The use of the free and informed consent term in medical practice

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Abstract This article analyzes application of free and informed consent term (TCLE) in physicians' practice working at the University Hospital (HU) of the Federal University of Sergipe, located in the city of Aracaju. The survey that gave origin to this work verified the attribution of importance to the application TCLE in medical practice. Five physicians from the HU were interviewed, as well as 72 medical records of interned patients were analyzed, in accordance to Brazilian bioethics, legislation, and doctrine. It concluded that, despite seen as important, TCLE is used only in two services at that unit, despite advances on civil medical accountability in Brazil.

Key words: Consent forms. Informed consent. Bioethics. Damage liability.

Bioethics is field of study and research that intends to establish the balance between scientific progress and human values [1]. To achieve this goal, according to the principalist theory, four basic principles must be applied in professional practice: beneficence, non-maleficence, autonomy, and justice [2].

The term 'free and informed consent (TCLE)' is a document that aims to protect the autonomy of patients, in which they attest being aware of their conditions as research subjects or of being submitted to medical procedures considered invasive. As a formal requirement, it is widely used in research involving human beings, but not yet in medical practice.

Considering the definitions above, this article analyses the application of medical informed consent in the medical practice at the University Hospital (HU) of the Federal University of Sergipe (UFS), located in the city of Aracaju. It must be highlighted that

the HU is school-hospital, reason why it was chosen. It was intended to find out if the Code of Medical Ethics was being complied with at the place of future professionals' formation. Furthermore, it sought to identify if there is any concern in regard to the bioethics principles surrounding free and informed consent.

A worldwide phenomenon at its peak was observed: the increase of lawsuits against physicians. In the United States (US), for instance, one fourth of physicians faced lawsuits for medical malpractice in 1970 [3]. It is no different here in Brazil: data from Federal Council of Medicine (CFM) suggest that the number of suits against doctors jumped from 77 to 380 in five years [4]. This reality has concerned doctors enormously, for they fear being prosecuted even when they have conduct medical procedures correctly, however without the expected result: cure.

In this context, the free and informed consent emerges as a priceless document for physician's protection against legal action. The patient agrees to undergo a certain procedure - even if it means unwanted effects, but foreseen and previously explained by the physician - and provides a written declaration of the professional's goodwill, taking on joint responsibility for treatment choice. In relation to doctors, it is necessary to note that they are not exempt from errors, but actually sharing the responsibility of treatment and eventual results. The document has relative validity. It is presumably valid, but it can be rebutted in court. This fact alone does not remove its importance, given that there is presumption of validity. The only way to invalidate it would be to prove that it was obtained illegitimately, in spite of being signed. It protects equally doctors and patients. The latter, a laypersons, sometimes are not duly informed on the treatment, especially with regards to the possibilities of failure - even if perfectly executed. It is known that medicine cannot be legally regarded as obligation of result, but as a means; however, hiding this variable from the patient is nonetheless an error. Thus, it is noted that the TCLE has fundamental importance in medical practice both for doctors - protecting them against possible lawsuits from patients in bad-faith - and for patients - protecting them from doctors who do not provide essential information.

The research aimed at studying the use of free and informed consent in medical procedures and the perception of the doctor on its importance to the patient-physician relation, as well as its application if day-to-day medicine. For this, it was important to identify in which circumstances free and informed consent was being solicited from the patient, as well as investigating if there was informed consent terms attached to bedside assessments. In positive cases, it was checked if the term contained all the necessary information and followed accepted standards.

Bioethics

The term *bioethics* was coined in 1971, in an oncology article by Van Ressenlaer Potter, from the Wisconsin University, thinking up a balance between science and human values [1]. With this aspect at hand, bioethics focuses on establishing a consensus between the various principles and beliefs. According to its principalist line of thought, the process of analysis must observe four basic principles: beneficence, non-maleficence, autonomy, and justice.

Autonomy is the respect for people and their opinions and choices according to their values and beliefs. Beneficence is the obligation of always promoting welfare,

maximizing benefits. Non-maleficence is the principle of not harming others. Justice is the distribution of risks and benefits [2].

These principles do not work as a precise manual - which informs how to act in each circumstance. They are rather general norms or references to be adopted [1]. The fact that there is no vertical relation between them calls for equilibrium; consensus - to avoid the prioritization of only one principle in detriment of others [5].

