



The Perspective of Surgeons and Patients on the Importance of Validity on Informed Consent Before Undergoing an Operative Procedure in the Philippines: A Qualitative Study

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1. Introduction

BACKGROUND OF THE STUDY

Informed consent creates trust between doctor and patient by ensuring good understanding. It also reduces the risk for both patient and doctor. With excellent communication about risks and options, patients can make choices which are best for them and physicians face less risk of legal action. Informed consent means patients receive enough information to make an educated decision about their treatment. This may mean a physician explains the possible side effects, risks and benefits of a course of treatment or informs a patient of what other treatments may be available. It can mean patients are given enough time, if possible, to consider their options and seek a second opinion, if appropriate. Informed consent can also mean patients are informed if treatment is recommended, as well as what might happen if they get no treatment.

No one can guarantee positive outcomes in healthcare settings, but informed consent at least ensures patients understand the risks they undertake with treatment. Informed consent creates trust between doctor and patient by ensuring good understanding. It also reduces the risk for both patient and doctor. With excellent communication about risks and options, patients can make choices which are best for them and physicians face less risk of legal action. To work effectively, informed consent must allow patients to make the decisions right for them (Gallagher,2018). This means medical professionals must offer enough information to patients to enable them to make a choice and provide enough time, where possible, so patients don't feel pressured to decide. Pain, medication and some medical conditions can affect judgment and understanding, so doctors must consider these factors when seeking consent from a patient.

Every person has a right to health and medical care corresponding to his state of health, without any discrimination and within the limits of the resources, manpower and competence available for health and medical care at the relevant time. The patient has the right to appropriate health and medical care of good quality. According to (DOH,2020) the patient has a right to a clear, truthful and substantial explanation, in a manner and language understandable to the patient, of all proposed procedures, whether diagnostic, preventive, curative, rehabilitative or therapeutic, wherein the person who will perform the said procedure shall provide his name and credentials to the patient, possibilities of any risk of mortality or serious side effects, problems related to recuperation, and probability of success and reasonable risks involved.

Cholecystectomy is the surgical removal of the gallbladder and one of the most common surgical procedure all over the world. It is done as an open procedure or as a minimally invasive / laparoscopic procedure. Laparoscopic cholecystectomy began in the early 90's and now it is the standard surgical care for elective calculous cholecystitis particularly in advanced countries (90-95% of all cholecystectomies are done laparoscopically). In 2013, the Philippine General Hospital recorded 895 cases of elective cholecystectomies and 55% were done laparoscopically and it continue to rise in our health institutions particularly in those with accredited surgical training program (Jones, 2023). Cholecystectomy in the Philippines is one of the most commonly performed elective general surgical procedure. In a year, more than 8,000 patients undergo elective cholecystectomies in hospitals with accredited surgical training programs (Perez,2016).

Laparoscopic cholecystectomy has received nearly universal acceptance and is currently considered the criterion standard for the treatment of symptomatic cholelithiasis. Laparoscopic cholecystectomy has rapidly become the procedure of choice for routine gallbladder removal and is currently the most commonly performed major abdominal procedure. Laparoscopic cholecystectomy provides a safe and effective treatment for most patients with symptomatic gallstones and has become the treatment of choice for many patients. This procedure has more or less ended attempts at noninvasive management of gallstones (Sherwinter,2022).

A review of consent for surgery is timely. As the length of surgeons' operations diminishes, despite the increasing interest in the content of the surgical curriculum, the law governing the process of gaining consent has been given scant attention. The advent of non-medically qualified surgical professionals

raises questions about the breadth of knowledge that is required to ensure that valid consent is obtained. Consent is as fundamental as any other basic principle on which surgery relies. In order to protect the doctors from the accusation of an unwanted touch and to operate patients accordance to ethical consideration, this study will focus on the informed consent sessions between the surgeon and the patient. It is to explore a surgeon's role, responsibilities, insights, and experience in performing his part in the informed consent session. On the other hand, to review the patient's perception about informed consent, his/her comprehension for the need of surgical management, the emotions felt, and the reason for the decision to grant or deny informed consent.

LITERATURE REVIEW

Laparoscopic cholecystectomy

Laparoscopic cholecystectomy is a minimally invasive surgical procedure used for the removal of a diseased gallbladder with stones. Since the early 1990s, this technique has largely replaced the open technique for cholecystectomies. Laparoscopic cholecystectomy is currently indicated for the treatment of acute or chronic cholecystitis, symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis, and gallbladder masses or polyps. This activity describes the indications, contraindications, and potential complications of laparoscopic cholecystectomy and highlights the role of the interprofessional team in the management of patients with gall bladder disease (Collins,2023).

