AN AUDIT OF THE INFORMED CONSENT PROCESS AT THE SURGICAL DEPARTMENT OF KORLE BU TEACHING HOSPITAL, ACCRA

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Abstract

Background: Surgeons carry out procedures on patients daily, many of which are invasive and may be associated with some risks and complications. The concept of informed consent in surgical practice was introduced after certain legal issues arose. Today patients are entitled to know and be accorded the right to determine what happens to their bodies. This study set out to determine if there had been any improvement in the informed consent process over the years, taking a closer look at the various aspects of the information given.
Method: This was a cross-sectional study carried out at the Department of Surgery, Korle Bu Teaching Hospital. One hundred consecutive post-operative patients were recruited and interviewed on information discussed at various stages during the preoperative period and on the administration of the consent form.
***Results*:** Thirty seven (66.0%) out of 56 elective cases felt they had been given enough information to their understanding to enable them give informed consent. Thirty (68.1%) out of 44 emergencies also felt they had been given enough information. Forty (71.4%) of elective cases were able tell what their diagnosis was but only 23 (41.0%) knew what procedure had been done. Similarly 32 (72.2%) emergency cases were able to tell what their diagnosis was but only 16 (36.3%) knew what procedure had been done.
Conclusion: Informed consent in the Department of Surgery of the Korle Bu Teaching Hospital is unsatisfactory and needs to be improved.

Keywords : Informed consent, consent form, alternatives, complications.

Introduction

Surgeons carry out procedures on patients daily, many of which are invasive and may be associated with some risks and complications. This was not of concern to the physician or patient in ancient medical practice but over the ages this has changed. Current thinking is captured in the decision of Justice Benjamin Cardozo who summarized it as "every human being of adult years in 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 a battery for which he is liable in damages"[1]. This has led to the concept of informed consent in surgical practice. Today patients demand to know and be accorded the right to determine what happens to their bodies.

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment[2]. It may also be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/permission/choice by the latter for the doctor to act in a particular way[3]. This process begins from the moment the patient walks into the consulting room to the time the written consent is administered. For consent to be considered valid and truly informed the patient should be aware of the diagnosis, the process through which the diagnosis was arrived at, the procedure to be performed in a descriptive manner and any reasonable alternatives to the proposed intervention[1]. They should also be aware of the relevant risks, benefits, and uncertainties related to each alternative as well as the outcomes.

The patient must be of sound mind and capable of making the decision. Unless a doctor acts within this set of parameters he/she opens him/herself up to litigation. Medical practice in Ghana is no exception. There is now increasing awareness among patients, and the public have openly questioned the quality of the medical care they receive with a number of medicolegal cases in court. An earlier publication in 2005 at the Korle Bu Teaching Hospital (KBTH) revealed that the informed consent process was unsatisfactory[4].This study set out to determine if there had been any improvement, taking a closer look at the various aspects of the information given.

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Methodology

This was a cross-sectional study carried out at the Department of Surgery, Korle Bu Teaching Hospital (KBTH). One hundred consecutive post-operative patients were recruited and interviewed in January 2017. A total of 131 patients had surgery over a two week period. Included were inpatients and outpatients who had emergency or elective surgery and aged over 13

years. Excluded were patients on admission yet to have surgery, those who had undergone general anaesthesia within 24 hours or were sedated, those at the theatre recovery wards and intensive care unit and those who had surgery more than 14 days prior to the interview.

Data collected included patient demographics, information discussed at various stages during the preoperative period and on the administration of the consent form.

Results

One hundred questionnaires were administered to 51 males and 49 females. Ages ranged from 15 to 80 years with a mean age of 43. They were of varied educational and religious backgrounds (Table 1).

Table 1. Demographic data

Characteristic	Number
Age in years	
11 – 20	11
21 – 30	12
31 – 40	26
41 – 50	16
51 – 60	23
61 – 70	9
71 – 80	3
Total	**100**
Gender	
Male	51
Female	49
Total	**100**
Marital status	
Single	29
Married	62
Divorced/separated	9
Total	**100**
Religion	
Christianity	87
Islam	13
Total	**100**
Education	
None	7
Primary	19
Secondary	45
Tertiary	29
Total	**100**

Fifty six per cent had elective procedures done of which 19% (11 of the 56 elective patients) were done as day cases. The rest, 44% had emergency procedures with only 1 done as a day case.