To protect patient autonomy, the same must consent to the treatment. Kfouri Neto [6] states: *consent is the behavior by which a determined action is authorized.* Therefore, for the doctor to prove that he correctly informed the patient, the informed consent was created. The idea, which came up in 1947 under the American name `informed consent`, in the founding of the principle of respect for people and their values [7]. The term free consent is a document *in which the patient or their legal representative is informed on the disease and reversibility chances, treatment alternatives, expected side effects, and prognostics*. This document is read and signed by the patient at the moment of diagnosis covenanting the conduct to be implemented [8].

Thus it is important to stress that informed consent must not be the standard document, in which the doctor only replaces the name of the patient. It must be individual, pursuant to each case, and bring details on patient conditions and the effective need to execute treatment according to their clinical conditions. Motta [8] highlights that term must also be signed when there is necessity for *consent by the patient for execution of invasive procedures* or in case of alteration of the agreed treatment. Besides, it is necessary that the term be detailed and provided with clear, true, intuitive information for the patient's understanding, leaving the doctor responsible to present the relation between benefits and risks and indicate the level of efficiency. Moreover, physicians must provide the percentage of treatment success and its total cost [9].

The specificity and integrality required from the doctor in relation to the informed consent are really necessary in virtue of the patient's choice for a procedure, on which their lives are dependent on and of which death could outcome [9]. It is important stress that consent must be free, voluntary, conscientious, not allowing for vice and error. Furthermore, it cannot be obtained by means of physical, psychological, or moral coercion or deceitful practices, or any other forms of manipulation that impedes free manifestation of personal will [10].

An implicit hindrance to informed consent application is psychological coercion that doctors involuntarily exert upon their patient, in light of the higher level of knowledge. Besides, patients may feel embarrassed to read the document and sign it all the same. The signing of the document represents a historical change in patient posture, for as Kfouri Neto notes: *the obtainment of consent represents the result of the 'dialogic process and information exchange' between doctor and patient - with a view to initiating treatment* [6].

Another question to be contemplated is the utilization of the term in any invasive medical treatment. Opinion 22/04 from the Federal Medicine Council (CFM) considers it necessary for research and mutilations indispensable to the maintenance of life or restoration of patient health, but the information forwarded to patients relative to the execution of medical procedures need not be written. Despite this decision, Dr. V.A.

C.J., justice attorney of Goias state notes that the great indoctrinators of civil liability *defend that if doctors do not provide information in writing, obtaining consent by collecting the patient's signature, then he will be obliged to pay compensation, should doubts come up if clarification was provided or even if it was done so in adequate fashion* [11].

Informed consent, despite being comprehensively used in research with humans beings, representing a current prerequisite to the conduction of this type research, still present some problems. One of them is making sure patients conscientiously sign the term and understand the real proposition and/or conditions of the treatment in question. What is being questioned is the possibility of its use in invasive medical procedures. One example of this necessity would be colonoscopy, which according to Calache Neto [12], is *an endoscopic exam that permits visualizing the whole interior part of the colon*. The procedure, demonstrates clearly that in virtue of its invasive nature it needs to be done, most times, with sedation because it requires special care. Another issue pursuant to the informed consent use is how patient and doctors perceive it. Doctors see it as a document which frees them completely of charge in case of complications and/or a documental proof that they have complied with the duty of informing [13]. Correspondingly, patients can sometimes feel suspicious over the safety of medical procedures, for the exposition of treatment failure risks lead laypeople to think it is a way of escaping responsibility. In the years to come, there could be considerable increase of suits against doctors which have not required the signing of informed consent terms. Our legislation offers mechanisms that impute responsibility of damage reparation in virtue of lack of adequate information on service. The main one is put forward in civil code article 15, which states: *no one shall be forced to undergo, with risk of life, medical treatment or surgery intervention;* additionally, article 927 determines the civil liability to he who injure another person by means of illicit act [13]. Thence, since Brazilian legislation protects patients from physicians' misinformation and eventual constraint, it is probable that the number of suits filed against doctor increase unless they prepare themselves.

Precepts to informed consent admittance

A legal act is any which interests the realm of Law. Its existence depends on a declaration of will. The contract of service provision of clearly a legal act, the declaration of which can be merely verbal or written, formalized by means of a free and informed consent term. In order to be valid, the term must fulfill the criteria covenant to article 104 of the Civil Code of 2002: I - that the agent be capable; II - licit, possible, determined or determinable object; III - prescribed form or not defense in law [13]. Beside these generic precepts, which must be obeyed in all legal acts, there are the specific ones.

