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## INFORMED CONSENT IN SURGERY: AN AUDIT OF PRACTICE IN ILE-IFE, NIGERIA

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### ABSTRACT

**Objectives:** This study was conducted to assess patients' knowledge of their diagnoses and proposed surgical procedures before giving consent for such procedures in the various surgical units of Obafemi Awolowo University Teaching Hospitals Complex, (OAUTHC), Ile-Ife.

**Materials and Methods:** A structured questionnaire was administered to 80 consecutive patients who had just undergone an elective major surgery in general surgery, gyneacology, orthopaedics and surgical subspecialty units of the hospital.

**Results:** Sixty patients (75%) gave consent themselves, while other consents were obtained from close relations. Thirty-seven (46.25%) respondents were informed of the diagnoses and procedure by the unit consultants but no consultant was involved in the completion of the consent form. Seventy-five (93.75%) respondents had a knowledge of the diagnoses, 68(85%) understood the procedure but only 21(26.25%) knew any alternative to the procedure, 29(36.25%) knew at least one complication of the procedure and 12(15%) knew an option or complication of anaesthesia. Forty-five (56.25%) of the consent forms were properly filled while other forms had one error or another.

**Conclusion:** Well structured and standardized method of obtaining informed consent from surgical patients should be adopted. While educating patients, the various alternatives to the procedure and possible complications should be carefully explained to the patients who should be carried along in decision making.

**Keywords:** Informed consent, Surgical practice.

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### INTRODUCTION

Informed consent is an established ethical and legal requirement for most diagnostic and therapeutic procedures as well as for recruitment into clinical trials worldwide<sup>1,2</sup>. In surgical practice, an informed consent is very important for medico-legal reasons. In some instances, information disclosure to a patient may also be stress reductive.<sup>3</sup>

A "proper" informed consent entails adequate information about the patient's condition and the need for surgery, the proposed procedure, its nature, benefits, risks and possible alternatives as well as possible short and long term outcomes. The consequences of not having treatment should also be explained to the patient.<sup>4,5</sup> It has been advocated that these should be a continuous communication between the patients and the caregivers in the preoperative and postoperative periods.<sup>1,6,7</sup>

Apart from information from caregivers, various other factors may influence a patient in decision making. Socio-cultural and religious considerations can affect the patients' acceptance and understanding of the entire process.<sup>8,9</sup> The experience and

communication skills of the caregiver may also influence the process of obtaining an informed consent.<sup>10</sup>

This study was undertaken to evaluate the practice of informed consent in the different surgical units of the Obafemi Awolowo University Teaching Hospital, Ile-Ife, Nigeria, to assess the adequacy of information given to patients before gaining consent, identify any area of deficiency and to make appropriate recommendations.

### MATERIALS AND METHODS

This prospective study was carried out between January and June 2004. Structured questionnaires (Appendix 1) were administered to 80 consecutive patients in the first 24-48hr following an elective major surgery. These consist of 20 consecutive patients in each of 4 surgical units of General Surgery, Orthopaedics, Gynaecology and Surgical Subspecialties (comprising 5 consecutive patients each in Paediatric Surgery, Neurosurgery, Urology, and Plastic Surgery). In each case the individual who signed the consent form was interviewed. Cases where the individual who gave consent was not available were excluded from the study.

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The questionnaire consisted of 2 parts. The first section is for the bio-data of the respondent. The second section sought to know the respondents' knowledge of the diagnosis, the surgical procedure performed, its alternatives and complications and the respondents' source(s) of knowledge. The completed consent form was then studied to identify the medical personnel gaining consent and to evaluate the adequacy of its completion. The consent form was regarded as properly filled if all information required is supplied appropriately.

