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Assessment of the Informed Consent Process in the Provision of Dental Care in Mulagohospital, Uganda

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Abstract

Background: Informed consent is grounded in the principle of autonomy and represents patients' rights to participate in clinical decisions regarding their treatment. It is equally an ethical and legal requirement in dental care. The dental practitioner must offer appropriate information about all aspects of the treatment and ensure that a patient understands and makes an informed decision. There is limited literature on informed consent for dental care in Uganda. The aim of the study was to assess patients' comprehension of the informed consent process and dental practitioners' practices in obtaining informed consent.

Methods: This was a cross-sectional descriptive study conducted in the Dental Outpatient Department of Mulago Hospital. Two separate questionnaires were employed to collect data from dental patients and dental practitioners, respectively. Data were entered into Epi-data, coded and imported into STATA 14 for statistical analysis.

Results: Overall, the level of patients' comprehension of the informed consent process was 91.1%, with 96.3% who felt the dental practitioners satisfactorily explained to them the treatment received and, 65.1%understood very well the information given to them. About 93.5% of the patients confessed that they were given other options of treatment while 98.5% consented before the dental practitioners started treatment.

Most (94.7%) dental practitioners followed good clinical practices in obtaining informed consent and 98.7% gave information before initiation of treatment while 85.3% obtained consent from patients before starting any procedures. However, only 4 (5.3%) of the dental practitioners obtained written informed consent from patients.

Conclusion: There is a need to devise ways of improving patients' understanding of the treatment information given to them to support them make better and informed decisions regarding their care. Dental practitioners need to put more emphasis on the use of written consent in dental care because documentation helps in providing accountability and protects dentists from medical litigation in case the patients were to sue them for any treatment-related complications.

Introduction

Informed consent is an important aspect of clinical care ethics (1). It is grounded in the principle of autonomy (2) and symbolizes patients' rights to participate in clinical decisions regarding their treatment (3). Informed consent to treatment is equally an important aspect of the proper provision of dental care and it is a legal requirement for every dental procedure(3).

The need to obtain informed consent has been acknowledged in different health care specialties given the associated complications, invasiveness of the procedures, and the costs involved (4). There is increasing support for the doctrine informed decision-making as a way of ensuring patient autonomy in healthcare; the need to assess, protect and enhance patients' capacity to freely make decisions about

their health care, which has been recognized as a way of lessening physicians' paternalistic practices and make them more accountable to their patients (2). With the increasing technological advancement in the medical field leading to easy access to education and information, there is a need to encourage greater personal independence and the respect of patients' rights in decision making (5).

The dental practice is guided by the same principles that regulate the doctor-patient relationship, hence the shared decision-making process is a requirement of good dental care practice (6). Therefore, in a dentist-patient relationship, the dentist must offer appropriate and easily understood information about all aspects of the treatment as well as commitments after treatment (6).

According to the Uganda Patient's Charter, each patient has the right to be given adequate and accurate information about the nature of one's illness, diagnostic procedures, and the proposed treatment for one to make an informed decision.

In Brazil, a study (7) on the use of informed consent forms, 95.5% of the dentists provided verbal explanations on the treatment plan to their patients, 14.5% used informed consent forms every time in dental practice while 48% used the forms occasionally and only in special cases and 37% did not use informed consent forms in clinical care. In a similar study (8) in Nigeria, 61.6% of dental practitioners obtained written informed consent from their patients, majority (70.1%) of which were for surgical procedures. In Uganda, Ochieng et al (9) reported that 48.8% of medical surgeons received informed consent from patients before performing surgery while 88.6% reported obtaining informed consent at the last surgical operation (9). However, there is no published study that specifically looked at informed consent in general dental care in Uganda. The purpose of the present study was to investigate dental patients' comprehension during informed consent process and dental care practitioner's practices in obtaining informed consent in Mulago Hospital, Uganda.

Material And Methods

Study site

This was across-sectional study conducted among patients and dental care practitioners in the dental clinic in Mulago Hospital. Mulago Hospital is a national referral and teaching facility located in Kampala City, the capital of Uganda.

The hospital has a capacity of 2,000 beds and number of specialized clinics including dental clinic which attends to approximately 100 outpatients per day (personal communication, Medical Records Registrar).

Selection of study participants

A total of 324 patients aged 18 years and above who received treatment at the dental clinic and gave informed consent were recruited into the study using a consecutive sampling procedure. In addition, a total of 75 dental care practitioners (including dental surgeons, dental interns, and public health dental officers) who consented to participate in the study were purposively selected using census.

