ORIGINAL ARTICLE

An Evaluation of the Informed Consent Process for Elective Surgery at a University Hospital

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ABSTRACT

***Background**: To evaluate on a limited scale the process and quality of the consenting process in our local environment following the increasingly important issue of informed consent and its validity to most physicians and hospital administrators in the face of an emerging litigious Nigeria society.*

***Methods**: A 22 item questionnaire was administered on 60 consecutive patients admitted for elective surgery into the general and specialty surgical wards of the University College Hospital over a one month period.*

***Results**: No question in our study achieved the ideal standard of 100%. At the time of admission, 57 of the 60 patients knew their clinical diagnosis from the primary surgical team with 90% (n=54) of the subjects expressing varying degrees of satisfaction with the information they had on their condition.*

Only about 32% of the patients got additional information on the diagnosis and planned surgery from sources other than the admitting surgical team. In this group of participants there was no significant difference in the sufficiency of information obtained between the two sources (p>0.05)

Ninety percent of the subjects however preferred they had all the information about their operation much earlier than the pre-operation day. Patients satisfaction with overall information obtained during the consenting process was only 'very sufficient' in 35% of the cases.

***Conclusions**: Notwithstanding the information derived by patients from their primary surgeons in addition to alternate sources, satisfaction with overall information obtained was marginal at 35%.There is a need to look into methods of improving the process, quality and validity of informed consent.*

KEYWORDS: Informed consent; Process; Elective surgery; Satisfaction.

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INTRODUCTION

The issue of informed consent is becoming increasingly important and there is now increasing educational exposure and legal awareness in the society.[1] Physicians have an ethical and legal duty to provide their patients with adequate information during the informed consent process and failure to do so may breach these responsibilities making the doctor liable of battery and professional negligence.

In Nigeria, there are no statutes outlining the basic and general principles of obtaining an informed consent. The validity of consent requires three major components: the delivery of adequate information, a mentally competent patient and a voluntary decision on the part of the patient. This prospective study was undertaken to evaluate the process of informed consent in our practice and to quantify the quality of patients consent.

PATIENTS AND METHODS

60 consecutive fit patients admitted over a one month period in March 2005 into the general and specialty surgery wards of the University College Hospital, Ibadan for elective operations were recruited into the study. Patients under 18 years of age, with history of psychiatric disorders, acute confusional states or dementia were excluded from the study. A 22-item questionnaire was administered by the investigators to consenting patients after the informed consent -for- surgery process by the admitting unit's surgical staff.

The age, sex and educational status of patients were noted and questions were asked about knowledge of the clinical diagnosis, the planned surgical procedure and the surgical team, depth of discussion with the surgical staff and if there were alternate or additional sources of patient information on the diagnosis and operation. The patients were also required to assess how sufficient the overall information available to them was at the time they consented to have the operation. The results were recorded as simple expression of each of the questions as a percentage of positive response and further analyzed using the SPSS 11.0 software with the level of significance taken as $p< 0.05$.

RESULTS

The study population consisted of 38 males and 22 females with an M: F ratio of 1.7:1.The age ranges were < 30 years (35%), 31-64 years (51.7%) and > 65years (13.3%). The highest attainable education of the patients were higher education in 21(35%), secondary education in 20 (33.3%), primary education in 15 (25%) and non-formal education in 4 (6.7%).

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The period from the initial diagnosis to actual consent for surgery (which in our practice is commonly on the pre-operation day) was less than 3 months in 26 patients, between 3-6 months in 12 patients, 6-12 months in 6 patients and was more than one year in 16 patients.

At the time of admission for operation 57 out of the 60 patients knew their clinical diagnosis.

Of the study subjects, only 19 patients sought additional information on their clinical diagnosis and the planned surgery from sources other than the admitting surgical team. (Table I).There was no significant difference in the sufficiency of information obtained between the two sources ($p > 0.05$) in these 19 cases.

Ninety percent (n=54) of the study population rated the information on the aetiopathogenesis, intended treatment and possible complications of their condition from the admitting surgical team as between 'very sufficient' to 'sufficient'. In addition, the key sources for further information about the condition were from other doctors (15, 25%) and people who have or have had similar conditions (3, 5%).

However a similar percentage preferred they had all the information so obtained at a much earlier period than at the actual consenting process on the immediate pre-operation day (Table II).

Overall, the information upon which they consented to have the operation was graded as very sufficient, sufficient and barely sufficient in 21 patients (35%), 35 patients (58.3%) and 4 patients (6.7%) respectively.

Table I. Sources of information for patients other than the admitting surgical team

Sources	%
People who have/have had similar condition	5
Internet	0
Books, Magazines, other patient information materials	1.7
No other sources	68.3
Other physicians	25

Table II. When patients desire to have all information about surgery

Point of Information	No	%
While still being seen at out-patient clinic	31	51.7
As soon as admitted for surgery	23	38.3
On the immediate pre-operation day	6	10

DISCUSSION

The process, quality and validity of informed consent prior to operation are now issues of significant debate. Previous studies have looked into methods of obtaining valid informed consent. A survey by Byrne *et al*.[2] revealed that signing a consent form does not guarantee that a patient is fully aware of the exact nature and extent of treatment. Patient's recollection of information given by surgeons at the time of consenting is invariably poor and needs to be improved. Some investigators have demonstrated that patients recall was better by a combination of teaching them to recite the operations benefits and risks to the doctor as well as providing them with written information sheets as part of the consenting process[3, 4]. Any improvement in the consenting process is desirable and the need to continue to research into new methods of improving patients understanding and consenting is welcome.

No question in our study achieved the ideal standard of 100% as is usually the case in patient- related studies.