In relation to the capacity of the agent, it is important to highlight that it is necessary *condition for a person to be able to fulfill individually the acts of civil life* [14]. The incapacity requires that the person be represented or assisted by another party, so as to validate the acts. Therefore, the informed consent term of a patient at 14 years of age shall be signed by their legal representative, provided that a youngster is not capable of producing a complex legal act.

Beside the merely age-wise criterion, the single nature of the medical treatment requires adoption of supplementary measures. The capacity to consent to a certain health treatment relates to the possibility of the patient freely and rationally discern the values (cost-benefit ration of the treatment), the fact, alternatives (consequences and risks) and thence opt or not for its carrying out [15].

It is also necessary for the object to be licit, possible, and determined when possible of being so. On that account, the term cannot must verse in correspondence to the law, moral, and good customs [14]; or establish something absolutely unfeasible, either by physical or legal hindrance. Furthermore, there is the need for this object to be determined or determinable, given that a informed consent term cannot be valid should its object be undeterminable. The will of the patient must be free, as a result of autonomy. The informed consent term must be exempt from defects resultant from the will expression, as listed in article 138 and following articles of the Civil Code of 2002: error, deceit, coercion. Error is considered as false notion of reality. Authorizing the conduction of a given treatment, believing the disease is lethal, when the person does not even have this disease is a clear example. On the hand, deceit is *the artifice or elaborate means employed to induce someone to practice an act that harms them, and benefits the author and a third party* [15]. Coercion, in particular, is considered to be *all threats or unjust pressure over an individual to force them against their will to practice an act or do business* [15]. The presence of such defects has the ability of making legal acts invalid. Pursuant to form, article 107 of the Civil Code of 2002 sets forth that a declaration of will is done so deliberately, except in the case of legal provision in contrary [13]. If not prescribed by law, consent can be obtained in any fashion, including orally. However, the weakness of this type of declaration must be stressed, considering that the doctor usually does not have the means to prove if he provided due information and that the patient consented. Thus, it is recommended that consent be obtained in documental fashion: the term.

Regarding information

It is the doctor's duty to explain the patient the details of their physical conditions and treatment options, along with risks etc and request signature of the term. This task must not be assigned to nursing staff, neither to the clerk responsible for scheduling exams. It is a doctor competence, non-transferable, especially in cases when the other professional does not possess the necessary technical knowledge [15]. Due provision of information on the health status and treatment conditions are patient's rights and physician's duties. Such prerogative is consolidated in article 6, clause III of the Consumer Protection Code, which provides that information must be adequate and clear, containing adjacent risks. There are cases where this duty of informing is mitigated, as suggested by Roberto [15], in light of particular needs, as described next.

Emergency treatment

When the patient finds themselves in extreme conditions, which calls for urgent medical intervention, the doctor does not need to obtain their consent. In such situations, it is supported by the 1940 Penal Code, the article 146, paragraph 3, clause I of which puts forward that there is no crime of illicit constraint *the medical intervention or surgery, without consent from patient or their legal representative, if justified by eminent risk of*

life. Exceptionally, the lack of due time to obtain consent frees the doctor from complying with this establishment.

Therapeutic privilege

It occurs when the physician believes that information will be harmful to the health of patient and thenceforth, decides not to inform them. This exception is guaranteed to doctors by the Code of Medical Ethics - who article 34 permit's the non-provision of information *when direct communication* [with the patient] *could harm them, in this case, communication must be done with their legal representative* [16] -, but it must be previously discussed with other physicians and documented, in order to make it legitimate. If not, the therapeutic privilege becomes but a way for the doctor to not obtain consent without justification.

Mandatory treatment

If the patient is infected by illness threatening life, health, and welfare of society, then the treatment does not require patient consent - in virtue of the 2002 Civil Code prioritize collectivity over individual will. Thus, in the case of a patient not wanting to undergo treatment for an infirmity that poses threat to the collectiveness of society, the latter is held above liberty and self-determination.