According to (Rao,2022) cholecystectomy is the most common procedure in hepatobiliary surgery. Cholecystectomy consists of open cholecystectomy and laparoscopic cholecystectomy (Song,2023). Both surgical procedures are effective in the treatment of patients with gallbladder stones combined with chronic cholecystitis. With the development of medical technology, minimally invasive surgery has captured more clinical attention, which has resulted in the substitution of traditional open cholecystectomy by small-incision cholecystectomy and laparoscopic cholecystectomy, both of which are considered safe and classical procedures. Laparoscopic cholecystectomy effectively shortens the operative time and length of hospital stay in patients with gallbladder stones and chronic cholecystitis, reduces intraoperative bleeding, attenuates the inflammatory response, and enhances the gastrointestinal function with less surgical trauma and high safety.

Laparoscopic cholecystectomy provides better surgical results, mitigates the inflammatory response, lowers the incidence of complications, and improves the quality of life of patients versus open cholecystectomy, so it is worthy of application in clinical treatment.

Informed Consent

Informed consent (IC) is a voluntary authorization given by a patient or research subject after fully comprehending the risks involved in various procedures and treatments. Though a patient may fulfill all the aspects of consent by completing an informed consent form (ICF), it indicates poor execution of the IC process by ill-informed patients with little comprehension. (Patil,2023) revealed that a better understanding of the informed consent by the patients is a vital component of the process as it helps exercise autonomy in the decision-making process. However, the lack of information in the informed consent forms critically affects the quality and adequacy of the IC, thus posing ethical and legal challenges to genuinely informed consent.

According to (Shah,2023) informed consent is both an ethical and legal obligation of medical practitioners and originates from the patient's right to direct what happens to their body. Implicit in providing informed consent is an assessment of the patient's understanding, rendering an actual recommendation, and documentation of the process. Several exceptions to the requirement for informed consent include (1) the patient is incapacitated, (2) life-threatening emergencies with inadequate time to obtain consent, and (3) voluntary waived consent. If the patient's ability to make decisions is questioned or unclear, an evaluation by a psychiatrist to determine competency may be requested.

The overall level of knowledge regarding informed consent for surgery was significantly lower than that of other national and international figures. Patient satisfaction and patient to provider relationships were associated with knowledge of surgical informed consent. Adequate information should provide before surgery to improve patients' knowledge regarding surgical informed consent and to improve the consent process to make it better suited to fit the needs of all patients. Several factors may affect surgical informed consent, including patients competence, provision of limited information, unsuccessful communication between patients and professionals, hospital environment, privacy issues, and inadequate time (Kabede,2023). The surgical informed consent process is vital to patients, however, patients vary in their views of its purpose with the dominant view enabling patients' self-decision-making.

Informed consent is an integral component of good medical practice. Prior to any examination or treatment, clinicians should discuss with patients the potential harms, benefits and alternatives of the proposed care (Convie,2020). Shortcomings in this process can lead to a breakdown in the clinician-patient relationship and occasionally litigation. A series of high profile court proceedings have redefined how the consent process is conducted. The courts now expect doctors to advise their patients of all risks that an individual patient would determine to be of 'material' importance to him or her, regardless of how unlikely that risk might be.

The principle of informed consent originates from a patient's right to self-determination. This means that patients can make decisions about their bodies independently without influence from anyone. Informed consent may be used for different purposes in different contexts: legal, ethical and administrative. Informed consent is a relatively novel practice in surgery, which became a standard procedure as surgical practice became more patient-oriented. Several problems affect obtaining a quality informed consent. To mention the few;

patient comprehension, patient's use of disclosed information, patient autonomy, demand on care providers (time, being free from bias), difficulty of physicians to meet minimum requirements (Change,2020).

Legal Aspects

The informed consent doctrine is a legal principle that holds healthcare providers accountable for ensuring that their patients are fully informed about any medical procedures or treatments before they agree to them.

According to Senate Bill 1402, the law explains the Right to Informed Consent - The Patient has a right to self-determination and to make free decisions regarding himself/herself, however, the attending physician shall inform the Patient of the consequences of his/her decisions

The Hospital Licensure Act or Republic Act 4226 was enacted in 1965 to mandate the Bureau of Medical Services to set standards in hospital consultations and operation, as well as to register ad grant license to operate to hospitals (HREP,2020).

In the course of his/her treatment and hospital care, the patient or his/her legal guardian has a right to be informed of the result of the evaluation of the nature and extent of his/her disease, any other additional or further contemplated medical treatment on surgical procedure or procedures, including any other additional medicines to be administered and their generic counterpart including the possible complications and other pertinent facts, statistics or studies, regarding his/her illness, any change in the plan of care before the change is made, the person's participation in the plan of care and necessary changes before its implementation.

The patient or his/her legal guardian has the right to be informed by the physician or his/her delegate of his/her continuing health care requirements following discharge, including instructions about home medications, diet, physical activity and all other pertinent information to promote health and well-being.

