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## Informed-Consent Taking Procedure for Elective Surgery in Gaza strip: Patient's Satisfaction with Doctor's Communication

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### Abstract

#### BACKGROUND:

Widespread dissatisfaction and mistrust exists among patients in the Gaza Strip towards doctors. A sense of a lack of sufficient information regarding diagnosis, risks and benefits of interventions and subsequent management plans is present among patients. All of these areas are considered essential components in the surgical consent process. A gap between patients' actual understanding and that perceived by doctors has been shown to exist in different settings.<sup>1</sup> Unfortunately, no former study has been done on this topic in the Gaza-Strip.

#### OBJECTIVES:

This study aims to assess the satisfaction of patients in Gaza with the information provided to them during the consent process prior to an invasive procedure and compare this to the current practice and attitudes of surgeons.

#### METHODS:

A five-section self-designed questionnaire was administered using convenience sampling to the first 60 patients and first 60 surgeons who met the selection criteria in the two hospitals in the Gaza Strip: Al-Shifa Hospital and the European Gaza Hospital.

#### FINDINGS:

Among the surgeons surveyed, 55% answered that informed consent should be obtained by doctors only, 3% thought that it can be obtained by nurses only, while 45% stipulated either doctors or nurses can obtain it. In total only 38% of those healthcare professionals taking the consent from the patient, actually performed the procedure. During consent procedures, 73% of surgeons reported providing written documents 30% drawings explaining the procedure, 3% giving videos or animations and 8% suggesting website links for more information.

The survey of patients revealed that only 25% of surveyed surgeons identified themselves to their patients, and 12% asked for the patients' signature without a complete discussion of the intervention. Around 35% of surgeons depended on verbal communication only.

Surgeons identified barriers for best practice as time constraints, as well as lack of hospital policies and informational resources. However, 87% of surgeons believed that informed consent has an impact on patient wellbeing.

A total of 90% of surveyed patients thought they received the right treatment and were satisfied. While 43% of patients prefer to travel overseas to get treatment, 77% of these because of a perceived lack of medical equipment and facilities.

#### Keywords:

Informed-Consent - Elective Surgery - Satisfaction

## 1. Introduction:

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication which entail thorough understanding between a patient and physician that results in the patient's willful and sound authorization or agreement to undergo a specific medical intervention.

Ideally, during communications process, the treating physician (providing or performing the treatment and/or procedure) and not a proxy should disclose and discuss the followings with his/her patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance)
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

It is not possible however, to provide complete information or to predict outcomes or assess risks with certainty, and patients need to be aware of this uncertainty.

Information should be provided in a form and manner which help patients understand the problem and treatment options available, and which are appropriate to the patient's circumstances, personality, expectations, fears, beliefs, values and cultural background. It may sometimes be helpful to convey information in more than one session. The doctor should:

- Communicate information and opinions in a form the patient should be able to understand;
- Allow the patient sufficient time to make a decision. The patient should be encouraged to reflect on opinions, ask more questions;

and consult with the family, a friend or advisor. The patient should be assisted in seeking other medical opinion where this is requested;

- Repeat key information to help the patient understand and remember it;
- Give written information or use diagrams, where appropriate, in addition to talking to the patient;
- Pay careful attention to the patient's responses to help identify what has or has not been understood.
- Doctors should give advice. There should be no coercion, and the patient is free to accept or reject the advice.
- Patients should be encouraged to make their own decisions.
- Patients should be frank and honest in giving information about their health, and doctors should encourage them to be so.

Rationale for the study:

In Gaza Strip, it has been noticed sadly increase in mistrust among patients and other negative effects such as long patients stay in hospital, pain post operation and patient dissatisfaction with the results of the interventions all have strongly related to lack of sufficient information regarding the diagnosis, management plan and risk and benefit of any intervention which are considered essential components in the surgical consent form .

In addition to, doctors exposed more to answer the medical courts as a consequence of patient dissatisfaction with the results of the intervention. This is mainly due to improper way of obtaining the consent prior any invasive intervention.

We conducted this study by means of cross-sectional descriptive exploratory research, with qualitative and quantitative approach.

## Study objectives

- To recognize the used methods of informing and obtaining the consent from the patients who are going to undergo surgery.
- To explore whether the consent process can answer patient concerns about the surgical intervention.
- To document how the consent forms can affect the return to normal daily function after the intervention.

## Methods

A cross sectional study was conducted in two main public hospitals in the Gaza Strip (European Gaza Hospital "EGH" and Al-Shifa Hospital) after the approval of the Ethics Committee for research. Following convenience sampling procedures, the first 30 patients who meet the selection criteria in both hospitals asked to answer a written questionnaire with total number 60 Surgeons who did the operations for the 60 patients identified through the patient questionnaire and they asked to answer another questionnaire.

