

Obstetrics and gynaecology residents' knowledge of the informed consent process and its practice in their training institutions

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Abstract

Introduction: The ethical principle of autonomy as expressed in the practice of informed consent is a core tenet of clinical practice and good patient physician relationship.

Aim: The aim was to identify specific gaps in the knowledge of trainee obstetricians and gynecologists in Nigeria about the informed consent process and its content. It also sought to describe the practice of informed consent in their respective institutions.

Materials and Methods: A survey of Residents in obstetrics and gynecology attending the revision course of the Faculty of obstetrics and gynecology of the national postgraduate medical college was done to determine their knowledge of the informed consent process and its practice in their institutions.

Results: None of the residents was able to give responses that contained all five conditions for informed consent to be valid. Furthermore, only 3 (2.22%) Residents mentioned that the name of the surgeon to perform the surgery should be part of the information provided to patients during the informed consent process. Similarly, only 8 (5.93%) mentioned that consequences of not having the surgery should be part of the informed consent process. The concept of the 'emancipated minor' being competent to give consent was known by 38% of the residents.

Conclusion: Although Residents in obstetrics and gynecology in Nigeria have some knowledge of the informed consent process, this knowledge is deficient in key areas such as competence to give consent, content and scope of information to be disclosed to patients for surgery. There is a need to teach residents the rudiments of informed consent and bioethics in general.

Key words: Informed consent, obstetric and gynecological procedure, residents' knowledge

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Introduction

Informed consent is the expression of the fundamental ethical principle of autonomy. It is the recognition of the basic human right of the patient to self-determination. Over the past few decades clinical practice has shifted from being paternalistic to emphasizing patient autonomy, transparency and shared decision making.^[1,2] The right of the patient to accept or decline treatment even if it may be against his physical wellbeing was upheld in some landmark judgments.^[3,4]

One of such landmark judgments is the Schloendorff, and Society of New York hospital.^[3] Mary Schloendorff visited the Society of New York hospital with a complain of stomach pain. On examination, the doctor discovered a lump in the abdomen. Schloendorff agreed to an examination under anesthesia to further evaluate if the lump was benign or malignant. On examination, under anesthesia, the doctor decided that it was in her best interest to have the lump removed and proceeded to remove the lump. However,

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Schloendorff sued the hospital alleging that the doctor performed the surgery without her consent. In the ruling, Justice Cardozo stated that,

“In the case at hand, the wrong complained of is not merely negligence. It is a trespass. 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, for which he is liable in damages”.^[3]

In Nigeria, a landmark judgment that upheld the right of the patient to give consent for treatment or refuse treatment was the case of Okonkwo, and Nigerian Medical and Dental Disciplinary Tribunal.^[4] In the judgment, Justice Uwaifo of the Supreme Court in his ruling said,

“I am completely satisfied that under normal circumstances no medical doctor can forcibly proceed to apply treatment to a patient of full sane faculty without the patient’s consent, particularly if the treatment is of a radical nature, such as in amputations or other radical surgery. Hence, the doctor must ensure that there is a valid consent and that he does nothing that will amount to a trespass to the patient”.

However, the ethical principle of autonomy as expressed in the practice of informed consent goes far beyond the fulfillment of legal provisions. It is a core tenet of clinical practice and good patient physician relationship. Informed consent is a process which ultimately ends up with signed informed consent document.^[1,5,6] The duration and contents of the consenting process would vary depending on the complexity of the procedure being planned. Nonetheless, all informed consent procedure must fulfill the following criteria.^[7]

1. Capacity of the patient to give consent
2. Disclosure of all necessary information related to the procedure
3. Comprehension by the patient of disclosed information
4. A voluntary decision by the patient, and
5. Documentation of the informed consent process and decision of the patient.