At the end of his/her confinement, the patient is entitled to a brief, written summary of the course of his/her illness which shall include at least the history, physical examination, diagnosis, medications, surgical procedure, ancillary and laboratory procedures, and the plan of further treatment, and which shall be provided by the attending physician. He/she is likewise entitled to the explanation of, and to view, the contents of medical record of his/her confinement.

STATEMENT OF THE PROBLEM

The study aims to determine the perspective of Surgeons and Patients on the importance of the validity of Informed Consent before undergoing an Operative Procedure – Laparoscopic Cholecystectomy in the Philippines.

Specifically, we seek to answer following questions:

1. What is the experience of surgeons and patients on signing an Informed consent prior to undergoing Laparoscopic Cholecystectomy?
2. What is the perception of the surgeon and the patient on the validity of informed consent prior to undergoing Laparoscopic Cholecystectomy?
3. What are the difficulties and barriers that the surgeons and patients encountered in signing the informed consent prior to undergoing Laparoscopic Cholecystectomy?
4. What are the recommendations to improve the Hospital Guidelines in signing the Informed Consent prior to undergoing Laparoscopic Cholecystectomy?

Significance of the Study

Patients and Guardians. This study is to ensures patients and the guardians to have an awareness towards the importance of informed consents before going for further medical procedures and treatments. It is their right to be informed of any risks and considerations before and after the operation/treatment. Thus, it increases satisfaction and is associated with a better patient-health care provider relationship.

Health care Providers. This study shows the healthcare providers carries out the efficiency of informed consents utilizing ethical principle of respect to the patient and the families on the procedures, requirements, diagnosis, and results of the examination. Hence, it is a safety standard ensuring the security and confidentiality of both parties.

Researchers: This study can benefit the researchers as well. They will improve and enhance their knowledge and skills for conducting research. Moreover, to explore the importance of conducting informed consent and able to apply it in the service.

Future Researchers – Information derived from this study will be greatly beneficial to future researchers who may have a similar topic from study which they can use as a form of reference.

DEFINITION OF TERMS

Informed Consent - Permission granted in the knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with full knowledge of the possible risks and benefits.

Surgeon – A medical practitioner qualified to practice surgery.

Patient - Is a person who is receiving medical treatment from a doctor, medical or surgical.

Perception – A way of regarding, understanding, or interpreting something; a mental impression.

Validity – The state of being legally or officially binding or acceptable.

Operative Procedure – A medical procedure involving an incision with instruments; performed to repair damage or arrest disease in a living body.

Competent- A person's ability to make and communicate a decision to consent to medical treatment.

Coercion- every (medical) measure taken against the (natural) will of the person affected.

Morality- principles concerning the distinction between right and wrong or good and bad behavior.

2.0. Methodology

The methodology serves as the foundation of any research, offering readers insight into the structured processes and techniques employed to gather and analyze data. In this chapter, we delve into the intricate layers of our research approach for the study "Informed Consent in Clinical Practice: Qualitative Study on Surgeon and Patient's Experiences and Perspectives in the Philippines." The focus will be on presenting a comprehensive overview of the study design, participant selection, data collection tools, and analytical methods, ensuring the research's validity and reliability. By presenting these methods and procedures in a systematic manner, this chapter aims to offer transparency to the readers, allowing them to understand the rationale behind each decision made during the research process and appreciate the depth and breadth of the study.

2.1 Study Design

A qualitative phenomenological research design will be chosen for this study to get a deep understanding of the experiences and perspectives of surgeons and patients regarding informed consent in clinical practice. Qualitative research, by nature, prioritizes depth over breadth, focusing on understanding individual experiences, perceptions, and contexts rather than generalizing findings to larger populations. In fields like medicine, where individual perspectives and nuanced interactions play a pivotal role, such a design becomes particularly relevant.

Specifically, face-to-face, semi-structured interviews were utilized. This design was deemed suitable as it allowed the participants to express their feelings, thoughts, and experiences in a comprehensive manner. Within the qualitative framework, the choice to conduct face-to-face, semi-structured interviews was deliberate. Face-to-face interactions offer the interviewer the advantage of gauging non-verbal cues, which can be as telling as verbal responses. This type of interaction aids in building trust between the interviewer and the participant, thereby creating an environment where participants feel more comfortable sharing personal experiences and feelings.

Semi-structured interviews, on the other hand, strike a balance between structured and open-ended questioning. They provide a clear direction to the conversation, ensuring that critical aspects of the research topic are addressed. Simultaneously, they offer flexibility, allowing participants to expand on points they deem essential and share experiences that might not be captured through strictly structured questions. Such an approach ensures that while the research objectives guide the conversation, there is ample room for unexpected yet valuable insights to emerge.