Exclusion criteria

Patients who were very sick and unable to speaks and dental care practitioners who were absent during the data collection or unwilling to consent were excluded from the study.

Data collection procedure

Standardized questionnaires were developed and pretested for errors and clarity before data collection. A structured questionnaire was administered by a research assistant to patients in form of an oral interview to obtain information about their comprehension of the informed consent process. The level of patients' comprehension of the informed consent process was measured using a Likert scale which ranged from 1- to 5, where 1 represented strongly disagree and 5 represented strongly agree.

The dental practitioners (n = 75) were given a self-administered questionnaire to assess their practices in obtaining informed consent from patients.

Data management and analysis

The collected data were entered into Epi data version 3.1 software, cleaned, and double checked for errors, and completeness. They were then exported to STATA version 14 software for analysis. Descriptive statistics in form of frequencies and proportions of the participants were used to determine the overall level of patients' comprehension of the informed consent process. Chi-square statistics were used to determine the association between independent and dependent variables. P-value < 0.05 was considered statistically significant.

Ethical consideration

Ethical approval was obtained from Mulago Hospital Research and Ethics Committee (Reference Number MHREC 2099) as well Cardiff School of Sports and Health Sciences Ethics Committee (Reference Number PGT-4393). Permission to carry out the study was obtained from the administration of Mulago Hospital.

Written informed consent was obtained from all participants who took part in the study. The purpose of the study was explained to the participants and their participation was voluntary and agreeing to participants did not waiver their rights in any way in accordance to Helsinki Declaration (10). All the data collected were kept securely in a cabinet under lock and key and only accessible to the investigator.

Results

A total of 324 patients participated in the present study and about half (52.2%) of them were male (Table 1). The mean age of the respondents was 34 ± 14.5 years. Most (49.7%) of them were aged between 18–29 years. Most patients were married (54.6%) and had at least attained tertiary education (42.9%). The majority of the participants was Moslems (28.7%) and had previously received dental treatment (90.7%), Table 1.

Overall, the level of comprehension to informed consent process was 91.1% (Table 1). Most (96.3%) agreed that the attending dentist explained to them the treatment that was going to be carried out and 93.5% explained that they were given other options of treatment. About (98.5%) of the respondents consented to the treatment.

Of those who gave consent to treatment, (93.7%) was verbal consent, 0.3% was written while (5.96%) was both verbal and written consent. About 95.1% asked questions about the treatment (Table 1).

Table 1
The frequency distribution of patients according to socio-demographic characteristics (n = 324)

Categories	Frequency (n)	Percentage (%)
AGE IN YEARS	159	49.1
18–29	58	17.9
30–39	52	16.1
40–49	55	16.9
50above		
GENDER		
Male	169	52.2
Female	155	47.8
MARITAL STATUS		
Single	127	39.2
Married	177	54.6
Divorced	3	0.9
Widow/Widower	17	5.3
LEVEL OF EDUCATION		
Informal education	12	3.7
Primary	28	8.6
O-Level	58	17.9
A-Level	87	26.8
Tertiary	139	42.9
RELIGION		
Catholic	83	25.6
Anglican	74	22.8
Seventh-Day Adventist	24	7.4
Pentecostal	49	15.1
Muslim	93	28.7
Did you have comprehension?		
YES	295	91.1

Categories	Frequency (n)	Percentage (%)
NO	29	8.9
Have you ever received dental treatment before?		
YES	294	90.74
NO	30	9.26
Do you feel the dental practitioner explained the treatment he/she carried out?		
YES	312	96.30
NO	12	3.70
If yes, how well did you understand the explanation?		
I didnot understand	4	1.28
I somehow understood	11	3.53
I understood	94	30.13
I understood very well	203	65.06
Were you told of the other options of treatment?		
YES	303	93.52
NO	21	6.48
Did you give the dental practitioners permission for the treatment done to you?		
YES	319	98.46
NO	5	1.54
If yes, was it verbal, written or both?		
Verbal	299	93.73
Written	1	0.31
Both	19	5.96
Did you ask any questions, and did the doctors answer you?		
YES	308	95.06
NO	16	4.94
Do you know the name of the dental practitioner who gave you the treatment?		

Categories	Frequency (n)	Percentage (%)
YES	290	89.51
NO	13	4.01
If no, why?		
Have forgotten	10	3.09
Was not told	11	3.4

BIVARIATE ANALYSIS

In bivariate analysis, there was no independent variable that was statistically significantly associated with the patients' level of comprehension of the informed consent process (Table 2).