## RESULTS

Eighty individuals met the inclusion criteria. Their ages ranged between 22 and 65 years with a mean of 42.5 years. Forty-two respondents (52.5%) were males while 38 (48.5%) were females. Sixty individuals (75%) gave consent themselves, 9 (11.25%) were parents of the patients, 7 (8.75%) were patient's siblings, 2 (2.5%) were patient's spouses while 2 (2.5%) were patient's in-laws. (Figure I) Two (2.5%) of respondents were illiterates, 16 (20%) had primary education while 32 (40%) and 30 (37.5%) had secondary and tertiary education respectively. (Figure II)

Out of the 80 respondents, 37 (46.25%) were informed of the disease condition and the procedure by the managing consultant and 27 (33.75%) by the unit senior registrars. (Table I) No consultant was involved in the completion of the consent forms while only 4 (5%) forms were signed by senior registrars. (Table II)

Seventy-five respondents (93.75%), had a knowledge of the diagnoses (Table III), while 68 (85%) knew the procedure that was done (Table IV). 21 (26.25%) knew an alternative to the

procedure (Table V), 29 (36.25%) knew at least one possible complication of the procedure (Table VI), and 12 (15%) knew any option and or any complication of anaesthesia (Table VII). Forty-five (56.25%) of the consent forms were properly filled, while 34 (42.5%) of the forms had various aspects of the form left uncompleted.

Figure I: Person Giving Consent

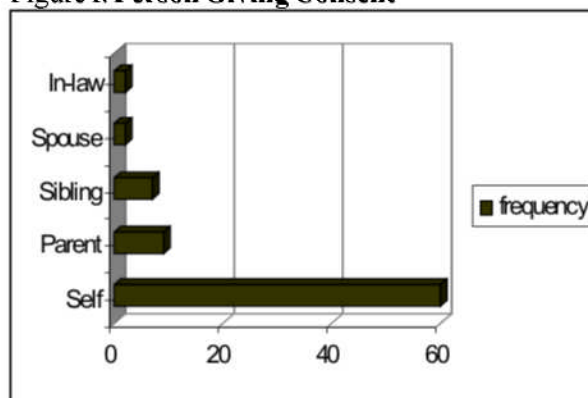


Figure 2: Educational level of Respondents

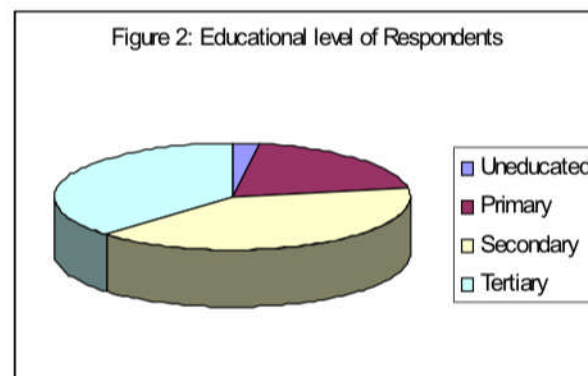


Table I: Sources of information

Unit	Gen.Surg.	Ortho	Gynae	Sub Specialties	Total (%)
Consultant	5(25%)	14(70%)	8(40%)	10(50%)	37(46.25%)
Senior Reg.	5(25%)	6(30%)	12(60%)	4(20%)	27(33.75%)
Registrars	8(40%)	-	-	4(20%)	12(15.00%)
House Officers	1(5%)	-	-	2(10%)	3(3.75%)
Nurses	1(5%)	-	-	-	1(1.25%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table II: Medical Personnel Gaining Consent

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Consultant	-	-	-	-	-
Senior Reg.	-	-	2(10%)	2(10%)	4(5.00%)
Registrars	1(5%)	6(30%)	2(10%)	16(80%)	35(43.75%)
House Officers	9(45%)	14(70%)	16(80%)	2(10%)	41(51.25%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table III: Knowledge of Diagnosis

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Knows Diagnosis	16(80%)	20(100%)	20(100%)	19(95%)	75(93.75%)
Did not know diagnosis	2(10%)	-	-	-	2(2.50%)
Not sure	2(10%)	-	-	1(5%)	3(3.75%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table IV: Knowledge of Procedure Performed

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Knows Procedure	16(80%)	18(90%)	20(100%)	14(70%)	68(85.00%)
Did not know Procedure	4(20%)	2(10%)	-	6(30%)	12(15.00%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table V: Knowledge of Possible Complications of the Procedure

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Knows complications	6(30%)	10(50%)	5(25%)	8(40%)	29(36.25%)
Did not know complications	14(70%)	10(50%)	15(75%)	12(60%)	51(63.75%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table VI: Knowledge of Alternatives to the Procedure