2.2 Research Locale

The study was conducted in two major hospitals in the Philippines specifically Metropolitan Medical Center, East Avenue Medical Center, Valenzuela Medical Center and Veterans Medical Center. These hospitals were chosen because of their diverse patient populations and their prominence in providing surgical care in the region. This diversity and prominence ensured a wide range of experiences and perspectives on the topic.

2.3 Participants (Inclusion Exclusion Data- Post op days/weeks-Department of the Surgeon etc.)

The participants of the study were divided into two groups. The first group consisted of 10 surgeons who had been practicing for a minimum of five years. The second group included 15 patients who had undergone surgical procedures within postoperative day one and the past 5 years. Participants were chosen using a purposive sampling method, ensuring varied ages, genders, and surgical experiences. The researchers utilize purposive sampling in choosing the participants. Purposive sampling improves the rigor of the study and the reliability of the data and outcomes by better matching the sample to the research's goals and objectives (Campbell et al., 2020). It is also sometimes referred to as judgmental or subjective sampling and is a technique that depends on the researchers' judgment as regards choosing the factors that will be analyzed in the study (Sharma, 2017).

2.4 Instruments

The primary instrument used in this study was a semi-structured interview guide. This choice of format was grounded in its ability to combine both structured questioning and flexibility, ensuring a balance between consistency and the exploration of varied experiences. Separate guides were created for surgeons and patients, each tailored to solicit relevant information from the respective groups. Firstly, the two groups inherently have different experiences and perspectives in relation to informed consent. Surgeons, as medical professionals, approach the concept from the standpoint of medical ethics, procedural necessities, and communication with patients. Their questions, therefore, were tailored to explore their training, understanding, and implementation of informed consent processes. Patients, on the other hand, experience informed consent as recipients. Their questions delved into their

understanding of the procedure they underwent, the clarity of communication they received, and their comfort level in the entire process. By tailoring separate guides, the study ensured that questions were relevant and resonated with the individual experiences of both groups.

2.5 Data Collection Procedure

One of the foundational steps in ensuring the validity and integrity of a research study is the meticulous planning and execution of the data collection procedure. This study followed a structured yet considerate approach to data collection, recognizing the importance of maintaining both the privacy and trust of the participants. First and foremost, obtaining permission from the selected hospitals was essential. This not only facilitated a smooth execution of the research process within these institutions but also signified the study's commitment to adhering to ethical and institutional guidelines. Navigating the administrative and procedural aspects of hospital permissions ensured that the research was conducted in an environment that was both supportive and aware of the study's objectives.

Equally crucial was the act of securing informed consent from all participants. Informed consent, beyond being an ethical necessity, also built a foundation of trust between the researcher and the participants. By being transparent about the study's aims, methods, and implications, participants were made fully aware of their roles, rights, and the extent of their involvement. This transparency likely encouraged more open and genuine sharing during the interviews. Conducting the interviews in private rooms within the hospitals underscored the study's commitment to maintaining participant confidentiality and comfort. A private setting ensured that participants could speak freely, without fear of being overheard, and also minimized potential distractions. The decision to allocate a time frame of 30 to 45 minutes for each interview struck a balance between obtaining in-depth responses and respecting the participants' time constraints.

The use of a digital voice recorder during the interviews served a dual purpose. With the explicit consent of the participants, recording the interviews ensured that no detail, no matter how minute, was overlooked. This method eliminated the potential pitfalls of relying on memory or hand-written notes, which can sometimes miss nuances or misrepresent statements. Furthermore, these recordings proved invaluable during the transcription phase, allowing for a more accurate representation of the interviews and thus providing a solid foundation for subsequent analysis. In essence, the data collection procedure was meticulously crafted to prioritize the integrity of the research while ensuring the comfort and trust of the participants. Through careful planning and a commitment to ethical principles, the study ensured that the data gathered was both rich in detail and grounded in genuine experiences.

2.6 Limitations of the Study

Every research has its constraints. One limitation of this study is that it focused only on Manila hospitals, which might not represent the views of those from rural areas or other cities. The participants' recall bias might also affect the accuracy of the information shared, especially with patients recounting past experiences. Furthermore, the qualitative nature of the study means that findings may not be generalizable to the larger population.

2.7 Data Analysis

Following the meticulous data collection process, the next critical step was the transcription of the interviews. Each interview was transcribed verbatim, ensuring that the participants' expressions, emotions, and emphasis were accurately captured. This verbatim approach is crucial in qualitative research, as it preserves the authenticity of the participant's voice and prevents the introduction of researcher bias during the transcription phase. Once transcribed, these documents underwent a rigorous review process. This step was essential not only to cross-check the transcriptions against the original recordings for accuracy but also to familiarize the researcher with the depth and breadth of the data at hand.

