ORIGINAL ARTICLE

Contents and readability of currently used surgical/procedure informed consent forms in Nigerian tertiary health institutions

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Abstract

Background: Surgical informed consent forms should have evidence that their use will enhance a shared decision-making which is the fundamental objective of informed consent in clinical practice. In the absence of any guideline in Nigeria on the content and language of informed consent forms, we sort to examine the surgical and procedure consent forms used by Federal tertiary health institutions in Nigeria, to know whether they fulfill the basic elements of informed consent.
Materials and Methods: The surgical and procedure informed consent forms of 33 tertiary health institutions in Nigeria were assessed for their readability and contents. Adequacy of their content was evaluated based on provision for 28 content items identified as necessary information to be provided in a good consent form. The potential of the forms to be comprehended were assessed with Flesch readability formula.
Results: The contents of majority of the forms were scant. None of the forms made provision for documentation of the patient's permission for blood transfusion, tissue disposal, awareness of the risks of not undergoing the prescribed treatment, and the risk of anesthesia. Risk disclosures were only mentioned in specific terms in 11.4% of the forms. Less than 10% of the forms made provisions for an interpreter, signature of anesthetists, alternative to the procedure to be mentioned, and answering of the patient's questions. The Flesch reading ease scores of the forms ranged from 34.1 (Difficult) to 67.5 (Standard), with a mean score of 55.2 (Fairly difficult level). Field evaluation of the forms show that they shall be partly understood by 13- to 15-year-old patients with basic education but are best understood by literate adult patients.
Conclusion: The content of majority of the informed consent forms used in Nigerian tertiary health institutions are poor and their readability scores are not better than those used in developed parts of the world. Health Institutions in Nigeria should revise their informed consent forms to improve their contents and do a usability trial on the sample forms before deployment in order to ensure that they are comprehensible for their patient population.

Key words: Contents, informed consent forms, Nigeria, readability, surgery

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Introduction

Informed consent is the foundation of the patient-physician relationship. It is the basis upon which the physician is allowed to carry out on the patient, all forms of treatment and procedures, some of which may be potentially very harmful for the patient. The availability of standard informed consent forms in busy clinical settings means that as a practical matter, the forms have become the primary, if not the sole, source of a patient's information about a proposed therapy.[1] In more developed areas of the world, consent forms with extensive amount of information are often administered on stressed patients, parents, and families on

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their surgical/invasive procedures.[2] This information is often provided rapidly by health professionals who are themselves under increased pressure from the demands of managed care to see more patients in less time.[2] In developing countries like Nigeria, low literacy levels, religious and cultural hindrances, uneducated and unsophisticated patient population, as well as pressure of work pose serious challenges to conveying adequate information to the patient.[3] Unlike most developed countries, Nigeria has no national guidelines on the nature of the information to be provided to patients in informed consent. Each hospital developed its own surgical/procedure consent forms or just copied from sister institutions. In the absence of national guidelines, one will expect the forms of individual health Institutions to give insight into the nature of information a physician should communicate to the patient and the necessary interaction between the patient and the physician during the consent process.

This study was undertaken to assess the content and textual readability of surgical/procedure consent forms used in Federal public tertiary institutions in Nigeria, so as to know to what extent they satisfy the key elements of informed consent. Hopefully, this evaluation will provide a reference point in improving the informed consent and informed consent forms used in health institutions in Nigeria.

Materials and Methods

Nigeria has 49 Federal tertiary health institutions, comprising Teaching Hospitals, Specialist Hospitals, and Federal Medical Centers.[4] Solicitation for copies of the consent forms used for invasive and surgical procedures in these institutions was made to resident doctors attending the Ordinary General Meeting of the National Association of Resident Doctors of Nigeria in June 2007. Reminders were sent through text messages and e-mails. The use of resident Doctors for collection of the consent forms was a matter of convenience to reach a large number of colleagues from different institutions in a fixed place. It also allowed us direct face-to-face communication with our contacts to ensure higher response rates. Equally, the Chief Medical Director of each hospital was sent a letter explaining the nature of our study and requesting their permission and a copy of their surgical/procedure consent forms. Once received, each form was digitized and the resultant computer files compared with the original to ensure accuracy. These forms were then analyzed for their content and readability to evaluate how easily they can be comprehended by the patients. Exemption from ethical clearance was confirmed from the University of Nigeria Teaching Hospital Health Research Ethics committee.