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Knows alternative(s)	2(10%)	8(40%)	5(25%)	6(30%)	21(26.25%)
Did not know	18(90%)	12(60%)	15(75%)	14(70%)	59(73.75%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table VII: Knowledge of Options and Complications Of Anaesthesia

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Knows	2(10%)	8(40%)	2(10%)	-	12(15.00%)
Did not know	18(90%)	12(60%)	18(90%)	20(100%)	68(85.00%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

Table VIII: Completion of Consent Form

Unit	Gen.Surg.	Ortho	Gynae	Sub-specialties	Total (%)
Properly filled	12(60%)	12(60%)	8(40%)	13(65%)	45(56.25%)
Improperly filled	7(35%)	8(40%)	12(60%)	7(35%)	34(42.50%)
Missing	1(5%)	-	-	-	1(1.25%)
<b>Total</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>20(100%)</b>	<b>80(100%)</b>

## DISCUSSION

There is a growing concern about litigations in surgical practice.<sup>11</sup> An informed consent when properly done can however promote mutual understanding between the surgeon and the patient and hence substantially decrease litigations.<sup>12,13</sup>

Most of the respondents in this study (97.5%) had formal education and hence could be adjudged capable of understanding the concept of informed consent. Of the 80 respondents, 60(75%) were the patients who gave consent themselves. However, many of the 20(25%) respondents who were not the operated patients had a poor understanding of the diagnoses and the procedure. It was observed in the course of the study that many adult patients withheld consent for surgery even after adequate information until an important family member who they believe should take such a decision for them agreed. That was in line with the culture of the Yoruba of South West Nigeria, where important decisions concerning any member were taken by the designated family head.<sup>14,15</sup>

Informed consent in surgical practice sometimes involved a process of sharing decisional authority with the patient when the choice hinged on personal values or preferences. This process, in which a continuous physician-patient decision making partnership agrees on an option of treatment, has been described as the best blend of physician expertise and the patient's choice.<sup>1, 5,16</sup> Such interactive decision making however depend largely on the caregiver's experience and communication skills. Mulcahy et al had shown that non-specialist and junior doctors may show significant misunderstanding of surgical procedures hence may not provide sufficient technical details to patients to obtain a valid consent.<sup>10</sup> In this study, about 80% of the respondents were informed about the disease and the procedure by the unit consultant and specialist registrars. However, completion of the consent form, which is the legal evidence of the process, was done in 95% of cases by junior registrars and house surgeons.

Many patients and their relations understood the diagnosis (93.75%), and the procedure performed (85%). It is evident that emphasis was placed on explaining these to the patients as other vital aspects of a proper informed consent were poorly understood by the patients. It has been observed that a full explanation of the possible complications may be frightening to some patients.<sup>17</sup> However, patients still need to be properly educated about the procedure they are to undergo. It will be reassuring if a patient is told about expected complications and how they can be successfully managed. Bernat and Peterson advocated that complications should be

discussed to the extent that they are common or serious<sup>1</sup>. We also feel that unexpected complications, which are the so called "frightening" ones, can be discussed with patients with evidence showing how rare such complications are in the unit proposing surgery.

The consent forms of this hospital were filled improperly in many instances. In many instances, procedures were written in abbreviations such as "TURP", "TAH+BSO" etc. For clarity, such procedures should rather be written in full. In one particular case, the procedure carried out (a myomectomy) was not indicated on the consent form.

Bernat and Peterson also advocated three initiatives to improve informed consent in surgical practice.<sup>1</sup> First, surgeons should see consent as an ongoing bidirectional process of communication throughout the period of care. Second, a surrogate decision maker should be identified in advance for any patient who may become incapacitated as a consequence of the surgery or the natural course of the illness. Third, surgeons should anticipate and discuss foreseeable complications with the patient and learn patient's general treatment preferences during and after the consent process. We find these three recommendations appropriate for our practice in this setting.

## CONCLUSION

Well structured and standardized method of obtaining informed consent from surgical patients should be adopted nationwide. While educating patients, the various alternatives to the procedure and the possible complications should be carefully explained to the patient among other things.

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