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A Content Evaluation of Informed Consent Documents for Invasive Procedures Used in Health Facilities in Southern Nigeria

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Abstract: Introduction: A properly-designed informed consent form could help in the use and preservation of relevant information as well as enrich the worth of patient-physician dealings. This research sought to find out if informed consent forms used in health facilities in Benin City, Edo State contained the essential elements of informed consent. **Methods:** The study was carried out in 38 health facilities (3 public health facilities, and 35 private health facilities) in Benin City, the administrative headquarter of Edo State, South-south, Nigeria. A checklist was utilized to appraise informed consent documents used in these health facilities to determine their adequacy in terms of the critical elements contained in it. The checklist was developed based on the contents of the prototype form (proforma) provided by the Medical and Dental Council of Nigeria (MDCN). The checklist consisted of "Yes" and "No" sections corresponding to the 16 items considered necessary for valid consent documentation. **Results:** None of the consent forms in public health facilities had a notation that the benefits of proposed management or procedure were clarified, that the patient clearly understood the language of presentation or that the choice to ruminate on the procedure for a while prior to giving assent was offered to the patient. Only 11.4% of forms examined in private health facilities had a notation that the benefits and risk of the intended management option or procedure were explained to the patient. **Conclusion:** Many consent forms currently in use in health facilities in Benin City did not wholly adopt the contents of the proforma provided by the MDCN. Most informed consent documents examined in this study lacked the essential elements of informed consent.

Keywords: Evaluation, informed consent, form, invasive procedures, health facilities, Nigeria.

Introduction

Over the years, informed consent has steadily grown in the health care industry with the increasing need to protect patient ethically before treatment, medical intervention or research are carried out on them. It has progressively signaled an ethical panacea countering the possible menace of authoritarian and despotic practices [1].

Informed consent, when used for a medical intervention or procedure is valid solely if the person involved in the procedure had previously been informed about the procedure, has understood the given information correctly and has given voluntary consent on this basis [2].

Beauchamp and Childress used seven analytical elements [3], in their analysis of the fundamentals of informed consent, grouped under three broad headings: Threshold, information, and consent. Those

of threshold include competence (to comprehend and make a decision), and this decision-making process done voluntarily. The information elements consist of disclosure of the content of medical facts, recommendation (e.g. of a treatment or management strategy), and testing of understanding of what had been said. Lastly, the two elements in the consent aspect consist of decision (which is the acceptance or refusal) and finally, the agreement or authorization process (e.g., by signature) [3].

The idea behind informed consent is, therefore, based on 2 basic premises: that the client has the right to be provided with the amount of information necessary to reach an informed decision on the proposed medical therapy or treatment and that he or she is at liberty to accept or refuse the physician's recommendations [3].

Ingeniously-crafted informed consent documents may facilitate the use and preservation of valuable information as well as improve the quality of patient-physician relations. Also, informed consent forms could assist in ensuring that the decisions about medical care are arrived at collectively between clients and their doctors.

The use of pre-printed consent documents and unusually short of dialogue and real conversation, are insufficient. Worthington cautions, therefore, that "clinicians can slip into the habit of asking patients to sign a piece of paper without any thought being given to either what is on the form or to its primary purpose. The ethical validity of consent hinges not on the written word, but the nature and quality of the interaction between patient and clinician" [4].

In many developing countries, informed consent documents are perceived as ordinary documentation conveyors and conceivably as legal security, notwithstanding if the procedure was achieved or of its trifling quality. Researches in clinical settings in Nigeria is in keeping with the fact that poor consent practices may not be connected to any specific characteristic of the Nigerian people [5,6].

However, what is apparent is the fact that similar causes as noticed in many developed countries as well as other developing countries, are deterring the practices of informed consent process in Nigeria: healthcare workers' inadequate knowledge of informed consent [7], faulty doctor-patients' communication [5], insufficient time for obtaining consent[8], use of technical language while explaining the consent process to patients, sharing minimal information, and over-dependence on signed documents [7], as well as patients' low level of education [6].

Methodology

An evaluation checklist was used to appraise informed consent documents for invasive procedures used in public and private health facilities in Benin City, Edo State to determine their adequacy in terms of the critical components of informed consent documents. The checklist was developed based on the contents of the prototype form (proforma) provided by the Medical and Dental Council of Nigeria (MDCN) (Figure 1).

Figure 1. MDCN Approved proforma for obtaining consent for anaesthesia, surgical operations, and clinical procedures

CODE (OF) MEDICAL ETHICS IN NIGERIA

MDCN/COMEIN/RG

APPROVED PROFORMA FOR OBTAINING CONSENT FOR ANAESTHESIA, SURGICAL OPERATIONS AND CLINICAL PROCEDURES

.....Hospital/Clinic
Address .....

