Legislation and Practice Regarding Mistakes, Criminal Offenses, And Recorded Cases in The Field of Medicine

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Abstract

In contemporary times, the escalating frequency of medical errors and criminal transgressions poses a pressing concern for both patient safety and the medical fraternity. This emergent issue places healthcare practitioners in a precarious position, subjecting them to potential legal repercussions and diminished professional morale. The peril emanates not only from an inadequately secure healthcare system but also from legal ambiguities that contribute to an environment of uncertainty. Jurisprudential interpretations, particularly within the realm of criminal law, about instances involving the culpability of medical professionals for errors and criminal acts have engendered a perplexing landscape. Notably, the legal framework has exhibited a disparate treatment of the concept of medical error.

This study employs a methodology combining case studies, and a comprehensive literature review to analyze documented cases, revealing a divergent approach within the justice system. Practitioners are subjected to punitive measures resembling those meted out for negligent medication practices. This incongruity in legal categorization results in multifaceted challenges. Sanctions have deleterious ramifications for the rehabilitation of the implicated individual, impacting personal integrity and professional relationships and eroding credibility vis-à-vis institutional trust. The confluence of these factors accentuates the urgent need for a more nuanced and coherent legal framework to address instances of medical error, safeguarding both the integrity of healthcare professionals and the broader healthcare system. This research calls for a comprehensive reformulation of legal paradigms, rooted in a nuanced understanding of medical errors, to foster a more equitable and just environment for healthcare professionals, enhancing patient safety and overall healthcare system integrity.

Keywords: patients, error, medical staff, legislation, sanctions

1. Introduction

When deliberating matters of life and health, objectivity and emotional detachment become challenging, as human judgment often intertwines with a deep sense of responsibility in cases where patients experience adverse outcomes. Instances involving the loss of life or deteriorating health tend to be labeled as medical mistakes, negligence, or even criminal offenses, all of which, under Albanian legislation, fall within the purview of negligent treatment as per Article 96 of the Criminal Code of the Republic of Albania (1995, as amended). This singular provision, alongside several more specific articles, addresses certain contexts. Notably, Article 93 and Article 94 of the Albanian Criminal Code delineate legal consequences related to the termination of pregnancy without consent and termination carried out in unauthorized settings, respectively. Additionally, Article 97 outlines the legal repercussions of the failure to assist in health institutions.

The legal system and the judiciary serve as indispensable mechanisms in rendering equitable, impartial, and objective judgments based on established legal rules and principles. This framework fosters clarity and objectivity on a case-by-case basis, contributing significantly to legal certainty.

While recognizing that doctors may not always succeed in saving a patient's life, societal expectations mandate that they employ their specialized knowledge and skills judiciously, prioritizing the patient's best interest. A recent study from the Johns Hopkins University School of Medicine (2016) posits that medical errors constitute the leading cause of death in the United States, with an annual toll of 251,454 deaths, surpassing the annual fatalities from car accidents nationwide.

Considering the multifaceted issues and consequences arising from legal implications outlined in the Albanian Penal Code, a call for revisiting Article 96 emerged from the Doctors' Order in 2000. The proposal sought to delineate medical negligence explicitly, differentiating it from medical errors. The recommended alterations encompassed revising procedures related to scientific evidence, advocating for the involvement of not only legal professionals but also expert doctors in relevant fields.

1.1 Literature review

The examination of medical errors and their legal implications is significantly enhanced through the integration of diverse theoretical frameworks. Systems theory provides a comprehensive paradigm for dissecting the interrelated components within healthcare systems that contribute to errors. A nuanced comprehension of systemic factors facilitates the development of interventions aimed at bolstering the overall safety of healthcare delivery, with an emphasis on addressing foundational causes rather than singular instances of human error

(Checkland, 1981; Senge, 1990). Human factors theory elucidates the dynamics of the interaction between individuals and their environments, with a specific focus on cognitive and ergonomic determinants influencing the performance of healthcare professionals. This perspective is indispensable for identifying contributory elements such as fatigue, workload, and communication issues, thereby enabling targeted interventions to ameliorate the human aspects inherent in healthcare systems (Reason, 1990; Carayon & Gurses, 2008).