Patient's right to refuse treatment

Also called disagreement, the right to refuse is expression of the autonomy principle [17]. This way, the fact that a patient denies themselves treatment, even after being completely informed of their physical condition and all the necessary details, calls for this decision to be respected, given that there is no risk of life. The cited refusal, however, must be completely documented and justified, preferably in writing, so as to protect the doctor that even after informing the patient was not granted the opportunity to carry out adequate treatment in virtue of this refusal. Besides informing correctly the patient, it is the duty of the professional to verify if they understood and absorbed the transmitted information. Should this information be confusing, then it must be explained again, preferably in another fashion, avoiding consent invalidation for lack of information. The *presumption of understanding is not sufficient, comprehension is of utmost importance* [18]. The latter is thence unequivocal. In certain situations, however, when patients enter the hospital they renounce their right to consent, granting a generic informed consent term to the health professional, demonstrating total and unlimited trust in relation to the doctor - the so called blank consent, considered valid by some authors is rebutted by others. Once again, one of the prerequisites to validate a legal act is object is determinability [1,7]. Based on this premise, authors question how valid could a term be, one which grants almost unlimited powers to a physician only counting on trust, given that its object in undeterminable in face of the array of possible procedures. Moreover, blank consent does not achieve the purpose of proving that the patient was duly informed by the doctor regarding their conditions and effectively agrees on the treatment to be conducted, despite there being risks [17]. It is stressed that the 'defect' in information provision can occur not only in virtue of its absence, but also when written in hermetic language, full of medical jargons, and with a consent term in technical terms, which would all undermine understanding by patient. Scholars mention that the exaggeration of information is harmful to understanding, since data profusion would

hinder the interpretation by the layperson (patient) of the content explained. It is recommendable that physicians avoid propagating unnecessary information that aggregate nothing to the decision [17].

Informed consent effects

Signature of informed consent term does not imply in non-liability to health professionals in relation to harm incurred by malpractice, but instead, in relation to expected and informed damage, since it is not a *lato sensu* result of doctor malpractice. A doctor, which out of negligence injures a patient has the duty of repairing it - even if they have informed and were granted consent by the patient. The teachings of Seguin are very clarifying: *patient clarification or informed consent term on risks of failure does not minimize the responsibility for unsatisfactory result. Informed consent is not a free pass for a doctor. If a doctor has acted imprudently or negligently, in spite of there being an informed consent term, there will be damage liability* [19].

Methodology

This work used the exploratory descriptive method, with qualitative approach. The research was carried out in the city of Aracaju and the population was composed by doctors that worked in the University Hospital (HU), due to the fact that it is a school-school and therefore it should be more attentive to the ethical dimension of its function, which is to form health professionals, serving as reference to them.

Sampling was accidental, chosen for convenience, the criterion for inclusion contemplated surgeons and/or professionals that conducted invasive exams. In the case of bedside assessments, the analysis contemplated patients undergoing treatment in the hospital in the period of data collection – September 2007 to June 2008.

The instruments employed in this research were the observation cards for patient bedside assessment and a script of interviews with nine questions, applied to doctors that accepted to participate [20]. The interviews were audio recorded, with the consent of the subjects, and only then were they transcribed wholly. Documental analysis was the technique utilized for the bedside assessments and content analysis for interviews with doctors.

Ethical aspects

This work was analyses beforehand by the ethics committee, as is required for every research involving human-beings. Special authorization was obtained from the hospital, given that bedside assessments were manipulated in order to locate the informed consent terms. According to Resolution 196 of October 10, 1996 of the National Health Council, doctors – research subjects – signed an informed consent term before participating in the interview. Moreover, they were informed on the liberty to abandon the interview at any moment should they choose to do so. They were ensured confidentiality in relation to the information and told that each subject was being represented by names of freshwater fish species in order to preserve their anonymity.

Data analysis and discussion

The results – after codifying and tabulating information – were ordered and organized so that they could be analyzed and interpreted. The chosen method was content analysis, which according to Mianyo consists of a *set of techniques of communication analysis with a view to obtaining - through systematic procedures and goals of content description of the messages - indicators (quantitative or not) that allow for the inference of knowledge on the conditions of production/reception of these messages* [20].

The reason for this choice lies on the fact that it tries to capture that which is beyond the expressed content of the message, comprising the expression in terms of its context and circumstances. For its conduction the thematic analysis technique was selected, which is the interpretation of the core meanings that compose a sentence. Hence, the following steps were taken:

1. Pre-analysis with confrontation of documents and initial research goals, preparation of some indicators that guide the understanding of the material and final interpretation; *floating reading* to establish exhaustive contact with the material, allowing it to become impregnated with the content; and *corpus constitution*, the organization of the material in such a way that it could respond to some validity norms;
2. Material exploration with codification, transforming raw data to grasp the core understanding of the text;
3. Treatment of the results obtained and interpretation that allowed for highlighting obtained information.