CONSENT FOR SURGERY / PROCEDURES

I.....of.....
(Full names, surname first) (Full address not P.O. Box)

Hereby after detailed explanation of the advantages and disadvantages to me by

Dr.....willingly consent to the
(Full names, surname first)

procedure of .....On
(Specify)
Myself/child/spouse/mother/father/others .....
(indicate as applicable)

I affirm that I clearly understand the language of presentation. The option to think over the procedure for a period before assenting was also presented to me.

I further affirm:
(a) That the extent of this procedure and mode of anaesthesia are left to the discretion of the physician
(b) That any additional surgery or procedure to that described above will only be carried out if necessary and in my best interest and can be justified for medical reasons.

Signature: .....
Or Thumb print: .....
(Patient or Guardian)
Date: .....

Signature .....
Full Names.....
Address .....
(Witness)
Date: .....

31

The checklist consisted of "Yes" and "No" sections corresponding to the 16 items that were deemed necessary as crucial information for binding consent documentation. The presence or absence of individual element was noted and cross-checked for accuracy. Forms were inspected for names of the patient, health facility, clinician, the witness, and the procedure, anesthesia. Similarly, the forms were examined for permissions for additional procedures if the need should arise, provision for broad and/or precise information to be revealed on the nature of the treatment options, benefits, risks, and risks of the procedure. The notations that the client comprehended the information, and that they were provided with sufficient time to think over the procedure before given assent, as well as provision for signatures (with dates) of the patient/guardian and witness(es), were also checked.

The items considered as informed consent fundamental essentials in this work were notations for the name of the proposed treatment/procedure, explanation of benefits of the procedure, and explanation of potential risks of the procedure. Other elements considered were notations that the patient clearly understood the language of presentation and that the option to think over the procedure was presented to the patient.

Results

A total of 38 informed consent documents (3 from public health facilities and 35 from private health facilities were) were examined in this study. All the consent documents used in public and private health facilities made provision for name and address of the hospital, name, and address of the client or legal guardian as well as provision for the patient and witness signatures (Table 1). None of the consent forms in public health facilities had a notation that benefits of intended management or procedure were explicated, that the patient clearly understood the language of presentation or that they had the opportunity to ruminate over the procedure or treatment option for a while prior to giving their assent. Only 11.4% of forms examined in private health facilities had a notation that the risk and benefits of the planned procedure or treatment were explained to the patient (Table 1).

Table 1. Contents of informed consent forms used in health facilities in Benin City

Consent Items	Public health facilities (n = 3)		Private health facilities (n = 35)	
	Frequency (%)			
	Yes	No	Yes	No
Name of the hospital	3 (100.0)	0 (0.0)	35 (100.0)	0 (0.0)
Address of the hospital	3 (100.0)	0 (0.0)	35 (100.0)	0 (0.0)
Name of the patient or if appropriate, legal guardian	3 (100.0)	0 (0.0)	35 (100.0)	0 (0.0)
Address of the patient or if appropriate, legal guardian	3 (100.0)	0 (0.0)	32 (91.4)	3 (8.6)
*The name of proposed treatment or procedure	1 (33.3)	2 (67.7)	6 (17.1)	29 (82.9)
*Notation that benefits of proposed treatment or procedure were explained	0 (0.0)	3 (100.0)	4 (11.4)	31 (88.6)
*Notation that risks of proposed treatment or procedure was explained	1 (33.3)	2 (67.7)	4 (11.4)	31 (88.6)
Name of the clinician(s) performing the procedure	1 (33.3)	2 (67.7)	10 (28.6)	25 (71.4)
*Notation that the patient clearly understood the language of presentation	0 (0.0)	3 (100.0)	2 (5.7)	33 (94.3)
*Notation that the option to think over the procedure for a period before assenting was presented to the patient	0 (0.0)	3 (100.0)	1 (2.9)	34 (97.1)
Notation that the extent of the procedure and mode of anaesthesia are left to the discretion of the clinician	1 (33.3)	2 (67.7)	8 (22.9)	27 (77.1)
Permissions for additional procedures if the need arise	2 (67.7)	1 (33.3)	10 (28.6)	25 (71.4)
Provision for patients'/guardians' signature with date	3 (100.0)	0 (0.0)	35 (100.0)	0 (0.0)
Provision for witness signature with date	3 (100.0)	0 (0.0)	33 (94.3)	2 (5.7)
*Basic elements of informed consent				

A third of forms (33.3%) examined in public health facilities had provision for the name of the intended management option or procedure, the name of the clinician(s) performing the procedure as well as a notation that risks of anticipated treatment option or procedure was explained to the patient. On most forms examined in private health facilities, there was no notation that the patient clearly understood the language of presentation and no notation that the option to think over the procedure for a period before assenting was presented to the patient. Provision for the name of the treating clinician performing the procedure was absent in 71.4% of forms (Table 1).

