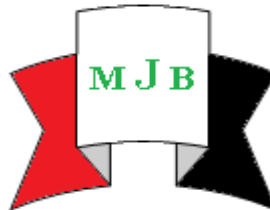


Evaluation of The Content of Preoperative Consent and Its Application in Karbala Maternity Hospital in 2012; A Descriptive Cross-Sectional Study

Mousa Mohsen Ali

Karbala University, College of Medicine.

Email: dr_mousaobgyn@yahoo.com



Received 29 January 2014

Accepted 6 May 2014

Abstract

The art of medicine and treating the other human is a complex issue consists of three elements those are (DOCTOERS, PATEINTS ,DISEASE) for long time the physicians use the medics and knife as only tool to treat their patient and forgotten that there was third tool to be used which is communications with patients . Nowadays, informed consent has replaced the old paternalistic notion of “the doctor knows best”, with a more collaborative patient-physician relationship.

Objectives: To evaluate the content and comprehensiveness of informed preoperative consent from patient and physician view, Express the important of the patient commitments to giving the pre-operative consent, Find out the effect of patient acknowledgment with pre-operative form on their consent and effect on the operation rates, To measure the level of doctor commitment to explain the preoperative form for their patients and the level of explanation given to them

Methods and Data Collection: A descriptive cross sectional study was carried out from first of august to 31 of december of 2012 . The sample 103 patient was extracted from patients, operated by different Obstetricians (working at Karbala Maternity Hospital).We developed two types of questionnaires(one for patients and other for the doctors) The questionnaire consists of several items organized in four parts: 1) The demographic data 2)The obstetric information 3) informed consent knowledge and 4) post interviewing data.Specialist obstetrician explained the purpose of the study to each patient atthe second postoperative day asked for her consent to be included in the study and to complete the questionnaire and to explain the form of consent found in patient file and the suggested informed consent that developed according the guideline of the WHO and universal consensual by different academic associations..The Chi square test was used tocompare the results Differences with a p value <0.05 were considered statistically significant.

Results and Discussion:In total, 103 patients operated by different surgeons, volunteered to respond to the questionnaire. Most of them were in 26-35 years age group.About 58.3% % of patient have previous surgery one or more , of them 51% they did not know about the consent form at all . About 92% haven't read the consent form. 99% of patients have understood the concept of consent just after we read the consent form ,while 100% of them agreed that they understood the consentmore after explanation . 84% of patients agreed that the consent should be changed. Regarding the response of the surgeons in the hospital there is mismatch between their answers and the patient answer about any explanation preoperatively ,43% of surgeons did not see the patient signature on consent form preoperatively , 61.9% not sure that their patient signed by themselves on the consent form 33.3% of surgeons preoperative don't give any information to the patient most of them state that is not their duty,23.8% Of surgeons don't share their patients in decision making, 43% of surgeons face problem with patient and family , 44% of these problems because of communications about 90% of them answer that we can prevent these problem by good informed consent ,53% of surgeons faced a patient who refused to do the operation after the consent only 33% of surgeons attended course about informed consent .

Conclusion and recommendations: unfortunately we haven't any protocol or education programs about preoperative informed consent and its follow-up by both surgeons and patients so we recommend to initiate

those protocols and programs and more courses to train the doctors and medical staff and administrative staff about those protocols . and to change the consent form to approved one.

Keywords: Preoperative Consent, Karbala Maternity Hospital, Karbala, Iraq.

تقييم محتوى استمارة الموافقة على العمية الجراحية وطريقة تطبيقها في مستشفى الولادة في كربلاء, دراسة وصفية