With the transcriptions in place, the study then moved to the analytical phase, employing a thematic analysis approach. This approach is particularly suited for qualitative data as it seeks to identify, analyze, and report patterns or themes within the data. The transcribed interviews were carefully examined, and data was coded, forming an organized collection of themes and sub-themes. These codes served as markers, highlighting recurrent ideas, sentiments, and experiences shared by participants. As the themes and sub-themes emerged, they began to form a coherent narrative, shedding light on patterns and relationships within the data. Through this analytical process, the study was able to distill the vast array of participant responses into structured insights, capturing the essence of their perspectives and experiences regarding informed consent in clinical practice.

Moreover, thematic analysis will be utilized in order to analyze the findings of the study. Thematic analysis is used to analyze qualitative data – that is, data relating to opinions, thoughts, feelings and other descriptive information. Qualitative analysis may be a highly effective analytical approach when done correctly. Thematic analysis is one of the most frequently used qualitative analysis approaches. It is a method that involves reading through a set of data and looking for patterns in the meaning of the data to find themes. It is an active process of reflexivity in which the researcher's subjective experience is at the center of making sense of the data.

2.8 Ethical Consideration

Ethical approval was secured from the ethics committee of each hospital before the start of the study. All participants were given a detailed explanation of the study's purpose, their rights, and what participation entailed. Written informed consent was obtained from every participant. Confidentiality and anonymity were maintained throughout the research process, ensuring that participants' identities and information were protected.

Confidentiality

All participants have a right to privacy, so you should protect their personal data for as long as you store or use it. Even when you can't collect data anonymously, you should secure confidentiality whenever you can, Bhandari (2023). The respondents were fully aware of the ethical considerations involved in participating in the study. The study's procedures and outcomes were clearly explained to the participants. The participants were not forced to participate in the study. The participants are well protected and informed of any harm that the study may cause to them. The participants are well assured that their identity and personal information are secured and will remain confidential throughout the study.

Data Privacy (Act of 2012)

The study integrates the "Data Privacy Act of 2012" (DPA of 2012) was established to protect and to safeguard the individual personal data in an information and communications systems within the government and the private sector while keeping the fundamental human right to privacy of communication" according to Pitogo (2021). The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about the respondents will have a number on it instead of name. The participant do not have to take part in this research if they do not wish to do so. They may also stop participating in the research at any time they choose. It is their choice and all of your rights will still be respected.

Informed consent

Informed consent is one of the founding principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent before they enter the research. Consent should be obtained before the participant enters the research (prospectively), and there must be no undue influence on participants to consent. The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to. The informed consent is described in ethical codes and regulations for human subject's research, Manti (2018).

3. Results

Surgeons Perception

The importance of Informed Consent in the practice of surgery particularly with patients undergoing Laparoscopic Cholecystectomy

According to the significant response of the surgeons, "Informed consent is very important especially for the patients to make an informed and sound decision", additionally persuaded by others as "to make sure the patient and family members understand what the procedure is, the indication, risks for the procedure and the benefits of undergoing the procedure". It was perceived by majority that before surgery, it's crucial to ensure patient understanding of procedure, indication, risks, benefits, and expectations before any Informed Consent agreement. This ensures they make an informed decision and understand the operation's implications.

Insights about the role of a surgeon in obtaining Informed Consent from the patient before undergoing Laparoscopic Cholecystectomy.

On the perception of the surgeon's insights towards its role in obtaining informed consent from the patient before the procedure, a significant response from the respondent said that "Surgeons play an important role in obtaining informed consent because the surgeons are the ones to explain the procedure details, associated risks and benefits for the patient. It is the surgeon's responsibility to foster patient understanding for the patient to have sound decision-making", "it is vital to develop rapport to the patient to make sure that the procedure is indeed indicated with his condition to avoid doubts and misunderstanding to the procedure that is needed", "the role of the surgeon is very significant because the patient and their relatives will rely on their expertise to gain their trust and confidence and obtain their approval for the procedure intended". This response discusses on the significance of the surgeon must thoroughly explain the procedure to the patient and their relative/s before surgery, ensuring informed consent. They should establish rapport, explain expectations and risks, and ask questions for clarification and transparency. Surgeons play a crucial role in fostering patient comprehension for sound decision-making.

Discussion to the patient the diagnosis, the need for surgical management, the outcome and possible complication of the procedure

"I created a calm, empathetic atmosphere while listening actively to the patients inquiries and concerns", "I presented the diagnosis clearly, discussed the necessity of the procedure and explained in plain language potential outcomes and procedure related complications. This is to ensure that the patient is well informed" and * and i used photos, gave examples and relate to simple procedures and language a layman can understand". These were some of the responses from the surgeons that explains patients diagnosis, the need of the surgical management, the outcome and possible complication of the procedure. Thus, it emphasizes the importance of thorough, objective explanation of surgical procedures to patients and their families, including pre-clinic and bedside rounds, informed consent, pros and cons, and a calm, empathetic atmosphere, to ensure that patients are well-informed.