## Selection criteria of patients:

- Adult Patient (above 12 years old who decide for them self)
- Underwent an elective surgery and still staying in the ward.
- Conscious, oriented and not under CNS suppression drugs that interfere with patients comprehension and concentration.

## Data collection instrument

The data were collected from face to face semi structural interviews. As there is no specific form to assess the interpretation of an Informed Consent, we drew on self designed questions that could assess the understanding of the content and meaning of

words. The patient questionnaire contained 42 items, including demographic information data and specific multiple-choice questions and open-ended questions regarding informed consent components and information about the pre and post operation status.

Besides the Demographic information which include age, sex, hospital, department, marital status, socioeconomic status, employment status, we assessed their educational level considering the following levels:

1. Elementary/middle education .
2. High school .
3. Higher education, considering complete or incomplete studies.

Regarding General information and background the following questions included:

1. Where do you prefer to seek the medical consultation? Options: 1-Public sector, 2-private sector, 3-Both.
2. Did you study about the human rights? Options: 1-Yes, 2-No, 3-others.
3. Do you think that you receive your right in treatment? Options: 1-Yes, 2-No, 3-others.
4. How do you evaluate the health service that is provided to you? Options: 1-Poor, 2-Good, 3-Excellent.

As to specific understanding of the matter regarding informed consent information provided, the following were yes or no questions: 2.1- Were you informed about the diagnosis? 2.2- Of the investigation that is done since admission? 2.3- Of the management plan? 2.4- Of alternative treatment? 2.5- Of the nature and the purpose of the treatment? 2.6- Of risk and the complication of the procedure? 2.7-Of the benefit of the procedure? 2.8- Of the outcome if the procedure was not performed?

Then questions about preoperative were asked: 2.9- Have you been informed about the preparations prior to surgery? If the answer is Yes, patients asked to check (x) next to one or more of the following: 1- How long should be kept null by mouth, 2-Need to stop some drugs prior to surgery, 3- Patients will be

given some drugs prior surgery, 4-the type of anesthesia and risks, 5-Shaving the area that will be exposed in the operation.

Then questions about procedure itself were delivered: 2.10- Have you been informed about the procedure itself? If the answer is Yes, patients asked to check

(x) next to one or more of the following: 1-Site of incision, 2-type of surgery whether open or laparoscopic, 3-if any organ/tissue should be removed, 4-If any surgical tube will be inserted during the operation, 5-expected time of the operation.

The following questions were asked regarding post operative condition: 2.11- Have you been informed about post operation condition? If the answer is Yes, patients asked to check (x) next to one or more of the following: 1-time to wake up after the procedure, 2-time to start feeding orally, 3-how to start feeding, 4-time to return to normal daily function, 5-how to keep the wound clean, 6-when you should seek a medical advice, 7-fellow up timeline and purpose. 2.12- Have you been informed about the possibility of blood transfusion? 2.13- Have you been informed that there is no guarantee to solve the problem completely?

Then, the questions were specifically directed to the methods of obtaining Informed Consent: 3.1- Have you been provided with written documents? 3.2- Of drawn pictures explaining the procedure? 3.3- Of videos and animations describing the procedure? 3.4- Of website links to get information of the procedure? 3.5- Have you been asked for signature without balanced discussion with you, 3.6- Do doctors depend on verbal information only? 3.7- Did the doctor let you ask questions before signing the form? 3.8- Were you Provide with the contact details of the surgeon who will do the procedure? 3.9- When doctors take the consent form? Options: 1- Immediately prior to intervention, 2-Once you admitted to the department, 3-After the intervention.

Then the following questions were asked: 3.10- Where do doctors take the consent form from you? Options: 1-Doctor office, 2-Patient bed, 3-Operation

room. 3.11- Have you been provided with any resources of information prior to their admission to hospital? If the answer is yes, patients asked to check (x) next to one or more of the following: 1- Handwritten papers, 2-Preprinted papers, 3-Website address, and 4-Verbal information. 3.12- Do doctors introduce themselves to you prior of obtaining the consent form? 3.13- Do doctors use a medical terms during obtaining the consent? 3.14- Does the person who takes the consent form perform the procedure? Have you been forced to sign the consent form?

The patient questionnaire included also yes or no questions about patient evaluation and prospective: 4.1- Do you feel satisfy with the procedure that was offered to you? 4.2- Did you understand your condition properly? 4.3- Did the doctor answer your concerns? 4.4- Do you recommend this centre to others? Then, an open ended question was made: 4.5- If you have any comment, please use the space below .