الخلاصة

المقدمة: ان فن الطب وعلاج المرضى يعتبر عملية معقدة وتعتمد على ثلاثة عوامل وهي الطبيب المعالج والمريض الذي يكون عرضة للعامل الثالث وهو المرض ولطما كان للطبيب ثلاثة ادوات لعلاج المرضى وهي مهارة الكلام والتواصلو العقار والمشرط وغالبا لايهتم الاطباء او المؤسسات التعليمية والصحية بالسلاح الاهم لدى الاطباء الا وهو مهارات التواصل والنصائح مع المرضى التي يمكنها ان تجنبهم الكثير من المشاكل التي تعتبر موافقة المرضى على العملية قبل اجرائها من اهم مصاديقه اهداف البحث: ان لهذا البحث مجموعه من الاهداف تسعى لمحاولة تحقيقها ومنها تقييم محتوى وشمولية استمارة الموافقة على العملية من وجه نظر المرضى و الاطباء وبيان مدى اهمية اصرار المريض على ان يعطي الموافقة بنفسه وبيان مدى اثر معرفة المريض الوافية بمحتوى الاستمارة على قرار المريض حول العملية ونسبة العمليات الجراحية وبيان مستوى والتزام واصرار الاطباء على الاستخدام الامثل لموافقة المرضى على العملية وبيان مدى المعلومات التي يشرحها الاطباء لمرضاهم قبل العملية

الطريقة والمواد: دراسة وصفية للفترة من ٢٠١٢-٨-١ الى ٢٠١٢-١٢-٣١ في مستشفى الولادة في كربلاء شارك في الدراسة ١٠٣ مرضى ممن اجريت لهم عمليات جراحة من قبل مختلف الجراحيين واعتمدت الدراسة على اعداد استبيان خاص تم تطويره بعد تجريبه وبمساعدة اطباء من فرع طب الاسرة في جامعة كربلاء وجامعة بابل يتكون من اربع محاور رئيسية في اليوم الثاني بعد العملية تمت مقابلة لكل المرضى المشاركين في الدراسة من قبل اطباء اختصاص في امراض النسائية والتوليد واخذت موافقة المرضى للاشتراك بالدراسة بعد بيان اهدافها لهم مع توضيح ضمان خصوصية المعلومات التي سيتم اخذها وباستخدام الاستبيان الخاص للمرضى واثاء المقابل تم اكمال الاستبيان مع قراءة استمارة الموافقة الموجودة في ملف المريض وبعدها تم شرح نموذج الموافقة المفروض توافره للمشاركين والذي تم اعتماده من قبل منظمة الصحة العامة والكثير من الاكاديميات الطبية .

النتائج والمناقشة : من اصل ١٠٣ مرضى تطوعوا للمشاركة في الدراسة اغلب المشاركين في المرحلة العمرية من (٢٦-٣٥) سنة حوالي ٥٨.٣% منهم لديه عملية جراحية سابقة او اكثر و ٥١% من هؤلاء ليس لهم علم بوجود استمارة الموافقة على العملية الجراحية في ملف المريض مطلقا و ٩٢% لم يقرأوا الاستمارة في اخر عملية جراحية لم يحصل ١٠٠% من المرضى لشرح حول الاستمارة قبل اخر عملية وكل المشاركين في الدراسة اجابوا بأنهم فهموا محتوى الاستمارة التي قام الباحث بشرحها لهم وعن رأي المشاركين باستمارة الموافقة على العملية الموجودة في ملفات المرضى اجاب حوالي ٨٤% بضرورة تغيير محتواها وعنوانها حيث انها معنونة على شكل تعهد قانوني. واعتماد النموذج الذي تم شرحه لهم. وفيما يخص اجابات الاطباء فهناك تباين بين اجابات المرضى حول ماتم شرحه لهم من الاستمارة وما اجاب به الاطباء وان ٤٣% من الاطباء لم يشاهدوا توقيع المريض على الاستمارة ٦١.٩% لم يتأكدوا بأن المريض وقع على الموافقة بنفسه و ٣٣.٣% لم يعطوا للمريض اي معلومة قبل العملية والسبب حسب قولهم انها ليست من مسؤوليتهم وحوالي ٢٣% من اطباء لم يشركوا مرضاهم باتخاذ قرار العملية و ٥٣% منهم واجهوا مرضى رفضوا اجراء العملية بعد اعطاء معلومات عن العملية لهم ٤٣% من الاطباء واجهوا مشاكل مع المرضى وعوائلهم ٤٤% منها بسبب عدم التواصل والكلام بين الطبيب والمريض فقط ٣٣% من الاطباء دخلوا دورات تثقيفية حول اهمية الموافقات ومهارات التواصل والنصائح .

