

# Disclosure of information in medicine: analysis of judicial cases

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## Abstract

Consent expresses a voluntary decision, taken after disclosure of information, to accept treatment considering risks, benefits, and possible consequences. This study analyzed the role of consent forms in decisions by the São Paulo State Court of Justice. Bibliographic search was conducted using the keywords “consent form” and “medical error.” The 65 rulings identified were analyzed using Excel. Of the 15 cases in which patients were not presented with a consent form, 12 showed lack of information disclosure. In 31% of the cases, the defendant was found guilty, and most of the plaintiffs who received financial compensation were awarded moral damages. Plastic surgery, gynecology and obstetrics were the branches that most often featured as defendants. The findings attest the relevant role played by the consent form and the medical expert.

**Keywords:** Informed consent. Consent forms. Expert testimony.

## Resumo

### Dever de informação em medicina: análise de processos judiciais

Termo de consentimento é a expressão de uma decisão voluntária, tomada após processo informativo, no sentido de aceitar um tratamento considerando riscos, benefícios e possíveis consequências. Este estudo analisou o papel do termo de consentimento em decisões do Tribunal de Justiça do Estado de São Paulo. No período de um ano, realizou-se busca com as palavras-chave “termo de consentimento” e “erro médico”, e os dados dos 65 acórdãos estudados foram expostos mediante recursos do programa Excel. Em 15 casos não se utilizou o documento, dos quais 12 demonstraram falta do dever de informar. Em 31% dos processos houve condenação do réu e a maioria dos autores que receberam compensação financeira fez jus a indenização por danos morais. As áreas de atuação na medicina que mais figuraram como réis foram cirurgia plástica e ginecologia e obstetrícia. Ficou demonstrada a relevância da aplicação do termo de consentimento e da atuação do perito médico.

**Palavras-chave:** Consentimento livre e esclarecido. Termos de consentimento. Prova pericial.

## Resumen

### El deber de informar en medicina: análisis de las demandas

El formulario de consentimiento expresa una toma de decisión voluntaria al aceptar el tratamiento después de informados los riesgos, beneficios y posibles consecuencias. Este estudio analizó el papel del formulario de consentimiento en las decisiones del Tribunal de Justicia del Estado de São Paulo. Durante un año se realizó una búsqueda con las palabras clave “formulario de consentimiento” y “error médico”, y los datos de las 65 demandas se expusieron en el programa Excel. En 15 casos no se utilizó el documento, de los cuales 12 demostraron haber una falla del deber de informar. El 31% de los casos lo condenó al acusado, y la mayoría de los autores que recibieron una compensación económica tenían derecho a indemnización por daño moral. Las áreas de la Medicina que recibieron más demandas fueron la cirugía plástica y la ginecología y obstetrícia. Son fundamentales aplicar el formulario y la actuación del perito médico.

**Palabras clave:** Consentimiento informado. Formularios de consentimiento. Testimonio de experto.

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*Informed consent is the patient's authorization obtained by the professional to perform a medical procedure*<sup>1</sup>. The expression in Portuguese, "Consentimento informado," derives from the English "informed consent," which has been translated into Portuguese and used in Brazil as "consentimento pós-informação," "consentimento consciente," "consentimento esclarecido," "consentimento informado," or "consentimento livre e esclarecido"<sup>2</sup>. This is a voluntary decision, which can be verbally expressed or written, made after an information process, by an autonomous and capable person, to accept specific treatment being aware of the risks, benefits, and possible consequences<sup>1</sup>.

The information process followed by patient's consent is opposed to the hierarchy that has historically marked medicine. Thus, the technical power that was reflected in the physician's decision on the patient's health has been replaced by a growing respect for individual autonomy. However, despite the ethical and legal basis that sustains this change, there is still resistance, which is reflected in the weakening of the physician-patient relationship<sup>3,4</sup>.

Medical malpractice, also called medical error, can be conceptualized as *inappropriate conduct that presupposes a technical breach, capable of producing damage to the life or harm to the health of others, through malpractice, recklessness, or negligence*<sup>5</sup>. Malpractice occurs when the physician acts with lack or deficiency of technical knowledge of the profession, not complying with the norms and manifesting practical unpreparedness to perform a given activity<sup>6,7</sup>. *Inexpert professionals do not know, in their way of acting, what a physician should know*<sup>8</sup>.

