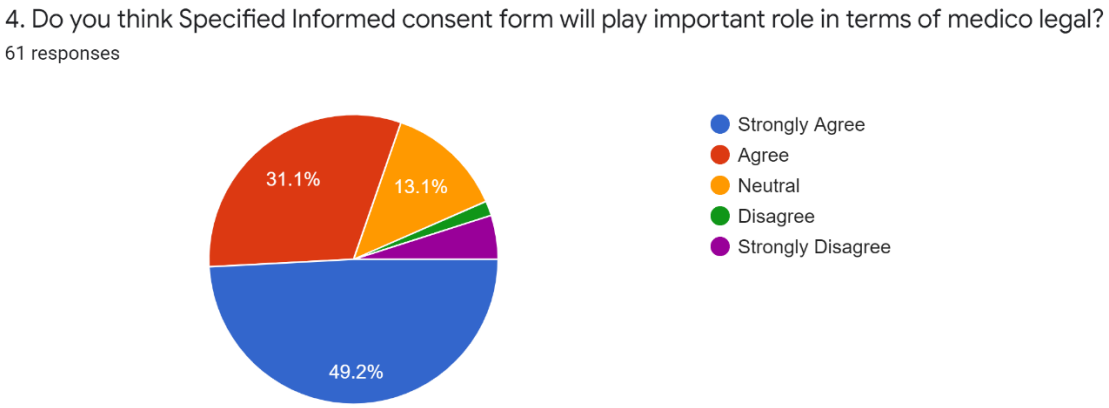


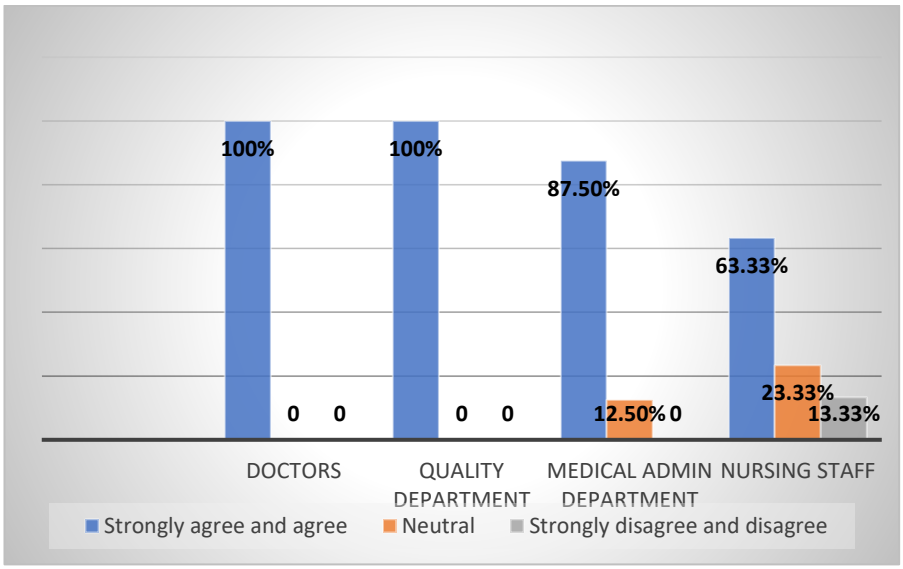
Fig. 3 Experience or know about Medico legal issues that happened due to problems of consent form

4. **Do you think Specified Informed consent form will play important role in terms of medico legal?**

- Response from the total respondents (Fig. 4)



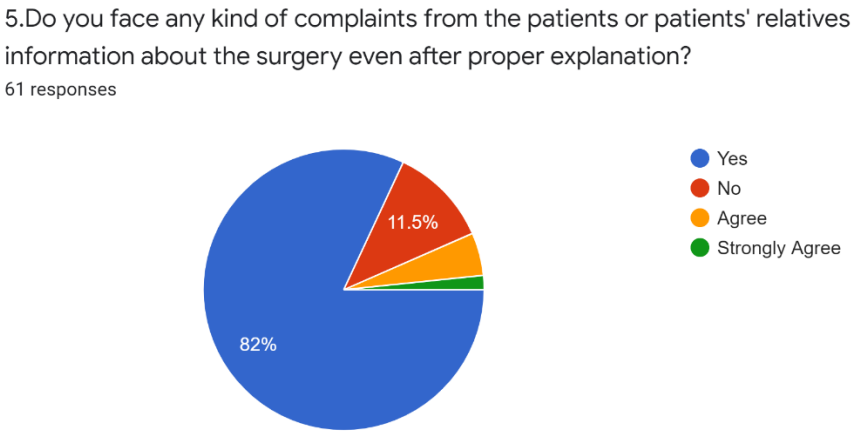
- Response from different department:



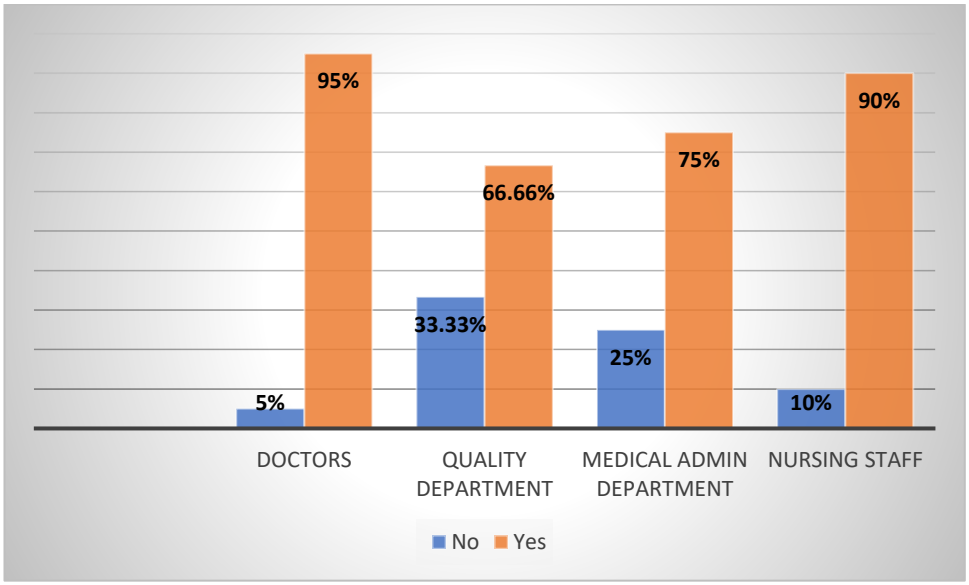
(Fig. 5)

5. **Do you face any kind of complaints from the patients or patients' relatives regarding lack of information about the surgery even after proper explanation?**

- Response from the total respondents (Fig. 6)



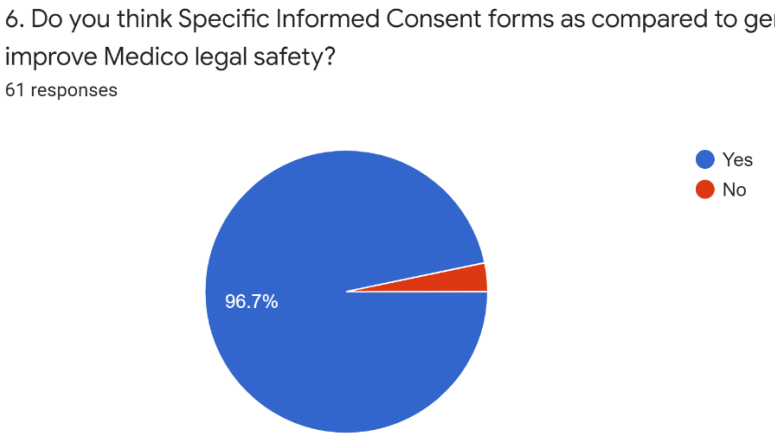
- Response from different department:



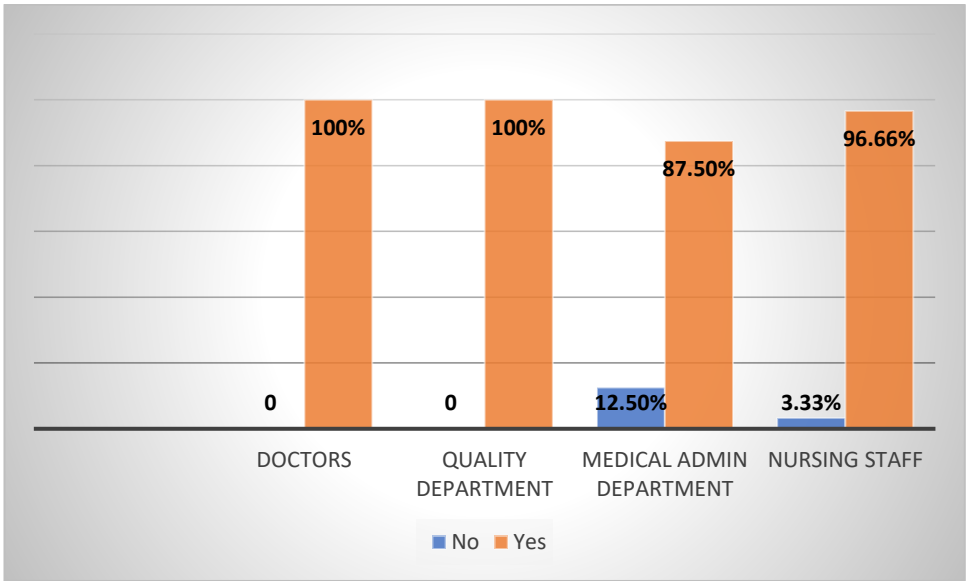
(Fig. 7)

6. **Do you think Specific Informed Consent forms as compared to general consent forms will improve Medico legal safety?**

- Response from the total respondents (Fig. 8)



- Response from different department:



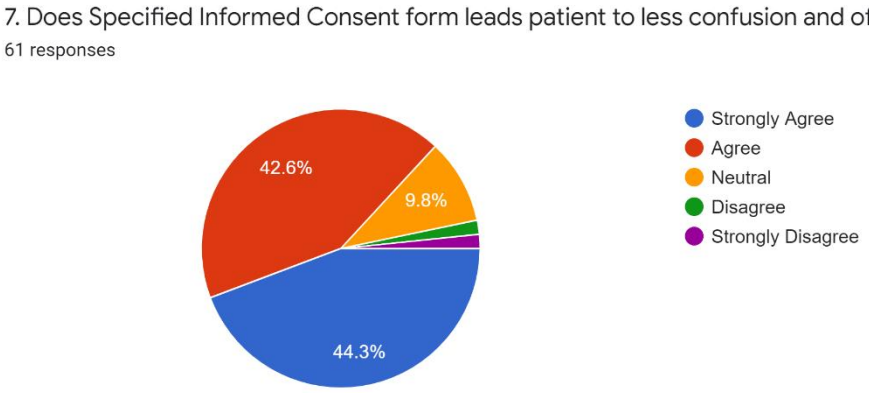
(Fig. 9)

If yes, then please explain why,
Only 3 Respondents which are doctors
Reasons given by them are: -

- Risks and complications according to surgery
- Compared to general Consent it shows more clarity in procedure, risks and benefits
- General consent contains common complications of surgery while specific informed consent contains surgery specific information

7. **Does Specified Informed Consent form leads patient to less confusion and offers more clarity?**

- Response from the total respondents (Fig. 10)



- Response from different department:

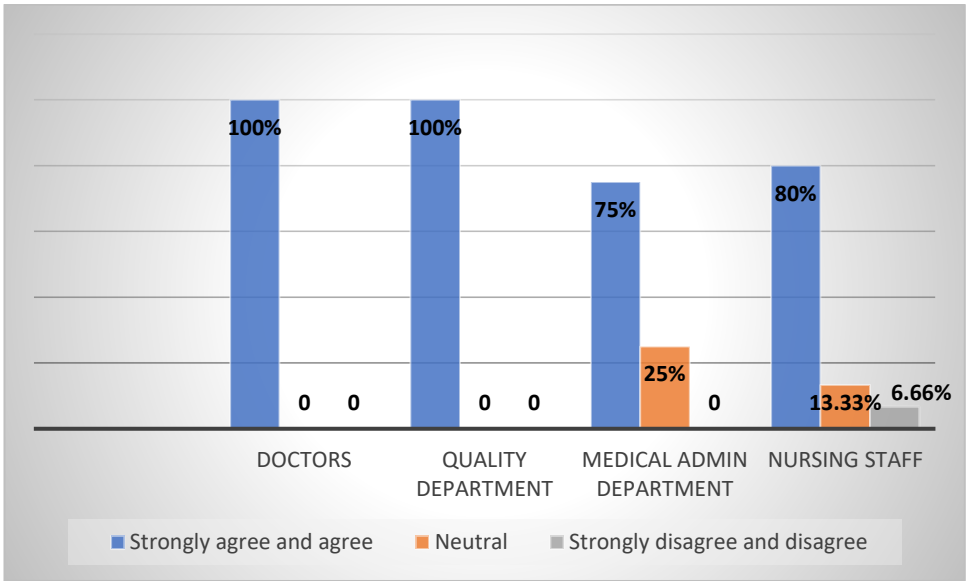
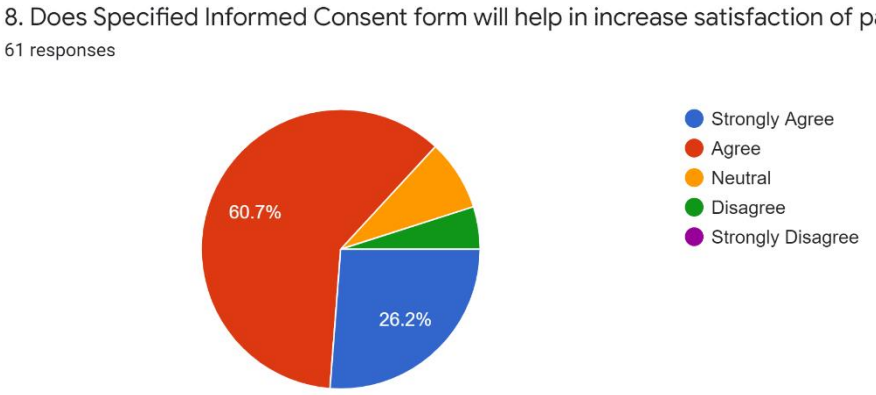


Fig. 11

8. **Does Specified Informed Consent form will help in increase satisfaction of patient?**

- Response from the total respondents (Fig. 12)



- Response from different department:

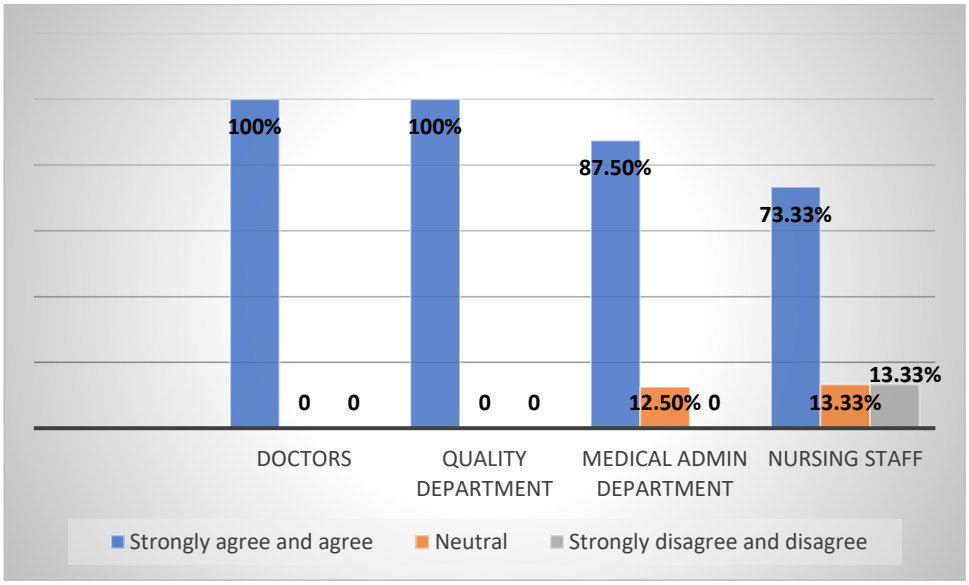
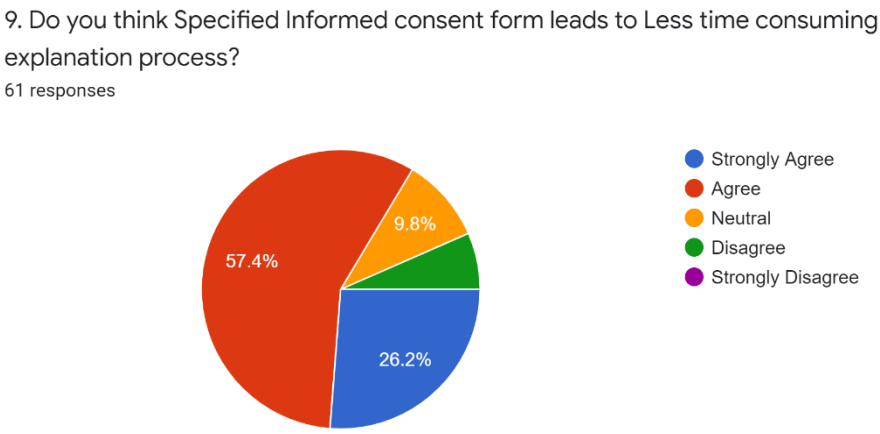


Fig. 13

9. **Do you think Specified Informed consent form leads to Less time consuming and easy explanation process?**

- Response from the total respondents (Fig. 14)



- Response from different department:

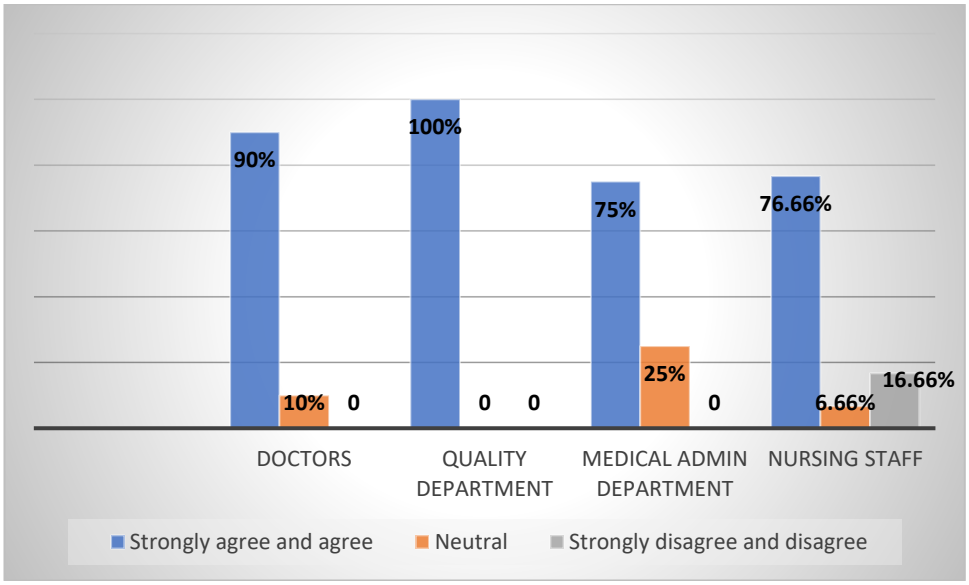
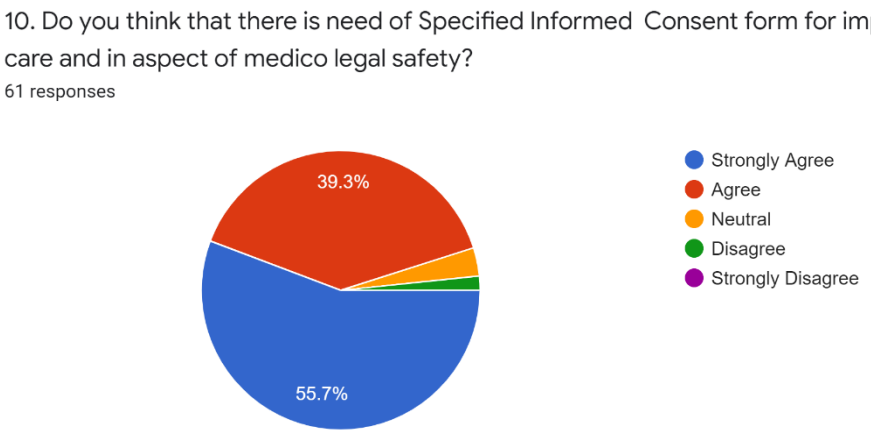


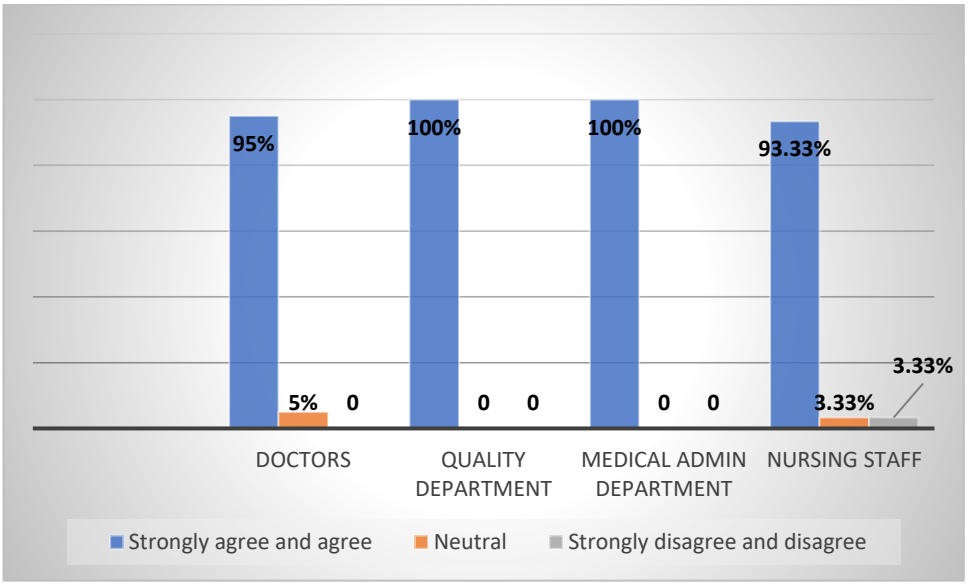
Fig. 15

10. **Do you think that there is need of Specified Informed Consent form for improved quality of care and in aspect of medico legal safety?**

- Response from the total respondents (Fig.16)



- Response from different department:



(Fig. 17)

PREPARED INFORMED CONSENT FORMS OF 3 DEPARTMENTS

1. ORTHO

a. Total Knee Replacement (7)

TOTAL KNEE REPLACEMENT PATIENT CONSENT FORM

Patient's Name: ID no.:

Contact no.: Address: Emergency Contact:

By signing at the bottom of this form you are consenting to a total knee replacement on your _____ knee. Your signature confirms that you have read it in its entirety and agree to proceed with surgery.

