INFORMED CONSENT: THE MEDICAL AND LEGAL CHALLENGE OF OUR TIME

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ABSTRACT
Objective: To assess the real importance of obtaining informed consent, through an appropriate form, and its role in the outcome from civil liability claims. Methods: The wordings of the current Brazilian law and jurisprudence were compared with rulings from the State Court of the State of Rio de Janeiro, in 269 civil liability claims against healthcare professionals and hospitals. Results: Favorable and unfavorable outcomes (i.e. acquittals and convictions) were compared, and possible variations in the verdicts were discussed in relation to whether informed consent forms had been filled out or not. Conclusions: Obtaining informed consent, by means of appropriate forms, is still not a widespread practice in the Brazilian healthcare or judicial systems. It is recommended that this practice be adopted in the manner described in this paper, since this is prescribed in Brazilian law.

Keywords – Informed consent; Bioethics; Evaluation

INTRODUCTION
Back in 1767, in England, with the aim of continuing with treatment for a leg fracture, a certain Mr. Slater went to Dr. Baker, who worked together with Dr. Stapleton, to find a solution for his pathological condition. However, completely without their patient’s knowledge, at a time when anesthesia did not even exist, the two physicians deliberately refractured the limb in order to test a new and unconventional surgical technique that would cause traction throughout the consolidation process.

This action caused sequelae in the patient that were not even dealt with as inherent risks of the procedure used, in the same way that no authorization to perform the procedure had been sought. In view of these events, the patient took the matter to the courts under the allegation of medical damage caused by ignorance and ineptness. The court-appointed experts gave full backing to the patient, and the physicians were found guilty (1).

In 1894, in Germany, and more precisely in the “Reichsgericht” (state court), it was expressly ruled that a lack of authorization from the patient was an absolute impediment on carrying out any medical action, and that professionals who defied this ruling could be sent to prison.

In 1914, in New York, United States, a legal ruling that was fundamental to patients’ rights was made, with the recognition that patients could reject the treatment that had been proposed to them. This was the first case involving a patient and a hospital unit (2).

The term Informed Consent was used for the first time in a verdict in the United States, in California in 1957. Two years earlier, the Supreme Court of the State of North Carolina, United States, had defined that failure by a physician to provide information regarding the risks of a surgical procedure constituted negligent conduct (3).

CONCEPT
Today, in Brazil, informed consent is defined as: “a voluntary verbal or written decision by an autonomous and capable person that is made after a process of information provision, in which this person accepts a specific treatment or experimental procedure while aware of its risks, benefits and possible consequences” (4).

Thus, obtaining a patient’s consent to perform a given medical action translates into an agreement that can be revoked at any time, preceded by provision of
clear information that relates to a particular time and is wide-ranging and satisfactory such that the patient can understand his real state of health.

This informed consent is a right of the patient and is included among the rights of personality. It expresses the patient’s autonomy regarding his physical and psychological integrity, and is the opposite of heteronomy, in which the physician’s will prevails. Informed consent is manifested as the patient’s power to make informed decisions regarding agreement with treatment or medical diagnoses.

In situations such as severe diseases or in cases of diagnoses and treatments that might take a long time, contact between the physician and the patient, or the adult responsible for that patient, with the aim of communicating information and providing explanations about the patient’s clinical situation, should not be restricted to an interview. The information supplied also needs to be adapted to the psychological state that patients may present at that particular time.

When patients are making decisions about the lines of their treatment, it cannot be said that the decision is made on the basis of awareness and voluntary action if the patient’s will is contaminated with ignorance. In such cases, the patient lacks knowledge about the subject of the decision that he will make. The consent may be deemed invalid because of the existence of this substantial error (i.e. lack of knowledge about what is to be decided). Such consent would consist of a preformulated and incorrect declaration of wishes, without precise notions regarding the investigative, diagnostic, treatment-related and prognostic characteristics of the patient’s disease.