Table 2
The frequency distribution of patients according to association of patients' socio-demographic characteristics with level of comprehension (n = 324).

Categories	Comprehension		Chi-Square	P-value
	YES n (%)	NO n (%)		
Age in years	146 (91.8)	13 (8.2)	2.43	0.5
18–29	50 (86.2)	8 (13.8)		
30–39	49 (94.2)	3 (5.8)		
40–49	50 (91.9)	5 (9.1)		
50 and above				
Sex	152 (89.9)	17 (10.6)	0.532	6
Male	143 (92.3)	12 (7.7)		
Female				
Marital status	114 (89.8)	13 (10.2)	0.798	0.9
Single	162 (91.5)	15 (8.5)		
Married	3 (100)	0 (0.00)		
Divorced	16 (94.1)	1 (5.9)		
Widowed				
Religion	70 (94.6)	4 (5.4)	9.468	0.09
Anglican	11 83 (86.7)	11 (13.3)		
Catholic	0 24 (100)	0 (0.00)		
Seventh-day Adventist	41 (83.7)	8 (16.3)		
Pentecostal	8 87 (93.5)	6 (6.5)		
Muslim				
Level of Education	12 (100)	0 (0.00)	2.252	0.7
informal education	25 (89.3)	3 (10.7)		
Primary	54 (93.1)	4(6.9)		
O-level	80 (91.9)	7(8.1)		
A-level	124 (89.2)	15 (10.8)		
Tertiary				

Categories	Comprehension		Chi-Square	P-value
	YES n (%)	NO n (%)		
Occupation	84 (92.3)	7 (7.7)	0.883	0.8
Unemployed	16 (94.1)	1 (5.9)		
Subsistence farmer	108 (89.3)	13(10.7)		
Self-employment	87 (91.6)	8 (8.4)		
Formal employment				

Socio-demographic characteristics of dental practitioners

The mean age of the dental practitioners was 32 ± 5.86 years with about half (48%) aged 30 to 39 years (Table 3). Males constituted 66.7% (n = 50). About 61.3% of the dental practitioners were married. Half (50.7%) of the practitioners were public health dental officers (PHDO). Most (69.3%) of the practitioners had practiced for 1–10 years and majority (33.3%) were Catholics (Table 3).

Table 3
The frequency distribution of dental practitioners according to socio-demographic characteristics (n = 75)

Variables	Frequency (n)	Percentage (%)
AGE IN YEARS	26	34.7
1–29	36	48.0
30–39	13	17.3
40–49		
GENDER		
Male	50	66.7
Female	24	32.0
No response	1	1.3
MARITAL STATUS		
Single	29	38.7
Married	46	61.3
QUALIFICATION		
Public Health Dental Officer	38	50.7
Bachelor of Dental Surgery	36	48.0
Master of Dentistry	1	1.3
Years of dental practice		
0–10	52	69.3
11–20	22	29.4
21–30	1	1.3
RELIGION		
Catholic	25	33.3
Anglican	22	29.3
Seventh-Day Adventist	3	4.0
Pentecostal	22	29.3
Muslim	3	4.0

Informed consent process of dental practitioners

Most (94.7%) of the dental practitioners followed good informed consent process (informing the patient of the available treatment options before initiating treatment, documenting findings and treatment to be followed, and obtaining patients' signature). About (98.7%) provided information before initiating treatment and (85.3%) obtained consent (Table 4).

Dental practitioners who obtained written informed consent were 4 (5.3%) while 57 (80.3%) and 14 (19.7%) obtained verbal informed consent and both, respectively.

For illiterate patients, 68 (90.6%) of the practitioners obtained verbal informed consent while 64 (85.3%) would willingly give the form to their patients and 51 (68.0%) practitioners sought informed consent from parents before treating their children (Table 4).

Table 4
The frequency distribution of dental practitioners according to informed consent process (n = 75)

Patient characteristics	Dental practitioners' practice	
	YES n (%)	NO n (%)
Clinical practices followed by dental practitioners	71 (94.7)	4 (5.3)
Information is given before initiation of treatment	74 (98.7)	1 (1.3)
Do you take consent from patients before starting any procedures?	64 (85.3)	11 (14.7)
I do administer written informed consent	4 (5.3)	71 (94.7)
I do verbal consent	57 (80.3)	14 (19.7)
I do both verbal and written consent	14 (19.7)	57 (80.3)
Type of consent obtained from Illiterate patients		
Verbal consent	68 (90.6)	7 (9.4)
Patient's thumbprint	30 (40)	45 (60)
Signature next of kin	18 (24)	57 (76)
Verbal consent and thumbprint	34 (45.3)	41 (54.7)
If a patient asks to take a copy of the consent form, did you provide a copy?		
Provide the form willingly	64 (85.3)	11 (14.7)
Ask for a reason before giving a form	16 (21.3)	59 (78.7)
Refuse to give the form	70 (93.3)	5 (6.7)
Do you obtain parents' informed consent when treating their children?		
Yes	51 (68.0)	24 (32.0)
Always	21 (28.0)	54 (72.0)
No	2 (2.7)	73 (97.3)
In definite cases only	1 (1.3)	74 (98.7)