In the same context, the surgeon questionnaire contained 4 sections, including demographic information: Age, sex, department, Hospital, Resident/boarded, years of experience at the surgical department, Country of obtaining primary medical qualification, Country of post-graduation training. In addition to the information regarding informed consent components and methods of obtaining (the same part of patient questionnaire). Last section was about attitude of the hospital and informed consent applies, the following questions were asked:

-4.1 Do you think that doctors obtain the consent in proper way? If the answer were No, doctors asked to choose one or more of the following reasons: 1- Because of time pressure associated with workload, 2- Because of increasing day of surgery admission, 3- Because of lack of private area to communicate with patients, 4- perception that held by doctors about increasing the patient fear and anxiety by discussing their conditions, 5- Due to lack of sufficient knowledge of medico legal requirements for informed consent, 6- Most doctors have not good knowledge base to give patients information about

their condition, 7-due to lack of hospital policies on informed consent, 8-Use of medical jargon, and 8-due to patient factors like level of education and competence.

Then the following yes or no questions were asked: 4.2- Do you think that obtaining of the consent form in proper way can affect the patient well being? 4.3- Do you think that obtaining the consent form in proper way has a positive effect on doctors? 4.4- Does your hospital have guideline in obtaining the consent form?4.5-How do you evaluate the written consent form that is used at your hospital?4.5-Does your hospital have policy against doctors who do not apply consent form properly?4.6- Does every procedure have its own consent form at your hospital?4.7-Do you have special consent form for specific procedure<sup>6</sup>

### Statistical analysis

All responses were filtered, cleaned, coded and entered into SPSS software. The quantitative variables were analyzed in terms of averages and standard deviations. The classifying variables were presented in tables, pie charts and bar charts containing absolute (n) and relative (%) frequencies. The statistical analysis was conducted with the support of the software SPSS version 16.0. The values  $p < 0.05$  were considered statistically significant for the analysis. As for the analysis of descriptive data obtained through direct contact of researchers with patients by means of open-ended questions.

Table1

Characteristics	number	Frequency %
<b>Patient Age</b>		
less than 20	10	16.7
20 to 40	17	28.3
41 to 60	22	36.7
more than 60	11	18.3
<b>Patient sex</b>		

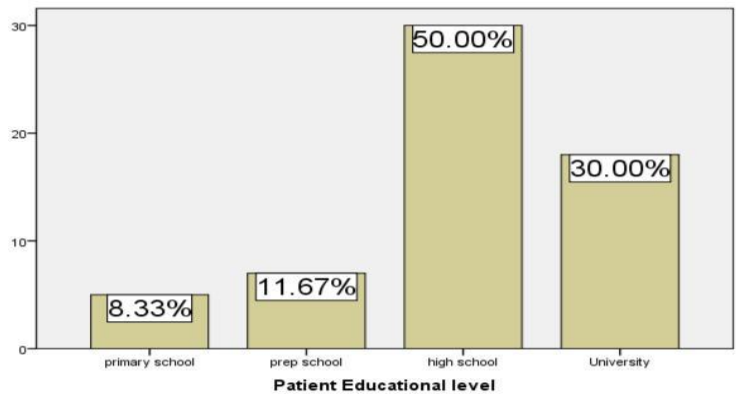
male	32	53.3
female	28	46.7
<b>Patient Marital status</b>		
single	18	30
married	42	70
<b>Patient Socioeconomic status</b>		
bad	12	20
acceptable	48	80
<b>Patient Educational level</b>		
primary school	5	8.3
prep school	7	11.7
high school	30	50
University	18	30

Table2

Characteristics	number	Frequency%
<b>Doctors Age</b>		
20 to 30	21	35
31 to 40	21	35
41 to 50	18	30
<b>Doctors are resident or boarded</b>		
Resident	32	53.3
Boarded	28	46.7
<b>Doctors hospital</b>		
Shifa	32	53.3
EGH	28	46.7
<b>Doctors Years of experience</b>		



less than 5 years	22	36.7
5 to 10 years	23	38.3
more than 10 years	15	25.0

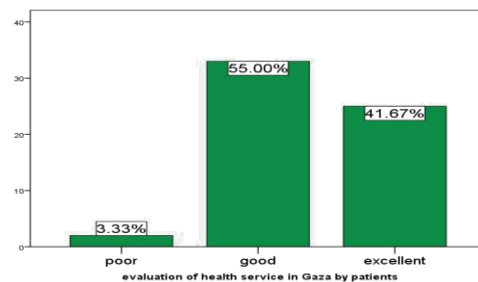


The general characteristics of the patients are on Table 1 and the general characteristics of the doctors are shown on Table 2.