In recent times, some attention has been focused on informed consent procedures in developing countries including Nigeria.^[8-14] Available literature in Nigeria indicates some deficiencies in the informed consent process in most hospitals.^[12] Jebbin and Adotey in 2004 surveyed 150 patients admitted for surgical procedures at the University of Port Harcourt Teaching Hospital. Only about 37% of the patients were informed of the possible complications of the surgery, and only 26% knew of the complications of anesthesia associated with the procedure.^[15] Similarly, in a study at the University of Benin Teaching Hospital, <25% of patients were informed of the

risks of their planned procedure, and no consent document was signed in 11.3% of them.^[16] In another study, about 55% of doctors in the surgical specialties agreed that sufficient information is not provided to patients when obtaining consent for surgery.^[13] These reports suggest that there may be gaps in the knowledge of doctors concerning the informed consent process and therefore corresponding gaps in the practice of the informed consent process.

Inclusion of bioethics in the curriculum of undergraduate medical students and postgraduate medical doctors would go a long way in correcting this deficiency.^[13] The positive impact of education on quality of clinical practice cannot be overemphasized.^[17,18] Chima, in his study on the evaluation of the quality of informed consent and contemporary clinical practices by medical doctors in South Africa, concluded that continuing medical education for doctors and other health care professionals in ethics and medical law will go a long way toward improving the overall quality of healthcare service delivery in South African hospitals.^[19] This was the similar conclusion of Leclercq when he surveyed the practice of informed consent process in general surgery in the Netherlands.^[20] In advocating this and in order to develop the content of a training curriculum, it is imperative to assess specific gaps in the knowledge and practice of informed consent process by doctors.

This survey aimed at identifying specific gaps in the knowledge of trainee obstetricians and gynecologists (OBGYN) about the informed consent process and its content. It also sought to identify the current practice of informed consent in their respective institutions. Findings from this survey may provide further justification for advocating for the introduction of informed consent process and practice within bioethics in the training curriculum and also provide information that may be helpful in designing the content of a training module.

Materials and Methods

This was a descriptive study using a self-administered pretested questionnaire. All trainee OBGYN residents attending the 2013 revision course for the parts I and II postgraduate examinations of the Faculty of Obstetrics and Gynecology of the National Postgraduate Medical College of Nigeria in Calabar, Cross River, state were invited to participate in the study.

The study questionnaire contained 33 questions grouped into three segments. The first segment elicited background information about the respondent. The second segment contained 18 questions that tested their knowledge of the informed consent process, while the third segment elicited information on the practice of informed consent in their respective institutions. The questions that tested their knowledge of the informed consent process were formulated

after review of relevant literature on the subject. It asked the following questions:

1. List five conditions/criteria that must be fulfilled for an informed consent to be valid
2. In obtaining informed consent from a patient for surgery, list the information that must be provided to the patient to assist the patient in making informed decision about the surgery.

The final part of the segment on knowledge, tested respondents knowledge of the legal person required to give consent in five different clinical scenarios. Each correct answer was given a knowledge score of one point. A maximum knowledge score of 18 points was obtainable for all complete and correct answers.

Sample size

The required sample size was calculated assuming a 95% confidence interval of 10% and an α (level of significance) of 0.05.

$$n = 1.96^2 \pi(1-\pi)/CI^2$$

Where n = minimum sample size; π = prevalence (assumed as 50%); CI^2 = level of significance (0.05).

Required minimum sample size was 96 respondents.

However, the questionnaires were distributed to all participants that attended the revision course.

Data analysis

The open responses in the filled questionnaires were reviewed by the author. The various open responses to the question that asked for five conditions that must be fulfilled for an informed consent to be valid were assessed for equivalence to these five conditions viz. competence, disclosure, comprehension, voluntariness, and documentation. Similarly, the various open responses to the question that asked for the information that must be provided to a patient booked for a surgical operation in order to make an informed consent about the surgery were assessed for equivalence to the following eight domains – diagnosis, surgical procedure, benefits of surgery, complications of surgery, consequences of not having the surgery, alternative forms of treatment, anesthesia and risk of anesthesia and name of the surgeon for the procedure.^[13,21]

The coded questionnaires were inputted into the computer using the Epi Info (version 3.5.1.) statistical software (developed by center for disease control and prevention, Atlanta, Georgia). A descriptive analysis was performed using measures of central tendency, percentages and proportions. Knowledge score below the median (50th percentile) score was rated as poor while knowledge score including median

and above was rated as good. Thereafter test for associations for the knowledge score was conducted using Chi-square and Fischer exact tests as appropriate. The level of statistical significance was accepted at a $P < 0.05$.