**CURRENT LEGISLATION IN BRAZIL**

The legal doctrine of informed consent refers to the Consumer Defense Code (CDC), which was created through Law no. 8,078 of September 11, 1990, with its fulcrum in article 5, XXXII, of the Federal Constitution, as applicable to consumer relations.

According to the CDC, patients are consumers to whom services are provided; physicians are suppliers who carry out service provision activities; and medical actions are activities provided for individuals or entities through remuneration without employment linkage.

The Brazilian Federal Constitution, which has been in force since 1988, attributes the characteristic of public service to service providers, in the light of what is expressed in the “caput” of article 6: “Health, work, leisure, safety, social security, protection of maternity and childhood and assistance for the destitute are social rights, in the form of this Constitution”.

In addition, article 196 of the Federal Constitution is categorical: “Health is the right of everyone and a duty of the State, ensured through social and economic policies that aim to reduce the risk of disease and other threats to health, and to provide equal and universal access to actions and services for health promotion, protection and recovery”. It does not leave any doubt regarding the public service nature of the activity of hospital service provision, even if conceded to private entities.

Civil liability consists of the way in which reparations for losses caused to others are imposed on a given individual, through indemnificatory action, relating to the event itself or to people or things that depend on it. Therefore, it should be understood as a successive legal duty that arises to make good the damage resulting from an original legal duty, i.e. it is subjective and the burden of proof falls on those who make the allegations, unless the inversion foreseen in the CDC is required.

Physicians’ personal liability is subjective, but the burden of fixed proof is in favor of the consumer. Prior to the Consumer Defense Code (CDC), the principle established in law was that the burden of proof fell to those who made allegations. However, today, this has been inverted and the current interpretation from articles 6, VIII and 14 of the CDC is the following: “Suppliers of services are responsible, independent of the existence of culpability, for reparation of damage caused to consumers through defects in the services provided, and for insufficiencies or inadequacies of the information relating to usage and risks. Paragraph 4 lays down that the personal liability of liberal professionals will be ascertained through verification of the culpability”. Hence, informed consent becomes an important weapon in physicians’ defense.

Predictability consists of a psychological link between the agent and the result, expressed by foreseen absence of predictions (informed consent). It places a limit on the liability of the agent (physician) for the results coming from his initial lack of diligence. The agent is only liable for the predictable results, while others that do not come from ineptness, imprudence or negligence are deemed to be professional misfortune.
If the criterion of predictability is eliminated, simple culpability becomes a hypothesis of obligatory condemnation, which is the opposite of the principle of culpability in the modern subjective sense\(^{(9)}\).

For civil liability to be demandable, it is insufficient for the patient to have suffered a loss or for the physician to have acted culpably. A third and final requisite also needs to be present: the existence of a cause-effect link between the culpability and the loss, i.e. the loss suffered has to be a consequence of the culpable action (causal nexus).

Even in cases of objective liability, the causal nexus between conduct and result is essential. Among the causes that exclude the physician’s liability is proof that when the service was provided, the defect did not exist. It is enough to prove that the event did not result from a defect in the service but, rather, from the patient’s own conditions or other unforeseeable factors. In this, a detailed and cautious informed consent statement may be of assistance\(^{(10)}\).

Since physicians’ personal liability is subjective, as in reality it is, it will not be enough for the clinical or surgical treatment merely to be unsuccessful, for a duty to indemnify to be caused. The victim will have to prove not only the loss, causal nexus and objective liability, but also the physician’s culpability. This would occur if, for example, through using the normal knowledge of medicine, a physician were to arrive at an erroneous conclusion regarding a diagnosis or a surgical intervention: however, only a gross error by such professionals would constitute penal culpability\(^{(11)}\).

In objective liability, culpability will be proven or presumed. This may consist of lack of informed consent in cases of elective surgery that result, for example in orthopedics, in limitations on the movements of a given limb or diminution of its functioning. In Brazil, individuals can only be sentenced to provide indemnification if there is culpability.

Today, with the inversion of the burden of proof enabled through the Consumer Defense Code, it falls to physicians to prove their own innocence, and no longer to patients to prove that the professional was culpable.