In 16 cases, consent was given by a relative. Out of these, only 7 (44%) felt they were given sufficient information before the form was signed on their behalf. Five (31%) were 18 years or less.

Of the remaining 11 (69%) 8 had emergency surgery and 3 had elective surgery. All 3 patients who had elective surgery were older than 60 years.

Tables 2 and 3 show the various stages at which information on the upcoming treatment was discussed with patients. For both elective and emergency procedures the diagnosis (87.5% and 77.3% respectively), what procedure was to be done (78.57% and 68.2% respectively) and the benefits (60.71% and 63.7% respectively) of the procedure were the most discussed, with more than half in each case being discussed at the OPD or Emergency room. On the other hand the alternatives (17.86% and 9.1%), cost (37.5% and 11.4%), complications (48.34% and 34.1%) and duration of the procedure (48.24% and 9.1%) were the least discussed for both elective and emergency procedures respectively.

Twenty eight per cent of patients did not know their diagnosis, the rest were able to give a diagnosis. 61% of patients did not know what procedure had been done, the rest were able to explain what procedure had been done.

Fifty per cent of patients read the consent form before signing, 50% did not. 43% of patients signed a completely filled form, 8% signed a blank form and 49% could not recall whether the form was filled or not.

Sixty per cent of patients were satisfied that everything had been explained to their understanding.

Figures 1 and 2 show when the consent forms were signed. Day cases formed the majority (65%; 11 patients out 17 patients) of those who signed consent on the morning of surgery.

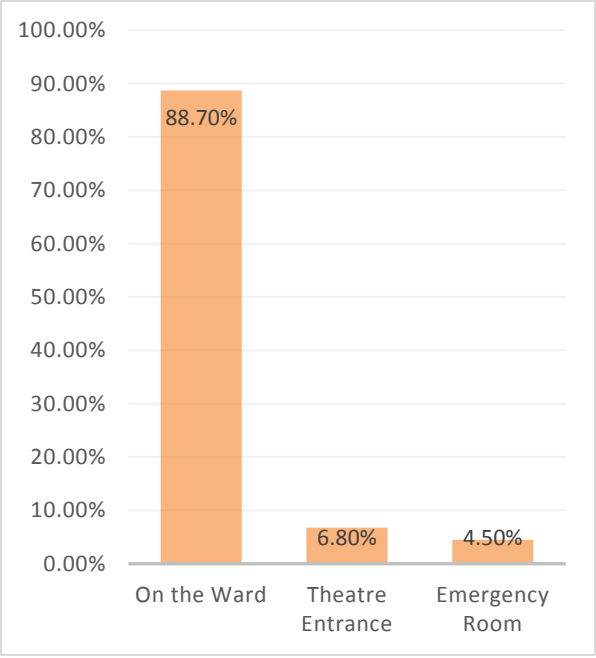

Fig 1. When consent forms were signed in emergency cases

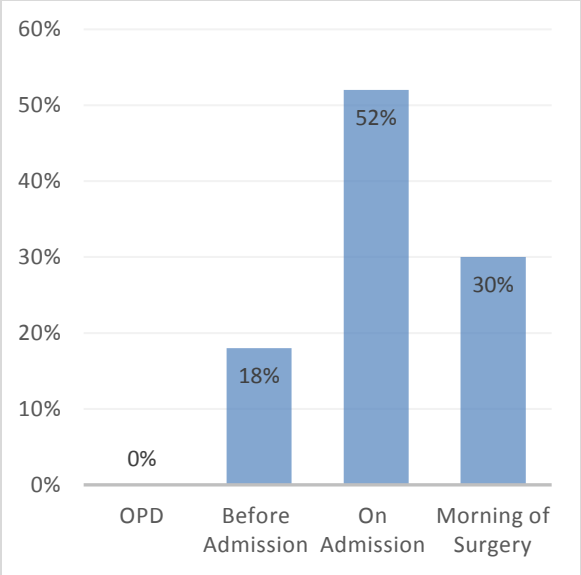

Fig 2. When consent forms were signed in elective cases

Sixty eight patients said the form was administered by a doctor but 45 of them (66%) were not sure by which category of doctor. Ten patients said it was administered by a nurse and 22 were not sure which category of staff administered the form.