Results and discussion

Five doctors were interviewed. They all perform invasive procedures at the University Hospital (HU) of the Sergipe Federal University (UFS). This small number of participants was due to the natural resistance to speaking about ethical-related issues and due to the time restraint physicians face in their profession. Beside the interviews, an analysis of 72 patient bedside assessments that underwent invasive procedures was conducted.

Interview analysis

The interview sought to find out how the issue surrounding informed consent was deal with by doctors. The content analysis culminated in the establishment of two categories. It is important to stress that no doctor stated using informed consent terms routinely in their practice at the HU. An interesting piece of data shows that some doctors use the term at other hospitals, but not at the school-hospital in question: "*I only use it over at Hospital X"* [private hospital] (Catfish); *"And… I was thinking here and we use it at Hospital X routinely for endoscopic procedures"* (Peacock bass).

The interviewee denominated Peacock bass did not even recall that one of the hospitals in which he worked used this document. This essentially represents a contradiction; a true teratology. As mentioned earlier, the institution under comment is school-hospital, the doctors of which are also teachers and should thence have a larger concern for execution procedures, especially regarding the ethical dimension, for they are developing future professionals. Moreover, this concern should be larger at public institutions, focusing on the avoidance of legal problems against the State.

The point of view of the interviewees regarding the informed consent term

In spite of there not being consensus, according to the viewpoint of doctors, the informed consent term is important. They note its importance to serve professional defense, as well as to forge a declaration that information are within the rights of patients and, thus, must be supplied:

> "*I think it is important, especially in legal terms and from a professional defense standpoint"* (Peacock bass);
>
> "*the client has the right to know the risks that are they are incurring. When the procedure offers bigger risk than I think it should be used"* (Catfish).

This stance is not unanimous, however. There are interviewees who judge patient consent unnecessary, when the procedure is not a research per say, but rather something duly established in medical science, as it is understood from reading of extracts of the interviews:

> *"That which we use in medical practice is very much instituted. There are plenty of scientific studies showing this and there is real need to ask the patient for consent"* (Wolf fish);
>
> *"It is important when in doubt about a procedure that you are carrying out, especially if it regards research, but truly, you do not even have to use it"*. (Wolf fish).

This viewpoint demonstrates complete lack of knowledge regarding the doctor's deontological code and the rights of the patient, especially concerning the choice given to patients to undergo or not certain procedures, considering the risks presented to them. The discourse show, moreover, that information omission effectively takes place not only because it is deemed unnecessary but also because the procedure is scientifically tested, and thus, not using the term becomes more practical:

> *"She will think twice and maybe will not even undergo the exam if I explain all the risks that she will be facing"* (Goldfish);
>
> *"It is not like we hide anything from the patient, but sometimes we omit some things"* (Peacock bass).

It is observed that there is a flagrant contradiction between what is said and practiced. Despite most of the interviewees having positioned favorably to consent term use, there is still "talk" of not being needed to transmit all information to the patient. Seguin (2005), dealing with this topic, asserted that *misinformation to the patient hides the fear of the doctor to be exposed professionally, for he says nothing then he has nothing to fear* [21]. Based on the Ethical Code, it is known that for the consent to be valid information transmitted must be *true*, clear, and *sufficient* [17]. However, for some doctors in this research, the informed consent needs not detail information. Ideally, for them, it would be to try to make patients unaware of the risks they incur, even though they note

it on the term: *"If you have ways to implicitly get this patient consent to what you are doing, without actually needing to explicit too much on this document…"* (Tilapia).

Problems in implementing the informed consent term as a routine

Time

According to some of the interviewees, the necessity performing a series of procedures every day is a problem, principally at public hospitals. The sheer volume of work makes time scarce and a predominant factor in the utilization of the consent term as a routine:

"*More time would be needed for the conduction of exams*" (Goldfish); "*We perform a lot of routine procedures and so we end up forgetting to do the informed consent, do we not?*" (Peacock bass); "So the folks at the receptions desk, otherwise there would not be time". (Catfish).

As one can tell from the extracts, consultations with doctors would become all the longer if all information were transmitted to the patient and signature required from the same by the doctor. It should be noted that this justification does not exclude the necessity of the referred request, representing the commercialization and personification of medical practice, as thought by Seguin: *the speed with which consultations can be executed makes service inhumane and professional behavior robotized* [22]. What must be done is a true restoration of the health sector, so as to allow for efficient and modern management that generate good working conditions for professionals to perform adequately.

