

Medical Responsibility in the Colombian Context: A Review of Negligence from the Legal Framework and Ethical Perspective

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Abstract

This article explores medical responsibility and negligence from an ethical and legal perspective within the Colombian context. It highlights causes of negligence such as deficiencies in professional training and organizational problems. The article emphasizes "objective imputation as key to determining the criminal responsibility of the physician" (Alvarado D. 2019). The objectives include analyzing the current legal framework in Colombia and assessing the link between medical ethics and legal responsibility. The methodology builds upon a thorough examination of specialized literature, including peer-reviewed scientific articles in medicine and law, as well as legal documents and ethical regulations. A targeted search was conducted across various bibliographic databases including Google Scholar, Redalyc, Scielo, Dialnet, Biomed Central, Miguel De Cervantes Virtual Library, and BVS virtual health library.

Keywords: Medical Responsibility, Medical Ethics, Negligence, Objective Imputation.

1. Introduction

The provision of medical services carries an unavoidable ethical and legal responsibility on the part of health experts. This commitment transcends the mere application of medical knowledge and techniques, extending to making informed and contextualized decisions for each specific clinical situation (Martínez, 2019; Gómez & Pérez, 2021).

According to Silva & Martínez (2020), the essence of this responsibility lies in the continuous pursuit of quality in medical care, characterized by avoiding preventable errors, proactively managing risks, and responding effectively to unforeseen situations.

Although medical errors are inevitable, negligence, defined as the lack of meticulousness and attention by the healthcare professional, constitutes reprehensible behavior. This can manifest in various ways, from misdiagnoses to failures in treatment administration (Hernández & Rodríguez, 2017).

When medical negligence occurs, the responsibility falls directly on the involved professional. Medical ethics, backed by legal regulations such as Law 23 of 1981 or Decree 3380 of 1981, require physicians to take responsibility for their actions, acknowledge mistakes, and take corrective measures to mitigate damages.

The Latin maxim "*artifex spondet peritiam artis*" emphasizes that whoever causes harm, by action or inaction, whether through fault or negligence, is obliged to remedy the damage caused.

In this vein, authors such as Méndez (2014) and Pardo (2016) consider that medical negligence is not merely a mistake but incompetence with legal consequences, the severity of which depends on the type of damage and the legal framework of each country.

Although the responsibility usually falls on the professional, it is essential to consider structural factors, such as the precariousness of health systems, which also impact the interaction between the patient and the doctor, as well as the ability to provide high-quality service. (Torres, 2022). The Constitutional Court of Colombia, in judgment T-319/20, highlights that medical negligence, even as an autonomous harm, is susceptible to compensation, demonstrating the importance of service standards (Constitutional Court of Colombia, 2020).

Experts like Amaya (2017) point out that "criminal medical responsibility arises from medical malpractice or infringement of the *Lex Artis*." Other studies, such as that by Artiles Granda, Balmaseda Bataille, and Prieto Valdés (2013), emphasize that negligence can be due to deficiencies in professional training, lack of responsibility and demand by the authorities, as well as as organizational problems.

Objective imputation, according to Ruiz (2011), is essential for determining whether a professional's conduct increases the allowed risk in medical care and whether that behavior is the cause of damage to the patient. This approach has become crucial in cases of criminal medical responsibility, as stated by Pedraza (2020).

Additionally, Vallejo-Jiménez (2017) advocates for a legal risk assessment to establish the criminal responsibility of the physician. This approach involves a detailed investigation, highlighting the need to evaluate the professional's conduct in relation to the permitted risk.

Vera (2013) notes that incompetence, imprudence, and negligence are common forms of medical fault, with significant legal consequences. The lack of technical skills, experience, or necessary competencies translates into incompetence, which can stem from inadequate training, forgetfulness, or lack of practice.