How do you know that your recommendation to the patient is well comprehended and accepted with regards to their ability to understand your explanations

The process for assessing patient comprehension, including asking questions and confirming understanding, following up with follow-up questions, allowing patients to express themselves, signing informed consent, and assessing comprehension through verbal confirmation and encouraging patient sharing of queries were the insights that of the surgeons' recommendation in determining a well comprehended and accepted with regards to their ability to understand your explanations. Based on the response, it was yielded such as: "I usually assess comprehension by verbal confirmation. I encourage the patient to share his/her queries going back and forth ensuring that the patient fully understands." Moreover, "Asking patient frequently if there are

clarifications or questions. Give them time to express themselves and speak freely”, “When they give a response when asked to respond regarding understanding the explained process”, and “By letting them signed an informed consent without any hesitations”.

Satisfaction on the current process of obtaining informed consent for Laparoscopic Cholecystectomy at your hospital/clinic

As analyzes in the responses from the respondents, it yields that a satisfaction remark was determined on the current process of obtaining consent from Laparoscopic Cholecystectomy at your hospital/clinic. Accordingly, “It is satisfactory however, regular evaluation and improvements in informed consent process ensures patient satisfaction and compliance” a significant response from the participant.

The extent of feeling that the informed consent process ensures clarity and transparency in communication between surgeons and patients

“It significantly enhances clarity and transparency especially when detailing procedure specifics, associated risks and possible alternative managements. This ensures a comprehensive understanding and open communication between surgeons and patients” although “there may be limitations since the consent form used for one operation is similar to the others” the surgeon participants answers. Furthermore, it was interpreted that the importance of clear, well-written consent forms, will ensure clarity, satisfaction, and confidence in the process. It also highlights the limitations of similar forms and their potential limitations in enhancing patient understanding and communication.

Satisfaction on the level of patient involvement in the informed consent process

As a very important matter, surgeons described that the level of patient involvement in the informed consent process was interpreted as satisfaction. It explains that patient involvement in shared decision making is very important. Being able to make the patient understand his/her diagnosis, planned procedure with associated risks and benefits and finally make an informed decision is very satisfactory.

Feeling on the current informed consent process adequately addresses and respects the rights and autonomy of patients

On the adequacy of informed consent, it addresses a satisfaction as it addresses the rights and autonomy of patients. A properly executed informed consent process should always uphold the patient’s rights and autonomy. Regular evaluation of such process ensures continual improvement.

Satisfaction on the overall quality of information provided to patients in the informed consent process, and the challenges that encountered on acquiring Informed Consent

“It is satisfactory. As long as there is comprehensive and clear communication of information during the informed consent process, there will be patient understanding and satisfaction”, the respondent explains. It pertains that in acquiring informed consent of the patients, the quality of information presented to them on the process, requirements, and other significant and confidential information was determined as satisfactory. It is important to deliver an accurate and clear details amidst of any hardships faced in order to informed the patients.

Challenges that you have encountered on acquiring Informed Consent and what will be your recommendation to overcome such difficult situation

According to the significant response from the interview, it tackles that “consent is crucial in medical procedures, especially for patients who are elderly, young, or minor. It is essential for the patient's companion or relative to understand the document. Informed consent is crucial to minimize confusion and ensure the patient's well-being. Language barriers and patient anxiety can be overcome by using interpreters and addressing concerns empathetically”.

A surgeon mentioned, “Explanation of major risk complication/s like iatrogenic biliary ductal injury and possible morbidity and mortality from the procedure”.

“Sometimes the patient and the relatives try to pass signing the consent form to each other- solution is to explain further who should be the one to decide and sign.”

Another participant pointed out that “ Most challenges I have encountered are language barriers and patient anxiety. To overcome such barriers, we should use interpreters as needed, present with additional resources while addressing patient concerns empathetically to ensure comprehensive patient understanding and shared-decision making”.

The importance of understanding the patient's consent form, especially for those who are elderly or minors. It also suggests that handwritten or video consent is recommended. The text also highlights the need for informed consent, explanation of major risks, and the role of the patient in decision-making. It also addresses language barriers and patient anxiety.

Patients

Perception on what is an Informed Consent before undergoing Laparoscopic Cholecystectomy?

Consent was obtained through a thorough briefing and understanding of the procedure's pros and cons. On the perception of the patients, a 58 year old, Male patient, “A little bit, I was informed prior to the procedure regarding the need for my consent and what that consent entails”. Another 48 year old female patient had an idea, “ It is a voluntarily written consent signed by the patient within 24 hours before proceeding to the operation”. Informed consent was being done for any procedural operations in order for the patient as well as the family to be knowledgeable on the necessary things that might undergone before, during, and after the operation.