Purpose

As we have discussed, the total knee replacement has been developed to aid patients with severe arthritis and destruction of their knee joints. The operation that will be performed on your knee is called a Total Knee Replacement.

Benefits

- Pain Relief
- Improved Mobility
- Better treatment response
- High Success and satisfaction rates

Procedure

The operation will consist of replacing the joint surfaces of the leg bone (lower half of the knee joint) and the thigh bone (upper half of the knee joint) with metal parts that are typically cemented into place. A high-density plastic called polyethylene, which acts like the cartilage is placed between the metal parts. The metal surfaces will move on the plastic piece.

Complications may develop: -

- Infection - The operation will be performed in a Class 100 operation theatre and the surgical team will be meticulously prepared in order to protect you from any bacteria which could cause an infection. Antibiotics will also be administered. However, despite all precautions, infection could still occur. It occurs in <1% of patients. Risk factors for infection are related to both patient and surgical factors. Patient factors include diabetes and low immunity.
- The operation could result in blood clots in lower limb veins. This is a potential complication following any surgery, particularly when the operation is done in the lower extremities. This could produce what is known as a thrombosis. Symptomatic Deep vein Thrombosis occurs in upto 2-3% patients.
- In some cases, a clot may break off in the vein and be carried by the blood stream to the lung (pulmonary embolism), resulting in severe chest pain and shortness of breath. ICU care and anticoagulants (blood thinners) may then be required. In extremely rare cases, pulmonary embolism can cause death; therefore, it is critical to follow directions on taking blood thinners after surgery. The true proportion of symptomatic Pulmonary Embolism would range from 0.02% to 1.06%
- In extremely rare cases, injury to the nerves or blood vessels near the knee joint can occur during surgery. This is extremely uncommon and very unlikely to happen.
- There will likely be a small area of numb skin on the outside part of the knee. The small skin nerve to this region must be cut in order to gain access to the knee. This numbness often diminishes with time and in no way will it affect the function of your knee replacement.
- It is likewise possible that the parts which we have inserted into your knee could, in the future, loosen up from excessive wear and use. This may require further surgery in order to replace part or all of the components.
- Occasionally, unforeseen conditions could arise during the course of the operation that, in your surgeon's judgment, may require an additional surgical procedure or procedures different from those that have been discussed. Your surgeon respectfully requests your authorization to allow such procedures to be performed should they become necessary under any circumstances.
- There are some instances where, even years after a total joint replacement, a patient has developed an infection in the joint that has been replaced. This could occur as a spreading of infection from a source such as an infected tooth, an acute gallbladder attack, a urinary tract infection, or any other type of severe infection in your system. This is not typical, but you should be aware of this fact. If you should, even months or years after the operation, be affected by severe infection, you may refuse a 2-stage revision replacement.

Alternatives: -

- Conservative Management
- Physiotherapy
- Medicines
- Rest

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.
Every effort will be made to obtain a successful result with as much motion as possible in your knee. If a satisfactory range of motion is not achieved within the first several weeks, we may ask you to allow us to manipulate your knee in order to loosen it up. This would be done in the operating room.
Your cooperation with exercising and rehabilitation after the operation is critical in maximizing the chances of a successful outcome.
I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date Date

b. Total Hip Replacement(8)

TOTAL HIP REPLACEMENT (THR) INFORMED CONSENT FORM

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

By signing at the bottom of this form you are consenting to a total hip replacement on your _____ hip. Your signature confirms that you have read it in its entirety and agree to proceed with surgery

Purpose: -

A hip replacement is an operation which replaces the severely damaged hip bone with an artificial ball and socket that does the function of the natural joint.

The main purpose of hip replacement surgery (a.k.a. hip arthroplasty) is to restore the integrity of the ball-and-socket joint between the thigh bone and pelvis, typically in patients with hip arthritis. The goals of this are to get relief from persistent hip pain and/or disability.

Benefits: -

- High success rate
- Offers relief from pain
- Enhanced mobility and function of the hip
- Improved strength.
- Improved coordination of the torso and leg.

Procedure: -

In a total hip replacement (also called total hip arthroplasty), the damaged bone and cartilage is removed and replaced with prosthetic components. The damaged femoral head is removed and replaced with a metal stem that is placed into the hollow centre of the femur.

The femoral stem may be either cemented or "press fit" into the bone.
A metal or ceramic ball is placed on the upper part of the stem. This ball replaces the damaged femoral head that was removed.
The damaged cartilage surface of the socket (acetabulum) is removed and replaced with a metal socket. Screws or cement are sometimes used to hold the socket in place.
A plastic, ceramic, or metal spacer is inserted between the new ball and the socket to allow for a smooth gliding surface.

Complications may develop: -

There are some risks and complications that may happen through a hip replacement surgery associated with anaesthesia, including respiratory or cardiac malfunction. Other complications that can happen right after surgery or even years later include:

- Blood clots. About 1% of people who go through a hip replacement will have a blood clot in their leg (deep vein thrombosis) or lungs (pulmonary embolism).
- Dislocation. Sometimes the ball can separate from the socket. The overall incidence is about 1% to 3%. About 70% of dislocations occur within the first month following index surgery.
- Infection. This is uncommon — it happens to 0.4% to 1.5% of people who undergo a hip replacement.
- Change in leg length. The lengths of your legs will be measured before, during and after your surgery. It may occur that individuals end up with one leg longer/shorter than another and need a shoe lift to even them out.
- Loosening. The loosening of the implant caused by wear and tear is a common long-term problem that happens far less than it used to. This happens less and less as prosthetic materials and surfaces get better.
- Breakage. Sometimes old implants can break down. Less than 0.1% of people end up with a broken implant.
- Injury to nerves and blood vessels.
- Fracture.

- Weakness.
- Stiffness or instability of the joint. Your joint may stiffen because of heterotopic ossification, which is where soft tissues harden into bone.
- Need for additional surgeries.

Alternatives: -

- Losing weight,
- stopping strenuous exercises or work,
- Physiotherapy and gentle exercises,
- Medicines, such as anti-inflammatory drugs (ibuprofen
- or steroids),
- Using a stick or a crutch,

Some of the above are not appropriate if you want to regain as much physical activity as possible, but you should discuss all possibilities with your surgeon.

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist. Every effort will be made to obtain a successful result with as much motion as possible in your hip. Your cooperation with exercising and rehabilitation after the operation will help immensely.

I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Signature Date

_____ _____

Witness Signature Date

c. Shoulder Replacement Surgery(9)

INFORMED CONSENT FORM FOR SHOULDER REPLACEMENT SURGERY

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:
By signing at the bottom of this form you are consenting to a Shoulder replacement surgery on your _____ shoulder.

Your signature confirms that you have read it in its entirety and agree to proceed with surgery.

Purpose:

Shoulder replacement surgery is done to relieve pain and other symptoms that result from damage to the shoulder joint. Shoulder replacement removes damaged areas of bone and replaces them with parts made of metal and plastic (implants). This surgery is called Total or Reverse shoulder arthroplasty.

Benefits:

Replacing the worn surfaces with a replacement surface (prosthesis) will reduce the amount of pain and increase the range of movement available from your shoulder joint. This should result in you being able to move your arm more comfortably to carry out activities that may be difficult.

Procedure:

Your shoulder is a ball and socket-type joint made up of two main parts – the humerus (arm bone, which is the ball) and glenoid (socket, which is part of the shoulder blade). This is known as the gleno-humeral joint. When arthritis affects the shoulder, it can cause the lining of these joint surfaces to wear, causing pain and stiffness. During a shoulder replacement, the joint surfaces are replaced.