*Recklessness is the agents' unpredictability in relation to the consequences of their act or action*<sup>8</sup>, in such a way that, although knowing the norms and even the risks, they *engage in hasty or daring conduct, lacking moderation*<sup>9</sup>. Negligence, in turn, is characterized by lack of care or precaution when performing the acts, manifesting inertia, passivity, indolence, and lack of action<sup>6,7</sup>, consisting, therefore, of *an omissive act, unlike diligence, which would act with caution, care, and attention, avoiding any distortions and failures*<sup>8</sup>. The physician's lack of the duty to warn and, therefore, of the patient's informed consent, fits medical malpractice and can be characterized as negligence<sup>10</sup>.

According to the *Universal Declaration on Bioethics and Human Rights*, of the United Nations Educational, Scientific and Cultural Organization (Unesco), *any preventive, diagnostic, and therapeutic medical intervention should only be carried out with the prior, free, and informed consent of the involved individual, based on appropriate information. Consent must, where appropriate, be manifest and may be withdrawn by the involved individual at any time and for any reason, without entailing disadvantage or prejudice*<sup>11</sup>.

Consent is obtained after clarification that will culminate in a safe decision of the patient or their representative, who, after being informed, must assume the responsibility of following all recommendations made by the attending physician<sup>2</sup>. Consent is generally received verbally; however, it is recommended to elaborate it in writing, in clear and accessible language, and to clarify all possible doubts of the patients or their representatives<sup>2</sup>.

It is the physician's duty to provide information and, according to the Code of Medical Ethics, in article 34, this professional is *prohibited to cease to inform to the patient the diagnosis, prognosis, risks and objectives of the treatment, except when direct communication may cause harm, in which case, the physician must communicate the patient's legal representative*<sup>12</sup>. Accordingly, the document also prohibits the *disrespect of the right of the patients or their legal representative to freely decide on the performance of diagnostic or therapeutic practices, except in case of imminent risk of death*<sup>12</sup>.

Informed consent arises from a principle of constitutional basis. In this sense, the duty to warn and the right to informed consent value the subject of right and emphasize their ability to self-govern, making choices and acting according to their own deliberations<sup>13</sup>. Likewise, the Brazilian Civil Code describes, in article 15, that *no one can be constrained to undergo, at risk of life, medical treatment or surgical intervention*<sup>14</sup>.

Moreover, the state of São Paulo (Brazil) has a legislation establishing as the right of users of healthcare services and initiatives to *consent or refuse, freely, voluntarily, and accordingly, with adequate information, diagnostic or therapeutic procedures to be undergone by them*<sup>15</sup>.

As there is no legislation specifically regulating this duty to warn, the Consumer Protection Code fulfills this purpose<sup>13</sup>. Thus, the law establishes as a basic right of the consumer *adequate and clear information on the different products and services, with correct specification of quantity, characteristics, composition, quality, taxes and price, as well as on the inherent risks*<sup>16</sup>.

Compliance with the duty to warn only takes place when the clarifications are specifically related to the case at hand, with generic information being sufficient<sup>13</sup>. Finally, Guz<sup>3</sup>, in a study on Brazilian caselaws, notes that in most cases, consent ultimately deviates from its original purpose. The focus of the courts seems to be much more on the simple fulfillment of the physician's legal duty to warn than on the exchange of information with the patient, and there is no certainty that communication was effective, with due understanding of the facts<sup>3</sup>.

## Objectives

The authors sought to analyze the role of informed consent in the decisions of the chambers of the judicial districts of public law and private law of the Court of Appeals of the State of São Paulo (TJSP), evaluating characteristics of plaintiffs and defendants, type of conviction and indemnification, most involved specialty areas, and presence of medical evidence.

## Method

The judicial processes were researched in the appellate decisions of lawsuits adjudged by TJSP within a period of one year by internal tool<sup>17</sup> of the court's own website. The keywords simultaneously searched were "informed consent" and "medical error." The data obtained from each appellate decision were: plaintiff and defendant in the processes, specialty area of the physician, presence of medical error, reason for error, indemnification, production of expert evidence, and presence of the informed consent.