However, a logical incoherence between two points in the interview must be noted. Despite Catfish and Peacock bass having listed the time factor as impediment to the application of informed consent term, the same affirmed above that they use it in private practice. So the inconsistency is patent: there is not time to practice such act in public teaching service, but it is usually applied in private practice. A hypothesis for this incongruence is that in private establishments informed consent is obtained from the nursing staff or reception clerks, in a generic way, with an end to creating defense mechanisms in possible legal contests.

Fear

There is a recurring belief that the patient when duly informed about their health conditions, treatment options and risks involved, would be afraid to undergo the procedure, even the risk was minimum. Therefore, the conduct practiced aims at avoiding the non-execution of the procedure, by omitting the risks involved:

"*They [patients] will think twice and maybe will not even undergo the exam if I explain all the risks that they will be facing"* (Goldfish); *the patient is always scared when they sign they sign the informed consent term, are they not? And… I was thinking here and we use it at Hospital X routinely for endoscopic procedures and the patients sometimes get scared when they read about the possibilities of risk, even if minimum, and sometimes they back up"* (Peacock bass).

Roberto adds that informed consent implies more than just the right of a patient to chose a doctor or refuse an unwanted treatment, and that it should not represent a mere device to free doctors from consequences of negligent consequences not should it be used with

the single purpose of convincing a patient to agree on the proposed intervention [15]. Patient autonomy must be respected when they do not feel safe to undergo a certain procedure in light of the presentation of the risks involved. A different approach seriously assails article 15 of the Civil Code, which leaves the decision on the procedure at the hands of the patient – subject of medical intervention.

Legal value

In conformity with the Civil Code interpretation, free and legal business when there is no legal predisposition in contrary. In the case of the term, there is no norm in our legal system that imposes a written form of consent in cases of invasive medical procedures. Thus, there is a misconception that this document is produced in practice, such conduct would have no validity whatsoever in court. This is clearly observed in the physicians' responses transcribed below: "*it is said that it would not influence when time called for defense"* (Tilapia); "*in the end I am not going to have a document, an instrument that protects the doctor"* (Tilapia); "*Because we know that, legally, it does not have that much value"* (Peacock bass).

In 1996, bill of law (PL 620/1) was submitted for appreciation by the Federal Chamber of Deputies – federal Deputy Euler Ribeiro sponsored the bill – which intended to make informed consent term mandatory for every dental operation. The term would have to be forwarded, after performance of the operation, to the Regional Medicine Council. The parliamentarian justified being necessary to regulate this document as a form of respect for ethics, so as to not leave patients at the doctor's or dentist's mercy. The project was filed and did not even get to be debated in the Senate. The Regional Medicine Council – through Opinion 10/96 – manifested favorably to the bill, but did not make mandatory that the term be in writing. Justification came from reporter Julio Cezar Meirelles Gomes who declared: *the introduction of this document in the patient-doctor relation, far from improving this act's quality, could corner doctors and reduce their chances of defense upon guilty error; or worse free them of charge in face of adversities from non-registered medical act* [23].

It is true that informed consent term presentation, by itself, is not enough to exempt doctors from reparation for lack of due information provision. However, to say that the same does not have value is erroneous. Even though it can be annulled in virtue of the existence of various vices – previously commented – its veracity is presumed. Such presumption can be proved inexistent with the presentation of proof that information was not effectively supplied. Thus, only in cases that there is evidence of non-compliance by the doctor the term will be invalidated. In spite of all that was said, it is worth mentioning that even though some consider it document with low value, it is in fact priceless to convincing the judge, reason which does support the arguments of those who deem is not necessary.

Extra difficulty to medical practice

Another factor that plays a role in the weakness of the habit of demanding term signature is that it would represent still another difficulty to practice, and would not bring any benefits, say doctors: "*I am also afraid of us increasing the level of difficulty of practicing, especially due to the cultural level of our patients"* (Tilapia); "*I would end up raising patient stress level and not having a document, an instrument to protect*

the physician" (Tilapia); "*This could harm medical practice in some way"* (Wolf fish); "*You could even worsen you patient-physician relation"* (Wolf fish). This discourse on the uselessness of consent reveals that the interviewees do not regard patients' autonomy as their effective right, leaving physicians with the decision on treatment in light of their technical expertise. Under this aspect, the commentaries of Vieira are of extreme value: *the infirm who trusts their health in the hands of a physician does not grant them a free pass, does not abdicate liberty; does not lose full age for the physician to, according to his professional morale, become owner and sovereign of*[24]. Difficulties that would make unviable the routine application of consent term were considered by the interviewees: "*I do not know if it would be feasible in our daily routine"* (Peacock bass). Even though it is valid to say that *practicing defensive medicine increases service provision costs, which ends up being inevitable passed on to the consumer* [26], certain right still cannot be overlooked as they essential. It would be absurd, for instance, for a measure to reduce surgery costs in public hospitals, to call for the stoppage of sterilization of equipment.