Thirty seven (66.0%) out of 56 elective cases felt they had been given enough information to their understanding to enable them give informed consent. Thirty (68.1%) out of 44 emergencies also felt they had been given enough information.

Forty (71.4%) of elective cases were able tell what their diagnosis was but only 23 (41.0%) knew what procedure had been done. Similarly 32 (72.2%) emergency cases were able to tell what their diagnosis was but only 16 (36.3%) knew what procedure had been done.

Discussion

This study looked at patients' recollection of aspects of the information that was given them in obtaining an informed consent. Comparing this with 2005 data from the same institution,[4] there is no significant difference in the number of patients who knew their diagnosis (76% in 2005 and 72% in 2017) and a decrease in those who knew what procedure was done (64% in 2005 and 39% in 2017) but an appreciable increase in information given on possible complications (13% in 2005 and 58% in 2017). The recent increase in information being given on postoperative complications may be a reflection of the era of medical litigation which has recently crept into our society. This should have also reflected in better information given in all the other aspects of informed consent, but was not found to be so. Similarly the educational backgrounds of our patients (Table 1) did not reflect in their responses; those with higher education were not necessarily better informed.

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Typically the Ghanaian patient is not enquiring enough. This attitude is also found in other cultures. In an Indian population 63.6% were not interested in knowing what would be done at surgery provided they got better, though most of them did want to know the complications, cost, duration of the procedure and the chances of a successful surgery.[5]

Unlike developed countries there are no national guidelines on informed consent and the population characteristics are different. Generally literacy levels are low and doctors are overwhelmed with work. In Nigeria where each hospital has its own consent form Ezeome et al carried out a review of forms from all the major teaching hospitals to assess their content and textual readability using the Flesch readability assessment tool. Twenty eight essential components were considered and it was found that most of the forms had scanty information and none of the forms made provision for documentation of patient's permission for blood transfusion, tissue disposal, risks of not undergoing the prescribed treatment, and the risk of anaesthesia. In addition, the forms were found to be too technical for patients to understand.[6] The situation in Ghana may not be much different. The poor readability, variability and inadequacy of contents forms is certainly not limited to less developed countries but also found across the U.S.[7]

In December 2009 the Ministry of Health (MoH)/ Ghana Health Service set up a working group to review the national informed consent forms used in public institutions. This culminated in a national consensus meeting in 2012 to approve three forms: the General Consent Form 1, a Consent Form 2 for minors and one for patients who lacked capacity to give consent.[8] Though the new consent forms have not been adopted nationwide, KBTH adopted its own improved consent form in 2010. The new consent form may be partly responsible for the above improvement. Implementation of comprehensive consent forms by the Ministry of Health is overdue. A valid form should have a portion for an independent third party witness. A section should also be included for the anaesthetist to obtain consent for anaesthesia as they would be in the best position to discuss anaesthetic complications. Perhaps a separate form may be designed particularly for high risk cases.[3,9] Informed consent must also be extended to non-surgical procedures including other invasive procedures such as endoscopy, radiologic examinations like CT scan and high risk medical treatments like chemotherapy and blood transfusion.[7] This is not the current practice at Korle Bu Teaching Hospital.

Not surprisingly, this study reveals that patients undergoing elective surgery were better informed in all aspects of informed consent compared to those undergoing emergency procedures (Tables 2 and 3). Similar findings in Edinburgh have also been attributed to the differing nature of the disease, the urgency of which would make the patients feel less in control and

Table 2. When and what information about the consent was given for elective cases