Content evaluation

A total of 28 items which were considered necessary information for valid consent documentation[1,5] were sought in each form using a checklist. The presence or absence of each item was noted and crosschecked by two of the authors for accuracy. The items reviewed were provisions for the following:

1. Names of the: patient, physician, consent administrator, person providing the consent, the witness, and the procedure.
2. Permissions for: the procedure itself, additional procedures if the need should arise, anesthesia, blood transfusion, and tissue disposal.
3. Provision for general and/or specific information to be disclosed on the: nature of the procedure, benefits, risks, alternatives, risks of not having the procedure, and risks of anesthesia.
4. Notations that: the patient understood the information, their questions were answered, and that there is no guarantee that the procedure must be a success and no guarantee for a particular surgeon to do the case.
5. Provision for signatures (with dates) of the: patient, physician, anesthetist, witness, and parent/guardian.
6. Provision for an interpreter.

Because of the vagueness of many forms, when in doubt, an item was counted as being present. For those items with both general and specific categories, if any mention of the item was made, the "general yes included" was checked. If the information provided was such that it gave impression that specific information were supposed to be mentioned, the "specific yes included" was also checked.

Readability assessment

The readability of the consent forms were assessed using Flesch document readability calculator automated in Microsoft Word (Word 2007, Windows Vista™ Home Premium). Readability assessment formulas have been used to test the readability of text materials meant for US school children and have been applied extensively to assess documents written for general public consumption, including consent forms.[6-8] Flesch readability assessment is the most widely used and tested readability assessment formula and has been demonstrated to be reliable and valid if appropriately applied.[6-8] Flesch readability calculator produces two scores; the Flesch-Kinkaid grade level and the Flesch reading ease scores. The Flesch reading ease score is calculated after determining the number of sentences, words, and syllabuses in a document. It yields raw scores that usually range from 0 (hardest to read) to 100 (easiest to read). Table 1 shows the interpretation of Flesch reading ease scores and the type of documents that can be read at each score.[9] The Flesch-Kincaid grade level (range, 0 to 12) assesses readability on the basis of the average number of syllables per word and the average number of words per sentence.[7] It predicts the approximate number of years of United States formal education an individual requires to

comprehend a particular document.

In order to ensure that the formulas are adaptable to the readership of our local population, 14 forms representing 31 institutions' forms (many of them are replicas of forms of sister institutions) were manually analyzed at the Linguistics Department, Institute of African Studies, University of Nigeria, Nsukka. Here, the forms were subjected to manual Flesch readability analysis and then administered to pupils in primary five (5) and six (6) in three urban primary schools at Nsukka and then to children in the fifth and sixth grades at the University of Nigeria Staff School, Nsukka. These grades of children were used so as to ensure that the readability evaluations will approximate the recommended fourth to sixth grade level of education required for documents addressing health issues meant for general public consumption.[7,10] The pupils were asked simple questions on the forms to test their comprehension of the content. The responses were also taken as a measure of textual readability of the forms. The forms were finally subjected to analysis in terms of their linguistic attributes. The language structure, the vocabulary, and the mechanical features were evaluated to assess conformity with the age grades specified in the result.

Summary statistics were performed for both readability and content data. For ease of comparison, both sets of data were summarized as percentages indicating the presence of such items. The readability of each form and the mean readability score of all the forms were calculated.

Results

A total of 33 consent forms were received from among the 49 Federal tertiary health Institutions in Nigeria (15 from Federal Teaching Hospitals, 17 from Federal Medical Centers and Specialist Hospitals, and one prototype consent form designed by Medical and Dental Council of Nigeria for the use of all hospitals in Nigeria). The forms of all the major Teaching Hospitals in the Country except one were included. None of the eight neuropsychiatric hospitals in the country sent their form for the study. Many of the forms were similar in design, format, and content. Table 2 shows the grouping of forms according to similarity.