It is instructive that 41 patients (68.3%) did not refer to any alternate source of information besides their primary surgical team meaning this group of patients did not bother to seek a second opinion. Furthermore, electronic and written sources unfortunately played very little role in the consent process suggesting that they were also did not consult any written or electronic patients- information text. Considering that over 68% of our patients had more than primary school level education and could therefore read and write, this is rather unfortunate.

Only 41 patients (68.3%) could identify by name the Consultant Surgeon who was in overall charge of their case. Furthermore just about a quarter of the study population of was aware that trainee surgeons might be performing the operation under his supervision. This is a major lacuna in the information transfer as it is common knowledge that in an institution like ours and indeed as elsewhere, junior surgical staff do perform some of the operations.

Two additionally important aspects of the informed consent process to be considered are the information provided to patients and their understanding of the medical terminologies used. It is incorrect to assume that patients understand all medical language used in the consenting process. The verification of this deduction was however not the objective of this study.

The cadre of doctor who administered the informed consent could not be identified by 41patients (68.3%).When the remaining 19 patients were asked to hazard a guess, only fifteen thought correctly that he or she must have been a resident doctor, while four

thought it was the consultant; a very unlikely scenario in our environment where the informed consent process is usually performed by the resident staff. This underscores the fact that the information given and the explanations proffered to patients varies either due to a lack of consensus on the part of the surgeon as to what risks in a particular operation are significant to discuss or as a result of inconsistency in knowledge amongst junior surgical staff and between doctor grades[5,6].

This survey highlights the limitations of the consenting process in our practice. A guideline outlining the basic and general principles of obtaining a valid informed consent is desirable. Overall, the level of satisfaction with the consenting process was very sufficient in only 35% of our patients and although we did not specifically measure the time taken by the doctors to do the consenting formality, we recommend that any future evaluation of informed consent may include a measurement of the actual duration of the formality.

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APPENDIX 1

AN EVALUATION OF THE INFORMED CONSENT PROCESS FOR ELECTIVE SURGERY AT A UNIVERSITY HOSPITAL

Dear Sir/Madam,

Informed consent is now an important aspect of medical practice. This study is to determine what you know about the operation which you have consented to have.

Any information you provide will be made confidential and will be used to improve the service we offer. Please be assured that this questionnaire is completely anonymous.

Age _____

1. Sex: Male___ Female___
2. Clinical Diagnosis (as extracted from patients case note)
3. Highest attained educational status: Higher education_____ Secondary_____ Primary_____ Non-formal_____
4. Profession:_____
5. How long after the diagnosis of your surgical problems are you having the operation?
   < 3 months___ 3-6 months___ 6-12 months _____ > 1year _____
6. Have you been told by your doctor the diagnosis of the condition for which you are going to be operated? Yes___ No ___
7. How would you grade the information you have from or doctor as to the aetiopathogenesis, treatment and complications of your condition?
   Very sufficient_____ Sufficient_____
   Barely Sufficient_____ Insufficient_____
   Extremely insufficient_____
8. From which other source did you get information as to the aetiopathogenesis, treatment and complications of your condition?
   a. Other doctors apart from my primary doctor____
   b. People who have/or have had similar condition _____
   c. Internet_____
   d. Books, Magazines, other Patient information materials ____
   e. No other sources_____
9. How would you grade the information from the sources 9 (a-d) above as to the aetiopathogenesis, treatment and complications of your condition?
   Very sufficient_____ Sufficient_____
   Barely Sufficient_____ Insufficient_____
   Extremely insufficient_____
10. Did your doctor discuss other treatment options outside this operation with you?
    Yes___ No____
11. Do you know the purpose and the benefit of this operation? Yes___ No____
12. Before you answer Q 13 below, how would you

grade the information you have presently about the operation?
Very sufficient_____ Sufficient_____
Barely Sufficient_____ Insufficient_____
Extremely insufficient_____

13. Now, how much information do you have about;
    a. The likelihood success of the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    b. The likelihood failure of the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    c. The type/technique of anesthesia you would need for the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    d. The immediate complications, long-term problems, future life-style changes and medication use that could happen after the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    e. The technique the surgeon would use to do the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    f. Post-operation recovery on the ICU and/or Ward?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    g. Return to normal activity after the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
    h. The consequence of not having the operation?
       Very sufficient_____ Sufficient_____
       Barely Sufficient_____
       Insufficient_____
       Extremely insufficient_____
14. Do you know the name of the Consultant Surgeon who is in overall charge of your case?
    Yes_____ No_____
15. Were you told that trainee surgeons MIGHT be performing your operation under Consultant Supervision? Yes_____ No_____
16. Would you change your mind about having the operation if your answer to Q 15 above was YES?
    Yes_____ No_____
17. Were you told you were allowed to change your mind as to whether to have the operation right up to the last minute? Yes_____ No_____
18. Were you told you have a right to seek a second opinion about your treatment?
    Yes_____ No_____
19. Did you seek a second opinion about this treatment option you were offered?
    Yes_____ No_____
20. Do you know the cadre of doctor who administered the informed consent on you?
    Yes_____ (please tick one)
    (i) Consultant_____
    (ii) Trainee Surgeon___No___
21. At which point before the actual operation would you have wished to be informed about all you now know about the operation?
    a. While still being seen at the OPD Clinic_____
    b. As soon as admitted for surgery_____
    c. On the immediate post-operation Day_____
22. Overall, how would you grade the information you had upon which you gave your consent for the operation you are about to have?
    Very sufficient_____ Sufficient_____
    Barely Sufficient_____
    Insufficient_____
    Extremely insufficient_____