Depending on the type of joint damage you have, your doctor may recommend one of the following shoulder replacement options: (Tick mark what is applicable / strike out what is not applicable)

- **Anatomic total shoulder replacement.** Both the ball and the socket are replaced. The implants resemble the natural shape of the bones.
- **Reverse total shoulder replacement.** Both the ball and the socket are replaced, but the implants are reversed. The ball is attached to the shoulder blade and the socket is attached to the upper arm bone. This option typically is preferred if the rotator cuff is severely damaged.
- **Partial shoulder replacement/ Shoulder resurfacing:** Only the head (ball) of the joint is replaced. It may be recommended when only the ball side of the joint is damaged.

Complications may develop:

- **Blood clots.** Clots can form in the veins of the leg or arm after surgery. The rate of symptomatic Venous Thromboembolism following shoulder arthroplasty is 0.5% to 1%
- **Infection.** Significant measures are taken to avoid it, for example you will be given antibiotics to try to guard against it. If an infection develops, further operations may be needed to remove the implanted joint in order to get rid of the infection. Infection rates following primary total shoulder arthroplasty range from <0.1% to 3.9%.
- **Dislocation.** It's possible for the ball of your new joint to come out of the socket.

- **Nerve damage.** Nerves in the area where the implant is placed can be injured. Nerve damage can cause numbness, weakness, and pain.
- **Fracture.** The humerus bone, the scapula or the glenoid bone can break during or after surgery.
- **Rotator cuff failure.** The group of muscles and tendons that surround the shoulder joint (the rotator cuff) occasionally wear out after a partial or total anatomic shoulder replacement.
- **Implant loosening.** Shoulder replacement components are durable, but they may loosen or become worn over time. In some cases, you may need another surgery to replace the loose components.
- **Revision Surgery.** If the artificial shoulder joint wears out or otherwise fails, a surgeon may recommend a revision surgery to remove and replace the joint prostheses. Revision surgeries are often elective, meaning the patient can take time to decide whether to undergo another surgery.

Alternatives:

- Physiotherapy
- Medicines

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

Every effort will be made to obtain a successful result with as much motion as possible in your shoulder. Your cooperation with exercising and rehabilitation after the operation will help immensely.

- I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Signature Date

_____ _____

Witness Signature Date

2. GASTRO DEPARTMENT

a. Frey's Procedure (10)

INFORMED CONSENT FORM FOR FREY'S PROCEDURE

Patient's Name: ID no.:

Contact no.: Address: Emergency Contact:

Purpose:

Abdominal pain with or without back pain is one of the cardinal features of chronic pancreatitis. The purpose of this surgery is to alleviate pain by providing drainage to the obstructed pancreatic duct.

Benefits:

- Pain relief in majority of the patients
- Pancreatic function preservation in some patients

Procedure:

Frey's procedure is a surgical technique used in the treatment of chronic pancreatitis in which the diseased portions of the head of pancreas is cored out, the main pancreatic duct is laid open and joined to a designated loop of the small bowel

Complications may include:

- Early Complications:

➢ Bleeding and blood clots ➢ Injury to other nearby organs such as bile duct, stomach, duodenum, spleen, transverse colon ➢ Wound Infection	➢ Pancreatic leak ➢ Bile leak ➢ Intra-abdominal fluid collection and infection

- Late Complications:

➢ Intestinal Adhesions ➢ Intestinal obstruction ➢ Incisional Hernia	➢ Recurrence of pain ➢ Diabetes mellitus ➢ Pancreatic enzyme deficiency

Patient Specific Risks Factors:

_____

_____

_____

Alternatives:

- Conservative Therapy

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

- I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date

b. Ileostomy Closure

INFORMED CONSENT FORM FOR ILEOSTOMY CLOSURE

Patient's Name: ID no.:

Contact no.: Address: Emergency Contact:

Meaning:

Ileostomy is a stoma (surgical opening) constructed by bringing the end or loop of small intestine (the ileum) out onto the surface of the skin, or the surgical procedure which creates this opening.

Purpose:

An ileostomy closure surgery is done to reverse your ileostomy so you can have bowel movements like you did before your surgery.

Benefits:

- Able to have bowel emptying in normal way
- No longer need of stoma bag

Procedure:

A cut (incision) is made around the stoma and the section of small intestine is pulled out of the tummy (abdomen). The area that had been divided to form the stoma is then stitched back together and placed back inside the abdomen.

Complications:

- Early Complications

➢ Anastomotic leak (Stool leaking into inside your belly or leaking outside your body) ➢ Temporary bowel paralysis. ➢ Small bowel obstruction	➢ Bleeding and blood clots ➢ Injury to other loops of intestines ➢ Pain ➢ Wound Infection

- Late Complications

➢ Stricture of the anastomosis (narrowing of the joint created)	➢ Intestinal Adhesions ➢ Intestinal obstruction ➢ Incisional Hernia

- **Patient Specific Risk Factors**:

_____

_____

_____

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

· I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Patient Signature Date

_____ _____ _____

Witness signature Date

c. Whipple's Procedure

INFORMED CONSENT FORM FOR WHIPPLE'S PROCEDURE

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:

- The Whipple procedure or pancreaticoduodenectomy, is used to treat tumours and other disorders of the pancreas, duodenum, and bile duct. Surgery to remove a tumour offers the best chance for long-term control of all pancreatic cancer types.

Benefits:

- The goal of a Whipple procedure is to prolong a patient's life and potentially cure them of cancer. For some patients, the goal might be to prevent or relieve symptoms such as pain or blockage of the bile duct or stomach.

Procedure:

The goal of the Whipple procedure (pancreatoduodenectomy) is to remove the head of the pancreas. This is where most tumours occur. Because the pancreas is so integrated with other organs, the surgeon must also remove the first part of small intestine (duodenum), the gallbladder, the end of the common bile duct and sometimes a portion of the stomach. In the reconstruction phase of the operation, the intestine, bile duct and remaining portion of the pancreas are reconnected. A tube is inserted in small intestine to feed patients directly into the small intestine in postoperative period. That tube will be removed later on in follow up period on OPD bases.

In some cases, patients may undergo a modified version of the Whipple procedure, which keeps the entire stomach, and the stomach valve called the pylorus. This is called a pylorus-preserving Whipple.

Complications:

- Early Complications:

➢ Bleeding at the surgical areas ➢ Injury to surrounding structures ➢ Pain ➢ Infection of the incision area or inside your abdomen	➢ Delayed emptying of the stomach, which may make it difficult to eat or to keep food down temporarily ➢ Leakage from the connections of pancreas & intestine, bile duct & intestine and stomach and intestine ➢ Complications related to feeding jejunostomy such as leak, infection, blockage of intestine ➢ Intra-Abdominal infections ➢ Intra-Abdominal bleeding

- Late Complications:

➢ Adhesions ➢ Intestinal obstructions ➢ Incisional Hernia	➢ Weight loss ➢ Diabetes, temporary or permanent ➢ Recurrence of the disease, locally or in other

Patient Specific Risk Factors:

_____
_____
_____
_____

Alternatives:

- Chemotherapy
- Radiotherapy
- Clinical trials
- Bile duct stenting

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

· I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date

d. **Ventral Hernia Repair** (11)

INFORMED CONSENT FORM FOR VENTRAL HERNIA REPAIR (incisional/epigastric/umbilical/other)

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Meaning:
A hernia, sometimes referred to as a rupture, occurs when a part of an internal organ, sometimes the bowel, pushes through a weak point in the abdominal wall. Ventral means through the abdominal wall. Ventral hernias can be described by their location more specifically. An incisional hernia can develop in scars after surgery. An epigastric hernia is in the stomach area. Umbilical or paraumbilical means of or around the belly button.