Table 1: Interpretation of Flesch reading ease scores[9]

Raw score	Difficulty level	Representative reading
<30	Very difficult	Scientific Journal
30-50	Difficult	General academically oriented magazine
50-60	Fairly difficult	Quality magazine
60-70	Standard	Digests
70-80	Fairly easy	Science fiction
80-90	Easy	Pop fiction
90-100	Very easy	Comic books

Content evaluation: There is marked variation in the contents of the 33 consent forms [Table 3]. A notable finding in majority of the forms is the scanty nature of their contents. The word content of the forms vary from as low as 43 words in some group 1 forms to just under 300 words in some group 7 forms, with the average word content being 104 words. All the forms made provisions for inclusion of the following five requirements: the patient's name and signature, patient's authorization of the procedure, permission for anesthesia, and permission for additional procedure, if needed during the surgery. None of the forms made provision for documentation of the following four requirements: patient's permission for blood transfusion, tissue disposal, awareness of the risks of not undergoing the prescribed treatment, and the risk of anesthesia. An idea that the procedures were described in specific terms was given in 57% of the forms, while benefits of the procedures were specifically mentioned in 54% of the forms. On the other hand, risk disclosures were only mentioned in specific terms in 11.4% of the forms. Less than 10% of the forms made provisions for four other requirements which are as follows: Interpreter, signature of anesthetists, alternative to the procedure to be mentioned, and answering of the patient's questions. The form of one institution requested that spouses of patients may sign the forms in addition to the patients, when the marital rights of the spouse may be

Table 2: Groupings of the consent forms according to similarity

Group 1	FMC Abakaliki
	FMC Gusau
	FMC Owerri
	FMC Umuahia JUTH
	NAUTH Nnewi
	UDUTH Sokoto
	UNTH Enugu
	UPTH
Group 2	ABUTH Zaria
	AKTH Kano
	FMC Azare
	FMC Bida
	FMC Birnin-Kudu NATIONAL EYE HOSP Kaduna
	NOH, DALA, Kano
Group 3	FMC Gombe UMTH Maiduguri
Group 4	FMC Yenegoa OAUTH Ife
Group 5	FMC Ido-Ekitti LUTH
	UBTH Benin
Group 6	FMC Lokoja UCH Ibadan
Group 7 (forms that do not resemble that of any other institution)	FMC Yola
	FMC Keffi
	MDCN NATIONAL HOSP Abuja
	NOHE Enugu
	UNIABUJA UNIYO
	UCTH Calabar

affected by the procedure.

Readability assessment

The 33 forms also showed a wide diversity in their readability scores [Table 4]. The automated Flesch reading ease scores of the forms ranged from 34.1 (Difficult, Generally academically oriented magazines) to 67.5 (Standard, e.g., Digests), with a mean score of 55.2 (Fairly difficult level). The Flesch-Kinkaid grade level scores ranged from 5.0 to 14.7 with a mean grade level score of 8.1 years. Stated otherwise, the required level of formal education needed for an individual to understand the textual language of the forms ranged from 5 years (Primary 5 level) to more than 14 years (University level), with most of the forms at the seventh to eighth grade level (Junior secondary school). The readability scores of the 14 forms that were manually assessed at the Linguistic Department of the University of Nigeria ranged from 18.3 (Very difficult; Scientific materials) to 76.4 (Fairly easy; Science fiction), with the mean score at 31.8 (Difficult; generally academically oriented materials). The results of the evaluation of the forms by the Linguistic Department implied from the Flesch Readability test that on the average, the forms shall be partly understood by 13- to 15-year-old patients with basic education but best understood by literate adult patients.

Although the readability scores from the manual assessments by the Linguistic Department follows a similar pattern to the automated readability assessment, there were significant differences in the scores of the readability assessment by the two methods for each institution and for the overall score. It is noteworthy that the forms that contain the least amount of information were not necessarily the ones with the best readability scores [Table 4]. Group 1 forms, for example, have no information on 19 of 28 necessary content items for a good informed consent form, yet their readability scores are not better than that of some institutions in group 8 that have a much higher content.

Table 3: Summary of the contents of the forms

Content item	% of forms with provisions for
Address of patient	88.6
Signature of parent/guardian needed	88.6
Witness named	74.3
Benefits mentioned In specific terms	54.3
In general terms	8.6
Procedure described In specific terms	57.1
In general terms	5.7
Risks disclosed In specific terms	11.4
In general terms	51.4
Name of consent administrator	60
Procedure named	57.1
Signature of witness	54.3
No guarantee on particular surgeon to operate	54.3
Consent provider named	51.5
Signature of physician needed	31.4
Physician's name	20
Patient understood information	11.4
No Guarantee for success mentioned	5.7
Alternatives to procedure mentioned	5.7
Patient's questions answered	5.7
signature of anesthetist needed	2.9
Interpreter needed	2.9

All the forms included the patient's name and signature, patients' authorization of the procedure, permission for anesthesia, and permission for additional procedure if needed. None of the forms made provision for documentation of patient's permission for blood transfusion, tissue disposal, awareness of the risks of not undergoing the prescribed treatment, and the risk of anesthesia.