The inclusion criteria were: appellate decisions adjudged between July 2018 and July 2019 and addressing the topic of informed consent in the medical environment. Interlocutory appeals,

requests for reconsideration and civil motions for clarification—as they are not intended, or are only provisionally intended, for the adjudication upon the merits—were excluded, as well as appellate decisions that did not address medical error. The collected data were organized in spreadsheets and subsequently analyzed for producing graphs and result tables in the Excel software.

## Results

The search obtained 74 appellate decisions adjudged by TJSP, four of which were excluded: one interlocutory appeal, one request for reconsideration, and two civil motions for clarification. After reading the remaining 70 appellate decisions, three were excluded because they were not related to medical professionals, but to the field of dentistry (in two cases) and to an aesthetic clinic (in one case), and two because they did not deal with the use of informed consent—the expression was only cited in the appeal. Therefore, 65 appellate decisions adjudged in São Paulo in the period of one year, between July 2018 and July 2019, were analyzed.

By classifying the selected documents according to the plaintiffs of the process, 55 (84%) lawsuits were filed by the very patient who suffered the alleged damage; five (8%), by the patient along with family members; and five (8%), only by family members. In case patients themselves had filed the process and died in the course of it, the cause passes to their heirs, which was observed in two cases.

Of those who filed the process along with family members, they were their spouse or mother. The family members who filed the process did so because the patient died in the medical procedure under trial. In these cases, the family members were: widow or widower, children, and siblings.

The defendants in the process were the hospital or clinic where the procedure or care took place (50), the health insurance operator/plan hired by the patient (10), and the physicians themselves (43). In most cases (38), the plaintiff sued more than one entity/person in the same process, notably, the hospital/clinic and physician. Also, regarding the defendants, two processes involved medical professional insurance companies

and one of them involved, in addition to the health insurance operator, the company that operates the management of the health insurance plan, organizing and managing the system of authorization of procedures to beneficiaries.

Physicians deemed as defendants in the processes were also classified according to their specialty areas. The most frequent area was plastic surgery, followed by gynecology and obstetrics (Table 1). In five appellate decisions, the specialties of the involved physicians were not mentioned.

**Table 1.** Specialty areas of physicians deemed as defendants in the processes

Specialty area	Number of defendants
Plastic surgery	18
Gynecology and obstetrics	14
Gastrointestinal surgery	4
Neurosurgery	4
Anesthesiology	3
Vascular surgery	3
Urology	3
Ophthalmology	2
Orthopedics and traumatology	2
Otorhinolaryngology	2
Radiology	2
Cardiology	1
General surgery	1
Outpatient clinic	1
Endoscopy	1
Pathology	1
Not mentioned	5

In 42 (65%) processes the physician was not convicted, and in 21 (32%) there was conviction. In two (3%) processes the appellate decision annulled the judgment, because it was necessary to re-instruct the process: one of these cases occurred due to lack of production of expert evidence, and the other because the expert evidence was not enlightening. In one of the cases in which no medical error or malpractice was found, the physician in question (plastic surgeon) was sentenced to indemnify the patient for moral and aesthetic damages.

In the analysis of reasons that led to convictions of medical professionals, it was found that most cases, 15 (71%) of the convictions, involved the lack of the duty to warn, precisely the purpose of consent. Inadequate technique—the second most frequent reason for conviction, with six cases—was considered as the fact of not employing all available/state of the art knowledge; less frequently was the non-performance of the agreed procedure (3) and the use of inappropriate material in the procedure (1). In some cases, more than one reason led to conviction.

The association between physician's specialty area and reason for conviction is demonstrated in Table 2.

Among plastic surgeons, a professional was sentenced both for lack of the duty to warn and for the use of inadequate technique. Among the appellate decisions in which the specialty areas were not mentioned, two convictions included both lack of duty to warn and inadequate technique.

As for the convictions—with the exception of unmentioned specialties—, it is possible to observe the complaints that motivated the plaintiffs to file the processes (Table 3).