Regarding numbers of patients prefer to travel outside Gaza to get treatment, unfortunately 43% of patients preferred to do that. The main reason we found is the deficiency of the facilities in Gaza hospitals such as surgical tools, 70% of patients confirmed that. other reasons include that some patients 16.7% think that Indoor doctors have no sufficient knowledge, on the other hand, 83.3% of patients trust the knowledge of Gaza doctors which is very important for consent form this agrees with study conducted among patients with ESRD about delivering informed consent for the renal replacement therapy (One thing that plays an important role in determining the adequacy of the informed consent is the medical experience and knowledge of the doctor regarding the procedure ).<sup>8</sup>

Most of patients 86.7% confirmed that doctor communicate well with patients and explain their illnesses to them, and about 78% of patients are satisfied with the health service provided inside local hospitals.

Most of patients are familiar with human rights, they studied about it in schools and universities, 50% confirmed that they received their rights in treatment and 96% evaluated the health service provided to them between good and excellent.



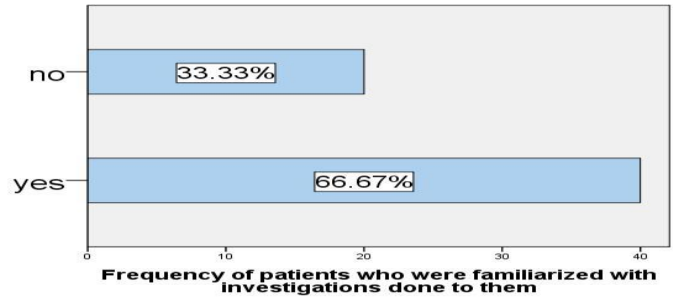
We think that most patients trust their doctors and convinced in their knowledge and abilities but the main problem is the lack of facilities in Gaza hospitals that prevent doctors from doing advanced operations.

On the other hand, after analyzing the collected data from doctor's questionnaire, we see that no doubt between doctors about the necessary of consent form, and about 88.3% learnt about consent form in their undergraduate studies. 91.7% of doctors believe that consent form should be taken in any interventional procedure while others said it should have been taken only under specific interventions. 55% of doctors believe that is the job of the doctor

to obtain the consent while others think that both doctors and nurse have a role on this, only few doctors see that it is only the nurse role.

The consent form can be obtained by			
	Frequency	Percent	Percent
Nurses	2	3.3	3.3
Doctors	33	55.0	55.0
Both	25	41.7	41.7

- information regarding established treatment alternatives).12

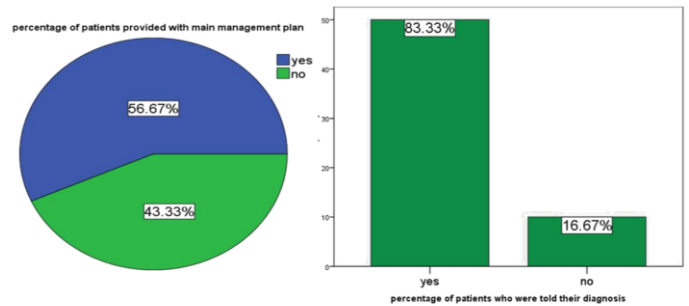


### Data related to the Informed Consent information provided

From the patient's perspective, it is crystal clear that not all the information patients should receive about their condition were effectively delivered, the main information delivered to most patients include their diagnosis, investigations done, the main management plan and the benefit of the procedure they will go through. While the alternative treatment were discussed with only 25%. In the same context, only 46.7% of patients have known the nature and purpose of their treatment and the outcome if the procedure was not performed. The Risks and the complications were discussed with only 30% of cases.

We think that additional information should be emphasized to patients as a study confirmed that (The minimum requirements for valid consent documentation in elective procedures should include

- a plain language description of the intended procedure;
- an explanation of the purpose and intended benefit;
- information regarding material risks; and



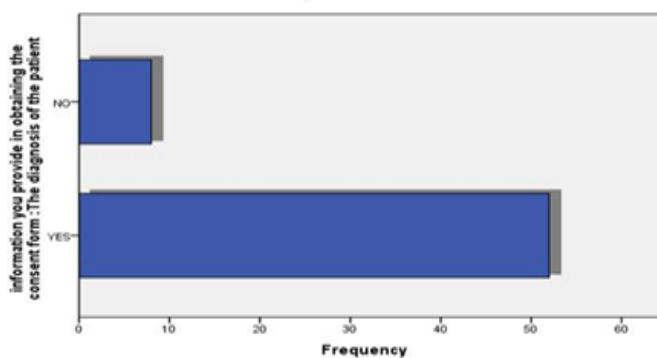
### Looking to the information doctors were provided while obtaining the consent

we found that 86.7% were told The diagnosis and that's the ideal in many study says that the patient must know his/her diagnosis before make any interventions for him, while 51.7% of doctors explain to patient about the investigations that were done since admission and the benefits of the procedure, on the other hand we found that only 88% explain the management plan to the patients, but Alternative treatment were discussed with only 60% of patients and refer some cases have no alternative other than surgery, 56.7% discuss the nature and purpose of patient treatment and The outcome if the procedure was not performed, the Risks and the complications were discussed with

90% of cases and this is related to nature of the procedure. But only 71% of doctors inform the patient about the outcome and benefit from their surgery because other factors play role in the outcome of procedures depending facilities and equipment of hospitals.