التوصيات : ليس لدى المستشفى والكثير من المستشفيات بروتوكول ثابت وواضح ومحدد حول نموذج وطريقة اخذ موافقة المريض على العملية بحث يجب على الجميع الالتزام به وهذا يتطلب اشاعة ثقافة هذا الموضوع من قبل كل المعنيين من مؤسسات صحية وتعليمية وتربوية واجتماعية لذلك يوصي الباحث بضرورة استحداث بروتوكول خاص لهذا الموضوع والاتفاق على تغيير الاستمارة الموجودة حاليا بواحدة اخرى مناسبة متفق عليها عالميا وليس كما هي الان بصيغة التعهد الخطي من جهة قانونية وليست استمارة طبية وضرورة تدريب الكوادر الطبية والطبية المساعدة والادارية للمستشفى حول موضوع البحث ويوصي الباحث بأن هذا الموضوع في اغلب فقراته يحتاج لبحوث اخرى متعمقة.

Introduction

Violations in the ethical treatment of humans have resulted in the development of ethical codes and regulations that affect research protocols. Two famous unethical studies are the Nazi experiments conducted during World War II and the Tuskegee syphilis study,. Third Reich committed unethical and atrocious activities in the 1930s and 1940s, including human sterilization and euthanasia, as well

as numerous medical experiments, such as exposing participants to high altitudes, freezing temperatures, poisons, and malaria. Prisoners who could not refuse participation were subjected to surgical procedures. Unfortunately, this type of research was not performed ,treating the other human is a complex issue consists of three elements those are (DOCTOERS, PATEINTS ,DISEASE)

Certain aspects of obtaining and giving informed consent (IC) became an issue in biomedical ethics for the first time during a period stretching from the mid-17th to the early 19th century; IC was concerned with the same principles that prevail today [1]. An international legal precedent was established by a statement made by Justice Cardozo in *Schloendorff v New York Hospital* (1914): "Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patient's consent, commits an assault..."

Nowadays, informed consent has replaced the old paternalistic notion of "the doctor knows best", with a more collaborative patient-physician relationship. Patients expect to be informed of the risk of surgical interventions[2]. Communication is a key component especially in the case the patient has to weigh the risks and benefits of a recommended treatment, and the overall quality of patient care[3]. On the other hand, it seems that even though patients welcome the collaborative spirit, they may not all be interested in taking complete charge of their medical decisions[4], some prefer the physician to be the primary decision maker[5] and a few are even willing to surrender utter control to their physician[6], [7].

The most important goal of informed consent is to effectively inform patients about the recommendations and reasoning process of the doctor and help the patient make the final decision about their healthcare[8]. This process involves the discussion of several elements including the nature of the proposed medical intervention, duration of hospital stay, alternative therapeutic options, risks, benefits, inconveniences, and uncertainties related to each alternative. The doctor assesses the patients' level of

comprehension and provides the information in a way and to an extent that satisfies the individual's needs and ensures that all questions have been answered. Finally, it should be clear that patients may change their mind at any point[8].

Information, regarding the procedure for which consent is asked, Consent can be obtained in different ways but basically there are three types of valid consent. Consent can be written, oral or non-verbal.

- Consent in writing. By far the best form of consent as this provides a record of evidence the patient has consented.
- Consent by word of mouth. "Are you ready to have your injection?"
- Non-verbal consent. Often defined as implied consent such as when a patient holds out their arm to have their blood pressure checked [9]. Either method has certain advantages and drawbacks. Documents often present complex information that is hard to be understood by patients. On the other hand, verbal information is rather difficult to retain[7]. It should be mentioned that ethicists consider that a signed written form is not equivalent to IC itself. They believe that IC is a dialogue between doctor and patient. A written form promotes the dialogue process, and helps to ensure that the patient has talked with the doctor and agrees to proceed. The written form should not replace the personal contact and informed consent should not only be written. A signature on a consent form does not itself prove the consent is valid. The point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. The healthcare organization must have a policy setting out when written consent should be obtained. The requirement for adequate documentation is integral to the regulatory professional codes of conduct. Documentation provides a tool for communication between

members of the healthcare team to ensure continuity and consistency of care[10]