Advantages of the informed consent use

Patient clarification

Information is the crucial point of the autonomy paradigm. *Free and informed consent is a great manifestation of patient involvement in medical decision-making, that is, the true essence of autonomy* [26]. Seen as the main fundament present in the informed consent term, information only appears once amongst the discourses of interviews, which somewhat demonstrates the disregard for this duty - as previously mentioned in this work: "*I think it is important, especially from the patient clarification viewpoint."* (Peacock bass).

This clarification is what reduces the gap between physicians and patients, derived from the disparity of information amongst the subjects of this relation, as noted by Ragazzo regarding the importance of the duty to inform: *In fact, the precarious health condition and information asymmetry are factors that collaborate to the vulnerability of the patient. It should be highlighted that vulnerability, however, does not imply in the incapability of the patient to consent, but rather it singles out and qualifies the obligation of the physician, imposing them the task of fixing the situation. It is needed, thus, to consider the vulnerable state of the patient at the moment of consent obtainment*[27].

Legal defense

The prevention of legal demands is a concern for those physicians who rally should be worrying about facilitating them in order to avoid larger moral and financial setbacks. Even though they do not demonstrate interest in relation to the fulfillment of patient autonym, they should at least be egotistically worried about their own legal defense. In spite of these considerations, concern over such aspect only appears in the discourse of one interviewee: "*I think it is important, especially in legal terms and from a professional defense standpoint, is it not?"* (Peacock bass). This concern is not abstract. It is based on a increasing number of lawsuits against physicians, which reflected the increase in the acquisition of health professional insurance – as this phenomenon was identified in the USA. According to Seguin, t*here is an ever growing number of*

'damage liability insurance' being sold to health professionals, to ensure lawyer's fees and compensation payments, even among professionals that were never sued, who fear the volume of unfounded charge [28].

Strengthening of the patient-physician relation

The physician, who was seen previously by society with notable respect, now is *service provider*, according to the Consumer Protection Code. The relation with their patients was in the past based on trust and now is guided by contractual terms. All of these transformations occurred gradually, changing the professional of the past – the family physician - into a physician 24 hours on duty responsible for attending to a great number of patients. All of these transformations cause a dispersonification of medical practice and a loss of mutual trust. Thus, interviewees see the signing of informed consent as motive that would reinforce the patient-physician relation: *"The positive side would be for patient trust in the physician"* (Peacock bass); "*most patients feel more confident when they have the term"* (Catfish).

Some authors point out the term besides serving as a document for legal defense of the physician would also reduce the incidence legal action in light of the relational improvement between subjects of medical practice: *Doctrine was able to identify, through short researches, that the motivation for legal action against physicians was the deterioration of patient-physician relation* [29].

Notion of the term defensive medicine

Defensive medicine is conceptualized as being the medical practice that, within ethical limits, seeks to avoid legal litigation promoted by patients. When questioned about it, almost generalized lack of information on this practice by physicians was noted. It is a current practice: "Based on *what I can grasp, on what I read there* [informed consent term], *it is…"* (Goldfish); *Well, I do not... It is the first time I hear this term 'defensive medicine'"* (Goldfish); *"In general very superficial, it is a medicine… it is complicated, is it not? You have to give me options… a research in which the guy is not given options…"* (Wolf fish); *"Not much"* (Catfish). These extracts show that the professionals that teach at the HU of the UFS do not know the term, thus, not utilizing the informed consent term as a routine, under various different excuses.

Bedside assessment analysis

During the visits made to carry out the interviews, information was gathered on the bedside assessment with a view to checking in which cases the term was applied at the HU and if these terms were in conformity with what most authors prescribe. This part of the project confirmed without a doubt the information extracted from the analysis of the discourse of interviewed physicians: at HU the informed consent term is not used. Despite the fact that this research studied the bedside assessments of patients undergoing surgery, biopsy, colonoscopy, endoscopy, among other procedures, not one term was found. This fact alone compensates for the low number of interviews, which leads us to believe that the lack of availability to grant interviews can be associated to the non-use of the term in hospital operations.