This bibliographic review article addresses medical responsibility and negligence from an ethical and normative perspective, aiming to understand medical responsibility and negligence from a comprehensive perspective that considers the interaction between medical ethics and current legislation. Additionally, it seeks to analyze the existing legal framework in Colombia related to medical responsibility, to ultimately evaluate the connection between medical ethics and legal professional duty in light of the legislation.

This paper is based exclusively on scientific articles reviewed by experts in medicine and law. "The methodology focuses on the thorough review of specialized literature" (Pisanty, I., Urquiza, E. & Vargas, A., 2016), including academic publications, legal documents, and ethical regulations that outline the structural elements of the responsibility that falls on the physician in Colombia.

1.0 What is Medical Responsibility According to Romero (2014)?

To address medical negligence, it is essential to begin by defining the fundamental concept of medical responsibility. This responsibility has various facets, which means that health care providers may encounter legal and ethical consequences in different contexts such as administrative, disciplinary, civil, and criminal, each with its own specific implications and legal requirements. This comprehensive approach leads to an understanding of the legal and ethical dimensions surrounding medical practice and the possible occurrence of medical negligence.

It is clear that medical negligence does not solely arise from the responsibility of an individual (although it is here where the blame usually falls), but there are various factors that correlate. Romero (2014) defines it very well.

Firstly, administrative responsibility is recognized as the set of obligations that health professionals have regarding the effective, ethical, and safe management of resources and administrative processes in medical settings. This dimension encompasses decision-making management related to the administration of clinics or hospitals, supervision of medical and non-medical staff, management of medical records, implementation of "quality and safety policies, as well as the effective coordination of available resources" (Irekia, 2011).

In the medical field, administrative responsibility seeks to ensure that administrative practices and processes comply with ethical, legal, and quality standards. From this, it can be inferred that a doctor's responsibility is permeated by the work environment since it is subject to norms and regulations that must be adhered to.

On the other hand, "disciplinary responsibility is the obligation that health workers have" (Momblanc, L. 2021) to maintain ethical behavior and comply with the standards of the regulatory entities that govern them. This includes adherence to professional codes of ethics, participation in continuing education to maintain and improve skills, and compliance with specific regulations issued by the disciplinary bodies of the medical profession.

In turn, this type of responsibility ensures the quality of medical service and protects the guarantees of the patients. "Law 23/81 and Decree 3380/81 are the regulations that govern medical ethics in Colombia" (Alvarado, D. 2019), and they establish the principles that govern the conduct of the medical professional to ensure it conforms to ethics.

In the civil realm, medical responsibility involves the duty of health professionals to compensate for the harm caused to patients as a result of inadequate or negligent care. In this context, affected patients may seek compensation for damages through civil lawsuits. As previously cited in the judgment T-319/20, the court pointed out that “medical negligence or the arbitrary denial of service constitute, in themselves, unlawful harms, susceptible to compensation, regardless of their causal relationship with other damages” (Constitutional Court, 2020).

Finally, “criminal responsibility carries the possibility that health professionals” (Deza, R., 2022), which also includes those who manage health systems, face criminal legal consequences if it is determined that they have committed illicit acts, such as gross negligence or malpractice, resulting in harm to patients. Criminal medical responsibility calls for the protection of legally protected goods in legal systems, such as life and personal integrity. To better understand this topic, various research studies and investigations have been conducted addressing different aspects of this type of responsibility.

One of the experts who has delved into this topic is Amaya (2017). According to his arguments, criminal medical responsibility arises from medical malpractice or infringement of the *Lex Artis*. This occurs when a health professional does not meet the required medical service standards, leading to circumstances that may result in harm to the patient. In other words, criminal medical responsibility materializes when there is a deviation from accepted medical practice, and this results in acts that contravene the norms and protocols for medical practice.

Medical responsibility is a broad concept that encompasses different aspects or areas, such as administration, discipline, civil, and criminal. These components are interconnected and define the ethical and legal obligations of health professionals.