Purpose:
The goal of ventral hernia surgery is to repair the hole/defect in the abdominal wall so that the intestine and other abdominal tissue cannot bulge through the wall again. The surgery often restores the tone and shape of the abdominal wall by repairing the hole and bringing the muscles back to their normal position.

Benefits:
Most hernias will not get better without surgery. Hernia surgery is safe and effective for most people. Repairing a hernia will:

- Pain Relief
- Remove any bulge or lump.
- Prevent complications. In some cases, part of the intestine can become trapped in the weak area of the abdominal wall. It can also cause bowel blockage (obstructed hernia). This can cut off the blood supply (strangulated hernia). Both situations are medical emergencies. Repairing the hernia will prevent this from happening.
- Help reduce discomfort.

Procedure:
The type of operation depends on the hernia size, location, and if it is a repeat hernia. Your health, age, anaesthesia risk, and the surgeon's expertise are also important. An operation is the only treatment for a hernia repair.

- Open Hernia Repair

The surgeon makes an incision near the hernia site. The bulging tissue is gently pushed back into the abdomen. Muscle defect is closed by sutures. Mesh is used to re-inforce the muscle. With complex or large hernias, small drains may be placed going from inside to the outside of the abdomen. The site is closed using sutures, staples, or surgical glue.

- Laparoscopic Hernia Repair

The surgeon will make several small punctures or incisions in the abdomen. The abdomen is inflated with carbon dioxide gas. Ports or trocars (hollow tubes) are inserted into the openings. Surgical tools are placed into the ports. Hernial contents are reduced. Mesh is sutured, stapled, or clipped to the muscle around the hernia site.

Complications:

- Early Complications:

➢ Bleeding and blood clots ➢ Injury to intestines/bowel	➢ Urinary Retention ➢ Urinary Tract Infection

➢ Wound Infection ➢ Pain	➢ Heart Complications ➢ Kidney Failure ➢ Pneumonia

- Late Complications:

➢ Intestinal Adhesions ➢ Intestinal obstruction	➢ Recurrence

Patient Specific Risks Factors:

_____
_____
_____
_____

Alternatives:

- Watchful waiting is an option for a hernia without symptoms. All patients should get treatment if they have sudden sharp abdominal pain and vomiting. These symptoms can indicate an incarcerated hernia and bowel obstruction.
- Customized belts made to apply pressure on a hernia can be used in the patients who are unfit for surgery.

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

- I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date

e. Laparoscopic Fundoplication

INFORMED CONSENT FORM FOR LAPAROSCOPIC FUNDOPLICATION

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:
Fundoplication is a surgical procedure that helps prevent the stomach contents from flowing back up the food pipe, called the oesophagus due to weakness of the valve like mechanism at the lower end of food pipe. It is a surgical treatment for gastroesophageal reflux disease (GERD) and hiatus hernia. This essentially strengthens the valve like mechanism at the lower end of the food pipe.

Benefits:

- Patients get relief of symptoms of heart burn and the situation of food returning back to food pipe. Patients are often able to reduce or eliminate medications.
- As it is a laparoscopic / keyhole surgery, there is Less pain, less scarring, shorter hospital stays and faster return to normal activities as compared to traditional open surgical procedure.

Procedure:
During laparoscopic Nissen fundoplication, the surgeon:
Makes four to five small holes on your abdomen.
Inserts a laparoscope (small tool with a camera) into your abdomen.
Uses the camera images and tiny operating tools to wrap the upper stomach around the lower oesophagus. The lower end of food pipe will be wrapped by stomach all around (that is 360°) or partial (that is 270° or 180°)
Closes the holes with stitches.

Complications:
Any laparoscopic surgery may need to get converted into open surgery if required. Such decisions are made on table by the surgeons in the long-term benefit of the patient.

- **Early Complications:**

➢ Bleeding and blood clots ➢ Injury to food pipe, stomach, other loops of intestines, liver, blood vessels ➢ Pain ➢ Wound Infection	➢ Acid reflux may continue ➢ Inability to swallow solids or liquids which may need endoscopy or even reoperation ➢ Pneumothorax- air gets trapped in the area around the lungs and may require to insert a tube in the chest to allow the lung to inflate properly ➢ Inability to vomit or belch after surgery, resulting in increased flatulence (gas)

- **Late Complications:**

➢ Intestinal Adhesions ➢ Intestinal obstruction ➢ Incisional Hernia	➢ Acid reflux may continue or re-occur.

Patient Specific Risk factors:

_____
_____
_____

_____

Alternatives:

- Medications
- Open surgery
- There are surgical alternatives to a Nissen fundoplication such as a partial wrap and placing magnetic beads around your oesophagus (linx procedure).

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the major risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

- I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date

3. Urology Department

a. Cystoscopy (12)

INFORMED CONSENT FORM FOR CYSTOSCOPY

Patient's Name: ID no.:

Contact no.: Address: Emergency Contact

Purpose:

Doctors use cystoscopy to diagnose, monitor and treat conditions affecting the bladder and urethra. Common reasons your doctor may recommend a cystoscopy include:

- Investigating causes of bladder signs and symptoms.
- Diagnosing bladder and urinary tract diseases and conditions.
- Treating bladder diseases and conditions.
- Diagnosing an enlarged prostate.

Benefits:

Cystoscopy is a procedure that lets the healthcare provider view the urinary tract, particularly the bladder, the urethra, and the openings to the ureters. Cystoscopy can help find problems with the urinary tract. This may include early signs of cancer, infection, narrowing, blockage, or bleeding.

Procedure:

A cystoscopy may feel uncomfortable, but anaesthesia keeps you from feeling pain during surgery. A diagnostic cystoscopy usually only takes about five minutes but may take a little longer. If you're having a biopsy or treatment, the procedure may take longer.During a cystoscopy, your doctor:

- Slides a lubricated cystoscope through the urethra to the bladder.
- Injects sterile salt water through the cystoscope into the bladder. A stretched, full bladder makes it easier to see the bladder lining. You may feel like you need to pee.
- Looks at the inside of the bladder and urethra.
- Inserts small instruments through the cystoscope. Your provider uses these tools to remove tissue samples or tumours, if needed.
- Drains the injected liquid from the bladder or asks you to empty your bladder in the restroom.

Complications:

- Infection
- Bleeding
- Urinary retention due to irritation and swelling from the procedure
- Bladder perforation (poking a hole in the bladder with the cystoscope)
- Swollen Urethra
- Burning sensation while urinating
- Blood in the urine after procedure is common

Alternatives: There is no surgical alternative to a cystoscopy. Sometimes an ultrasound and/or X-ray of the bladder and kidneys (KUB) as a non-surgical alternative may be advised. But these are anyway done before performing cystoscopy.

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

• I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Signature Date

_____ _____

Witness Signature Date

b. Visual Internal Urethrotomy/ Direct Visual Internal Urethrotomy (13)

INFORMED CONSENT FORM FOR VISUAL INTERNAL URETHROTOMY (VIU)/DIRECT VISION INTERNAL URETHROTOMY

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:

Direct vision internal urethrotomy (DVIU) is surgery to repair a narrowed section of the urethra. This is referred to as a stricture. The urethra is the tube that carries urine from the bladder to the outside of the body.

Benefits:

- Stronger force of stream
- decreased waiting for urination
- decreased need to push
- loss of splitting and/or intermittence of the urine stream

Procedure:

Procedure takes less than an hour depending on the length, density, and location of the stricture. Once you're fully under anaesthesia, the surgeon will insert a urethrotome or cystoscope with a surgical knife attached to your urethra.The strictured area will be opened up in specific areas with the cutting blade or knife. The surgeon will then reassess the stricture. If the area appears to be open and easily accessed, there'll be no need for further cuts to be made. If it's still not sufficiently opened up, more incisions will be made. After that is done, your bladder will be completely emptied of urine and filled with irrigation fluid. A catheter will be put in place in your bladder and used to drain the irrigation fluid.

