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Legal review of the civil, criminal, and administrative consequences of informed consent violation in medical practice

Revisión jurídica de las consecuencias civiles, penales y administrativas por la vulneración del consentimiento informado en la actividad médica

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Palabras clave: Consentimiento Informado, Autonomía Personal, Libertad, Responsabilidad Legal, Relaciones Médico-Paciente

Abstract

Introduction: The informed consent (IC) ensures respect of the patient's rights to information, freedom, and autonomy. However, when the physician neglects the obligation to inform, legal consequences may follow, including the award of damages or even imprisonment.

Objective: To analyze the legal implications for a medical practitioner who fails to obtain the patient's IC.

Methodology: Based on the relevant jurisprudence and legal decisions. With regards to the former, the decisions and legal precedents of the Colombian High Courts with regards to IC and medical practice were studied, emphasizing the rulings of the State Council and the Supreme Court of Justice (civil and penal chambers). With regards to the legal decisions, the analysis enabled the review, systematization and interpretation of the discussions generated around the topic of interest, pursuant to the doctrine or research on civil administrative, and criminal law.

Results: There is consensus in the Colombian jurisprudence about the liability of the healthcare professional and of the state when the IC or any of its component parts is missing in the doctor-patient relationship. Nevertheless, there are different standpoints, particularly in the criminal arena, where a lack of unanimity exists with regards to this issue.

Conclusion: Any violation of the IC or the lack of an IC, could give rise to the practitioner's civil liability and disciplinary actions, in addition to the administrative liability of the State, but there should be no criminal liability for the physician.

Resumen

Introducción: El consentimiento informado garantiza el ejercicio de los derechos a la información, libertad y autonomía del paciente; pero cuando el médico desatiende la obligación de informar es posible que se generen consecuencias jurídicas de carácter patrimonial o incluso de privación de la libertad.

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Objetivo: Analizar las consecuencias jurídicas que conlleva para el médico omitir el consentimiento informado.

Metodología: Se acudió a la línea jurisprudencial y a la dogmática del derecho. En cuanto a la primera, se estudiaron las decisiones y los precedentes judiciales de las altas cortes en Colombia en materia del consentimiento informado en la actividad médica, con énfasis en los fallos emitidos por el Consejo de Estado y la Corte Suprema de Justicia, Sala Civil y Sala Penal. Respecto a la segunda, su análisis permitió revisar, sistematizar e interpretar las discusiones que frente al tema objeto de estudio se han generado en la doctrina o en las investigaciones de derecho civil, administrativo y penal.

Resultados: Existe consenso en la jurisprudencia colombiana con relación al tipo de responsabilidad que debe endilgarse al profesional de la salud o al Estado, cuando en la relación médico-paciente hay ausencia del consentimiento informado o de alguno de sus elementos. No obstante, en la doctrina existen diferentes posturas, en especial en la penal, donde se observa falta de unanimidad en relación con este tema.

Conclusiones: La infracción o ausencia del consentimiento informado podría generar para el médico responsabilidad civil y disciplinaria, y responsabilidad administrativa para el Estado, pero no responsabilidad penal para el galeno.

Introduction

For many years, the so-called medical paternalism prevailed in healthcare. This meant that in order to protect the patient's wellbeing, the practitioner makes the decisions about treatment, procedure, and cure options. However, this concept changed in the 20th century, when the principles of patient autonomy, independence, and freedom prevailed.¹

The informed consent (IC) is the authorization that the patient gives freely and voluntarily to the physician to conduct procedures, treatments, or research to take care of his/her health and wellbeing.² Signature of the IC by the patient involves the physician's obligation to inform the patient about the means, purpose, diagnosis, process, prognosis, treatment options, risks, benefits, and cure potential,^{3,4} so that the patient may freely and voluntarily express his/her acceptance or rejection of the intervention.⁵ The IC is applicable for medical and surgical treatments that are indispensable for the patient's health and that may have a physical or psychological impact, due to the risks involved with the particular action.

The IC has a dual connotation for the patient and for the physician. With regards to the former, it is an expression of the acknowledgement of the rights to autonomy,⁶ free will,⁷ and dignity.⁸ With regards to the latter, it is no longer a right but an obligation to inform the patient⁹ about the risks, treatment options, and benefits of the procedure. The communication between the doctor and the patient is essential for a proper acceptance of the IC.¹⁰

In brief, the IC is based on at least 3 criteria: first, the treating physician or the practitioner in charge of conducting the procedure has the obligation to inform the patient honestly and thoroughly about his/her condition, treatment, and risks involved; second, the consent must be given without any coercion whatsoever, and third, the person consenting must have the capacity to accept or reject the treatment, procedure, or intervention.¹¹

Due to the current relevant nature of the IC, any inaccuracy or omission of any of the abovementioned aspects, in addition to infringing on the rights of the patient, results in legal consequences for the practitioner.