1.1 What is Medical Negligence According to Artilles Granda, Balmaseda Bataille, and Prieto Valdés (2013)?

Once the concept of medical responsibility and its collective as well as individual implications have been defined, it is pertinent to analyze what medical negligence is in light of authors and legislation.

According to Artilles Granda, Balmaseda Bataille, and Prieto Valdés (2013), omission or failure by a healthcare provider to meet the expected standard of care and competence in their practice results in harm or injury to the patient. Reasons for medical negligence can include deficiencies in professional training, lack of accountability and demand by the authorities, organizational problems, as well as non-compliance with regulations and the lack of foresight regarding typical risks in medical care.

Furthermore, the World Medical Association defines medical negligence as the doctor's lack of conformity with, and failure to meet, the standards of care in treating a patient's condition, or a lack of knowledge or negligence in providing care, directly resulting in an incident that affects the patient.

Castrillon N. (2023) defines it as behavior involving an omission or a breach of the duties incumbent upon a healthcare professional, which generates “a legally disapproved risk that materializes in harm to the patient” (Mercado, M., Buelvas, K., & León, J. 2021). In this context,

medical negligence can be considered as conduct that creates a risk to the patient's health and, therefore, can be attributed to the professional in charge under the theory of objective imputation.

2.0 Objective Imputation in the Context of Medical Responsibility

"The principle of objective imputation is a legal concept used to determine criminal liability in a crime" (Morillo, M. 2018). According to Gunter (1997), this principle establishes that someone can only be considered guilty and, therefore, criminally responsible, if their conduct objectively causes a criminal outcome and if such an outcome can be objectively attributed to their action or omission. Its purpose is to ensure that only those truly responsible for a criminal act are criminally charged, thus preventing unjust or disproportionate attribution of responsibility (Puig, S. 2003).

In the same vein is Ruiz (2011). According to the author, objective imputation is used to determine whether a healthcare professional has acted recklessly or without due diligence, increasing the permitted risk in medical care and if that behavior has been the cause of the harm to the patient.

"In summary, objective imputation invokes the attribution of a result to conduct, regardless of the subjective culpability of the agent; that is, it focuses on the causal relationship between the action or omission and the result, without considering the intention of the agent. Now, in the context of medical negligence" (Puig, S. 2003), it facilitates the assessment of the responsibility of healthcare professionals in cases where a patient suffers harm.

From the above, in certain circumstances, a person may be considered responsible for an outcome if they have created a legally significant risk that results in harm. In the field of medical responsibility, this means that a healthcare professional can be held responsible for harm to a patient if their conduct has generated a prohibited risk that leads to harm to the patient, regardless of whether the professional acted with the necessary diligence and care.

Objective imputation is used to determine if the conduct of the healthcare professional has created a prohibited risk that results in harm to the patient. This involves assessing whether the professional has followed the accepted standards of medical practice (*lex artis*), that is, whether they have applied the practices recognized as appropriate in a specific situation. Even if the professional acts according to the *lex artis*, they could still be held responsible if they generate a prohibited risk that causes harm to the patient.

In this sense, objective imputation in cases of medical negligence focuses on the relationship between the healthcare professional's conduct, the created risk, and the harm suffered by the patient. This perspective seeks to ensure the protection of patients and establish a framework of responsibility that transcends the mere intention of the professional, emphasizing the consequences of their actions or omissions.

In summary, for objective imputation to be configured in medical negligence, it is necessary that 1) there be the existence of real and effective harm caused by the healthcare professional's conduct; 2) an adequate causal relationship between the professional's conduct and the harm, that is, the harm would not have occurred if the professional had not acted in the way they did; 3) the

creation of a legally relevant risk, where the professional's conduct generated a foreseeable and avoidable risk.

Objective imputation has become a powerful tool for resolving situations linked to criminal medical liability, as it allows for a more precise evaluation of whether the healthcare professional's conduct has been the cause of the harm to the patient, considering the concept of permitted risk and the elevation of that risk in medical practice (Pedraza, I. 2020).