Discussion

In all healthcare facility settings, the informed consent document ought to offer a birthplace of steady facts on the management option with the loftier goal of protecting clients from harm and safeguarding their autonomy [9]. This study determined that the majority of the forms examined did not contain the name of the planned treatment/procedure. Furthermore, notation of enlightenment of the benefits and risks of the planned management option or procedure was also absent in the majority of forms used in public and private health facilities, respectively. These findings indicate that certain content and exhibition criteria were lacking in many of the consent documents examined. The finding of a lack of content and presentation criteria in this study is consistent with the finding study on informed consent documents in Nigeria among 33 tertiary health institutions [10]. It was determined that specific mention of benefits and risks of the procedure was absent in over half of the forms, and disclosures of risk were only stated in specific terms in less than a fifth of forms [10]. The finding is also in tandem with the findings of a study in the United States, which showed that less than 50% of the forms provided specific information about risks and alternative treatment options [11]. The finding is also corroborated by the finding of hospital surveys of hospitals in the United States [12], and Spain [13]. The researchers discovered that it is either that the forms were not standardized and often missed vital elements such as risks and benefits, alternatives, and confidentiality or had defects in the information on consequences or contraindications with the purpose of the procedure, statements of having understood and clarified doubts, and the treatment options.

The findings in this study of absence of content and presentation criteria also highlight the fact that forms used for informed consent currently avail little substantive information to assist clients in making decisions, or even meet essential criteria for informed consent. In clinical settings, verbal consent may not suffice, even if the elements of informed consent are elucidated by the attending health worker. Consent documentation, therefore, provides an avenue for consenting individuals to exercise their autonomy after full disclosure of treatment options, understanding the information provided and assenting to the intended procedure by signing the consent document.

However, the presence of all essential elements of informed consent does not guarantee that the form is genuinely informative. Clients assenting to such a document may have little or no information on their treatment option and no sense of what to do to enhance their ability to share the decision. The real content and worth of the information encompassed in informed consent documents are exclusively germane for the fact that many clients consider that they are expected to sign them as a routine before a medical or surgical procedure. Parts of many informed consent documents, such as the necessity of a witness counter-signature, add to their legal look and may further distance clients. Combined with concerns about the use of legal jargon, these format issues may help to underscore the reason why clients think these documents were created not for their overall benefit, but to protect hospitals or physicians. Anything that backs to such assertions or perceptions is likely to deter, if not thwart, the aims of informed consent. Substantial enhancements in informed consent will entail advances in the information content of the documents as well as the redesigning them so that they can facilitate the ingredient of a collective decision-making process. Avenues should be explored to foster better patient understanding using language, which is clearly understood by patients/clients and impressing on them the importance of documentation in the consent process. A proper consent form in use in health facilities in Nigeria should, therefore, make available records for all the five

rudimentary critical components of informed consent and also be as vast in some disclosures as is the case in some developed countries.

A remarkable finding in the bulk of the forms was how scanty their contents were. The MDCN has made available a proforma which serves as a guide for health facilities regarding the characteristics of the type of message to be made available to clients regarding informed consent. (Figure 1). However, this study has shown that this proforma has either not been wholly adopted or partially adopted by many health facilities in Benin City. Each hospital facility may have invented or copied its own surgical/procedure consent forms from others. This is a worrying trend because one would expect the documents of the respective health facilities to give intuition into the characteristics of information a medical doctor would avail his/her client as well as the significant interface amongst the clients and their doctors during the informed consent documentation procedure. This is especially worrying in public health facilities, where the pressure of work on health workers coupled with the low literacy levels of patients and clients, religious and cultural barriers and limitations, unschooled and semi-literate client/patient population already pose staid challenges to passing suitable information to clients/patients.

Conclusion/Recommendations

Many consent forms currently in use in health facilities in Benin City did not wholly adopt the contents of the proforma provided by the MDCN which serves as a standard for health facilities on the characteristics of the information to be made available to clients and patients regarding informed consent. Most informed consent documents examined in this study lacked the essentials of informed consent. The MDCN should ensure that its proforma serves as the template for the design of consent documents; thus ensuring that consent forms in use in health facilities not only adhere to the contents of the form but also encompass the fundamentals of the informed consent process. Methods and techniques such as audio-visual aids should be explored by both private and public health facilities to foster improved patient's comprehension of the informed consent procedure.

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