**Regarding the information about preoperative preparation,** most of patients were familiarized with this part of the consent form, which is emphasized by a study showed that (It's advisable to give patient a clear information about the procedure intended to be done and not depend on the written informed consent only).<sup>4</sup>

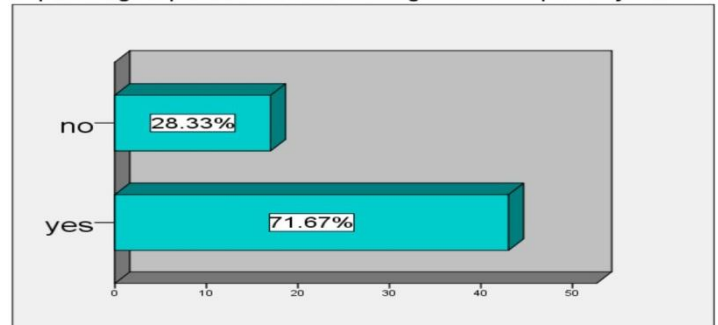
information you provide in obtaining the consent form :The diagnosis of the patient



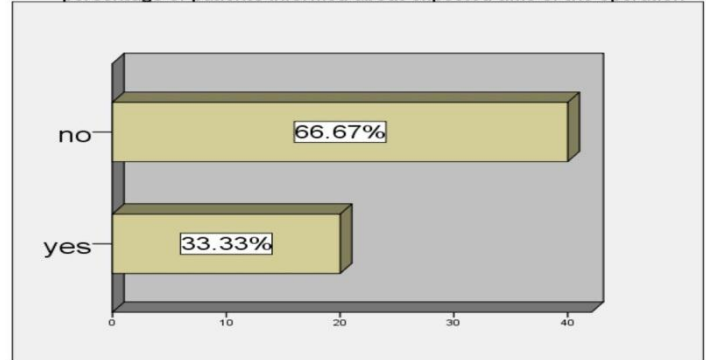
72% of them were told how long they should be kept null by mouth. Depending on whether the patients were on some drugs before their operations and whether they need medications before or after surgeries, 48.3% of Patients were told to stop some drugs prior to surgery and 31.7% were told that they will receive some drugs prior and or after the operation. Around 40% were familiarized with the type of anesthesia and its risks, about the site of incision of the operation and whether the surgical operation is open or laparoscopic. Around one third of cases were told if they need shaving the area that will be exposed in the operation, if any organ or tissue should be removed, if any surgical tube will be inserted during the operation and the expected time of the operation. Of course all of that depend on the

type of operation and its circumstances for example not all patients need Shaving prior to procedure or organ removal in the procedure. 23.3% were told about the possibility of blood transfusion.

percentage of patients informed How long should be kept null by mouth

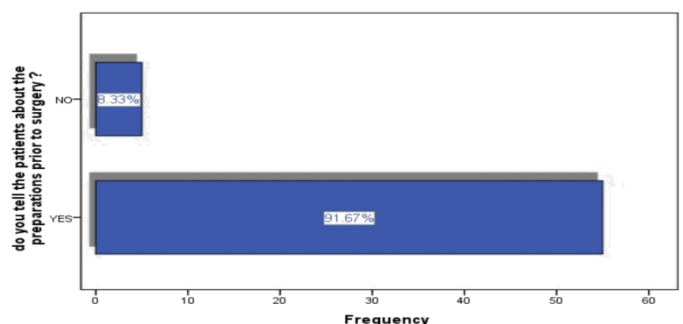


percentage of patients informed about expected time of the operation



**Regarding the preparations prior to surgery** we see about 91% of doctors explain to patients the required preparation for surgery, 73% tell about the time required

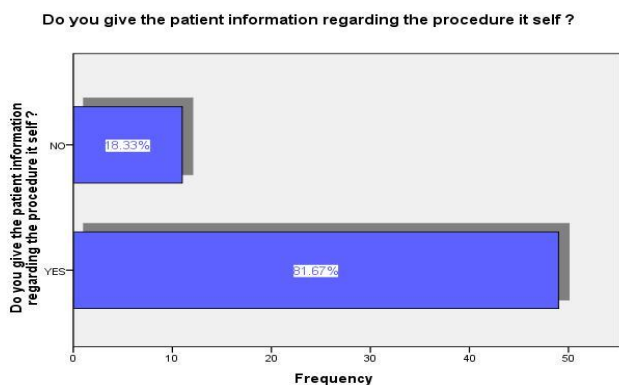
do you tell the patients about the preparations prior to surgery ?



to keep NPO and 85% talks about drug to stop or to continue and 78.3% told the patients about type of anesthesia required in the operations.