The just culture framework cultivates an environment fostering transparency wherein individuals feel secure reporting errors devoid of apprehension regarding punitive measures. Grounded in principles of equity and accountability, just culture seeks a balanced approach, reconciling individual responsibility with systemic enhancement. This approach advocates for a learning culture that encourages open discourse surrounding errors, thereby contributing to overall patient safety (Dekker, 2007; Marx, 2001). Ethical decision-making models, exemplified by principles articulated in biomedical ethics, provide a conceptual lens through which the ethical dimensions of medical errors can be scrutinized. Deliberation of principles such as autonomy, beneficence, non-maleficence, and justice serves as a framework for evaluating the intricate ethical dilemmas confronted by healthcare professionals in the aftermath of errors (Beauchamp & Childress, 2019; Jonsen et al., 2015).

Cultural-historical activity theory (CHAT) delves into the socio-cultural facets influencing activities and practices within healthcare. An exploration of the cultural and historical context is imperative for comprehending how shared norms, values, and historical factors shape practices related to errors. This perspective casts illumination on the broader organizational and societal influences governing the occurrence of medical errors (Engeström, 1987).

Within the academic discourse, several studies collectively contribute to a nuanced comprehension of medical errors, human factors in healthcare, legal consequences for healthcare practitioners, and the overarching landscape of medical malpractice litigation. These studies underscore the imperative of addressing systemic intricacies, embracing a comprehensive systems approach, and navigating the intricate legal dimensions surrounding medical errors. Carayon et al. (2014) adopt a human factors systems approach to healthcare quality and patient safety, thereby elucidating the role of human factors in the genesis of medical errors and accentuating the significance of a systemic vantage point in augmenting the safety and quality of healthcare delivery. Makary and Daniel (2016) conducted a seminal study on medical errors that accentuates medical errors as a substantive contributor to mortality in the United States, ranking as the third leading cause. The research underscores the urgency of heightened attention to comprehending and mitigating medical errors to enhance patient safety. Dove and Schneider (2014) engage in a discourse concerning the escalating trend of prosecuting medical malpractice cases in the United States. Their work sheds light on the legal ramifications confronting healthcare practitioners and provides insights into the evolving terrain of medical malpractice litigation.

Studdert et al. (2006) undertake a comprehensive examination of claims, errors, and compensation payments in medical malpractice litigation. Their study offers valuable insights into the multifaceted dynamics influencing malpractice claims and compensation processes, thereby contributing to a nuanced understanding of the complexities inherent in medical malpractice cases.

2. The approach of medical error and negligence in the Albanian legislation and the recorded cases

Within the realm of the Albanian legal doctrine, the term "medical errors" remains conspicuously absent, with contemporary discourse addressing such occurrences as inherent facets of medical carelessness or negligence, as delineated in Article 96 of the Albanian Criminal Code (1995, as amended). The legal doctrine emphasizes the special legal protection accorded to human life and health in the healthcare domain. This is manifested in the criminalization of actions or inactions by medical practitioners or pharmacists that result in severe harm, endanger the patient's life, or lead to fatality, with a requisite emphasis on establishing the causal connection.

The Aydoğdu v. Turkey case (30 August 2016) serves as an illustrative example, showcasing the legal ramifications for medical staff concerning the causal connection. Instances of negligent treatment include but are not limited to, the imprudent determination of diagnoses, prolonged denial of prescribed medication, failure to implement recommended therapies, or the administration of treatments inconsistent with established protocols. Judicial scrutiny extends to encompass all actions and inactions of doctors and medical personnel throughout the prevention, diagnosis, and treatment processes (Elezi, 2002). Decision No. 15, dated January 23, 2013, from the Criminal College of the Supreme Court Actions, mandates the evaluation of actions or inactions based on the conclusions of medical-legal expertise reports, serving as foundational evidence in trials involving medical negligence.