Communication has become a significant feature of consent [11]. Recommendations in informed consent have advised practitioners to improve communication with patients in order to help reduce complaints and litigation claims and to increase patient autonomy. The ever-increasing availability of NHS guidelines and publications has encouraged patients to obtain additional information regarding their health and decision-making. Yet only a few patients will understand, remember and use the information they receive correctly. Communication skills are not innate; some see them developing through experience [11] while others argue that they may not necessarily improve with practice and need to be taught. Developing communication skills in informed consent ensures that patients receive relevant information in a way that they are able to understand, which will ultimately help them to make an informed choice regarding consent for surgery. In a truly successful informed consent, patients fully comprehend the procedure, their rights and responsibilities[12]. However, the amount and type of information that should be given to patients is questioned and many believe that too much information increases pre-surgery anxiety' [13]. For low-risk medical procedures physicians may not inform their patients in detail, however, consent should be a requisite' [14]. Finally, patients with poor literacy should be identified and the information provided should have adequate continuum, readability and comprehensibility[14].

The degree of physicians' control over the process of decision-making is controversial. Physicians should preferably act as navigators for their patients' decision-making by providing a reasonable

amount of information that will help the patient comprehend the ramifications of choice. They should not make decisions for the patient, even if he or she wishes so. The consequences of a patient's choice cannot be shared, and medical decisions should not be shared with the doctor either. Perhaps, shared medical decision makes choices easier for the patient. However, this is not the goal of informed consent. Patients have to understand all the risks and uncertainties of their decision[5]. When patients come to the point of having the procedure, there must be some way to show that they have been informed of the risks and benefits and that they agree to have it done (Fortes-Mayer 2002). The essence of informed consent for health professionals is their duty to ensure that, before any treatment or intervention, the patient is fully informed and gives agreement voluntarily

The Greek legislation has not set specific rules defining in detail the way IC should be communicated to patients. Thus, it is left to the judgment of physicians to choose the way to inform patients and acquire the latter's consent on performing medical procedures[15,16]. Greece was among the first European countries (1992) to enact legislation directly addressing the rights of mentally healthy patients to IC. However, partial measures were taken for the wide implementation of the legislation. Five years later, in 1997, patients' rights act were extended to impose the provision addressed by the law 2071/92[17].

We sought to record and evaluate patients' views of the way surgeons communicate IC in the Greek health care setting. Furthermore, we aimed to record the information that patients really comprehended as well as their perception of the significance of IC. This is an exploratory pilot study. It has been confirmed in English Law that informed consent has no application. So when you hear the expression informed consent

remember this doctrine has no legal standing in English Law

Study problem: Preoperative informed consent

Study location and time: Karbala maternity hospital during 2012

Objectives of the Study

1. To evaluate the content and comprehensiveness of informed preoperative consent from patient view .
2. To evaluate the content and comprehensiveness of informed preoperative consent from physician view
3. Express the important of the patient commitments to giving the pre-operative consent.
4. Find out the effect of patient acknowledgment with pre-operative form on their consent.
5. Find out the effect of patient acknowledgment with pre-operative form on the operation rates.
6. To measure the level of doctor commitment to explain the preoperative form for their patients.
7. To measure the level of doctors explanation of preoperative form for patients.

Methods and Materials

A descriptive cross sectional study was carried out from first of august to 31 of december of 2012 . There were 103 patients enrolled in the study from those patient operated by different Obstetricians (working at Karbala Maternity Hospital). There was no specific protocol or methodology on the selection of the participants of this survey as this was a convenience sample. We develop two type the questionnaires(one for patients and other for the doctors) by special obstetrician with statistical assistance from special member of community medicine department in college of medicine in karbala university and Babylonuniversity, after pilot test for these

questionnaires to evaluate its validity we reach the final version that is used ,special obstetrician explained the purpose of the study to each patient atthe second postoperative dayand get her consent to be included in the study and to complete the questionnaire and to explain the form of consent found in patient fileand the suggested informed consent that developed according the guideline of the WHO and universal consensual by different academic associations that should be contain the following data in detail **(diagnosis, Course of disease and outcome, operative procedure, evolution of the disease with or without treatment, operative risks, postoperative care, Complications of the operation, Benefit from operation, Options of treatment, Course if surgery is not performed, Success and failure rate, , Duration of operation, and Stay at hospital)**. The questionnaire was developed taking into consideration current literature regarding the goals and requirements for informed consent .The doctor questionnaire was distributed to the all surgeons, anesthetists that worked at karbala maternity hospital constituting 21 doctors in total.The patient questionnaire is consists of several items organized in four parts:

- a) The demographic data: includedgender, marital status, age, education level, profession and place of residence general information questions
- b) The obstetric information include :questions regarding number of pregnancies, number of children, number of previous surgeries, place of last surgery, type of last surgery and whether it was emergency or cold
- c) informed consent knowledge include: We have asked many question to the patients to indicate their previous knowledge about the presence of preoperative consent and the process of how to get the consent and process of signature and who is the one responsible

for accepting the surgery and signing on the consent

- d) post interviewing data included: Questions regarding the patients' opinion on the questionnaire itself after explanation by competent doctor taking into account the international component of proper informed consent including)

The data were analyzed with SPSS version16software .The Chi square test was used tocompare the results Differences with a p value <0.05 were considered statistically significant. The data are reported as the mean $\pm$ standard deviation.

Results

In total, 103 patients operated by different surgeons, volunteered to respond to the questionnaire. About 41.7 % were in 26-35 years age group, 31.1% were in the age group between 18-15 years and only about 10.7% were below 18, 2.9% were older than 45 years. Regarding the marital status, 7.8%, 87.4%, 4.9%, of the respondents were single, married and widowed, respectively. About 63.1% of the respondents were of low educational level (elementary school) while 36.9% of the respondents had high education level. 78.6% of the patients were housewives, 14.6% were employees the rest were students(Table1).

Table 1Demographic Data

Age (years)	Number	Percent
less than 18	11	10.7
18-25	32	31.1
26-35	43	41.7
36-45	14	13.6
46-55	2	1.9
56-64	1	1.0
Total	103	100.0
Marital State	Number	Percent
Married	90	87.4
Unmarried	8	7.8
Widow	5	4.9
Total	103	100.0
Education Level	Number	Percent
Low Education*	65	63.1
High Education**	38	36.9
Total	103	100.0
Occupation	Number	Percent
House Wife	81	78.6
Student	7	6.8

Employee	15	14.6
Total	103	100.0
Social State	Number	Percent
high		High
Borderline		Borderline
Low		Low
Total		

* Completed only primary school or less.

** Completed high school or more .

58.3 % of patients have previous operations including 38% of them having more than one previous surgery and most of them were

done in governmental hospitals. 49.5 % were emergency and 50.5 % elective operation (table 2).

Table (2)operation information's

Previous Surgeries	Number	Percent
None	43	41.7
One	22	21.4
More than One	38	36.9
Total	103	100.0
Place of Last Surgery	Number	Percent
Governmental Hospital	53	88.3
Funded Hospital	7	11.7
Total	60	100.0
Type of Current Surgery	Number	Percent
Obstetric	83	83.0
Gynecologic	17	17.0
Total		
Emergency vs. Elective	Number	Percent
Emergency	51	49.5
Cold	52	50.5
Total	103	100.0

51%of previous operations did not know about the consent form at allThe P value for this association is 0.101(table 3).

Table (3)Relation between number of Previous Surgeries and Knowledge on Pre-operative Consent

			Do You Know about the Presence of Pre-operative Consent?		Total
			Yes	No	
Number of previous operations	One	Count	14	8	22
		% within Number of Previous Surgeries	63.6%	36.4%	100.0%
	More than One	Count	14	24	38
		% within Number of Previous Surgeries	36.8%	63.2%	100.0%
Total		Count	45	58	103
		% within Number of Previous Surgeries	43.7%	56.3%	100.0%

56.3% of patients have no idea about presence of consent in file, about 62.1% knew their role in accepting or refusing the operation, 45% of patients give the consent by themselves and 55% by others, 54.4 % of

patients don't know that they must sign by them self on consent form, In this operation 92.1% didn't ever read the consent, No one ever explained the pre-operative consent to the patient (table 4).