**Table 2.** Physician's specialty area and reason for conviction

Specialty area	Reason for conviction			
	Lack of duty to warn	Inadequate technique	The previously agreed procedure was not performed	Inappropriate material
Anesthesiology	1	1		
General surgery	1			
Plastic surgery	5	2	1	
Gynecology and obstetrics	1		2	
Neurosurgery	1			1
Otorhinolaryngology		1		
Urology	1			
Not mentioned	5	2		

**Table 3.** Physician's specialty area related to the complaint that motivated the plaintiff to file the process

Specialty area	Plaintiff's complaint to file the process
Anesthesiology	Cardiorespiratory arrest after spinal anesthesia
General surgery	Open bariatric surgery (instead of laparoscopic), with worse aesthetic result
Plastic surgery	Breast implant without the expected aesthetic result
	Poor abdominoplasty healing
	Deformity after otoplasty
	Poor aesthetic result of abdominoplasty and liposuction
	No breast reduction was performed in the patient as previously agreed
Gynecology and obstetrics	Mastopexy with prosthesis replacement that evolved to nipple necrosis
	Breast reduction that worsened with wound dehiscence and hypochromia of the nipple-areolar complex
	Pregnancy after tubal ligation
Neurosurgery	The contracted tubal ligation was not performed
	No tubal ligation was performed as previously agreed
Otorhinolaryngology	Perforation of the esophagus and lung by spine surgery for cervical herniated disc
	Fracture of screws used in spinal arthrodesis
Urology	Inferior rectus muscle injury in septoplasty
	Wife's pregnancy after vasectomy

Of the 65 appellate decisions, 41 did not result in the payment of indemnification. Among the indemnified damages, most referred to moral damages (22), followed by pecuniary (7) and aesthetic damages (5). In some appellate decisions, the presence of more than one type of damage was adjudged, combining moral damage with pecuniary and/or aesthetic damages.

The medical evidence was produced in 56 (86%) of the cases and it did not occur in eight (12%). As previously mentioned, one appellate decision did not present expert evidence, so the judgment was annulled because of it. And, in one case (corresponding to 2%), despite producing the expert evidence, such was considered unsatisfactory, which also led to the annulment of the judgment for the production of new evidence.

Informed consent was used in 50 (77%) cases, and in other four cases, despite being applied, the document was inadequate to the particularities of the cases, which characterized failure in the duty to warn. In 15 (23%) appellate decisions, no use of the informed consent was proven, and in three of these cases the impartial expert considered that the information was verbally passed on and the judges adjudged it

accordingly, not verifying medical error nor failure in the duty to warn.

In 14 appellate decisions, it was adjudged that the physician would have the obligation of result and not the obligation of means and, therefore, the burden of proof was shifted. Of this total, 12 were plastic surgeons who performed strictly aesthetic procedures; one was a vascular surgeon also performing an aesthetic procedure for varicose veins; and one was a pathologist who released test results for testing of the human immunodeficiency virus (HIV). Of these 14 physicians, nine were not convicted because they were able to prove that they acted within good medical practice.

### Discussion

The frequency of appellate decisions with the topic medical error involving the use of an informed consent is low when compared with the contingent of physicians in the state of São Paulo. In November 2020, Brazil surpassed the mark of 500 thousand physicians<sup>18</sup>, of whom more than 145 thousand are in São Paulo<sup>19</sup>.

In turn, the plaintiffs, in 92% of the cases, were the “victims” themselves, who claimed indemnification for allegations of error. Mendonça and Custódio<sup>20</sup>, when studying the feelings of victims of medical error, found that they feel disrespected and without rights. They also complained of the physicians’ unwillingness to help and lack of accountability.

The same authors stress that the establishment of a good physician-patient relationship could avoid some errors and most lawsuits<sup>20</sup>. They state that *the establishment of an empathic relationship, which allows trust not only between physicians and their patients, but also with their families, can be the way to avoid unsafe situations and increase in the occurrence of medical errors*<sup>21</sup>.

Despite the “medical error” designation, physicians are not the only defendants in the actions proposed by patients dissatisfied with medical services. The present study showed that hospitals, health insurance operators, clinics, laboratories, the government, and others are often called upon to respond to action for damages arising from allegations of failures.

In most of the studied appellate decisions, more than one defendant was prosecuted, the most frequent being hospitals/clinics (50) and physicians (43). Private healthcare network establishments and health insurance operators, according to the Consumer Protection Code<sup>16</sup>, respond objectively. In this case, the conduct of the agent is not verified, that is, the duty to indemnify is mandatory, regardless of who caused the damage having acted with fault or fraud<sup>6</sup>.