This article discusses the legal foundation of the IC in Colombia, the considerations of the Supreme Court of Justice (SCJ) and of the State Council (SC) when facing civil, administrative, and criminal actions in cases of potential IC violations, either through omission or inaccuracy, as well as the academic analyses in terms of physician's liability within the framework of civil and administrative law, and in particular under criminal law which is widely debated, considering the type of punishment that could be awarded.

Legislative support for the informed consent in Colombia

In Colombia, the IC is acknowledged under the Medical Code of Ethics, Law 23 of 1981, article 15. Similarly, Decree 3380 of 1981, that regulates Law 23 of 1981, says in Article 13 that it is not mandatory for the physician to inform about the unforeseeable risks that may arise in the practice of the medical profession, since due to their nature it is impossible to identify those risks in advance, and therefore should not be listed in the IC. Moreover, Resolution 13437 of 1991 establishes the right to information which should be interpreted as a prerequisite for the IC.¹²

Jurisprudence and doctrine review of the legal consequences of omissions or violations of the IC in medical practice

With regards to the IC, for several years the Constitutional Court, through a tutelage process has been underpinning the opinion of the legislator regarding the obligation to sign the IC.¹³ Likewise, a recent Court decision ruled that the IC is autonomous and should be given out free will¹⁴; therefore, the omission of the IC defies the dignity of the patient and is a violation of his/her freedom of choice.¹⁵

Giving the right information to sign the IC and making sure that the patient signed without coercion or intimidation, is the responsibility of the healthcare professional in charge of the procedure or treatment¹⁶; therefore, omitting or hiding any information, any mistakes in the process of implementation, or exceeding the limits of the allowable actions, may lead to legal or economic consequences, and even imprisonment of the physician or the practitioner in

charge,¹⁷ as well as consequences for the State if the State has been the service provider.

So this paper dwells on the legal considerations that the SCJ, the Civil and the Criminal Tribunals, and Section 3 of the SC have taken into account, to determine the liability or acquittal of the physician or the public institution when dealing with presumptive IC violations. A review of the decision published in the reports by these jurisdictions was conducted, using terms such as “medical liability” and “informed consent” in the search engine. Considering that there is a larger number of medical liability decisions in the Civil Tribunal of the SCJ, and in Section 3 of the SC, the review was restricted to the period between 2014 and 2017; while in the case of the Criminal Tribunal of the SCJ, with a smaller number of rulings, the search was extended from 1995 to 2018. A comparison was also made against the doctrine of civil and administrative law, with particular emphasis on criminal law (since this is the area of stronger debate), to determine the type of liability that should be attributed in these cases.

Between 2014 and 2017, 44 rulings were passed by the Civil Tribunal of the SCJ associated with medical liability; 6 of them involved IC issues. Similarly, over the same period of time, Section 3 of the SC issued 136 rulings in the medical area, 11 of which are directly associated with the IC. On the other hand, In the Criminal Tribunal, between 1995 and 2018, 17 rulings have been passed, of which only 2 involved IC issues.¹⁸ Tables 1–3 show each of the SCJ and

SC decisions found in the search engine of the respective reports; an academic discussion follows each table.

In all the rulings listed, the civil Tribunal of the SCJ ratifies the dismissal of the claims submitted by the claimants, and absolves the healthcare practitioner from any liability. When all of the elements in the IC have been observed, the correct information has been shared, the patient has accepted or rejected therapy without coercion, and the foreseeable risks have been discussed (communicating unforeseeable events is not mandatory), there is no reason whatsoever to convict and financially penalize the physician.

Nevertheless, if for any reason the IC is infringed, and considering that the doctrine that studies the extra-contractual civil liability interprets such violation as part of *lex artis*, the practitioner will be liable and shall compensate the patient for any damages resulting from his/her actions. As an exception however, Galán¹⁹ believes that the physician shall be relieved from any liability when despite any IC omissions, the therapy was successful.

Table 1. Supreme Court of Justice—Civil Tribunal.