Table (4) Patient Knowledge about consent and its procedure

Do You Know about the Presence of Pre-operative Consent?		
	Number	Percent
Yes	45	43.7
No	58	56.3
Total	103	100.0
Do You Know that You Should Accept or Refuse By Yourself?		
	Number	Percent
Yes	64	62.1
No	39	37.9
Total	103	100.0
Do You Know that You Should Sign By Yourself?		
	Number	Percent
Yes	47	45.6
No	56	54.4
Total	103	100.0

Who Did Sign Instead of You?		
	Number	Percent
Husband	30	47.6
Brother	10	15.9
Mother	14	22.2
Mother of Husband	1	1.6
Other	8	12.7
Total	63	100.0
Educational Level of the Person Signed		
	Number	Percent
Low Education	41	65.1
High Education	22	34.9
Total	63	100.0
Total	103	100.0
In This Operation Have You Read the Consent?		
	Number	Percent
Yes	8	7.8
No	95	92.2
Total	103	100.0

100% of patients have understood the modified form of consent better after undergoing the surgery, 32.4% of patient change their decision and refuse to do operation if they have this explanation before surgery , 97.9% agreed that consent is necessary , 84.5% suggested that the content

of the pre-operative consent should be changed according the modified form for better understanding, 8% of the participant evaluate the concept as comprehensive , 6% suggested changing the title and content of the consent, 1% suggested adding item and another 1% suggested adding item (table 5).

Table 5 Patient's perception about modified consent and their suggestions to improve the consent.

After we read the consent in the file Have You Understood the Concept of Consent?		
	Number	Percent
Yes	102	99.0
No	1	1.0
Total	103	100.0
After Explanation Of Modified Consent Did You Understand Concept		

of Consent Better Than Before?		
	Number	Percent
Yes	103	100.0
Total	103	
If Yes Would You Agree to be Operated On?		
	Number	Percent
Yes	70	67.7
No	33	32.3
Total	103	100.0
Is Pre-operative Consent Necessary?		
	Number	Percent
Yes	100	97.1
No	3	2.9
Total	103	100.0
Your Evaluation of the Consent?		
	Number	Percent
Thorough	8	7.8
Change content	87	84.5
Add Item	1	1.0
Change Title and Content	6	5.8
Change Content and Add Item	1	1.0
Total	103	100.0

42.9 % of doctors explained the pre-operative consent to the patient while 14.3% have never explained the consent to the patient , 66.66% being not their duty and being very busy in 33.33% of cases, 42.9% not seen the signature of their patient on consent form , 61.9% from them not sure that their patient sign the consent form by themselves. Pre-operatively (66.7%) give the patients information about their operation while 33.3% of the surgeons have not explained the operation(71.4%) stating

the cause to be not their duty , (14.3%) blaming the patients to be of low educational , 76.2%of surgeons shared their patents in decision making regarding management , 81% of surgeons think that content of pre-operative informed consent is comprehensive while 19% don't agree with them and suggested the followings: Need more details to protect the surgeon and anesthetist , No enough information about complication , No enough information about failure and success rates(table 6).

Table6consent taking and patient signature.

Have you explained the consent to your patient?		
	Number	Percent
Yes	9	42.9
No	3	14.3
To Some Extent	9	42.9
Total	21	100.0
If Not.Why?		
Frequency	Number	Percent
Not My Duty 2	66.66	2
Very Busy 1	33.33	1
3	100.0	3
Pre-operatively did you see the patient signature?		
	Number	Percent
Yes	12	57.1
No	9	42.9
Total	21	100.0
Are you sure that the patient signed by herself?		
	Number	Percent
Yes	8	38.1
No	13	61.9
Total	21	100.0
Pre-operatively, Did you give your patient information about operation?		
	Number	Percent
Yes	14	66.7
No	7	33.3

Total	21	100.0
If Not, Why?		
	Number	Percent
Low Patient Education	1	14.3
Not My Duty	5	71.4
more than one	1	14.3
Total	7	100.0
Did you share your patient in decision making regarding management?		
	Number	Percent
Yes	16	76.2
No	5	23.8
Total	21	100.0

53% of surgeons faced a patient who refused to do the operation after the consent. 42.9% of doctors faced problems with the patient and family postoperatively and the most common cause suggested being communicative 90.5% agreed that these problems can be prevented by proper

application of informed consent, 95.2% insisted on their colleagues on proper application of informed consent, most of surgeons (66.7%) haven't received courses on importance of informed consent in their medical schools (table 7).