On the other hand, when we analyze the data of the procedure itself, we found that about 87.9% tell the patient about operation that will done for him include 56.7% provide data about Site of incision, 71.7% about type of surgery open or laparoscopic, 61.7% if any organ/tissue should be removed, and 43.2% about expected time of the operation.

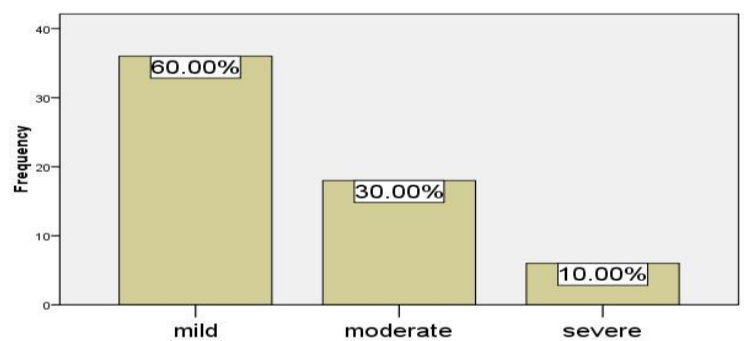


Clearly, there are main preoperative preparations should be informed to patients and there are minor preparations depend on the type of surgery, the essential topics include, patient medical condition, co morbidities and current or chronic drug use. Providing patients with information regarding the potential risks is long debatable subject. Too much information can be confused patients rather than help them to take the decision. In other hand, some founds that its helpful to provide patients with all potential risks. Currently, doctors have been advised to:

1. Should warn the patient of anything that poses a substantial risk of grave adverse consequences.<sup>16,17</sup>
2. Should mention significant risk that would affect the decision of a reasonable patient.<sup>16,17</sup>
3. Is under a clear and legal obligation to tell the truth if asked a direct question<sup>16,17,18</sup>

In our cases, it is also crucial to mention that only 76.7% of our patients followed the guidelines and the information that was given to them before the procedure.

Regarding post operation condition, around half of patients had a direct discussion with the doctor but in some other cases the discussion have been done with the relatives or the main care giver, 36.7% were told how much time needed to return to normal daily function, 45% were told when and how to start feeding orally directly in 1st discussion after operation but others were told when the time was suitable to eat. 31.7% were learned how to keep the wound clean, and 23.3% were familiarized when they should seek a medical advice and how to follow up their condition. Depending on whether patients were or were not given analgesics and its types this chart shows patients ranking of pain post operation:

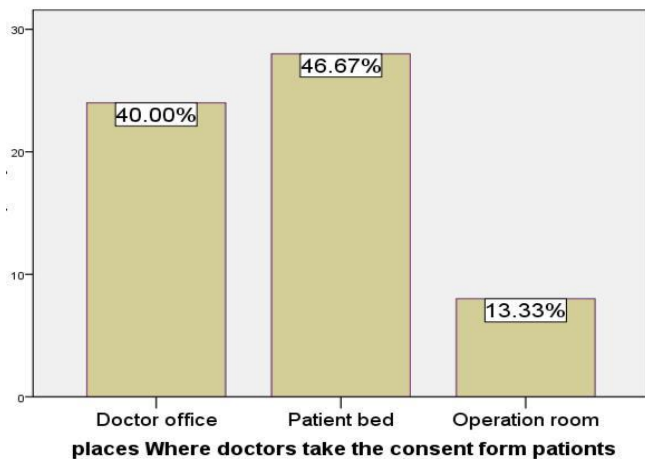


### Data related to the Informed Consent obtaining methods

(The informed consent form is considered a vital step in order to get the permission from the patient to proceed in the management plan whether its medical or surgical. So, it necessitates to let the patient understand each point included in the consent form.).<sup>1</sup>