Filed	Decision
SC12449-2014 Files 11001-31-03-034-2006 00052-01	No economic penalty imposed on the physician
SC15746-2014 Files 11001-31-03-029-2008- 00469-01	No economic penalty imposed on the physician
SC9721-2015 Files 05001-31-03-017-2002- 00566-01	No economic penalty imposed on the physician
STC9855-2015 Files 11001-02-03-000-2015- 01617-00	No economic penalty imposed on the physician
SC2506-2016 Files 05001-31-03-003-2000- 01116-01	No economic penalty imposed on the physician
SC7110-2017 Files 05001-31-03-012-2006- 00234-01	No economic penalty imposed on the physician

Source: Rapporteur's report of the Civil Tribunal of the Supreme Court of Justice.

Table 2. State Council.

Filed	Decision of the State Council
File 26660 (27-03-14)	The State is considered financially liable
File 32322 (26-02-15)	The State is considered financially liable
File 30419 (26-06-15)	The State is considered financially liable
File 21774 (29-09-15)	The State is considered financially liable
File 45459 (01-02-16)	The State is considered financially liable
File 36136 (05-07-16)	The State is considered financially liable
File 36288 (01-08-16)	The State is considered financially liable
File 41262 (05-12-16)	The State is considered financially liable
File 37553 (22-06-17)	The State is considered financially liable
File 38874 (22-06-17)	The State is considered financially liable
File 43378 (30-11-17)	The State is considered financially liable

Source: Rapporteur's report of the State Council.

Table 3. Supreme Court of Justice—Criminal Tribunal.

Filed	Court Decision
Proceedings 27357 (22-05-08)	The physician is charged for criminal liability for manslaughter
Proceedings 33920 (11-04-12)	The physician was charged with criminal negligence resulting in personal injury

Source: Rapporteur's report of the Criminal Tribunal of the Supreme Court of Justice.

Of the 11 cases analyzed by the SC, the high tribunal revoked 10 of the rulings of the Administrative Tribunal and decided to impose a financial penalty on the State for risks and damages caused to patients; only in 1 case was the decision confirmed, which initially was condemnatory. In these rulings, the underlying premise of the SC was that the interventions or procedures conducted without an IC represent a service failure, and hence the State represented by service provider must be held financially accountable.

In terms of State liability, the Spanish doctrine argues that any judgment shall be based on the violation of the legal and ethical obligation to inform, since the physician is subjecting the patient to risks that the patient is unaware of. Sardinero²⁰ considers that the State would have to be held accountable when the healthcare practitioner fails to disclose information, since that would lead to an unallowable risk that can be objectively attributed to a harmful result. This author suggests that when the patient undergoing the procedure without authorization decides to consent afterwards, the State organization could be relieved from any kind of financial liability.

In the 2 above-mentioned verdicts, the Criminal Tribunal of the SCJ ratified the adverse rulings initially awarded: in the first case the physician was charged for manslaughter and in the second case for negligence resulting in personal injury. In these 2 cases, the Court considers that the criminal liability is the result, among other factors, of the fact that physicians failed to educate on the foreseeable risks of the procedures conducted in patients.

In terms of criminal law, the lack of an IC or of any of its items leads to legal consequences that may result in imprisonment of the physician. A segment of the doctrine²¹ considers that the physician must be liable for criminal injuries, because his/her actions violated the right to self-determination of the patient, causing body injuries that the physician failed to consider.²² On the contrary, others^{23,24} feel that these actions involve a behavior other than criminal injury since the offense is against personal freedom and thus the physician would have to be accountable for illegal coercion or constraint, considering that his/her behavior impaired the rights of autonomy and self-determination of the patient,²⁵ but not the patient's health or physical integrity,²⁶ provided that the procedure was conducted in accordance with the healthcare standards applicable in medical practice.

On the contrary, other authors disagree with punishing the physician neither for an injury offense, nor for constraint. With regards to the former, these authors believe that it is an overstatement and encourages the practice of defensive medicine, even more so because if the treatment succeeds and is within the limits established by medical science, the life or the health of the patient remain unharmed.²⁷ With regards to the latter, they reject the idea of awarding a penalty for coercion or constraint, since in order for these offenses to be relevant from the criminal perspective, an act of violence has to be involved, forcing the patient to undergo the procedure,²⁸ a scenario that is hardly feasible in medical practice.²⁹ They suggest the creation of a special offense called "arbitrary medical treatment,"^{30,31} whereby the practitioner shall be punished for taking actions against the patient's will, which in the end is what the IC is expected to protect.

In contrast with the situation in civil and administrative law, in criminal law there is a manifest debate around the doctrine and jurisprudence of the type of liability and offense that should be attributed to the healthcare practitioner who fails to properly complete the IC. At any rate, what is clear is that in the legal realm, violation of the IC leads to legal consequences, either financially when dealing with a civil or State liability, or imprisonment in case of a criminal offense.