Discussion

Our review of 33 informed consent forms from Federal

Table 4: Summary of the readability scores and content deficits of the groups of forms

Group	Mean readability scores			Content lacking in
	Flesch reading ease score	Flesch-Kinkaid grade level	UNN assessment	
Group 1 forms	61.2	8.1	(20.4) literate adults	19 of 28 items
Group 2 forms	49.5	8.9	(53.6 - 22.8) 13 – 15-yr-old - literate adults	10 of 28 items
Group 3 forms	56.3	7.4	(46.5 - 33.1) 13 -15, best by literate adults.	12 of 28 items
Group 4 forms	34.7	8.3	(32.1 - 29.4), 13 - 15yrs old, best by literate adults	14 of 28 items
Group 5 forms	52.4	9.4	(23.4), literate adults	11 of 28 items
Group 6 forms	62.5	6.7	(51.6), literate adults	17 of 28 items
Group 7 forms	44.4	8.3	(40.3), 13 - 15, best by literate adults	9 of 28 items
MDCN form	60.1	6.5	(18.3), literate adults	11 of 28 items
NOHE	52.8	8.9	(43.8), partly by 13 - 15 years old, best by literate adults	9 of 28 items
UNIABUJA	48.9	7.5	(76.4), easy for 13 - 15 years old	10 of 28 items
National Hosp. Abuja	51.9	9.8	(60.4), easy for 13 - 15 years old	6 of 28 items
FMC Keffi	35.0	8.9		13 of 28 items
UNI Uyo	63.1	6.9	(27.6), literate adults	10 of 28 items
FMC Yola	59.8	5.8		16 f 28 items

tertiary health institutions in Nigeria showed a wide variation in both their readability and content. The average readability score of the consent forms range from "difficult" to "standard" with most in the "fairly difficult" level. Although the readability of many of these forms is not different from the ones used in developed areas of the world which are often loaded with information,[2,8] the content of majority of them are very scanty and therefore the information conveyed are highly limited. The forms with the least amount of information do not necessarily have the best readability scores. Figures 1 and 2 are illustrative of forms with very scanty information and ones with reasonable amount of information, respectively. Indeed, many of the forms, especially those in group 1, are so scant that content information omitted more than half of the necessary items in a good informed consent form [Table 4].

The effectiveness of any information form must be measured in the light of its purpose.[1] The patient-physician relationship is dynamic and judgment laden that such interaction cannot be matched or fully captured in a documented statement. The informed consent upon which this relationship is predicated is an interactive process that cannot be reduced to a document. A proper informed consent should be obtained from the patient during this dynamic interaction which can and is always adjusted to match the patient's capacity and level of understanding. Although such an interaction cannot be fully captured by a fixed document, the consent form is used not only to show that such an interaction took place, but also to enhance such interaction.[2,5] The fiduciary nature of the patient-physician relationship as well as time constraint and the need to concentrate on relieving the patient's problem imply that clinical informed consent forms should be as simple as possible. A good informed consent form, nevertheless, should contain enough information as to convey to an evaluator, the notion that the basic key elements of an informed consent were fulfilled during the consent process.

A key element of a valid informed consent is that the information should be communicated to the patient at a language level she/he understands. Consent forms must therefore be written at a language level that most patients can understand. The recommended readability level for health literature materials meant for general public consumption is Flesch-Kinkaid grade level 4 to 6.[7,10] Most of our forms are best suited for individuals at the seventh to eighth grade (13 - 15 years at Junior high school level). One can infer from our result that informed consent forms in Nigeria are written in too technical, a language for most patients to understand. This becomes more significant when we note that the average adult literacy rate in Nigeria is estimated to be 65.7%, and that 80% of children in Nigeria need at least 6 years of formal education in order to be literate.[11] It must however be acknowledged that comprehension of a text document is a complex process and readability formulas do not claim to measure comprehension. Also, there are many pitfalls in using readability formulas to assess technical documents and these may render results inaccurate.[1] Without testing the consent form on people, researchers cannot legitimately conclude that the form is understandable or not based only on a grade-level estimate.[12] The ultimate measure of readability is the reader's ability to read and understand written material and the only way to know if a document is understandable and useful is to test it with a sample of appropriate users.[13] Only then, can we take all the situational variables into account.[13] Although we tried to achieve this by applying the forms to the expected lowest readership group for our people, the best way to do it will be for each institution to administer their proposed informed consent forms to randomized samples of their patient population during the designing stage prior to its being deployed for actual use.