Vallejo (2017), in his work "The Legal Assessment of Risk as a Criterion for Determining the Criminal Responsibility of the Physician," points out that there must be a legal assessment of the risk to determine if the doctor has increased the allowed risk in medical care and if that behavior has been the cause of the harm to the patient, which undoubtedly requires that an investigation be conducted. Pedraza (2020) once again agrees with this idea.

It is important to highlight that objective imputation does not focus solely on the causal relationship between the doctor's conduct and the harmful outcome but also evaluates whether the professional has assumed a position of guarantor with respect to the patient and whether they have fulfilled the objective duty of care in their practice.

From the foregoing, the responsibilities of the doctor are then clarified. Regarding this, Vera (2013) indicates that incompetence, recklessness, and negligence are common forms of medical fault, with severe legal implications in the criminal sphere. The total or partial lack of technical knowledge, experience, or skills necessary for the practice of the profession translates into incompetence, which can arise from a lack of training, forgetfulness, or lack of practice.

Similarly, recklessness is manifested in the hasty execution of actions without due precautions, without assessing risks and carrying out dangerous practices that put the health and integrity of the patient at risk. Finally, negligence is directly related to the non-compliance or omission of professional principles.

These forms of medical fault, when duly proven, can trigger serious consequences for the healthcare professional in the criminal sphere, such as disqualification, detention, and sanctions. Thus, medical incompetence is based on the lack of capabilities, knowledge, and skills necessary to carry out medical practice, generating prohibited risks, dangers, and harmful outcomes.

Additionally, negligence arises when, despite having full knowledge, management, and awareness of the methods, techniques, and therapeutic procedures, the healthcare professional does not implement them correctly, affecting the health of the patient. Finally, medical recklessness is characterized by the execution of a medical act without the necessary diligence and without taking the necessary precautions, which can result in harm to the patient's health that could have been avoided or anticipated.

2.1 Objective Duty of Care

As outlined by Castilla (2015), the principle of trust establishes guidelines in a context of self-regulation and self-determination, where each active individual strives to perform their duties according to the protocols set forth in the procedure manuals of each medical specialty. In this

process, care is taken not to overlook the possibility that the actions of another active individual could lead to detrimental outcomes, endangering the life or integrity of patients.

On the other hand, the *lex artis*, as described by Amaya (2017), "is a highly significant tool for the systematic structuring of medical responsibility as a legal institution, as it imposes on the medical professional the duty to act diligently in each of their actions, for the benefit of the patient's and humanity's well-being, avoiding pain and suffering" (Mercado, M., Buelvas, K., & León, J. 2021).

In this context, the objective duty of care in medical practice defines several elements that allow for the evaluation of the quality and relevance of medical practice in technical, scientific, and procedural areas, always with the goal of improving the health condition and well-being of the patient as a passive recipient.

According to Solórzano (2014), "the active individual is directly linked to the doctor's position of guarantor, while the passive individual refers to the patient. In other words, the responsibility to maintain the line of objective medical care involves a complete and adequate knowledge of the techniques, as well as experience in the execution of each medical procedure" (Mercado, M., Buelvas, K., & León, J. 2021).

Regarding the criminal responsibility associated with medical practice, according to Castilla (2015), criminal law acts as a protection mechanism in social relations, establishing rules of coexistence and prescribing sanctions for those who commit punishable actions. This includes any action that infringes the rights protected by the constitution or violates the law. Therefore, it is necessary to demonstrate that the medical professional has breached the required objective duty of care to consider a crime of negligence.

In summary, medical practice is a complex discipline that requires comprehensive knowledge of techniques and adequate experience in performing each medical procedure. The *lex artis* and the principle of trust are fundamental in defining the general technical standards of the objective duty of care in medical practice. Additionally, the criminal responsibility associated with the exercise of the medical profession requires proving the violation of this objective duty of care to be considered negligence.