For your understanding, do you think that your surgeon needs to explain to you the diagnosis and his recommendation for surgical intervention? What do you expect to hear from your surgeon?

Based on the response, “Yes, I like to be explained to by the doctor if I should undergo the operation or if it can be delayed by limiting the oily food intake like eggs, milk, etc.” and “Good to hear the process of the entire procedure, what to expect before and after so we’re more aware. It helped us feel more relaxed because everything was explained well”, “of course, I want to know if it is painful and if the procedure will resolve my problem and not dangerous for me and how much is the total cost of the procedure”, “I want to have an idea of what may happen during surgical intervention and any effects that may occur after said intervention”, it was gained from the interview according to their understanding on the importance of explaining the diagnosis of their condition and the surgical interventions that maybe recommended.

The patient believes that the surgeon should provide clear explanations about the procedure, risks, and complications before and after the surgery. They also appreciate all the doctor's effort on the explanation of the procedure by videos, photos and/or drawings, any potential delays from further work-ups prior to intended surgery, and the potential effects on their well-being post-operatively. The patients’ feel more relaxed knowing everything is clear.

Satisfaction on the current process of obtaining informed consent for Laparoscopic Cholecystectomy at your hospital/clinic.

It was perceived based on the responses to be very satisfied on the perception and feelings on the current process of obtaining informed consent for Laparoscopic Cholecystectomy. It emphasizes that it caters patients satisfaction on the clarity and explanation on the purpose of the procedure.

To what extent do you feel that the informed consent process ensures clarity and transparency in communication between you and the surgeon

“I am very much informed and I understood well about the clarity and explanation of my surgeon”, “I feel safe”, “Everything was clear and it helped lessen the anxiety of both the patient and relatives”, and “By giving my consent I have accepted the intervention my surgeon had proposed to me”.

The patient feels safe and comfortable with the procedure, which is detailed and explained clearly. The procedure helps lessen patient and relative anxiety. The patient's consent confirms their acceptance of the surgeon's explanation.

As supported on the evidence on the transcribed data, the patient responded to the question, “I feel safe”. Additionally, “In a scale of 1 to 10, I could say that it is 10. It should be in full details so the patient would feel comfortable of the process”.

Satisfaction on the level of your involvement as a patient in the informed consent process

On the level of involvement as a patient in the informed consent process, “Very satisfied. By asking for my consent first before every procedure, the hospital gave me the feeling that it respects my choices”. Another patient said “I am very much satisfied, as a Patient I have contributed also for the success of the operation by means of cooperation and sharing my medical history prior to giving my consent”. “Very satisfied because I understood the advantages of laparoscopic procedure compared to the conventional one to allow me to make my choice”. By the morality and ethical consideration that the informed consent holds dearly on the efficacy and importance of informed consent, it yields to a very satisfied interpretation between the patient and surgeon relationship.

Feeling on the current informed consent process adequately addresses and respects the rights and autonomy of a patient.

“Yes I am very satisfied because I understand the advantage of the laparoscopic procedure for my cholecystectomy, totally I am aware of my choice and not violated in any way”.

The feeling of being aware, secured, and safe were the feelings felt by the respondents on the consent process adequately addresses and respects the rights and autonomy of a patient. This explains that patients were comfortable of the procedures and believes on its effectiveness.

Satisfaction on the overall quality of information provided to patients in the informed consent process

“Personally, it is fine with me as long as it provides every information that the patient should know”, “I think every information was clearly said to me”, “Very satisfied, the procedure was clearer so we barely have questions and knew what to expect”, are significant responses from the respondents that shows a satisfaction description on the case. The patient was very satisfied with the procedure, as it was clear and well-informed. The information obtained was mainly explained from the surgeon, before deciding to sign from the informed consent form. The quality of information receives of the patient was important as it calms and keep the patient secured for the success of the operation.

How significant is the informed consent process in preventing misunderstandings or disputes between patients and healthcare providers during or after the procedure.

“Informed consent is crucial for patients to understand the risks and benefits of procedures, reducing the risk of mistreatment. Proper explanation and understanding of the procedure can minimize disputes. Patients should be walked through the procedure to anticipate both positive and negative scenarios”, “Disputes can be minimized as long as proper explanation of the procedure is given along with possible complications that might arise” the respondents replied. According to the responses, it is important that patients are walked through properly so patients understand what they’re agreeing to therefore they need to know what to expect – both the best and the worst scenarios. It educates well a patient about the risks and some benefits of the procedures.

How satisfied are you with the overall quality of information provided by the surgeon in the informed consent process? What is the reason for granting your consent for the procedure?