Conclusion

According to the Colombian High Courts, the IC is considered part of *lex artis* and any violation, omission, or defective enforcement incontestably give rise to legal consequences, whether civil or financial penalties for the physician, administrative implications such as State liability, or criminal as a result of personal injury or manslaughter due to reckless behavior.

The authors of this article share the idea of the doctrine and jurisprudence that states that any omission or incomplete information for the acceptance of the IC, violates the patient's freedom of choice and autonomy; nevertheless, they also believe that as a general rule in the criminal arena, awarding punishment for the physician's liability for a crime is a disproportionate measure.

In the first place, the authors dismiss the idea that healthcare practitioners should be liable for offenses of personal injury or manslaughter. To solve the issue there

is a need to differentiate between compliance versus non-compliance with duty of care. When the practitioner failed to enforce the IC or a part thereof, but in actually conducting the procedure complied with the technical standards of medical practice and the outcome was positive for the patient, penalizing the practitioner for an offense is disproportionate and at most he/she could face disciplinary action before the ethics committee. So Gómez³¹ rightly argues that a conviction along these lines would exceed the authority of criminal law and is contrary to the idea of protecting the physical and mental integrity of the patient, since in the end the patient remained unharmed. It is clear then that the IC is a deontological or ethical standard and its omission infringes on the patient's freedom of choice but does not affect the patient's physical integrity.

Second, the authors disagree with the idea that the practitioner should be penalized for constraint (or coercion according to the term used in Spain), since omitting information or misinforming the patient is a violation to the patient's freedom and autonomy. In order for an offense to be materialized there has to be a malicious action on behalf of the physician, involving forcing someone to do, to tolerate, or to omit something; such situation may hardly occur in medical practice (unless there is proof that in fact the patient was forced to undergo the procedure). Finally, the justification to avoid punishing the practitioner as herein suggested, is the absence of malice, since constraint only occurs in malicious behavior; hence, in case of reckless constraint, this behavior would be atypical for lack of punitive damages.

Third, in terms of the suggestion to configure a special offense called "arbitrary medical treatment" in principle could be right, since this could be an approach to safeguard the rights of patients against abusive actions that infringe on their self-determination; however, the authors believe that since the Colombian legislator has not yet enshrined this punitive modality, IC violations may not be punished on this basis and hence there is no criminal liability for an inexistent offense.

In conclusion, the most consistent solution considering that a criminal intervention is only appropriate when it is strictly necessary—the *ultima ratio*—and exclusively in the absence of other equally or more effective legal mechanisms, is that the response to the type of responsibility to be attributed to the physician who fails to comply with one of the items in the IC, or omits the IC, belongs to the realm of civil or administrative law, notwithstanding the possibility of taking disciplinary measures according to the Code of Medical Ethics.

Ethical responsibilities

Protection of persons and animals. The authors declare that no experiments in humans or animals were conducted in this research.

Confidentiality of the data. The authors declare that no information about patients has been disclosed in this article.

Right to privacy and IC. The authors declare that no patient data are published in this article.

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Conflicts of interest

The authors have no conflicts of interest to disclose.

References

- García V. Informed consent understood as a fundamental right: physical integrity in research and medicine. 2011; Universidad de la Coruña, Gijón: [Cited 2018 Jul 9]. Available at: http://www.sibi.org/attachments/article/578/Libro_Premio_JGPA_SIBI_2011.pdf.
- Herrera FJ, Blanco NI, Guarnizo JA. Manual de Responsabilidad Médica. Bogotá: Leyer; 2008.
- Galán J. El consentimiento informado del usuario de los servicios sanitarios. Madrid: Colex; 1997.
- Guix J, Balaña L, Carbonell JM, Simón R, Surroca RM, Nualart L. Informed Consent Form Compliance and Comprehension in a Health Care District in Catalonia. *Rev Esp Salud Publica* 1999;76 6:669-675.
- Yepes S. La responsabilidad civil médica. 4th ed. Medellín: Biblioteca Jurídica Diké; 1996.
- Guianella G. Human rights and informed consent in clinical practice: Beyond the right to health. *Rev peru med exp salud pública* 2013;30 2:315-319.
- Yepes S. El daño indemnizable en el consentimiento informado del paciente. *Revista IARCE* 2009;25:125-139.
- Navarro FP, Argüelles M, Cicero R. Human rights and informed consent. *Cir Ciruj* 2004;72:239-245.
- Alpa G. Nuevo Tratado de la Responsabilidad Civil. Lima: Jurista Editores; 2006.
- Bocanegra JC, Arias JH. Characterization and analysis of adverse events in closed liability cases involving anaesthetists who received legal support from the Colombian Society of Anaesthesia and Resuscitation (S.C.A.R.E.), Colombia, 1993-2012. *Rev Colomb Anestesiol* 2016;44 3:203-210.
- Fernández J. El contrato de servicios médicos. Madrid: Civitas; 1998.
- Mendoza JM, Herrera LA. Consent informed in Colombia: A comparative analysis of the proposed law 24 of 2015 with the current code and other codes of ethics. *Rev CES Derecho* 2017;8 1:156-171.
- Corte Constitucional de Colombia. Sentencia rad. T-409/94. Doce (12) de septiembre de mil novecientos noventa y cuatro (1994). [Cited 2017 Sep 15]. 1994. Available at: <http://www.corteconstitucional.gov.co/relatoria/1994/T-401-94.htm>.