Discussion

In the present study, the overall level of patients' comprehension of the informed consent process was 91.1% which is comparable to 96% reported in an earlier study (11).This high value could be due to patient's awareness of the "right to know" conditions before treatment and ability to search about their ailment on the internet, improved communication techniques, provision of adequate time to the patients

by the dentists to explain treatments options and quality of the information provided to patients by the dentists.

In the present study, there was no factor found to be significantly associated with the patients' comprehension of the informed consent process, which in contrast with findings in other studies (12), (13), particularly, where patients' religious beliefs affected liberty and decision whether to accept or decline a recommended medical intervention. Additionally, having no influencing factor means participating patients had no bias concerning treatment at the time of data collection.

Although it was not statistically significant, female patients had a higher level of comprehension compared to male counterparts (Table 2). This could be contributed to the fact that females have a higher prevalence of health seeking behavior (14). Similarly, patients who had tertiary education had higher level of comprehension compared to their counterparts with a lower education (Table 2). This is because education may help the recipient understand the language used and information delivered by the dental care provider (15). It is imperative that how the information is explained to the patients should also vary depending on one's level of education to enhance their understanding.

Generally, 94.7% of the dental practitioners followed good clinical practices in obtaining informed consent comparable to 97.4% reported in an Indian study (16). About 80.3% of the dental practitioners got verbal consent from the patients (Table 2), which corroborates findings in a study (17) in Pakistan, but almost double the value (46.3%) reported in Bulgaria (5). These studies showed that most of the dental practitioners are not taking written consent which is very bad practice and may bring litigating issues. Therefore, more efforts need to be done to create awareness on this oversight among practitioners both in Uganda and the world over.

Implications of the findings

The present study showed that most of the dental practitioners do not obtain written consent from patients, which can lead to possible medical litigation in case a patient is harmed while undergoing a procedure. Therefore, apart from verbal explanations from dental practitioners, there is a need to promote documentation of the consent process, availing patients with written information about a procedure can help them to read and internalize the information over and over again and also give them time to reflect, consult and make proper decisions that are well informed.

Limitation

Considering that the study was conducted at a time when the country was in lockdown, due to the COVID 19 pandemic, it was not possible to observe the dentist-patient interaction during the consenting process, which may be prone to recall bias.

Further Research

This was a quantitative study, which calls for a need to use qualitative methods to explore more about the dental practitioners' experiences and perspectives of obtaining informed consent as well as patients' experiences during the informed consent process.

Conclusion/Recommendation

Overall, the level of patients' comprehension of the informed consent process was very good. The dental practitioners should put more effort into ensuring that this is maintained and the other few areas pointed out should be improved to ensure that all patients adequately understand the relevant information on the procedures that they are going to undergo.

Dental practitioners had good clinical practices in providing information before initiation of treatment, and got consent from patients before starting any procedures. However, most of the dental practitioners got verbal consent from their patients, which practice needs to be improved since written consent is a more recognized form of consent than the verbal one.

Declarations

Ethics approval and consent to participate

Ethics review approval was obtained from Mulago Hospital Research and Ethics Committee (Ref: MHREC 2099) plus Cardiff School of Sport and Health Sciences Ethics committee (Ref: PGT-4393). Administrative clearance was obtained from Mulago Hospital Out-patient Dental Department. The study enrolled male and female participants aged 18 and above who provided written informed consent before participating in the study. Participation was voluntary; the respondents' confidentiality was maintained through the use of special codes on the questionnaires. The study was conducted in line with the approved protocol and as per the local and international research guidelines and regulations.

Consent for publication

Not applicable

Availability of data and materials

Data sources are available on request. The request can be sent to the corresponding author at nndvd45@gmail.com

Competing interests

No competing interest.

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Author's contributions

EM and IO did the overall supervision of the study. DN and EM conceptualized the idea, designed this study, and developed data collection tools. DN analyzed the data. DN, EM, IO, and CMR drafted and approved the manuscript.

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