Ethical considerations

Ethical approval for the study was obtained from the Delta State University Teaching Hospital Health Research Ethics Committee and permission to administer the questionnaire obtained from the organizers of the revision course. Information about the survey was provided to all trainees, thereafter consenting participants proceeded to fill the questionnaire.

Results

One hundred and thirty-five questionnaires were filled out of the 182 distributed, giving a response rate of 74.2%.

Background characteristic of respondents

Eighty-eight (65.2%) participants were Residents in Federal Teaching Hospitals, 29 (21.5%) in Federal Medical

Table 1: Domains of information indicated by residents as content of informed consent process

Information	Number of residents that indicated it (%)
Diagnosis	80 (59.26)
Surgical procedure	99 (73.33)
Benefits of surgery	75 (55.56)
Complications of surgery	120 (92.31)
Consequences of not having the surgery	8 (5.93)
Alternative treatment	76 (56.30)
Anaesthesia and risk	29 (21.48)
Name of operating surgeon	3 (2.22)

Table 2: Residents identification of the legal person to give consent in various clinical scenarios

Clinical scenario	Legal person to obtain informed consent	Number of residents who identified legal person (%)
A 22-year-old married woman for CS	Woman	124 (91.85)
A 17-year-old married woman for CS	Woman	50 (37.04)
An unconscious pregnant woman for CS with husband and parents available	Husband	117 (86.67)
A 36-year-old married woman for bilateral tubal ligation	Woman	121 (89.63)
A 17-year-old unmarried girl for ERPC for induced miscarriage	Girl	52 (38.52)

ERPC=Evacuation of retained products of conception, CS=Caesarean section

Table 3: Status of personnel that obtains informed consent in residents' institution

Procedure	Nurse	House officer	Registrar	Senior registrar	Consultant
ERPC	3	49	64	4	1
Elective CS	4	29	74	11	8
Emergency CS	5	24	88	11	0
Ectopic pregnancy	3	17	91	16	1
Myomectomy	2	15	65	28	17
Abdominal hysterectomy	2	12	55	21	36
Vaginal hysterectomy	2	12	54	19	39

ERPC= Evacuation of retained products of conception, CS=Caesarean section

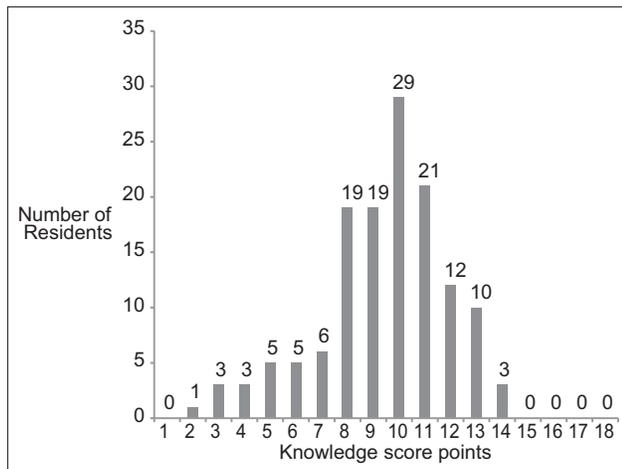


Figure 1: The knowledge score of residents about informed consent

Centers, 12 (8.9%) in State Teaching Hospitals, 5 (3.7%) in State Specialist Hospitals and 1 (0.7%) in the Mission Hospital. The mean number of years spent in residency was 2.78 years \pm 0.96 and 122 (90.4%) of the participants were Registrars, while 13 (9.6%) were Senior Registrars. Eighty-five (62.96%) Residents obtained their basic medical degree 5-7 years ago, with the modal duration being 5 years. Over 77.6% of the Residents were in the age group 30-39 years.

Fifty-five (41%) of the Residents have previously attended a lecture on bioethics, while 44 (32.8%) have previously attended a lecture on research ethics.