The patient expressed satisfaction with the clear information provided by the doctor about their procedure. They were reassured by the doctor's explanation of the procedure, which was clear and explained properly. The patient also felt the need to undergo the procedure after discussing it with their surgeon. The doctor was very helpful.

As proved by the statement from the transcribed record of the respondent, “Habang kinakausap niya ako kilala ko naman siya na doctor na mahusay, nung pinapaliwanagan niya ako naalis ang takot kasi nung una ay takot akong mag pa opera, nung napaliwanagan niya na ako nakuntento na ako at saka alam kong mahusay siyang doctor at alam niya kung ano ang dapat niyang gawin”, (while he was explaining about my condition and knowing him as a very reputable surgeon and knows very well the procedure, my fears dissipated about the procedure after his explanation, I am very satisfied).

To what extent does the informed consent process contribute to the overall safety of Laparoscopic Cholecystectomy procedure in your opinion? Do you have any recommendation for the improvement of the process in obtaining informed consent?

Clear communication with a doctor to ensure proper decision-making and safety during procedures. This information helps patients feel assured and can lead to better outcomes.

As the respondents says, “It involves communication of your doctor so you can make a proper decision of the procedure with the given adequate information.”, and “I think I was well informed by the doctor about everything I need to know including the safety of the procedure. I cannot come up with anymore suggestion because I think everything was clear.” “The informed consent process contributed well for the success and confidence of the patient to the surgeon, the procedure I have chosen and other hospital staff as it made me well informed about my surgery”. Based on the response, a good communication between the patient and the doctor assures both sides in ensuring a proper decision making that contributes to the safety of the procedure. Hence, it must be improved and strengthen through discussion and process of obtaining informed consent.

4. Discussion

The experience faced by the surgeons prior to the consent for Laparoscopic Cholecystectomy was described, to fully discuss the process to the patient and any family members prior to surgery. A good conversation, lay out the risks and expectations, and asked questions was mainly faced by the surgeons in order to keep patients and guardians aware and knowledgeable of the process. Thus, promoting patient comprehension for informed decision-making that is a critical responsibility of surgeons.

The necessity of well-written permission forms is emphasized in the text as they provide satisfaction, clarity, and process confidence. It also draws attention to the drawbacks of comparable forms and how little progress they may make in improving patient comprehension and communication.

The process is thorough and easily understood by the patient, who feels protected and at ease. Both patient and relative anxiety are reduced by the process. Acceptance of the surgeon's explanation is attested to by the patient's permission.

The validity of the necessity of providing patients and their families with a comprehensive, objective explanation of surgical procedures—along with pre-clinic and bedside rounds, informed consent, pros and cons, and a serene, compassionate environment—to guarantee patient well-informed is sufficiently established. But a routine review and enhancement of the informed consent procedure guarantees patient contentment and adherence.

The patient conveyed pleasure with the physician's lucid explanation of the procedure's goal. The doctor gave them a thorough and understandable description of the surgery, which gave them peace of mind. After talking with their surgeon, the patient felt compelled to have the surgery. The physician was really beneficial. As a result, the hospital respects the decisions made by patients and their guardians.

Involving patients in joint decision-making is crucial. It is a difficult but crucial responsibility to be able to explain to the patient their diagnosis, the proposed operation and its related risks and benefits, and ultimately help them make an educated decision. Furthermore, empathetically addressing issues included overcoming communication and language obstacles as well as patient fear. However, patient understanding and satisfaction will occur as long as there is thorough and unambiguous transmission of facts during the informed consent procedure.

In medical operations, consent is essential, particularly for young, old, or minor patients. The document must be understood by the patient's partner or family member. To reduce misunderstandings and guarantee the patient's welfare, informed consent is essential. To lower the possibility of mistreatment, patients must be able to give informed permission after learning about the advantages and hazards of a surgery. Having a clear grasp of the process and its explanations helps reduce disagreements. It is important to take patients through the process so they can prepare for both the good and the bad

Based on the findings, the management needs to be open to assessing patient comprehension, including asking questions and confirming understanding, asking follow-up questions, allowing patients to express themselves, having patients sign informed consent, assessing comprehension through verbal confirmation, and encouraging patient sharing of queries in order to improve hospital guidelines regarding the signing for informed consent prior to undergoing a laparoscopic cholecystectomy.

The patient feels that before to and following the treatment, the surgeon must to give thorough information regarding the risks, consequences, and method. They also value the doctor's description of the operation, the possible outcomes, and any delays. Expecting a clear explanation of their diagnosis, suggested course of action, and associated dangers, the patient may feel more at ease with their surgeon.

Moreover, it needs to enhance effective communication with a physician to guarantee appropriate decision-making and safety during treatments. This knowledge can improve patient outcomes by instilling confidence in patients.

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