It is interesting to note that teacher-physicians are not obtaining consent from patients as a routine and it is probable that students are wrongfully learning not to inform their patients as a time-saving and consultation process-easing mechanism. At the same time, students might be suffering introjection of the idea that the physician is who knows best for the patient and, for this, does not need to ask for consent. However, in some cases a document was found, which at first seemed like a informed consent term – but detailed analysis revealed that such similarity did not correspond. This document does not serve the purpose of informing the patient on their health conditions, explain treatment options, and expose risks, but instead it only removes liability from the hospital in relation to physical damage suffered by patients with mental diseases. Its aim is to merely exonerate the hospital. This document deserves criticism, given that the hospital, in spite of not being able to guarantee result, takes on position of ensuring the physical safety of its patients. So, if the State cannot avoid that a patient be injured by another, then it should be held liable.

This practice is already consolidated in relation to the obtainment of consent in cases of amputation, which is also the case at the referred hospital. However, because no such cases occurred during the research period, this term was not analyzed. At research's end a new service of bariatric surgery was implemented in the HU and the term was adopted as routine.

Final considerations

No consent term was found attached to the bedside assessment of patients that undergo invasive procedures in the University Hospital of the Federal University of Sergipe. When analyzing the discourse of the interviewees, a disproportional stress on the problems of using the term was found, in detriment of the benefits that it would actually bring. Concern was centered more on obstacles themselves than on issues involving patients, such as basic information and the fortification of patient-physician relation. The benefits brought by consent term use went almost undermined, which reveals the negative opinion the interviewees have of the document.

The main argument against term use is that signature request would raise patient fears of undergoing the procedure and would demand more time during consultation, given the amount of work. Such argument does not pay attention to the fact that these problems would be outweighed by respect for patient rights and reduction of legal actions. In relation to fear, it can be said that this argumentation is rebutted by the interviewees themselves that agreed that one of the few benefits of the practice is the strengthening of the patient-physician relation.

Even though physicians reported the absence of value of the term, such affirmations are not supported in the Brazilian legal system. It is not possible to assess if change occurs in the physician-patient relation due to the request for signature of the term, for it is not used habitually at the HU. However, there is no consensus among the interviewees in relation to this: there are those who believe such practice would reinforce the relation between the subjects of medial act; others, judge that it would bring unnecessary fear to the patient.

It is recorded herein that in spite of these findings, a reflexive effect is expected to be caused by the present work: raise the issue of medical civil liability to be debated by the professionals of the area.

Resumo

O uso do termo de consentimento livre e esclarecido na prática médica

Este artigo analisa a aplicação do termo de consentimento livre e esclarecido (TCLE) na prática dos médicos que trabalham no Hospital Universitário (HU) da Universidade Federal de Sergipe, localizado na cidade de Aracaju. A pesquisa que originou o trabalho verificou a atribuição de importância à aplicação do TCLE na prática médica. Foram entrevistados cinco médicos do HU, bem como analisados 72 prontuários de pacientes internos, de acordo com a bioética, a legislação e a doutrina brasileiras. Concluiu-se que apesar de visto como importante, o TCLE só é utilizado em dois serviços naquela unidade, apesar dos avanços da responsabilidade civil médica no Brasil.

Palavras-chave: Termos de consentimento. Consentimento livre e esclarecido. Bioética. Responsabilidade civil.

Resumen

La aplicación del término de consentimiento informado en la práctica médica

El término de consentimiento informado (TCLE) es un documento mediante el cual el individuo demuestra que es consciente de sus condiciones, sea como sujeto de una pesquisa o de procedimientos médicos considerados invasores. El presente estudio verificó la atribución de importancia a la aplicación del TCLE en la práctica médica a través de entrevistas con los médicos del Hospital Universitario de la Universidad Federal de Sergipe y de análisis de los registros médicos de pacientes hospitalizados, según la bioética y la legislación y doctrina de Brasil. A pesar de ser visto como importante, el TCLE solo es utilizado en dos de los servicios de la unidad, a pesar de los avances de la responsabilidad civil médica en Brasil.

Palabras-clave: Formularios de consentimiento. Consentimiento informado. Bioética. Responsabilidad civil.

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