Scholars Journal of Applied Medical Sciences (SJAMS) **ISSN 2320-6691 (Online)**
Sch. J. App. Med. Sci., 2014; 2(6H):3386-3388 **ISSN 2347-954X (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublishers.com **DOI:** 10.36347/sjams.2014.v02i06.107

Research Article

Defect of Consent to Care in Patients from Health Centers of Bamako

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Abstract: Informed consent of patient to healthcare is both a legal and ethical requirement. Any defect or vice of consent is an infringement to patient rights. We carried out a cross-sectional survey to find out the scope and the types of consent defects in Bamako. From February 2010 to September 2010, 360 adult patients were submitted a questionnaire. There was a defect of consent in 57.8% (n=208). The different types of defect of consent were: fraud (57.8%), violence (16.9%), and error (14.4%).The majority of the patients were housewives, 37.8% (n=136), followed by students, 20.7% (n=76). 29.2% of the patients were illiterate (n=105), 37.8% (n=136) had a primary level, 8.1% had a secondary level (n=29).
Keywords: Defect, Consent, Health care.

INTRODUCTION

The voluntary consent of the human subject is absolutely essential [l].The principle of consent is fundamental in medical law. Medical informed consent is ethically, morally, and legally mandated by the fiduciary responsibilities flowing from the patient-physician relationship. Negligence per se occurs when an actor's violation of a statute or regulation causes the kind of harm the statute was intending to prevent [2]. Informed consent has been defined as "the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned and unpressured decision as to whether or not to agree to a proposed therapy or procedure" [3] .There are four imperatives of the informed consent process, namely: (a) the nature of, risks associated with, and alternatives to treatment must be disclosed; (b) the consent giver considers that they understand this information; (c) consent must be given freely by the consent giver; and (d) the consent giver must be competent to give consent [4].

The European declaration on the rights of patients [5] states: "Patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment". According to the article 119 of the French civil code [6], "there is no valid consent if it has been given only by error (mistake) or if it was extorted by violence or surprised by fraud (dolus)".

The error, fraud and violence are the defects of consent and assume that the consent was not free and enlightened.

Prior to medical care, the informed consent of the patient must be obtained; in particular, any element which could cause the patient not to contract must not be hidden. In practice, many health professionals simply hand over to their patients a consent form they have to sign.

The objective of our study was to identify the defects of consent in patients treated in Bamako.

MATERIALS AND METHODS

We conducted a prospective cross-sectional study from February 2010 to September, 2010 in the 4th Commune of Bamako. Patients of at least 18 years old who already underwent medical care before our study were included in the survey.

The sample size was calculated using the formula N = P.Q. (εα/e) ²

- A prevalence rate (P) of 37% for defect of consent was assumed; Q=1-P
- The confidence or risk level = 95%; εα=1,96
- The level of precision=5%
- It was determined that a minimum sample size of 358 patients was necessary.

All the patients were administered a questionnaire after their informed consent

Data analysis were performed using the statistical package for the social sciences (SPSS) 12.0. Confidentiality of data was assured.

RESULTS

The study included 360 patients. The patients of the age range 28-37 years accounted for 48.3% followed by the age range 18-27 and 38-47 which accounted respectively for 27.7% and 18.3% (Table 1). Females accounted for 71.7% and males 28.3%. The majority of the patients were housewives, 37.8% (n=136), followed by students, 20.7% (n=76).

29.2% of the patients were illiterate (n=105), 37.8% (n=136) had a primary level, 8.1% had a secondary level (n=29). 72.8% of the patients did not know the diagnosis of their disease There was a defect of consent (Table 2) in 57.8% (n=208)

About the types of defect of consent: 57.8% of the patients were victim of fraud (dolus), 16.9% were victim of violence, and 14.4% were victim of error (Table 3). Only 39.4% of our patients claimed to have understood the information given by the doctor.

Table 1: Age of patients

Age range (year)	N	%
18-27	96	27.7
28-37	174	48.3
38-47	66	18.3
48-57	20	5.6
58-67	4	1.1
Total	360	100.0

Table 2: Consent of patients

Consent	N	%
Informed consent	152	42.2
Defect of consent	208	57.8
Total	360	100.0%

Table 3: Type of defect of consent

Defect of consent	N	%
Fraud	143	68.7
Error	35	16.9
Violence	30	14.4
Total	208	100.0

DISCUSSION

Of the 360 patients, 71.7% were females and 28.3% were males. 57.8 % (n= 208) had a defect of consent. Fraud or dolus which is the evil intent of making a person do something by deceit was the more frequent defect, it accounted for 68.7 % (n= 143), followed by error, 16.9 % (n= 35); violence accounted for 14.4% (n= 30).

Only 39.4% of our patients claimed to have understood the information given by the doctor; for the vast majority (60.6 %) the information given by their doctor was confused. Williams *et al*. in New Zealand [7] found that only 21% of the patients were satisfied with the information they received. By contrast, Bulois [8] in France and Song [9] in South Korea found respectively 95% and 91.2 % of their patients who understood the information they received.

The informed consent of a patient depends on the quality and the sincerity of information delivered by the doctor. Many doctors are unaware of the role of good information in the quality of care, as well as the legal consequences of wrong information.

Informed consent is defined as a physician's legal requirement to disclose information to his or her patient and enables the patient to understand, evaluate, and authorize a specific surgical or medical intervention [10]. The mere fact that an offer has been accepted is not enough to establish that valid mutual consent has been reached. Consent must also have been free and enlightened, in a nutshell; it must not have been vitiated [11].

The basic difference between consent and informed consent is the patients' knowledge behind the consent decision. Informed consent requires the patient to understand the diagnosis and uncertainties about it as well as the different treatment options (including doing nothing) including their advantages, disadvantages and achievable outcomes [12].

For consent to be informed patients rely on the information provided by their doctor. Honesty and truthfulness are required to make the process of consent valid [13].

In our study, 57.8 % of patients claimed to have been victim of fraud which consists in a deception from the doctor .The deception consist among others to

conceal the consequences of medical care and to show only its beneficial effects.

The patients who were victim of error or mistake accounted for 14.4 %. Very often, error occurs when the patient misunderstand the information, so his decision is biased.

Steve *et al*. in their study on the quality of informed consent in cancer clinical trials, found that many patients did not recognize, the potential for incremental risk from participation (63%) [14].

There is a mistake when a party was not aware of all material information when concluding the contract. A party has made a mistake if, had he known something at the time of the contract, he would not have concluded it or at least on very different terms [11].

There is violence, when consent was manifested coercively under threats or physical violence; it accounted for 16.9 %. Some physicians threat patients by emphasizing wrongly the consequences of his refusal to undergo medical care. By so doing, the patient has "no exit gate"; otherwise, he is coerced to submit totally to the doctor's will. The literacy level may play a role in the process of consent; since in our study, the majority of the patients whose consent was vitiated, had a primary level of education, 37.8% (n=136), 29.2% were illiterate (n=105). It is found that the factors associated with decreased comprehension of informed consent include limited education [15].

CONCLUSION

Defect of consent represents an infringement of patient rights; since it violates his autonomy. It can involve the doctor civil and criminal liability. The medical staff should avoid it by giving to the patients, accurate and truthful information.

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