Table 7 Postoperative problems encountered by surgeon and the role of consent in decreasing them.

Did you face any problem with the patient or her family post-operatively?		
	Number	Percent
Yes	9	42.9
No	12	57.1
Total	21	100.0
If Yes, mention the suspected cause?		
Administrative causes	1	11.1
Mismanagement causes	1	11.1
Communication causes	4	44.4
Over loaded job	2	22.2
Mismanagement and overloaded causes	1	11.1
Total	9	100.0
Did you think that these problems can be prevented with your commitment with proper IC application?		
	Number	Percent
Yes	19	90.5

No	2	9.5
Total	21	100.0
Did you insist on your colleagues to apply proper IC pre-operatively?		
	Number	Percent
Yes	20	95.2
No	1	4.8
Total	21	100.0
Have you attended any course on importance of pre-operative IC in Medical Practice?		
	Number	Percent
Yes	7	33.3
No	14	66.7
Total	21	100.0

Discussions and Recommendations

In our community there is large number of women are housewives and of low educational level so this need special program and clear regulation for health education including the preoperative counseling and informed consent that must be organized by health provider. In our study there is 63.1% of low education level 53.8% of them they did not know about the presence of consent form , and 36.9% of high level 60.5% of them don't know about the consent form that may reveal there is no difference between two groups which indicate the level of knowledge by informed consent , In our study 73% of our sample live in urban area so this need to concentrate of effort for health education in these area . About 58.3 % of patient have previous surgery one or more , 51% of them they did not know about the consent form and about 88% done those surgical procedure in governmental hospital and that unfortunately show there is no strict protocol or guideline or proses that may be followed in those hospital for this purpose. There is no difference in percentage of patient have emergency or cold surgery and because of large number of patient that don't know any information about the presence of consent form or about their role

in accepting and giving the consent and any information about the proses of giving this consent and large number of our patient 45% of patients give the consent by themselves and 55% by others even they are conscious and have not emergency operation while only (58.3%) in Pakistan study [18]. About 92% of our patients haven't read the consent form , unfortunately zero % of patients have explanation about the consent form or counseling preoperative compare to (87.7%) patients were informed about their condition [18]. We found that about 99% of patient include in our study have understand the concept of consent just after we read the consent form to the patient compare to 93% Of other study [19] while 100% of them agree that they more understand the modified form than before explanation . After explanation there is no change in decision about the agreement of undergone the operation in 67.7% of our sample . Only 7.8% of patient see that the consent form found in patient medical file is thorough and about 84% says it need change in content as that explained by us to the patient (modified form) , about 8% says it need some changes in title and add items as its seem to be legal paper .about 97% of our patients agree that the informed consent is important and

necessary. These findings are similar to those found in another study [19]

Regarding the response of the surgeons in the hospital there is mismatch between their answers and the patient answer about any explanation preoperatively , only 43% of surgeons explain the consent form to their patients About 10% of surgeons think that it's not duty to explained the consent form to the patient. Unfortunately about 43% of surgeons did not see the patient signature on consent form preoperatively and about 61.9% not sure that their patient signed by themselves on the consent form . About 33.3% of surgeons preoperative don't give any information to the patient most of them state that is not their duty, about 23.8% Of surgeons don't share their patients in decision making . There is about 53% of surgeons faced a patient who refused to do the operation after the consent .About 42.9% of doctors faced problems with the patient and family postoperatively and the most common cause suggested being communicative. Most of surgeons (66.7%) haven't received courses on importance of informed consent in their medical schools

Conclusion

This study highlights the poor quality of patient knowledge about surgical procedures and the inadequate information provided and process of information given or taken from patients .