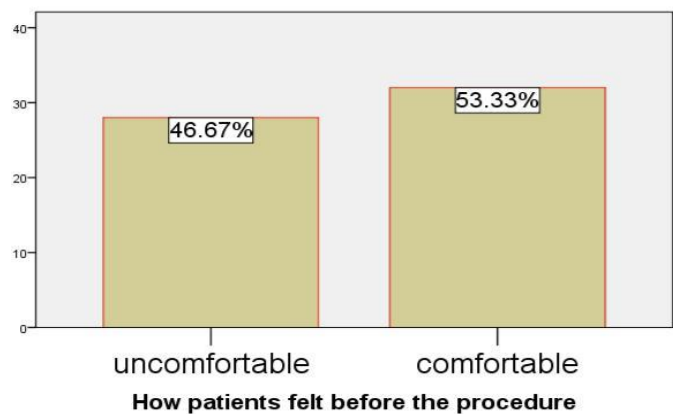
We think that it is very important to choose a perfect time and place to take consent form from the patient in which he would be comfortable to hear and make

a good decision), two thirds of consent forms were taken immediately prior to intervention and the rest of them were taken in the departments after admission.

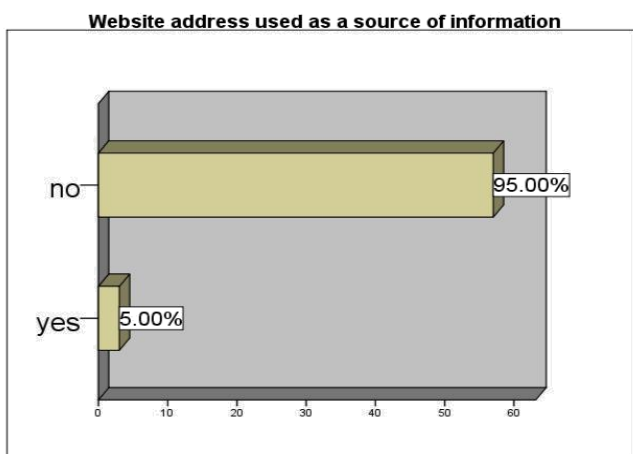


In our cases 38.3% of patients were also provided with written documents explaining the procedure but only 7% were given drawn pictures explaining the procedure and a few cases were provided with videos, animations and website links to get information, 18.3% of cases Signed the form without balanced discussion with doctors and 5% were forced to sign it which is a very few cases. 56.7% of doctors introduced themselves to patients prior of obtaining the consent form and 28.3% gave their patients their contact details and told them who will do the procedure.

**There are variety of Methods for obtaining the consent form**, in our cases around half of them described that Doctors depend on verbal information only as the main method to explain consent form and then they let them ask questions before signing the form and finally patients sign on the paper, on the other hands we think that other modalities as videos, animations, leaflets and websites are very important and useful for patients help, many studies confirmed that, e.g. (Many things can be used to increase patient's comprehension in addition to the written information such as pictures, videos and animations which have been greatly effective in enhancing patient's satisfaction.).<sup>6</sup> (Use of audio visual information and leaflets can be useful, and indeed are recommended) <sup>14,20</sup>

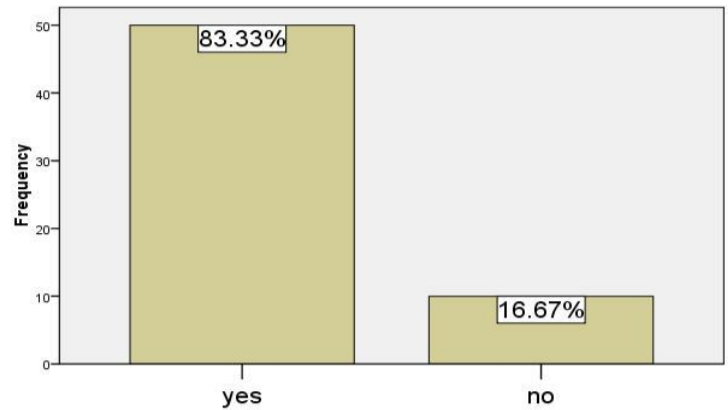


**From doctor's perspective** , majority of doctors provide the consent with written documents explaining the procedure but only 30% were given drawn pictures explaining the procedure and were the last studies approved that the consent form with picture and videos give the patient more chance to understand his/her condition and plan than verbal and written consent.