However, according to Kfoury Neto, *even in the context of objective responsibility, the hospital cannot be compelled to indemnify, unless the fault of the physician, its agent, is sufficiently clear and proven*<sup>22</sup>. In the studied processes, this line of reasoning is also followed in the trial, in such a way that some of them were directed to the government of São Paulo, as the alleged error occurred in the premises of hospitals under State administration.

When the defendant is the State, the responsibility becomes subjective. Thus, *the fault of the service or “lack of service” (faute du service) occurs when such does not work, should it work, it works poorly or runs late*<sup>23</sup>. For defining lack of service, it is necessary to demonstrate the occurrence of the damage,

*causal link between such, omission behavior of the Administration, and the existence of fault*<sup>24</sup>.

Among the physicians’ specialty areas mentioned in the processes, the most frequent were plastic surgery and gynecology and obstetrics, respectively. In a research conducted by the Regional Council of Medicine of the State of São Paulo (Cremesp), between 2000 and 2004 these two specialties also reached the top of the ranking of processes, but gynecology and obstetrics ranked first<sup>6</sup>.

Cremesp also developed another study to investigate only the ethical processes within the council in the period from 2000 to 2006. They developed a unit of measure, named the rate of ethical-professional processes, which considers the frequency of the specialty in the processes, the number of specialist physicians, and how long the physicians have been trained<sup>25</sup>.

Thus, the ten specialties with the highest rate of processes, in decreasing order, were: plastic surgery, urology, trauma surgery, neurosurgery, orthopedics and traumatology, gynecology and obstetrics, ophthalmology, oncology, general surgery, and angiology and vascular surgery<sup>25</sup>. Of these, only trauma surgery and oncology were not among the specialties of the defendants in the present study.

In this research, among the defendants, there is only one physician who works in a strictly clinical area (general practice), who provided hospital care to patients with perforated ulcer. One of the family’s complaints in the appeal was the lack of application of an informed consent concerning the procedure to which the examinee was submitted as treatment of their condition. The appellate decision was limited to the suspension of the judgment and indication of new expert evidence, as the one in the record was not enlightening<sup>26</sup>.

There are also two specialties of less contact with the patient, specifically focused on diagnosis (pathology and radiology). All other processes involve areas that commonly deal with invasive medical procedures, which is expected, considering that the informed consent is mostly used when invasive procedures are required and is rarely used in clinical practice.

Of the 65 appellate decisions studied, 21 (31%) resulted in conviction, which corroborates a similar study whose authors evaluated trials

of the Court of Appeals of the state of Santa Catarina (Brazil) in processes with medical defendants, demonstrating that, for ten years, 40% of civil actions and 36% of criminal actions resulted in conviction<sup>27</sup>. Regarding ethical-professional processes in the state of São Paulo, between 2000 and 2006, Cremesp acquitted 57% of the 2,922 physicians adjudicated<sup>25</sup>.

The main cause of conviction observed in the present study was the lack of the duty to warn (15 cases), and the second major cause was the performance of a procedure using inadequate technique (six cases). According to Diniz<sup>28</sup>, the absence of consent, if intentionally done, is a crime of professional negligence of the physicians, and the deficient information given by them to the patient makes them responsible for the harmful result arising from their intervention, even if it was technically correct, regardless of whether the damage derives from the risk inherent in any medical practice.

These convictions for lack of information could be avoided if the decision for a treatment was less dependent on the physician, individually, and had a more shared nature, so that the patient undergoing treatment had more autonomy. Therefore, it is recommended to allow the patient to refuse to undergo a certain procedure or consent to alternative treatment and not the one the physician believed to be the main treatment<sup>20</sup>.

When associating the physicians' specialty area with the reason that led the professionals to be convicted, the area of most of the defendants in the processes was also the one with the most conviction (plastic surgery) and for the most frequent reason (lack of duty to warn). As it is an area of impending elective procedures, adequate consent was expected to be a frequent practice.

In a debate proposed by the *Brazilian Journal of Plastic Surgery*, researchers suggested that the absence of the informed consent should be considered omission on the part of the surgeon. The mere fact of not having the document printed and signed does not impose on the physician the duty to indemnify, but it is a complicating factor with regard to proof of the duty to warn<sup>29</sup>. As in the present study, cases in which the poor aesthetic result of plastic surgery was not due to poor technique, but factors inherent in the patient, end up resulting in

indemnification, because it is not proven that information about possible complications was provided in detail<sup>29</sup>.