14. Corte Constitucional de Colombia. Sentencia rad. C-246/17. Veintiséis (26) de abril de dos mil diecisiete (2017). [Cited 2017 Sep 15]. 2017. Available at: <http://www.corteconstitucional.gov.co/relatoria/2017/c-246-17.htm>.
15. Corte Constitucional de Colombia. Sentencia rad. SU 337/99. Doce (12) de mayo de mil novecientos noventa y nueve (1999). [Cited 2017 Sep 15]. 1999. Available at: <http://www.corteconstitucional.gov.co/relatoria/1999/su337-99.htm>.
16. Alonso M. El consentimiento informado del paciente en el tratamiento médico, bases jurídicas e implicaciones penales. Autonomía personal y decisiones médicas. Cuestiones éticas y jurídicas. Navarra: Thomson Reuters; 2010.
17. Sáinz J. Intervención médica y consentimiento informado. In: Morillas L, director. Estudios jurídicos sobre responsabilidad penal, civil y administrativa del médico y otros agentes sanitarios. Madrid: Dykinson; 2009. p. 63–8.
18. Vallejo GA. Legal evaluation of risk as a criterion for determining criminal liability of medical professionals. *Rev Colomb Anestesiol* 2017;45 (suppl 2):58–63.
19. Galán J. Responsabilidad civil médica. Pamplona: Thomson Reuters; 2016.
20. Sardinero C. Responsabilidad administrativa, civil y penal por falta de información en el ámbito clínico. Criterios indemnizatorios. Valencia: Tirant lo Blanch; 2016.
21. Roxin C. Derecho penal: parte general. T. I. Fundamentos, la estructura de la teoría del delito. 2nd ed. Madrid: Civitas; 1997.
22. Malanda SR. Responsabilidad penal médica por ausencia de consentimiento informado: Un enfoque alternativo a las tesis dominantes. *Cuadernos de Política Criminal* 2013;110:73–113.
23. Jorge A. La imprudencia punible en la actividad médico-quirúrgica. Madrid: Tecnos; 1990.
24. Romeo CM. El médico y el Derecho penal I. La actividad curativa (Licitud y responsabilidad penal). Barcelona: Bosch; 1981.
25. López-Barja J. Derecho penal. Parte General, II. Introducción a la teoría jurídica del delito. Madrid: Marcial Pons; 2002.
26. Garrido J. Análisis causal del acto médico y su importancia en el consentimiento informado. In: Morillas L, director. Estudios jurídicos sobre responsabilidad penal, civil y administrativa del médico y otros agentes sanitarios. Madrid: Dykinson; 2009. p. 451–60.
27. Choclán J. Deber de cuidado y delito imprudente. Barcelona: Bosh; 1998.
28. Villacampa C. Responsabilidad penal del personal sanitario: atribución de responsabilidad penal en tratamientos médicos efectuados por diversos profesionales sanitarios. Madrid: Thomson Reuters-Aranzadi; 2003.
29. Sanz N. La responsabilidad penal del personal. In: Llamas E, director. Estudios sobre responsabilidad sanitaria. Un análisis interdisciplinar. Madrid: La Ley; 2014. p. 291–340.
30. Rodríguez V. El delito de tratamiento médico arbitrario: una propuesta de *lege ferenda*. *RECPC* 2017;19 3:1–59.
31. Gómez Rivero MC. La responsabilidad penal del médico. 2nd ed. Valencia: Tirant lo Blanch; 2008.