Information	OPD	Before admission	On admission	Morning of surgery	Not discussed	Total
Diagnosis	37(66.07%)	5(8.93%)	7(12.50%)	0(0%)	7(12.50%)	56 (100%)
Natural prognosis	19(33.93%)	5(8.93%)	5(8.93%)	0(0%)	27(48.21%)	56 (100%)
Procedure to be done	24(44.44%)	5(8.93%)	12(21.43%)	3(5.36%)	12(21.43%)	56 (100%)
Benefits	19(33.93%)	6(10.71%)	8(14.29%)	1(1.79%)	22(39.29%)	56 (100%)
Duration of procedure	19(33.93%)	3(5.36%)	5(8.93%)	0(0%)	29(51.76%)	56 (100%)
Cost	5(8.93%)	10(17.86%	6(10.71%)	0(0%)	35(62.5%)	56 (100%)
Alternatives	5(8.93%)	1(1.79%)	4 (7.14%)	0 (0%)	46(82.14%)	56 (100%)
Complications	7(12.50%)	6 (10.71%)	11(19.64%)	3(5.36)	29(51.76%)	56 (100%)

Table 3. When and what information about the consent was given for emergency cases

Information	Emergency Room	On the ward	Theatre Entrance	Not discussed	Total
Diagnosis	23 (52.2%)	8 (18.1%)	3 (6.8%)	10 (22.7%)	44 (100%)
Natural prognosis	14 (31.8%)	10 (22.7%)	0	20 (45.4%)	44 (100%)
Procedure to be done	18 (40.9%)	11 (25.0%)	1 (2.3%)	14 (31.8%)	44 (100%)
Benefits of procedure	18 (40.9%)	9 (20.45%)	1 (2.2%)	16 (36.3%)	44 (100%)
Duration of procedure	1 (2.2%)	1 (2.2%)	2 (4.5%)	40 (90.9%)	44 (100%)
Cost	2 (4.5%)	3 (6.8%)	0	39 (88.6%)	44 (100%)
Alternatives	2 (4.5%)	2 (4.5%)	0	40 (90.9%)	44 (100%)
Complications	5 (11.3%)	10 (22.7%)	0	29 (65.9%)	44 (100%)

more likely to give consent with minimal information and little discussion.[10] Pain and side effects of some analgesics also influence the quality of the informed consent process and patients are less likely to pay attention to details or read the forms.[10] It is usually the case that an emergency procedure would be done and consented by various levels of surgical trainees who may be less competent in handling the consent and engaging the patient in discussion of viable alternatives and complications. However, an elective procedure may be discussed with more senior surgeons and there would be ample time and several discussions for the patient to explore and understand treatment options before making an informed consent. This study found that 69% of those whose consent form was signed by a relative had emergency surgery and may have been deemed to be in pain and unwell to be bothered with a signature in addition to some being uneducated and illiterate.

The situation is not much different in Nigeria. It was reported in Calabar that 70.3% of patients had the surgical procedure explained pre-operatively but 27.5% of them did not understand it. Here also the majority (51.6%) were not satisfied with the information they had received. This has been attributed to the use of medical terminologies and junior level surgeons and in some cases nurses who may not understand the intricacies of the procedure being left to do the explanation.[11] This study found that during the consent process patients did not know the identity of the staff obtaining consent. Though 68 patients said the form was administered by a doctor, 45 of them were not sure by which category of doctor. Ten patients said it was administered by a nurse and 22 were not sure which category of staff administered the form.

It is of concern that in this audit, 28% of patients claimed they did not know their diagnosis and 61% did not know what procedure they had. It is not adequate that only 48.3% and 34.1% of elective and emergency patients remembered a discussion on possible complications. Overall only 67% of patients were satisfied that everything was explained to their understanding. The process of obtaining an informed consent in KBTH has to be improved upon.

Conclusion and recommendations

Informed consent in the Department of Surgery of the Korle Bu Teaching Hospital has seen some improvement over the past 10 years but is still unsatisfactory and needs further improvement. We recommend that 'Informed Consent' which is part of the first year curriculum of the surgical trainee be emphasised. New and improved consent forms should be adopted nationwide. It is also necessary that informed consent be extended to other procedures including endoscopic procedures, blood transfusion, chemotherapy and others.

Limitation

Patients may have forgotten some information given them as these interviews were conducted in the postoperative period.

Competing interests

The authors declare that we do not have any competing interests.

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