Controversies exist on the amount of information that should be disclosed in the consent process and which necessarily must be conveyed in a consent form. Although the requirements in most developed countries are guided by regulatory guidelines and adversarial legal proceedings, such do not exist in Nigeria. The few Legal adjudications in Nigeria however suggest that informed consent issues will be viewed by the courts in Nigeria along western models.[3] A good consent form in Nigeria should therefore provide documentation for all the five basic key elements of an informed consent but may not be as

THIS is to certify that I give permission for an operation to be performed on and an anaesthetic administered to:

……

And that I leave the extent of the operation to the discretion of the surgeon.

Signature……..

Relationship……

Figure 1: A typical form with very scanty content

XY HOSPITAL

PATIENT'S CONSENT FORM

(*Please read this form and the notes overleaf very carefully*)

A. TO THE CONSULTANT

TYPE OF OPERATION, INVESTIGATION OR PROCEDURE

……

……

(i) I confirm, that I have explained the nature of the surgery or other procedures to be performed upon the patient named below, as well as other appropriated options as are available and the possible risks involved. I have also advised them of type of anaesthetic (if any) proposed. No assurance has been given that the procedure will be performed by a particular individual. The explanation I have given is in my judgment suited to the understanding of the patient and/or the parent(s) or guardian of the patient.

Signed/Mark…… Date……

(ii) Non-English Speakers-English Interpretation

I confirm that the explanation stated in (i) above, was to the best of my knowledge and belief truly and faithfully interpreted to the patient.

Signed…… Date……

Witness Signature & Print name……

B. TO THE PATIENT/GUARDIAN/RESPONSIBLE PERSON

1. If you do not understand the explanation of the surgery or other procedures to be undergone, or if you require further information you should ask your consultant/Medical Practitioner.
2. Please check that all information on the form is correct. If it is and you understand the explanation, then sign the form.

I……of……hereby consent to undergo the proposed operation to be performed upon myself (upon……). The nature and purpose of which has been explained to me by Mr/Mrs/Dr……

I also consent to such further or alternative operative measures as may be found necessary prior to, during the course of, and after the operation, and to the administration of a general, local or other anaesthetic for any of these purposes.

(please delete as applicable)

Signed……Patient, Parent, Guardian, responsible Person

Address……

……

Figure 2: A sample form with good content information

expansive in some disclosures as will be the case in some western countries. Beyond the textual readability of a form, the understanding of the informed consent process can be shown to have been assured if the form provided for an interpreter and for the questions of the patient to be answered. These two are particularly important in our environment with low literacy level. Even the most complex of terminology can be understood by the average individual if properly explained and therefore the importance of providing for an interpreter. Indeed, it is remarkable that none of the forms submitted to us by any Institution has been translated into any of the local Nigerian languages. Such would have been a good guide for interpreters in the informed consent process. Fulfillment of other key elements like ensuring patient's proper capacity and voluntariness can be evidenced if the form makes provision for the name and signature of guardian, parents, and witness. Dating of a consent form confirms that the consent was taken when patient had enough time to consider the issues at stake and therefore able to act voluntarily without undue pressure.

Conclusions

None of the forms used in tertiary health institutions in Nigeria is an ideal form in terms of both content and readability. Majority of the forms sacrificed content in order to achieve easy readability and yet, the few that contains reasonable amount of information were not the least readable. A consent form in clinical settings will never be able to capture all that transpired in a consent process. The informed consent form must therefore take their proper position in the patient-doctor relationship—an evidence that a valid consent was taken and a guide in obtaining the consent. The best way for an institution to get a form that will serve this purpose is for the institution to design their forms to contain all the basic information needed for a valid informed consent and then by a field trial with samples of their patient population, determine and achieve appropriate readability among the majority of their patients.

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