Complications:

- Haematuria (blood in the urine)
- Infection
- Future re-procedure requirements (10-20%)

Alternatives:

- urethroplasty
- urethral dilation
- catheterization

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

• I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

_____ _____

Signature Date

_____ _____

Witness Signature Date

c. **Percutaneous Nephrolithotomy** (14)

INFORMED CONSENT FORM FOR PCNL (PERCUTANEOUS NEPHROLITHOTOMY)

Patient's Name: ID no.:

Contact no.: Address: Emergency Contact:

Purpose:

Percutaneous nephrolithotomy is a technique used to remove certain stones in the kidney or upper ureter (the tube that drains urine from the kidney to the bladder) that are too large (over 1-1.5 cm in diameter) for other forms of stone treatment such as shock wave lithotripsy or ureteroscopy.

Benefits:

- Less post-operative pain as compared to open surgery.
- Fewer complications as compared to open surgery due to the small incision and minimally invasive access to the kidney.
- Quicker return to activities of daily living and work compared to open surgery.
- Better stone free rates post-procedure for larger and more complex stones as compared to less invasive options.

Procedure:

PCNL is a keyhole surgery for removal of kidney stones. Typically, the length of the surgery is three to four hours. The surgery is performed by making a small < 1 cm incision in the patient's flank area. A tube is placed through the incision into the kidney under x-ray guidance. A small telescope is then passed through the tube in order to visualize the stone, break it up and remove it from the body. If necessary, a laser or other device called a lithotripter may be used to break up the stone before it can be removed.

Complications:

- Bleeding(intraoperative/postoperative) requiring blood transfusion
- bleeding from av fistula or pseudoaneurysm needing angioembolisation (0.5%),
- infection and sepsis(upto2.5%),
- failed access in (less than 5%),
- perforation of renal pelvis and/or ureter (less than 2%),
- Pneumothorax or pleural effusion requiring drainage (when supracostal approach used),
- failure of equipment.
- Possible migration of stone fragment and possibility of residual fragments/stones.

Alternatives:

- medical management
- Extracorporeal Shock Wave Lithotripsy (ESWL)
- open pyelolithotomy
- Retrograde intrarenal surgery

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

• I have read and fully understand the information presented above and its relation to the proposed surgical procedure. I also understand that there is no guarantee of the results of the surgery.

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Signature Date

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Witness Signature Date

d. Ureteroscopy(15)

INFORMED CONSENT FOR URETEROSCOPY(URS)

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:
Ureteroscopy is a form of minimally invasive surgery using a small telescope that is passed through the urethra and into the ureter to remove a stone or as a diagnostic modality.

Benefits:

- Ureteroscopy can treat stones located at any position in the ureter and kidney.
- Additionally, ureteroscopy allows the treatment of stones that cannot be seen on an x-ray.
- Certain patients who cannot be treated with ESWL (lithotripsy) or Percutaneous Nephrolithotomy, such as those who cannot safely stop taking blood thinners, women who are pregnant, and the morbidly obese, can be treated by ureteroscopy.

Procedure:
The procedure is typically performed with the patient under general anaesthesia or spinal anaesthesia. During this procedure, a ureteroscope is inserted through the urethra and bladder into the ureter (a tube that carries urine from the kidneys to the bladder) or kidney. X-ray images with a contrast agent (dye) in the ureters may be used to allow the urologist to see where the stone is located and to rule out other abnormalities. The ureteroscope is long and thin with a tiny fibre optic camera at the end that is used to see beyond the bladder into the ureters. Once the stone is located, it is pulled out directly with a 'stone basket' or a laser is used to break the stone into smaller pieces before they are extracted using the basket. Some ureteroscope are flexible like a thin, long straw. Others are more rigid and firm.

DJ Stenting:

A urethral stent is a soft hollow tube that acts like a straw to permit urine to pass from the kidney down the ureter into the bladder. It is very common to have a stent placed into your ureter at the end of a URS. Stents are placed for a variety of reasons, all to help keep the ureter open after the procedure. A "string" is typically left attached to the stent and dangles out the urethra. The string is used to remove the stent 2-5 days post-operatively.

Complications:
(A) common - burning or bleeding on micturition, frequent and /or painful micturition, temporary bladder catheter, need to remove or change stent needing another procedure,
(B)occasional - inability to get stone or movement of stone back into kidney needing another procedure, kidney damage or infection requiring further treatment, possibility of staged procedure, residual stone, failure to pass ureteroscope as ureter is narrow or kinked or tortuous, failure of stone breaking machine etc,
(C)rare - damage to ureter with need for open surgery or need to put PCN in kidney or stricture ureter formation needing further operative procedures, hospital acquired infection, damage to urethra leading to stricture urethra formation needing further treatment.

Alternatives:

- observation to allow spontaneous passage,
- lithotripsy (ESWL),
- other methods of surgical treatment like percutaneous nephrolithotomy (PCNL), open surgical procedure, laparoscopic procedure

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

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e. Transurethral Resection of the Prostate (16)

INFORMED CONSENT FORM FOR TURP (TRANSURETHRAL RESECTION OF THE PROSTATE)

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:
Transurethral resection of the prostate surgery is to treat symptoms caused by an enlarged prostate. This is frequently caused by benign prostatic hyperplasia (BPH). This condition is a normal aspect of growing older. When the prostate gland enlarges, it presses against the urethra, obstructing or blocking urine flow out of the body.
Benefits:

- Relief of urinary obstruction
- Improvement in urinary flow
- Improved urinary symptoms

Procedure:
The resectoscope is inserted into the tip of your penis and extended through your urethra and into the prostate area. Your doctor won't need to make any cuts (incisions) on the outside of your body. Doctor will use the resectoscope to trim tissue from the inside of your prostate gland, one small piece at a time. As small pieces of tissue are cut from inside your prostate, irrigating fluid carries them into your bladder. They're removed at the end of the operation.

Complications:

- Urinary tract infection
- Failure to void (6%) needing further management
- bleeding needing blood transfusion (1%)
- clot retention needing clot evacuation
- stricture urethra (<5%)
- bladder neck contracture (4%)
- incontinence (<0.5%)
- erectile impotency (4%)
- re-resection in about 8% over 10 years period of time.

Alternatives:

- medical management,
- Catheter/stent,
- Transurethral incision of the prostate (TUIP)
- other methods of surgical treatment like open prostatectomy, laser Prostatectomy

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

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f. **Retrograde Intrarenal Surgery** (17)

INFORMED CONSENT FORM FOR RIRS (Retrograde Intrarenal Surgery)

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:
Retrograde Intrarenal Surgery is performed to remove renal stones upto 10 mm (depends on location of the stone also), without making any incisions on the kidney while using a laser and a viewing tube called a fibre optic endoscope that goes through the urethra into the kidney.

Benefits:

- No incision required
- SAFEST procedure of kidney stones as of today
- FASTEST recovery
- Minimal or no blood loss
- Stones upto 10 mm safely treated
- Same day procedure
- All types of kidney stones can be treated unlike lithotripsy where certain composition is resistant.
- Fewer complications
- Both sides can be treated together
- Can be performed for both children and adults alike
- Since the procedure is done after giving Anaesthesia, the surgery is absolutely painless.

Procedure:
Retrograde intra renal surgery is a procedure for doing surgery within the kidney using a viewing tube called a fibrotic endoscope. In RIRS the scope is placed through the urethra (the urinary opening) into the bladder and then through the ureter into the urine – collecting part of the kidney. The scope thus is moved retrograde (up the urinary tract system) to within the kidney (intrarenal). RIRS is done to remove a stone. The stone is seen through the scope and can then be fragmented by a laser probe and grabbed by small forceps. The procedure is usually done under general anaesthesia.