3.0 Colombian Legislation on Medical Negligence and a Comparison with Spanish Law

Law 23 of 1981 regulates medical ethics in Colombia and is particularly important in cases of medical negligence. This law establishes principles such as beneficence, non-maleficence, autonomy, and justice, which should guide medical practice. Additionally, it defines the obligations of physicians towards their patients, including the provision of adequate and high-quality medical care.

Decree 3380 regulates Law 23 of 1981. It outlines the obligations of physicians regarding the patient, which includes the duty to provide adequate and high-quality medical care. Furthermore, it establishes penalties for physicians who violate ethical norms, which is particularly relevant when determining medical liability.

Decree 1011 of 2006 establishes the public health surveillance system in Colombia. This decree includes provisions that require health service providers to report notifiable diseases, the creation of a health information system, and the regulation of public health surveillance activities. Additionally, it defines the responsibilities of health service providers in the prevention and control of communicable diseases, including the obligation to provide adequate and high-quality medical care.

Moreover, the jurisprudence of the State Council, highlighted in a ruling on a guardianship action relevant for assessing medical liability in cases of negligence, adds to the above. In this ruling, the State's responsibility in the death of a patient caused by a nosocomial infection acquired during her hospitalization was examined.

The State Council concluded that the State was responsible for the patient's death, as an unauthorized risk to her health was generated by not taking the necessary measures to prevent the nosocomial infection, a responsibility attributed to the hospital and, particularly, to the health system. Despite these structural causes, the conduct of the medical staff was also evaluated, and it was determined that there was a failure in the provision of health services.

This case is representative in Colombia, as it underscored the importance of assessing the conduct of medical staff in situations of negligence and the need to implement preventive measures to avoid unauthorized health risks to patients. Furthermore, it demonstrates how the evaluation of the health professional's conduct, in relation to the outcome of their actions and the risk generated for the patient, subsequently provides evidence for objective imputation in assessing medical liability.

In Spain, the concept of patrimonial responsibility is discussed when there is proven damage by the health administration, which is equivalent to the health system in Colombia. In this regard, Martinez (2023) specifies some fundamental requirements for such protection to exist.

Firstly, the notion of "compensable injury" is highlighted. Not all damage is considered compensable; for this classification, the damage must be tangible, economically quantifiable, and individualized. Moreover, it must be contrary to the law, meaning it must have been caused by the normal or abnormal functioning of public services in the health sector. Although this aspect is regulated by other legislation, it also implies a responsibility different from that of the physician.

On the other hand, "imputation of responsibility" occurs when the health administration assumes economic responsibility for repairable damage caused by the normal or abnormal functioning of public health services. This situation can arise from cases of negligence or medical malpractice that result in harm to patients.

An additional crucial aspect is "causality," which requires a clear connection between the repairable damage and the normal or abnormal functioning of public health services. In other words, the damage must have been directly caused by the actions or lack of actions of the health administration.

Finally, "fault or negligence" determines the establishment of economic liability when there is evidence of fault or negligence on the part of the health administration. This occurs when

professional duties or the *lex artis ad hoc*, which includes the set of knowledge and techniques that should be applied in each specific case, are breached.

For economic liability to arise in the health sector, several requirements must be met: the existence of repairable damage, the attribution of responsibility to the health administration, the existence of a causal relationship between the damage and the functioning of public services, and evidence of fault or negligence by the health administration.

4.0 The Protection of Life According to the *Lex Artis*

Medical criminal liability is founded on the protection of legally protected rights within legal systems, such as life and personal integrity. This form of liability seeks to establish regulations and limits that ensure the safety and well-being of patients in the medical field.

The legal system recognizes the importance of medical work and, therefore, imposes a series of obligations and ethical standards to ensure that healthcare professionals act diligently and responsibly. These ethical standards are reflected in the set of rules and medical practices that professionals must follow, known as *lex artis*. This set of rules, as Vásquez (2010) aptly points out, is "a jurisprudential construction," encompassing the knowledge, skills, and procedures considered appropriate and necessary for competent and ethical professional practice. It includes both technical aspects and deontological norms that must be followed in providing medical care.