A fundamental condition for the existence of the criminal offense outlined in Article 96 of the Albanian Criminal Code is the occurrence of consequences, such as serious harm to the patient's health, endangerment of the patient's life, or causing the patient's death. These consequences parallel those outlined in the provision for “serious injury” in Article 88 of the Criminal Code. The establishment of a causal link between the actions or inactions of medical practitioners and the resultant harm is imperative. The case of Asiye Genç v. Turkey (January 27, 2015) exemplifies a situation where negligence resulted in the death of a baby transferred between hospitals without receiving adequate treatment. The subjective dimension of this offense, according to legal doctrine, is rooted in carelessness (Elezi, 2002). Committing a criminal offense with carelessness implies a person, while not desiring the consequences, foresees their potential occurrence and either naively hopes to avoid them or fails to foresee

them, despite having the opportunity to do so. Decision No. 15, dated January 23, 2013, and outlines two forms in which carelessness manifests as an element of guilt: excessive self-confidence and negligence.

Excessive self-confidence denotes a form of carelessness where an individual anticipates harmful consequences from their actions or inactions, does not desire these outcomes, but unwarrantedly hopes to avoid them. A case involving a pediatrician at the Përmet City Hospital in Albania, identified as defendant F. P., illustrates this form of carelessness. The court decision (no. 23, dated April 10, 2014) declared the defendant guilty of committing the criminal offense by negligence in the form of excessive self-confidence. Conversely, negligence is characterized by a person failing to foresee the consequences of their actions or inactions, despite being obliged and having the opportunity to do so.

In a comparative context, Italian criminal law lacks a specific criminal offense for negligent treatment, in contrast to the Albanian legal framework. Practical cases in Italy, such as the Parrillo v. Italy case (Decision of the ECoHR, August 27, 2015), involve interpretations of provisions related to injury or murder as crimes against health and life. The court convicted a doctor for performing an intervention without the patient's consent, classifying the behavior as abusive. This legal stance redefines the attribution of complicated guilt in surgical interventions, particularly when performed without patient consent, subject to specific conditions (Demneri, 2014). Addressing the issue of patient consent, the Glass v. United Kingdom case (2004) emphasizes the necessity of obtaining consent from legal representatives when a patient is unable to provide consent or refuse medical treatment, except in cases of emergency. The court recognizes the legal authority of a patient's legal representative, as demonstrated in this case involving a child operated on due to respiratory complications. Emphasizing the contractual nature of medical treatment between the patient and the doctor, any therapy administered without the patient's consent is deemed unauthorized and constitutes a potential criminal offense (Guidelines for Patient Orientation, 2016). The Albanian laws on mental health (2012) and the Code of Medical Ethics and Deontology (2011) explicitly outline the obligation to obtain patient consent before subjecting them to medical treatments or research activities. This obligation extends to cases involving mental disabilities, with legal guardians exercising patient rights for minors.

Initiatives in 2016 aimed at amending the Criminal Code, including provisions related to negligent medication, sought to redefine the limits of negligent medication by expanding its scope. Proposed changes introduced a criminal offense titled “Breach of medical ethics and alternative medical treatment,” encompassing actions or inactions contrary to the requirements of the code of professional ethics that cause significant harm to the patient's health. While these proposals addressed fines, removal of the right to practice the profession, and compensation for damages, they were not enacted and remained within the draft act by the Ministry of Justice.

A more recent proposal in 2019, addressing the amendment of Article 96, introduces a distinct category titled “Negligence in medical treatment.” The proposed content outlines specific

penalties based on the severity of the consequences, distinguishing between cases endangering life or causing permanent mutilation and those resulting in death. This proposed amendment awaits further examination and potential implementation.

The discourse surrounding medical negligence within the Albanian legal framework reflects ongoing efforts to delineate and refine the parameters of negligent treatment within the Criminal Code. Amendments, proposals, and jurisprudential considerations underscore the intricate interplay between legal frameworks, medical ethics, and patient rights in adjudicating cases of medical negligence. These evolving legal perspectives aim to strike a balance between safeguarding patient interests and ensuring accountability for medical practitioners, fostering a framework aligned with international standards and principles.

3. International practice and jurisprudence of the European Court of Human Rights (ECtHR)

Medical errors pose a significant challenge to public health and patient safety within the healthcare system, underscoring the need for a clear, comprehensive, and widely accepted definition. The term “malpractice” or bad medical practice is employed to describe a failure to act properly or legally in one's professional capacity, often leading to injury or loss. Although the American system provides a more extensive definition, the essence remains consistent, defining malpractice as the failure of a doctor or any other professional to perform their job with a reasonable degree of skill, causing damage or loss (Oxford Dictionary, 2023).