The process against a physician in the urology area, in turn, was filed by an occurrence of pregnancy of the partner after undergoing a vasectomy and it was found that the physician did not provide the appropriate information regarding the possibility of failure of the method. These processes are relatively common in contraceptive surgeries. Every patient who will undergo sterilization (vasectomy or tubal ligation) should be warned of the possibility of ineffectiveness of the method in some cases<sup>30</sup>.

The very Brazilian Society of Urology<sup>31</sup> provides an informed consent model to be applied before vasectomy surgeries, in which it is stated that, although vasectomy is a permanent sterilization method, there is a small possibility of spontaneous recanalization—that is, there can be the passage of sperm from one stump to another and they can be ejaculated again—so that the individual can remain fertile and cause pregnancy.

Among gynecologists and obstetricians, two were convicted of not performing tubal ligation as previously agreed with the patient. Problems related to sterilization surgery were also among the most frequent in the specialty in complaints registered with Cremesp between 1995 and 2001<sup>32</sup>. Another professional from the same area was sued by a patient who became pregnant after tubal ligation. This could be avoided by providing information about the fallibility of the method.

Regarding the indemnification that the defendants of this study were sentenced to pay, the most frequent were for moral, pecuniary and, lastly, aesthetic damages. In some cases, the plaintiff received more than one type of indemnification.

Moral damage is the injury of non-pecuniary interests of individuals or legal entities caused by the detrimental event<sup>33</sup>. Pecuniary damage affects the victim's property through loss or deterioration (total or partial) of tangible assets; financial assessment is possible for indemnification. The following are included in this category: pecuniary loss (what the victim has actually lost) and lost profit (the increase that their assets would have, but no longer have as a result of the detrimental event)<sup>33</sup>.

The aesthetic damage, in turn, is characterized by the morphological alteration of the individual. It comprises deformities, marks, and defects that imply the victim's deformation, which consist of a simple displeasing injury or a permanent reason for exposure to ridicule or inferiority complex, which exerts influence or not in their work capacity<sup>33</sup>. The most frequent indemnifications coincided with the study by Meurer<sup>27</sup>, in which 35% of the plaintiffs were sentenced to pay pecuniary damages; 10%, moral and pecuniary damages; 9%, exclusively pecuniary damage; 9%, the three types of damage; and 4%, pecuniary and aesthetic damages.

Forty-one plaintiffs were not sentenced to indemnify. This coincides with the 42 processes in which there was no medical error—within which a physician, previously mentioned, was sentenced to indemnify the victim even without proof of medical malpractice. In 88% of the cases, expert evidence was produced; however, in one of them (2%), it was considered unsatisfactory, causing the annulment of the sentence to produce a new expert evidence, which highlights its importance.

Pombo stresses the importance of the expert evidence, which, in practice, *is decisive when seeking, in Court, the affirmation of the responsibility of the physician, because it is a technical matter in which aspects of difficult understanding for the judge often intervene*<sup>34</sup>. Cremesp also found that expert evidence was produced in most of the studied actions involving medical error. *Only in 34.8% of the judgements the production of expert evidence is unmentioned, in such a way that it can be inferred a lack of expert evidence in these cases, or that, having occurred, this did not significantly influence in the court order*<sup>35</sup>.

Expert evidence is extremely important to ascertain the responsibility of professionals for the occurrence of the damage alleged by the patient<sup>6</sup>, in addition to focusing on the extent of the damages to assist the judge at sentencing<sup>6</sup>. Of the 65 appellate decisions studied, 77% had an informed consent. Nevertheless, in four cases, even with the presence of the document, the duty to warn was not adequately verified and the defendants were eventually convicted.

The most effective way for a physician to avoid legal action is to invest in a good

physician-patient relationship. Thus, an empathetic and trust-based relationship becomes a great facilitator of the professional's performance. In these conditions, even if unforeseen events take place, patients agree with a second surgical procedure, believe in the explanations of their physician, and collaborate even in the face of unexpected difficulties<sup>29</sup>.