Knowledge of the informed consent process

None of the residents was able to give responses that contained all five necessary conditions for informed consent to be valid. Competence as a precondition for validity of informed consent was mentioned by 56 (41.5%) residents; Disclosure was mentioned by 102 (75.6%) residents; Comprehension by 64 (47.4%) residents, Voluntariness by 52 (38.5%) residents and Documentation by 62 (45.9%) residents.

Table 1 shows the residents' response on information that should be provided to prospective surgical patients during the consent process. Only 3 (2.22%) residents mentioned that the name of the surgeon to perform the surgery should be part of the information provided to patients during the informed consent process. Similarly only 8 (5.93%) mentioned that consequences of not having the surgery should be part of the informed consent process.

One hundred and twenty-four (91.85%) correctly identified that the legal person to give consent in the case of the 22-year-old married woman for cesarean section (CS) is the patient herself. Only about 37% and 38.5% of the residents respectively identified that a 17-year-old married woman could legally give consent for surgery or a 17-year-old unmarried girl could legally give consent for an evacuation of retained products following an induced miscarriage [Table 2].

Figure 1 shows the knowledge scores obtained by residents. Overall, the highest knowledge score by a resident was 14 points out of a maximum 18 points (78%). The mean knowledge score was 9.41 ± 2.48 points (52.3%); the median score was 10 points (55.6%). Sixty-one residents (48.1%) scored below 10 points (poor knowledge) while 74 (57.8%) residents scored 10 points and above (good knowledge). More residents that claimed to have attended a lecture on bioethics had good knowledge compared with residents that had not attended a lecture on bioethics, 56.36% versus 53.16%. However, this did not reach a statistically significant level ($P = 0.85$). Similarly, more senior registrars had good knowledge compared with registrars, but the difference was not statistically significant ($P = 0.82$).

Practice of informed consent in the residents institutions

In the majority of health institutions (53.4%) where the residents practice the informed consent form was usually signed within 24 h of surgery, but not on the day of surgery. However, in 39.8% of health institutions, the consent form was usually signed more than 24 h before surgery, and in 6.8% of health institutions the consent form was signed on the morning of surgery. The venue where the consent forms were signed for elective surgeries was mostly the ward in 80.5% of health institutions and the clinic in 19.5% of health institutions. For emergency cases, consent forms were mostly signed in the ward in 69.7% of health institutions; Accident and Emergency room in 22.7%; Theatre in 5.3% and Clinic in 2.3% of health institutions.

Table 3 indicates the health worker who usually obtains the consent for various procedures. It showed an involvement of higher cadre of health worker with increasing complexity of the planned surgery in their respective institutions. In obtaining consent for elective CS, the consultant is involved

in 8 residents' health institutions, whereas, for vaginal hysterectomy, the consultant is involved in 39 residents' health institutions.

Discussion

This survey showed that none of the residents was able to mention all preconditions necessary for an informed consent process to be valid. Providing information – disclosure – was the condition mentioned by majority of the residents while voluntariness was the condition least mentioned. The fact that the condition of voluntariness was least mentioned is a reflection of the practice of informed consent process in most health institution which may possibly be due to the paternalistic attitude of the doctor.^[12,13,22] Most doctors convinced of the benefits of the intended surgery to their patient often forget that the patient has the right to either accept or reject the surgery.

Perhaps a major reason why residents were not able to mention all the five conditions for informed consent process to be valid, could be because they have not been well educated on the informed consent process.^[23] In our study, only 41% of the residents have previously attended a lecture on bioethics, however we did not seek information on the contents of the lecture. In a study by Agu in Enugu, 50% of consultants and senior residents have not received any formal teaching on informed consent.^[24] A formal lecture on informed consent would definitely include the conditions necessary for it to be valid. Most residents were involved in the informed consent process without being able to identify the various conditions or parts of the process. This is typical of knowledge gathered informally on the job, in contrast to knowledge gathered through formal lectures and structured training.