In the medical field, these regulations are used to assess the excellence of care and to determine whether a professional has followed recognized criteria. The implementation of these guidelines is essential to ensure the quality and ethics of patient care.

The importance of these regulations in the criminal liability of medical acts is seen in the need to apply them rigorously and adapt them to the particular circumstances of each case. This influence is evident in cases of involuntary manslaughter due to medical acts, where the application of these rules and the theory of objective imputation play a crucial role in resolving cases.

The importance of these rules in the legal and medical fields lies in their role as a guide for judging the due diligence required in medical practice. Their application allows for assessing whether healthcare professionals have reasonably followed recommended procedures and methods, considering the specifics of each clinical situation.

Casanova (2013) addresses the role of *lex artis* in medical practice by stating that it is a guide for judging the due diligence required in medical practice and its application allows for evaluating whether healthcare professionals have reasonably followed recommended procedures and methods, considering the specifics of each clinical situation.

Moreover, the author adds another highly valuable component: the patient's decision-making freedom and their right to be properly informed about the medical procedures to be performed. As has been proven in some cases, due to individual errors by medical staff, this procedure is often overlooked, which must invariably have written support for both authorization and rejection. Indeed, Gala (J., 1999) noted two decades ago that "informed consent is a

manifestation of the fundamental right to patient integrity" that involves a lack of information about the risks of the medical act, which can materialize.

However, what does informed consent imply? According to De Montalvo (2011), it specifically refers to autonomous authorization to carry out a particular medical intervention. In this process, the patient, capable of understanding and free from external influence, gives their consent voluntarily and deliberately. This not only implies that the patient accepts and follows a medical recommendation but also actively participates in the decision-making related to their diagnosis and treatment.

Informed consent is so crucial in all spheres of medical treatments that this step cannot be overlooked. A study by Velasco (2020) outlines three dimensions of informed consent and patient autonomy in intensive care settings.

"The patient's autonomy to make decisions according to their values and preferences, especially in relation to a specific treatment after receiving relevant information; the active search by healthcare professionals for the best options based on the patient's preferences, which reflects beneficence; and the establishment of a clinical relationship founded on respect, truthfulness, and loyalty, are fundamental aspects of the deliberative process. Studies have shown that patients wish to actively participate in decision-making, feeling convinced that the final decision should be theirs, even when faced with decisions that involve the possibility of death." (Da Silva, L., et al., 2021).

The introduction of informed consent has led to a significant change in the dynamics of the doctor-patient relationship. Previously, a paternalistic model predominated where the doctor, due to their greater preparation and knowledge, made decisions for the patient's benefit, often without considering their opinion. However, with informed consent, there has been a shift towards a model in which the patient has the exclusive right to decide on their treatment, guided by the principle of autonomy.

According to Sánchez (2009), informed consent (IC) represents a new orientation in the development of clinical interaction, demanding a higher level of respect for individuals compared to the past. IC should function as a safeguard for the patient's moral autonomy and not merely as a means to avoid legal responsibilities. This fundamental principle of IC prioritizes ethics over its legal dimension.

It is noteworthy that informed consent is an ethical practice, before being a legal one, whose purpose is always to prioritize the patient's will in light of clear truth, from which the risks of a procedure and the real possibilities of success or adverse situations are presented. However, there are various challenges and points for improvement, especially in countries where health or sanitary systems are not as efficient.

The Importance of Truthful and Complete Information For informed consent to be valid, it is crucial that the information given to the patient is accurate, comprehensive, and easy to understand. This requires the medical professional to clearly and accessibly explain the nature of the patient's illness, the risks and benefits of each available treatment option, as well as the potential consequences of opting not to receive treatment.

The Patient's Capacity to Make Decisions It is important to assess the patient's capacity to understand the provided information and make rational decisions. In some cases, such as with patients who have cognitive disabilities or are minors, it may be necessary to have the consent of a legal representative.