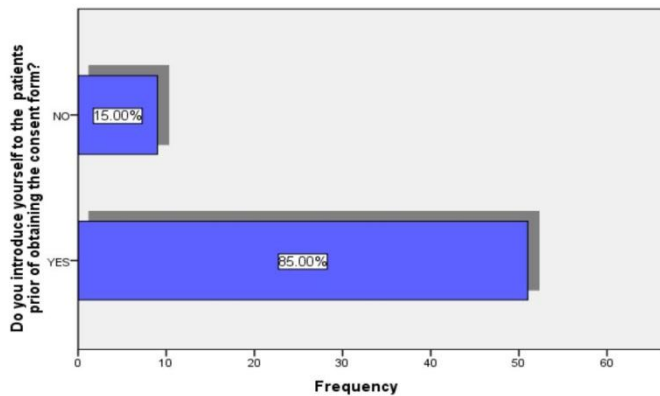


**We notice that only minority of patient Signed the form without balanced discussion with doctors**, that's was against our imagination on our health system, on other hand only 25% provide the contact details for the surgeon who will do the operation for the patient. Otherwise 53.3% of doctors obtain the consent form Immediately prior to intervention while the other Once the patient admitted to the department, 51% of them take it on the doctor's office.

When we asked the doctors if they introduce themselves to patients' prior obtaining the consent form, 85% of them answer yes. And about 36.7% of them use medical terms during obtaining the consent, only 38.6% confirm that the person who obtain the consent from the patient performs the procedure, 75% of doctors agree with the patient to ask other doctors for second opinion on the procedure.

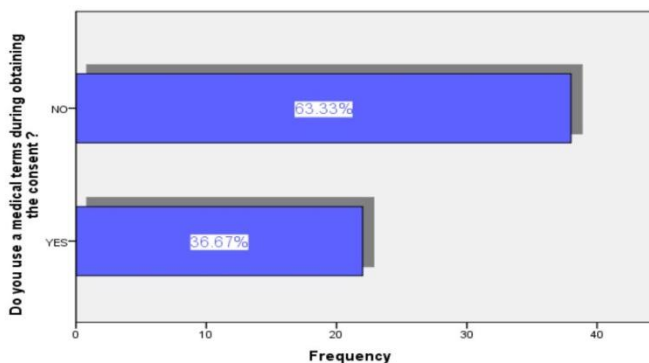


Do you introduce yourself to the patients prior of obtaining the consent form?

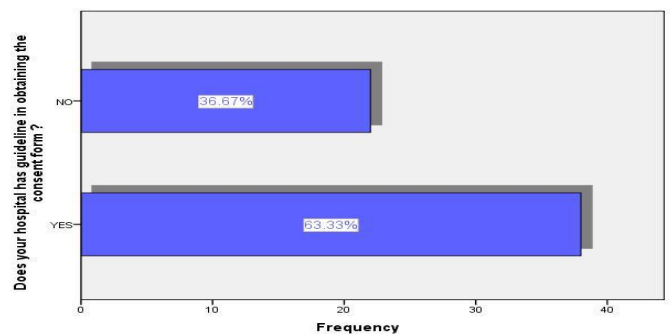


Finally, about the attitude of the hospital and informed consent apply, only 71% of doctors think that doctors obtain the consent in proper way, 23.3% of them refer that to time pressure associated with workload, while 11.7% Because of increasing day of surgery admission, 18.7% due to lack of hospital policies on informed consent, But 90% think that obtaining of the consent form in proper way can affect the patient wellbeing positively. Only 63.3% of doctors told that their hospital has guideline in obtaining the consent form, and about 11.7% of them see that written form of current hospital.

Do you use a medical terms during obtaining the consent ?



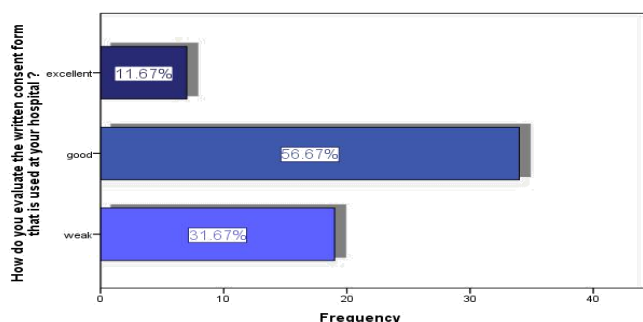
Does your hospital has guideline in obtaining the consent form ?



More than 90% of patients were satisfied with their procedure, and described their general condition after operation between good and excellent. More than two thirds of patients understood their condition properly and their doctors answered all their concerns, when we asked if they recommend their centers to other patients 83.3% said yes as this chart shows:

consent form do not need modification.

How do you evaluate the written consent form that is used at your hospital ?



### Conclusion and recommendation:

Most of the patients in Gaza strip are satisfied with treatment they have received. Most of doctors don't follow the standardized procedure for consent-form taking but still believe that the proper informed consent affect patient wellbeing, so we need to improve the way of obtaining the consent form by giving more details and discussion on the written documents, not to rely on verbal communication only. Surgeons should also focus more on pictures, videos that explain the procedure.

### Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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