Complications:

- Residual stone fragments
- fever
- flank pain
- urinary infection
- transient haematuria
- acute urinary retention
- ureteral or, pelvicalyceal abrasion
- subcapsular hematoma
- fornix rupture
- extravasation
- urinoma
- ureter avulsion
- bleeding requiring transfusion
- sepsis

Alternatives:

- medical management
- open pyelolithotomy
- Percutaneous Nephrolithotomy
- Extracorporeal Shock Wave Lithotripsy (ESWL)

- Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

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g. DJ Stenting (18)

DJ Stenting (DJS)/Double J Stenting

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:

A Stent is a soft, hollow, plastic tube. Ureteral stents are placed temporarily into the ureter which is the tube that drains the urine from the kidney into your bladder. The stent allows drainage around a stone or can speed up healing after stone surgery. A double J stent is a ureteral stent with curving ends that prevent the stent slipping into the bladder or the kidney.

Benefits:

- It maintains the Ureter open all the time.
- It has multiple holes and even if there is block in the path urine can travel through these holes and prevent back pressure changes and Kidney destruction.
- It helps the ureter dilate. The ureter or the passage from the Kidney to the urinary bladder enlarges to about two and a half to three times.
- It helps prevent strictures or narrowing during the healing process. If there is injury or obstruction due to a stone, the healing process would narrow the lumen [tube]. The DJ stent prevents this from happening.
- It can flush the stones out of the Kidney. The person's movement especially during walking or running creates movement of urine in the Kidney that facilitates movement of the stone out of the Kidney.
- It helps the Kidney push out stones. The DJ stent is a foreign body, and the body tries to push it out and these movements help the stones to come out.

Procedure:

The doctor will insert a cystoscope through the urethra and into the bladder, visualizing the opening to the ureter. A thin wire is then guided through the cystoscope, up the ureter, and into the kidney. The stent is inserted over the wire. A fluoroscope, a kind of x-ray machine, may be used to position the stent. The wire and cystoscope are then removed. When it is time to remove the stent, the same method is used. A cystoscope is inserted through the urethra and into the bladder and the stent is grasped with a small instrument and removed. You will be awake during this procedure and will only require a local anaesthetic.DJ stent has to be removed or changed **Within Three Months**, unless specified otherwise by the treating doctor.

Complications:

- **Common:**
  - mild bleeding or burning on passing urine(temporary)
  - discomfort, pain, and frequency due to stent (usually temporary)
  - further procedure to remove or change stent within three months, unless specified otherwise by the treating doctor
- **Occasional**:
  - urinary infection requiring antibiotics
  - failure to pass stent requiring alternative procedure.
- **Rare:**
  - stent may migrate up or down
  - delayed bleeding needing clot removal or transfusion or further surgery
  - injury to urethra, bladder or ureter needing further surgery
  - hospital acquired infection
  - stent may pass outside the ureter and may need further procedure

Alternatives:

- percutaneous nephrostomy
- open surgical procedure

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

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h. **Stent Removal** (19)

INFORMED CONSENT FORM FOR STENT REMOVAL

Patient's Name: ID no.:
Contact no.: Address: Emergency Contact:

Purpose:
Based on the life of the material that the DJ stent is made up of there is a need to remove the stent. In case the stent is not removed within the specified time complications like formation of stone over the stand, breakage of the stent into small pieces and passing of those pieces in urine, blockage to the flow of urine from the kidney to the ureter, infections, bleeding, and migration of the stent may take place. This will need ancillary surgical procedures to remove the stent.

Benefits:

- Timely removal of ureteral stent after the surgery decreases some complications such as urinary tract infection, bladder irritation symptoms, and persistent haematuria.
- It reduces the risk of stent encrusting and also leads easier stent removal.
- Removal of the ureteral stent shortly after the surgery reduces the hospitalization period and omits secondary admission of patient for removing the stent.

Procedure:
Some short-term (less than a week) ureteral stents have strings that hang outside the urethra, where pee comes out. Your healthcare provider gently pulls on the string to remove the ureteral stent.

If you need a ureteral stent for a week or longer, the stent won't have a string. Your provider removes the stent during a minor office procedure. You may get X-rays or an ultrasound before removal. This imaging assures the provider that your kidney stone or other issue has resolved.

To remove the stent during a procedure, doctor,

- Inserts a cystoscope through the urethra and into the bladder.
- Uses tiny clamps attached to the cystoscope to grab onto the stent.
- Gently removes the stent.

Complications:

After surgery,

- A frequent need to urinate without being able to pass much urine.
- Pain in the flank, which is just below the rib cage and above the waist on either side of the back.
- Blood in your urine.

This generally only last a few hours but should resolve over the next 2-3 days.

Every effort will be made to prevent all complications. Although they are not very common, it is important that you know about them in order to make an informed decision. You must be informed of the any risks involved in any operation. That is why this document is being included in your operative consent. It is not meant to frighten or upset you, but to point out the facts as they exist.

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Chapter 5: Discussion

According to the results of the study done in the KD Hospital at Ahmedabad, most of the employees believes that specific informed consent forms have great importance in the medical practices. Total 61 employees responded to the survey, 20 of them were doctors, 3 of them were from Quality Department and 8 from Medical Admin Department, and from Nursing Department 30 employees responded. According to results 15 out of 20 doctors who responded, experience or know about medicolegal issues that happened due to problems of consent form. All 3 respondents of Quality Department responded positively to the same and from medical department out of 8, 5 respondents were experienced the same and from nursing staff 50% of them respond positively and 50% of them didn't have any experience about it. Hence, from the observation we can say that more or less doctors and other participated departments' staff experience or know about medicolegal issues which happened due to consent forms. In response of the next question which is "Do you think Specified Informed Consent form will play important role in terms of medico legal", 80% of the participants are Strongly agree and agree with it, 13.1% respond neutral and only around 7% of the participants responded negatively. Among the participants all doctors, quality department staff and medical admin department staff were 100% strongly agree and agree with this but from the nursing department 13.33% were strongly disagree and disagree. So from the results we can say that most of the participants think that specified informed consent will play important role in terms of medico legal. According to the next question's results the highest respondents were 95% of the doctors and 90% of the nurses who face complaints from the patients or patients' relatives regarding lack of information about the surgery even after proper explanation. Almost every staff member responded positively to the question that specific informed forms as compared to general consent form will improve medico legal safety and that informed consent form leads patient to less confusion and offers more clarity, but 3% and 13% respectively responded negatively to these questions. Participants also respond very positively that specific informed consent will help in increase satisfaction of patient and also that specified informed consent form leads to less time consuming and easy explanation process for healthcare staff. More or less every department staff think that there is need of specified informed consent form for improved quality of care and in aspect of medico legal safety, highest positive response came from the doctors, medical admin and

quality department staff and only few of nursing staff which are 3.3% response negatively to it. From the results of the survey, we can say that more or less doctors and every department staff responded positively that informed consent is important for medical practices and there are need of specified informed consent forms.

Chapter 6: Conclusion

This study revealed the results that present that Specified informed consent form has a great importance in Medical Practices according to the majority of the doctors, and Quality, Medical admin and nursing staff of the KD Hospital at Ahmedabad and there are need of the Specified Informed Consent form for different surgeries of different departments. So according to the need of the informed consent, Specified Informed Consent prepared for 3 Departments Gastro, Uro and Ortho.

Hence some suggestions to the organization are that they should translate the specific informed consent form in 3 Languages which are English, Hindi and Gujarati so patient can easily understand it,

Implement the newly prepared Informed Consent forms as soon as possible, Spread awareness and arrange informative sessions about informed consent forms and medico legal topic among the staff especially for less experienced doctors and nursing staff and also prepare informed consent form for other treatment/surgeries of different department which remained.

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