In this survey, no resident listed the complete set of information that must be provided in the informed consent process. In particular, only 21.48% mentioned anesthesia and its complications as one of the information that should be provided to the patient and only 5.93% mentioned that they would provide information on the consequences of not having the procedure. About half of the residents indicated that they would mention alternative treatment options. These findings reflect the inadequacy of the disclosure in the informed consent process as practiced in most of our health institutions. Previous studies on informed consent process in Nigeria have highlighted the paucity of information provided to patients during the consent process. About half (54.9%) of the 102 consultants and surgical residents interviewed in South western Nigeria agreed that sufficient information is not provided to patients during the consent process.^[13] Similarly, in a review of the consent process at the Obafemi Awolowo University Teaching Hospital, Ile-Ife, in 2008, Adisa *et al.* interviewed 80 patients who just

had surgery in the various surgical specialties.^[8] Only 15% had been informed of the type of anesthesia and possible complications from it, and only 26.25% were informed of alternatives to the intended surgical procedure.

The least likely information to be disclosed in the informed consent process was the name of the surgeon for the procedure. Only 2.2% of the residents indicated that this particular information would be disclosed to the patient. This parallels the findings of Ogundiran and Adebamowo, in which the name of the surgeon likely to perform the surgery was disclosed only by 4.9% of surgeons. It seems that doctors and indeed health workers in Nigeria have not yet accepted the fact that it is the right of the patient to know the name of the health care giver.

Residents' knowledge of appropriate legal person to give consent was evaluated with the use of 5 different clinical scenarios. Incorrect response was obtained mostly in the clinical scenario involving patients < 18 years. This scenario was designed to test their knowledge of the concept of the "emancipated minor" – recognized by law as competent to give consent. In the 2 scenarios depicted < 40% of the residents recognized the 17-year-old as the legal person to give consent. In Nigeria, as in most countries, the recognized age of majority is 18 years.^[25] This is the legal age of consent, however, the doctrine of "emancipated minors" recognizes minors under the age of 18 as competent to give consent for treatment.^[26] The definition of emancipated minors includes those who are self-supporting and not living at home, married or pregnant, a parent, those in the military or any minor so declared by the courts.^[26] It is important that residents are familiar with this doctrine in order not to deny minors access to needed medical attention by insisting on the consent from their parents or husbands.

Surprisingly, although residents who claimed to have attended a lecture on bioethics scored higher than those who had not attended any lecture on bioethics, the difference was not statistically significant. It is difficult to precisely explain this finding, however several possibilities may exist. Perhaps the lecture on bioethics was an overview and did not adequately address the topic of informed consent. On the other hand perhaps our sample size was not large enough to detect any statistical difference, considering that the sample size was calculated primarily for descriptive purpose and not for comparative analysis. Finally, it is possible that our knowledge scoring system which gave a uniform score of one point to every correct answer was not sufficiently discriminatory. There is no doubt that improved knowledge of a subject can be impacted through lectures, other teaching methods and also through clinical practice.

Informed consent is a process that culminates in the signing of the consent form.^[1,5,6] The duration of the whole process vary according to several factors such as, the nature of

pathology, nature and complexity of surgical procedure, timing of the surgery and level of understanding of the patient. The process may involve more than one health care provider for a particular patient. Information about the diagnosis, treatment and other relevant information may have been provided during consultative visits by a higher cadre doctor and the signing of the consent form supervised and witnessed by a junior cadre doctor. It is the duty of the witnessing doctor to ensure that all necessary information and conditions of the consent process have been fulfilled before presenting the consent form to the patient for signature. To this end, it becomes imperative that the witnessing doctor or health care provider be equally knowledgeable in order to provide to the patient this information if it had not been provided before or gaps were identified in the comprehension of the information by the patient. Major and complex surgeries would demand the participation of the operating surgeon in the informed consent process.^[27,28] In this study, we expectedly observed a greater involvement of a consultant in the consenting process in planned major surgery. However, we also observed in this study that more consultants need to be involved in the consenting process, for example, while, in about 124 residents' institutions, the consultant would be the one to perform a vaginal hysterectomy; however in only 39 residents' institutions were the consultant involved in obtaining consent from patients. With the pivotal significance which consent for surgery holds in the overall patient care, and the gradually increasing level of litigation in Nigeria, it is imperative that more consultants be involved in obtaining consents from their patients for surgery. This will ensure that the patient is provided with all relevant and accurate information and that the patient has fully comprehended the information before deciding on accepting or rejecting the surgery.