Conversely, a simple informed consent, in clear language, appropriate to the patient's culture, without great technical refinement, is essential and the physician must demonstrate that this document is proof of good faith and mutual trust<sup>29</sup>. Diniz<sup>28</sup> addresses what should the consent form contain and how the informed consent should be: it should be written in accessible language; contain the procedures and therapies that will be used, its objectives, and justifications; provide for possible risks and discomforts as well as the expected benefits; clarify existing alternative methods; ensure the patients' freedom to refuse or withdraw their consensus without any punitive sanction or harm to their physician-hospital care; present a signature or dactyloscopy identification of the patients or their legal representative.

The authors also stated that, in three cases, consent had been adequately established even if only verbally. As the numbers well demonstrate, these are exception situations. Although there is dialogue, verbal consent and register on medical records, the Brazilian Federal Council of Medicine recommends the written elaboration of the informed consent<sup>2</sup>.

According to Aguiar<sup>36</sup>, the physician, in most cases, assumes an obligation of means. The professionals are those who comply with providing a service to which they will devote attention, care, and diligence required by the circumstances, according to their title, with the resources available to them and with the current development of science, without committing themselves to obtaining a certain result<sup>36</sup>. In other words, physicians are restricted to the use of all necessary or possible means without necessarily reaching a result (in this case, the cure of the patient).

The obligation of result, in turn, is demonstrated when the commitment to achieve a certain goal exists, *such as transporting a load from one place to another, or to repair and put into operation a certain machine (it will be guaranteed if, in addition,*

*it is stated that the machinery will achieve a certain productivity*)<sup>37</sup>.

However, as Lopez<sup>38</sup> states, in some cases the physician ends up assuming an obligation of result when someone who is in good health seeks a physician only to improve some aspect of their own, which they consider unpleasant, seeking exactly this result, not only the professional to do their job with diligence and scientific knowledge, otherwise it would not be worth risking and spending money for nothing.

Accordingly, of the 65 appellate decisions, it was adjudged that the physician has an obligation of result in 14 cases, being 12 plastic surgeons and one vascular surgeon, all performing procedures with aesthetic purposes. In addition, one was a pathologist who provided a medical report for HIV testing and, in this case, the appellate decision argued that tests in general have an obligation of result—which is supported by the literature<sup>31</sup>—, but the state of the art should be taken into account<sup>39</sup>. Cases of breach of technical knowledge or lack of duty to warn<sup>39</sup> are deemed errors, and no medical error in the pathologist's performance was characterized.

*Certainly, the mere fact of being an obligation of result does not make the responsibility of the physician objective. It remains subjective, but places to the physician the burden of demonstrating that the failure of the surgery resulted from external factors*<sup>40</sup>.

In the present study, eight of the 14 physicians who had the burden of proof shifted were able to prove their innocence.

## Final considerations

The present study demonstrated that there is a small volume of processes involving the medical professionals and the use of an informed consent

in relation to the number of physicians in the state of São Paulo. The importance of the physician knowing and using the document correctly—with all the necessary information and in a clarified way—was evidenced, fulfilling the duty to warn, and registering the patient's consent.

In the set of evaluated appellate decisions, mostly, the plaintiffs of the processes were the patients themselves, figuring as defendants the hospital/clinic, the physician, and the health insurance operator/plan, with more than one defendant in most cases. There was conviction in 31% of the processes, the main cause being the lack of the duty to warn.

Physicians from various specialty areas figured as defendants, the most frequent being plastic surgery and gynecology and obstetrics. Most of the plaintiffs were not entitled to indemnification for the defendant's non-conviction. Among those who received financial indemnification, the majority was for moral damages.

The importance of medical evidence in lawsuits of this nature was demonstrated, as in 57 of the 65 appellate decisions there was technical expert evidence of a medical nature. In three cases, although there was no informed consent, it was demonstrated by the expert evidence evaluation that the information was verbally passed on and the judge followed this line of reasoning.

The informed consent was also significantly important, being present in 77% of the studied cases. Among the 15 cases in which the document was not used, the failure of the duty to warn was verified in 12. Therefore, it is paramount to invest in more research and information on the topic to improve the relationship between physician and patient and, as a consequence, to reduce the number of failures and processes.

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Camila de Aquino Feijó performed data collection, analysis, and writing of this article. Valeria Maria de Souza Framil co-supervised and Daniele Muñoz Gianvecchio supervised the research. The three authors participated in the idealization and review of the study.

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