Effective Communication Between Doctor and Patient This is crucial in the informed consent process, which should be an open and honest dialogue. It is essential that the doctor listens to the patient's concerns and questions and responds in a clear and understandable manner. According to Cañete, Guillem, and Brito (2012), "informed consent represents a communication process between the healthcare professional and the user, which concludes with the authorization or refusal of a specific clinical intervention" (p. 125).

They also note that communication can be fragmented when the medical staff and the patient speak different languages, for which they state, "for this reason, international documents emphasize the need to clarify and simplify the language used in the written document and in the information verbally provided to the subjects" (Cañete, R., Guillem, D., & Brito, K; 2012).

Additionally, another factor that can lead to a breakdown in communication is the limited time usually available for medical consultations and the technical language used. Fink et al. (2010) showed that time is a high-value predictor for patient understanding. The more time, the better the understanding; however, unfortunately, the rush of medical staff prevents allocating considerable time for informed consent.

Furthermore, Pico and Neil (2022) explained that the technical language typical of medicine and the amount of information given in a short time drastically interfere with the understanding of informed consent.

Informed Consent in Special Situations There are some special situations in which the informed consent process can be more complex. For example, in emergency situations or when the patient is unconscious, it may be imperative to make decisions without the patient's explicit consent. In such circumstances, the doctor must act in the best interest of the patient and base their decisions on the ethical principles of beneficence and non-maleficence.

Informed consent, as both an ethical duty and a legal mandate, implies that the patient actively participates in clinical decisions, which has significantly changed the traditional doctor-patient relationship.

In fact, the legal analysis of how these regulations impact the criminal liability of diagnostic errors provides a detailed view of their application in the legal realm. This analysis helps understand how these rules affect the objective evaluation of the legality of medical acts, as well as the attribution of responsibilities in cases of incorrect diagnosis, which may constitute crimes against life, physical integrity, and health due to medical negligence or erroneous diagnoses.

Conclusion Ethics is a fundamental factor in medical responsibility, as it guides the actions and decisions of healthcare professionals in their interactions with patients. However, it is important to highlight that medical responsibility goes beyond merely following good practices; it involves complying with specific procedures that are mediated by the legislation in force in each country.

In this sense, the *lex artis*, often mentioned in this context, is a manual that establishes how to act in various clinical situations with patients.

Medicine, by its nature, carries certain inherent risks, and it is essential that patients are aware of this. Therefore, it is required that healthcare professionals follow best practices and that health systems implement measures to ensure the safety and well-being of patients at all times.

Ethics plays a central role in medical responsibility, as it guides the actions and decisions of healthcare professionals in their dealings with patients. Its importance lies in establishing fundamental principles that go beyond simple guidelines, which affects the integrity and respect for the rights and dignity of those served by medical professionals. Ethics generates trust and mutual respect between doctors and patients.

While there are numerous factors that can influence medical responsibility, many of them can be prevented through the application of solid ethical principles and compliance with the technical precepts established in the legislation and specific manuals of each medical area. By integrating ethics, legal norms, and technical standards into clinical practice, quality, safe, and ethical medical care is promoted, benefiting both patients and healthcare professionals, thereby strengthening trust in the healthcare system as a whole.

However, it is crucial to understand that medical responsibility is not limited solely to observing ethical practices. It goes further by involving the compliance with specific procedures that are mediated by the legislation in force in each country. Here is where the *lex artis* comes into play, providing a clear regulatory framework for medical practice.

In light of the technical, ethical, and legal complexities, medical responsibility invokes various accountable parties, although it is attributed to those who lead or order a procedure. As previously noted, to determine the responsibility of an action, it is more than necessary to conduct rigorous research within each legal system. Criminal liability, however, will be mediated by the unrestricted application of the applicable norm to each procedure and what legal mandates recognize as good medical practices. All of the above invokes ethics, as a premise of acting with rigor, professionalism, and care for the patient.

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