For rights to be exercised in a regular manner, it is essential to obtain patients’ consent or the consent of their legal representative, as expressed in the “caput” of article 46 of the Medical Ethics Code. Thus, physicians have the duty to give information to patients and, except in emergencies, patients have to be consulted regarding the medical options, so that they can make choices. They need to be informed about procedures and, whenever possible, give their consent, with full explanations about the possible risks of medical intervention and everything that will be done\(^{(12)}\).

Despite the use of the term informed consent, the medical or surgical intervention does not exclude criminal charges when there is ineptness, imprudence or negligence by the agent. This agent will be answerable for a culpable crime if it not a case of simple professional error\(^{(13)}\).

The following dictionary definitions should be borne in mind. Ineptness is incompetence or lack of expertise; imprudence is action without due care; and negligence is slothfulness, disregard or laxness\(^{(13,14)}\).

If patients allege medical errors, the responsibility for defensive proof may be optional, if it is considered difficult for users to assemble proof regarding their supposed rights, if only because at the time of the relationship, users were acting in good faith, in addition to the foreseeable obstacles against obtaining material proof (medical files).

The sanctions applied by the Consumer Defense Code in addition to fines are set forth in article 56: “Infractions of the consumer defense norms are subject to the following administrative sanctions, according to the case, without prejudice to those of civil or penal nature or those defined in specific rules: I – fine; IV – suspension of supply of services; IX – revocation of the license for the establishment or activity. The sanctions listed shall be applied by the administrative authority, within the scope of their attributed powers (Regional Medical Council), while full defense is assured”.

In article 951 of the Civil Code, the liability for indemnification is expanded, particularly in relation to the hypotheses of death, incapacitation for work and wounds, and brings in the new situation of aggravation of the patient’s ailments. In the case of wounds, greater coverage of the liability can also be accepted by studying the cause of the patient’s injury, which is more wide-ranging than wounds and also covers psychological disorders, for example, among other causes. These can be of any order (for example: family, social, professional, etc), given that the text does not mention any restriction.

Article 206 of the new Civil Code of January 10, 2003, states the following: “Art. 206. Prescription: § 3: for three years: V – intention of civil reparation”.

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The Civil Code of 2003 corroborates this liability in article 927, sole paragraph: “Art. 927. (...) Sole Paragraph. There will be an obligation to provide reparation for the loss, independent of culpability, in the cases specified in laws, when the activity developed by the perpetrator implies risks to the rights of others through its nature.”

For the importance of informed consent in the legal doctrine applicable to physicians to be comprehended, the damage needs to be understood conceptually.

Material damage is defined as damage that affects the individual physically in terms of the body or economic interests (for example, assets), whereas moral damage affects legal issues of a moral or subjective nature such as honor, dignity or social standing, for which pecuniary estimation is difficult.

**PREPARATION OF A CORRECT INFORMED CONSENT FORM**

In the light of the above, the following are the minimum requisites to be considered in an informed consent document:

– Name and surname of the patient and of the physician providing the information;
– Explanation of the nature of the ailment and its natural evolution;
– Name of the procedure to be performed and its constituent specifications, and how it will be carried out;
– Explanation of the benefits and risks that can reasonably be expected from the intervention and the consequences of denial;
– Information on the risks from the intervention, likely complications, mortality and sequelae;
– Alternative treatments, compared with the proposed treatment;
– Explanation regarding the type of medication required for the intervention and its risks;
– Authorization to obtain photographs, videos and graphic recordings before, during and after the intervention, in order to disseminate the results or for image analysis in medical journals and/or in scientific circles;
– Possibility of revocation of the consent at any time before the intervention;
– Patient’s satisfaction regarding the information received and dealing with all the patient’s queries;
– All of this in simple and easily accessible language, for full comprehension by the patient and/or his family;
– Signatures of the physician, patient and witnesses, if possible with the addition of the respective civil identification numbers (for example: identity card, tax number, address, etc).\(^{15}\)

**METHODS**

The dialectic method was applied, starting from analysis of the current Brazilian legislation covering the topic of obligation or lack of obligation regarding the use of informed consent statements and then making extensive direct observation of jurisprudence issued by the State Court of the State of Rio de Janeiro, solely during the year 2008.