In 1999, the Committee on the Quality of Health Care in America, through a report by the Institute of Medicine (IoM), defined medical error as the failure of a planned action to be completed as intended or the use of an incorrect plan to achieve a specific purpose. This includes execution errors, where planned actions are not carried out, and planning errors, involving the use of incorrect strategies. However, Grober and Bohnen (2015) argue that this definition is incomplete as it predominantly addresses errors attributed to actions and neglects cases where errors result from actions not taken. Medical errors are often referred to in various forms, such as harmful episodes involving unexpected events, complications, and accidents. In contrast, unwanted damage to the patient caused by medical management refers to the adverse consequences of hospital care, leading to unintended injury, complications, disability, death, or prolonged hospital stays unrelated to the patient's underlying illness.

Distinguishing medical errors from adverse consequences during treatment that are not due to negligence is crucial. In such cases, healthcare professionals, including doctors, nurses, or healthcare workers, adhered to an acceptable standard of care. An example of a medical error might involve treating a patient with a common antibiotic to which the patient is allergic, leading to further complications. However, if this crucial information is not documented in the patient's medical record or history, indicating the patient's allergy, the act would not be

considered negligent (Altuğ and Others v. Turkey, 30 June 2015). On the other hand, if the doctor was aware of the risk of an allergic reaction and prescribed the antibiotic without considering more suitable alternatives, a case for medical negligence could be established (Šilih v. Slovenia, 9 April 2009).

Foreign legal practices have established that negligence can be attributed to various medical professionals. Surgeons and anesthesiologists may be negligent in administering medical procedures to prepare patients for surgery, performing procedures without proper patient consent, or making preventable mistakes during procedures. Radiologists and oncologists can be considered negligent when they fail to diagnose cancer promptly. Hospital nurses and nursing home healthcare staff may be negligent when they fail to communicate crucial information about a patient to the attending physician or neglect to record essential data in the patient's medical chart. Primary care physicians can be deemed careless if they prescribe the wrong medication for a patient or neglect to consult with a medical specialist regarding the patient's condition. Obstetrics and gynecology, like other surgical specialties, are particularly susceptible to malpractice claims, as evidenced by a study reporting that 89% of American College of Obstetricians and Gynecologists members had faced lawsuits during their careers (Chervenak, 2007).

In the case of Valentin Campeanu vs. Romania on April 9, 2013, the victim, an 18-years-old boy abandoned at birth and placed in an orphanage, was diagnosed with HIV and a severe mental disability as a child. The European Court of Human Rights (ECHR) concluded that there was a violation of Article 2 of the ECHR (right to life) in both substantive and procedural aspects. The court specifically noted that the victim had been placed in medical institutions ill-equipped to provide adequate care for his condition and had been transferred from one unit to another without a proper diagnosis.

Under Article 2 (right to life) of the Convention, positive obligations require states to enact binding regulations for hospital institutions, adopt appropriate measures to safeguard the lives of patients and establish an effective independent judicial system to determine the cause of death for patients under the care of medical professionals, whether in the public or private sector. This obligation is evident in various cases, such as Mehmet Şentürk and Bekir Şentürk vs. Turkey on April 9, 2013. This case involved the death of a pregnant woman due to errors by medical staff at different hospitals and the subsequent failure to provide her with emergency medical treatment when her critical condition was known. The Court, given its findings on deficiencies in the criminal procedure, also identified a violation of the procedural aspect of Article 2.

The failure of a doctor and a hospital to meet healthcare standards inherently constitutes a liability. A wrongful act or breach of right is considered a civil wrong as opposed to a contractual obligation. Thus, a patient’s right to receive medical care from doctors and hospitals is essentially a civil right (Pandit and Pandit, 2009). The assumption that medical errors can be reduced or eliminated by identifying individuals at fault and disciplining them carries a

significant drawback. This judgmental attitude makes healthcare workers reluctant to report errors due to fear of job loss or other forms of punishment. Consequently, hospital managers and others concerned with patient safety often lack an accurate picture of how frequently certain types of medical errors occur (Institute of Medicine (US), 2000).