Our recommendations are:

- 1- We encourage on the ministry of health and health directorate to initiate local protocol for preoperative counseling form taking in consideration the level of education of our community.
- 2- We encourage the health directorate of karbala and all Iraqi health department to initiate and follow-up especial local protocol for valid preoperative informed consent form with assistance from ministry of higher education and scientific research representative by colleges of medicine in all

Iraqi universities and Iraq-association of physician

- 3- We encourage all medical colleagues to change their on curriculum to involve more information's and training session on (humanity of medicine ,communication skills, consent taking ,patient doctor relationships , patient writs
- 4- We encourage the ministry of justice for more participation in such issues by legal education workshop for all health giver
- 5- We encourage the media to take large role in people education about the patient – physician relationship and about preoperative informed consent
- 6- We encourage the ministry of health to make more workshops and training courses on (communications and preoperative counseling and preoperative informed consent)to all physicians and play role to increase the number of surgeons works in all hospitals .

References

- 1- Christopoulos P, Falagas ME, Gourzis P, Trompoukis C (1977) Aspects of informed consent in medical practice in the eastern Mediterranean region during the 17th and 18th centuries. World J Surg 31: 1587–1591. doi: 10.1007/s00268-007-9101-8.
- 2- Tobias JS, Souhami RL (1933) Fully informed consent can be needlessly cruel. British Medical Journal 307: 1199–1201. doi: 10.1136/bmj.307.6913.1199.
- 3- .Kusec S, Oreskovic S, Skergo M, Korolija G, Busic Z, et al. (2006) Improving comprehension of informed consent. Patient Education and Counseling 60: 294–300. doi: 10.1016/j.pec.2005.10.009.
- 4- Schneider CE (1998) The Practice of Autonomy. New York: Oxford University Press.
- 5- McNutt RA (2004) Shared medical decision making: problems, process, progress. JAMA 292: 2516–2518. doi: 10.1001/jama.292.20.2516.
- 6- Sutherland HJ, Llewellyn-Thomas HA, Lockwood GA, Trichler DL, Till JE (1989)

Cancer patients: their desire for information and participation in treatment decisions. Journal of the Royal Society of Medicine 82: 260–263.

7- Cox K (2002) Informed consent and decision-making: patients' experience of the process if recruitment to phase I and II anti-cancer drug trials. Patient Education and Counseling 26: 31–38. doi: 10.1016/S0738-3991(01)00147-1.

8- Cassileth BR, Zupkis RV, Sutton-Smith K, March V (1980) Why are its goals imperfectly realized. The New England Journal of Medicine 302: 896–900. doi:10.1056/NEJM198004173021605.

9- Dimond 2001.

10- Hutchinson 2005.

11- Wicker & O'Neill 2005.

12- Coyne CA, Xu R, Raich P, Plomer K, Dignan M, et al. (2003) Randomized controlled trial of an easy-to-read informed consent statement for clinical trial participation: A study of the eastern cooperative oncology group. Journal of Clinical Oncology, 21: 836–842. doi: 10.1200/JCO.2003.07.022.

13- Dawes PJD, Davison P (1994) Informed Consent: what do patients want to know?

Journal of the Royal Society of Medicine 87: 149–152.

14- Whitney SN, McGuire AL, McCullough LB (2004) A typology of shared decision making, informed consent and simple consent. Annals of Internal Medicine 140: 54–60.

15- Bass PF, Wilson JF, Griffith CH, Barnett DR (2002) Residents' ability to identify patients with poor literacy skills. Academic Medicine 77: 1039–1041. doi:10.1097/00001888-200210000-00021.

16- (Cable 2003).

17- Merakou K, Tragakes E (1999) Development of Patients' Rights Legislation. The European Journal of Health Law 6: 71–81. doi: 10.1163/15718099920522695.

18- M Jawaid , M Farhan , Z Masood , SMN Husnain(2012) Preoperative Informed Consent: Is It Truly Informed? Iranian J Publ Health, Vol. 41, No.9, Sep 2012, pp. 25-30

19- K Chee Saw , Alison M Wood , Karen Murphy John R W Parry , W Guy Hartfall (1994) Informed consent: an evaluation of patients' understanding and opinion. Journal of the Royal Society of Medicine Volume 87 March 1994