Quantitative investigations were conducted on 269 civil liability claims that were motivated by supposed medical errors. The parameters highlighted were the numbers of acquittals and convictions of physicians and/or the institutions in which they worked\(^{16}\).

The use or nonuse of informed consent by the physicians and magistrates was taken into consideration in the investigation: either as a source of defense or for drawing up sentences in which the grounds for the conviction consisted of alleged lack of knowledge of disagreeable results obtained after carrying out a certain medical procedure.

The specific realties of orthopedists were also highlighted within this set of cases, giving them special treatment and attention in the present study. These sentences were grounded in the laws and protocols described in the introduction.

This investigation was conducted using the internet, in the website of the abovementioned court, in scientific articles and in the current Brazilian and foreign technical literature relating to important studies of our time.

**RESULTS**

Contrary to what most physicians think, the judiciary is not so severe or impositional towards them. Rather, it seeks the version closest to the medical truth, with perfect comprehension of the profession, its anxieties and its aspirations, and with clear understanding of its difficulties and professional intercurrences, while expecting that physicians always seek the best rehabilitation for their patients, whenever possible, within appropriate therapies of good academic standard.
DISCUSSION

The proof of this is that, including cases that were shelved without determining their merit, there were 194 acquittals out of the total of 269 civil claims judged by the State Court of the State of Rio de Janeiro. The vast majority of the cases were dismissed under the argument of lack of the causal nexus proposed in the initial petition, in the light of the real medical conduct ascertained by the court’s expert witness.

As an example of causal nexus, taking a simple form, there might be a man with cerebral aneurism who died in a plane crash in which he was a passenger making a business trip. It would be concluded that there was no causal nexus between the aneurism (his disease) and the cause of death (the plane crash).

It should be noted that two of these acquittals were due to good and reasonable use of an informed consent statement, preceding the medical procedure, in line with the dispositions presented in the introduction.

The convictions, totaling 24, were mostly due to deaths of patients in which the minimum medical protocols had not been followed. This was to a large extent seen through the lack of precise description of all of the medical actions in the medical files\(^1\). There were also five cases that were generated specifically by patients who alleged that they did not know the future consequences of the medical acts to which they were subjected. In other words, an informed consent statement made prior to the procedure might have avoided the civil conviction.

Among the set of cases mentioned above, there were 13 cases specifically against orthopedists, which resulted in nine acquittals and four convictions. However, none of these could be linked with use or nonuse of informed consent statements.

The remainder of the cases due to medical error did not fit within the criteria for the present study, given that they were directed against health insurance plans, life insurance and others (total of 51 cases).

Looking at the indemnifications achieved in the cases of conviction, the minimum level was one minimum monthly salary, the maximum was R$ 200,000, and the mean ranged from R$ 30,000 and R$ 40,000. The physicians and the institutions in which they worked (public, private and/or philanthropic institutions) were jointly liable for these amounts\(^1\).

CONCLUSION

Although informed consent is still at the embryonic stage within the Brazilian medical-legal setting, it is fully supported by legislation and already has backing from many physicians and jurists. Through the laws that already exist, it should become a standard medical-legal practice and a component of the training for the values held by magistrates in drawing up their rulings.

The mere use of this term does not provide exemption in relation to application of the law in cases of error due to ineptness, imprudence or negligence by professionals, nor in relation to medical processes caused by such acts. However, their supposed errors can be dismissed with reasonable confidence when the academic means appropriate for the case of each patient are used, in association with full information for the patient. This becomes unquestionable through drawing up an informed consent statement that is written in an honest, clear, simple and transparent manner, thereby protecting physicians from heavy indemnifications applied by the courts.

REFERENCES