In the case of Codarcea v. Romania on June 2, 2009, the applicant specifically complained about the length of the criminal proceedings initiated as a civil party against a doctor due to the adverse consequences of a series of operations. The court considered nine years, six months, and 23 days between the initiation of the procedure and the application seeking compensation to be excessively long, resulting in a violation of Article 6 (the right to a trial within a reasonable time) of the Convention.

In Albanian legislation, the civil liability of doctors stems from causing damage (Demneri, 2014). With the new amendments to the Code of Criminal Procedure in the Republic of Albania (2017), Article 58 provides the right to trial a civil suit in a criminal process. This aligns with the new spirit of the proposed provisions for medical negligence, unequivocally providing compensation for damage in addition to other forms of interference.

French criminal law, along with Italian law, offers a broader range of access to criminal prosecution in cases of personal injuries caused by negligence. Victims may choose to use the criminal process as a civil party to obtain injury compensation rather than filing a civil claim analogous to a medical malpractice claim (Kazarian, 2014). However, the Albanian criminal code does not specifically define the lack of proper qualifications of medical staff specialists, interns, doctors, or pharmacists as a distinct form of negligence. In 2016, there was an attempt to include the lack of proper qualification of doctors as an element of a criminal offense, specifically in the provision proposed to be added to the Criminal Code titled "Fraud in medical treatment," which, as discussed earlier, remained within the framework of the draft act.

In the case of Reynolds v. United Kingdom on March 13, 2012, the applicant complained that there was no effective mechanism available to her to determine civil liability for the allegedly negligent care of her son and to obtain compensation for her loss. The European Court of Human Rights (ECoHM) found a violation of Article 13 (right to an effective remedy) concerning Article 2 (right to life) of the Convention. The court determined that the applicant did not have any legal remedy available for her non-material loss.

Criminal liability is excluded for subjects who acted in fulfillment of healthcare criteria, but the consequences resulted from external circumstances. Conversely, the contractual responsibility of public or private health institutions subjects the action against them to the usual ten-year period provided by Article 2946 of the Civil Code.

4. Conclusion

Health professionals may be vulnerable to making mistakes due to various reasons and circumstances. Medicine, being a skill-based profession, is constantly at risk of human error.

The challenge lies in identifying and preventing these errors, a process that is still in its early stages within the medical field.

The primary difficulty is recognizing when mistakes occur. Many errors made by healthcare professionals go unnoticed, as they often do not lead to an obvious negative outcome. Penalizing hospitals and healthcare providers for adverse events could lead us in the wrong direction in treating and preventing future medical errors (Kwok, 2012).

For effective progress, medical, legal, and governmental institutions must collaborate to shift the culture from guilt towards responsibility. Overcoming this challenge will enable healthcare institutions to measure all errors, regardless of whether they lead to undesirable outcomes, thus providing the most useful target for process improvement.

Medical errors represent a significant public health problem and pose a serious threat to patient safety. Raising awareness about the frequency, causes, and consequences of errors in health is crucial to improving understanding and developing practical solutions and preventive strategies (Grober and Bohnen, 2005).

The financial impact of medical errors burdens hospital budgets, as there is usually no special fund or separate item allocated for such cases. In Albania, international experiences offer various solutions, ranging from ensuring medical staff through relevant health institutions to individual insurance for doctors for medical errors. Some countries, like Scandinavian nations, have patient insurance funds, while others, like the German system, resolve cases out of court through advisory committees that examine and provide solutions to complaints in the majority of cases. Interventions in the management of provider institutions, especially hospitals, are recommended.

Key recommendations include:

- Legal interventions are in line with recent changes in criminal provisions, extending to organic healthcare laws and ethical codes.
- Establishing a separate budget item and insurance for compensating damages from medical errors, accompanied by the development of a dedicated law for insuring the medical profession.
- Enhancing hospital autonomy and management.
- Standardizing documentation and reporting of medical incidents and errors.
- Ensuring more accurate and substantiated documentation of all performed medical procedures.
- Implementing medical guidelines and protocols.
- Drafting and mandatorily implementing manuals related to “patient safety and clinical risk management.”

In conclusion, a collaborative and comprehensive approach involving legal, financial, and procedural aspects is necessary to address and prevent medical errors effectively. The recommendations aim to create a robust framework that ensures accountability, improves patient safety, and provides mechanisms for fair compensation and resolution.

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