Limitations of this study include the fact that the sample was not a probability sample, but rather a convenience sample of all residents that attended a particular revision course. None-the-less, since the residents came from training institutions probably spread all over Nigeria, the findings could to a large extent be representative of the whole country. Furthermore, our scoring of the knowledge may be better refined to show finer discrimination in the level of knowledge of the informed consent process. This may involve unequal weighting of answers – giving more points to certain correct answers that reflect deeper knowledge of the informed consent process.

Conclusion

Residents in obstetrics and gynecology in Nigeria have some knowledge of the informed consent process. However, this knowledge is deficient in many key areas such as competence to give consent, content and scope of information to be disclosed to patients for surgery. Detailed teaching on

informed consent should be part of bioethics that must be taught formally to residents. Institutional practices on informed consent and the consent form should reflect current best practices so that residents could also learn as they practice correctly. Due to limitations of this study further research need to be carried out to determine other factors and challenges that hinder adequate informed consent process in Nigeria.

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Survey Questionnaire

Questionnaire on knowledge and practice of informed consent by trainee obstetricians and gynaecologist in Nigeria

1. Your training centre? Federal Teaching Hospital []. Federal Medical Centre []
 State Teaching Hospital []. State Specialist Hospital []
 Mission Hospital []. Others (specify) _____
2. Number of years in residency training? _____
3. Designation? Registrar []. Senior Registrar []. Medical Officer []
4. Which examination are you preparing for? Part I []. Part II []
5. Number of years since obtaining medical degree? _____
6. Age in years? 20-24 [] 25-29 [] 30-34 [] 35-39 [] 40-44 [] 45-49 []
 50-54 [] 55 and above []
7. Have you had any formal lecture/training in Bioethics? Yes []. No []. Not sure []
8. Have you had any specific formal lecture/training in Research ethics? Yes []. No []. Not sure []
9. How many publications do you have? None []. 1-2 []. 3-5 []. 6-9 [] ≥10 []
10. List 5 conditions that must be fulfilled for an informed consent to be valid?
 - a) _____
 - b) _____
 - c) _____
 - d) _____
 - e) _____
11. In obtaining informed consent from a patient for surgery, list the information that must be provided to the patient to assist the patient in making informed decision about the surgery.
 - a) _____
 - b) _____
 - c) _____
 - d) _____
 - e) _____
 - f) _____

In each of the following scenarios described below, indicate the LEGAL person to obtain consent from

12. A 22-year-old married woman for ceasarean section _____
13. A 17-year-old married woman for ceasarean section _____
14. An unconscious pregnant woman for ceasarean section with husband and parents available _____
15. A 36-year-old married woman for bilateral tubal ligation. _____
16. A 17-year-old unmarried female for ERPC following induced incomplete miscarriage _____

In your centre, who usually OBTAINS CONSENT from patients for the following surgical procedures listed below. (Please tick only one for each procedure)

	Surgical procedure	Nurse	House officer	Registrar	Senior registrar	Consultant
17	ERPC					
18	Elective CS					
19	Emergency CS					
20	Ectopic gestation					
21	Myomectomy					
22	Abdominal hysterectomy					
23	Vaginal hysterectomy					

In your centre who would usually PERFORM the following surgical procedures listed below. (please tick only one for each procedure)

	Surgical procedure	Nurse	House officer	Registrar	Senior registrar	Consultant
24	ERPC					
25	Elective CS					
26	Emergency CS					
27	Ectopic gestation					
28	Myomectomy					
29	Abdominal hysterectomy					
30	Vaginal hysterectomy					

31. For most elective surgeries in which venue do you usually obtain consent for surgery?
Clinic []. Ward [], Theatre [] Other venue, specify _____
32. For most emergency surgeries in which venue do you usually obtain consent for surgery?
Clinic []. Ward [], Theatre [] Other venue, specify _____
33. For most elective surgeries, consent for surgery is obtained how many hours before surgery?
a) More than 24 hours before surgery [].
b) Within 24 hours before surgery, but not on the day of surgery [].
c) Morning of surgery [].