Permissible Risk in Medical Malpractice – the Criminal Law Perspective

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Abstract

The present paper deals with permissible risk in the context of potentially criminal conduct by healthcare professionals. In practice, we have come across several cases involving wrongful death or bodily harm committed by doctors, and in most of these cases the doctors have claimed strict compliance with professional standards. Although some of them ended up in the prosecution phase, a significant number of defendants were convicted. Also, checking the case law in the field, only 8% of cases of culpable homicide, respectively culpable bodily injury, ended with acquittals, acquittals that were wrongly based, as we will show in the article, on the provisions of Article 16 para. 1 letter b) sentence II of the Criminal Procedure Code. Romanian jurisprudence also reveals that defendants who have this status do not follow the procedure of admission of guilt, invoking precisely the respect of the professional standard, and the practice of the courts is in the sense of lack of guilt in this context, a solution that is incompatible with the simplified procedure of admission of guilt.

The aim of this paper is to clarify the concept of permissible risk and to frame it correctly within the architecture of the offence. At the same time, we will analyse a number of cases in the case law where either a breach of the professional standard has been found or where it has been held that this standard has been respected by the doctor.

Keywords: *criminal law; permissible risk; professional standard; healthcare professionals; lack of guilt*

I. Initial issues

The permissible risk is not regulated by law but it`s classified in the doctrine as a ground for excluding wrongdoing because conduct involving a danger of harm to legal values is nevertheless permitted or authorized by law, provided that a certain level of risk is not exceeded because precautionary or control measures are taken to keep it within socially and legally acceptable limits in a balancing of interests[1].

This concept is closely related to the theory of objective imputation of the result, considering that imputation will be excluded when the action that caused the result does not exceed the limits of the risk allowed by law. We note that the Argentinian author E. Bagicalupo links permissible risk to typicality, more precisely to causality[2]. Thus, foreign doctrine speaks of those risks that society tolerates because they are

[1] G. Jakobs, *Derecho penal. Parte general. 2ª edición ampliada y corregida*, trad. de Joaquín Cuello Contreras y José L. Serramo González de Murillo, Editorial Marcial Pons, Madrid, 1997, p. 44.

[2] E. Bagigalupo, *Derecho penal. Parte general*, Ed. Hammurabi, Buenos Aires, 1999, p. 273.

considered necessary for social development. For example, the installation of an atomic reactor entails certain risks, but these risks are accepted by society[3].

The treatment of patients by doctors in compliance with *lex artis* falls within the scope of permissible risk, and in those cases where the death or bodily injury of the patient occurs but the medical act is in accordance with professional standards, the act lacks typicality, and procedurally it must be closed, respectively acquittal under Article 16 para. (1) letter b) sentence I from Romanian Criminal Procedure Code[4].

In our view, medical risk is inherent to medical practice and proportional to the degree of scientific development on which a particular case is grafted. Thus, the doctor must be placed in an area of professional autonomy and compliance with professional standards must be verified by a specialist commission.

The medical standards are often laid down in medical guidelines without having the force of criminal law in the strict sense of the word because the recommendations are generic and are based on an abstract disease and patient, while in practice the doctor is called upon to make these standards specific to each patient.

According to Article 53 of the Medical Ethics Code, the doctor's obligation is a duty of care (of diligence). Hence, even in the event of an incomplete assessment of the patient's situation at a given time, the doctor cannot be held liable for malpractice, let alone criminal liability, if the way in which he acted was within the usual standards of professional practice[5].

The standard of practice is assessed according to the specialty and complexity of the medical procedure chosen and applied, on the one hand, and the state of medical science at the time, on the other. Thus, medical activity can be considered culpable if it contravenes a practice accepted by at least part of medical science at a given time, the harmful results being precisely the consequence of the violation of a standard of practice specific to a medical field.

Hence, a doctor will not be criminally liable if he is acting in accordance with a medical practice accepted at the time by at least part of the medical profession, even though there may be other doctors who adopt a different practice.

In the medical literature, reference has been made to various causes likely to appear on the line of causal relationship, causes that have received the name of "medical risk", the doctor being placed in an area of professional autonomy[6].

II. Permissible risk and the offence of culpable bodily harm under art. 196 para. 3 Romanian Criminal Code

According to Art.196 para. (3) of the Romanian Criminal Code, the offence of culpable bodily injury is considered aggravated if it is committed *"as a result of failure to comply with legal provisions or measures for the exercise of a profession or trade or the performance of an activity".*

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[3] M. Cancio, *Los orígenes de la adecuatíon social*, Ed. Universidad Externado, Bogota, 2017, p. 415.

[4] C. Roxin, *Derecho penal. Parte general. Tomo I. Fundamentas. La estructura de la teoria del delito*, Ed. Cìvitas, Madrid, 2014, p. 363.

[5] Code of Medical Ethics of the Romanian College of Physicians from 04.11.2016 published in the Official Journal, Part I, No 981 of 7 December 2016.

[6] R. Dumitrescu, *Fenomenul malpraxisului medical în România – perspective etice* in Medichub Media, available at www.medihub.ro.

Therefore, the discussion is carried out on the level of specialized conduct required by the activity, and then the conduct of the active subject is compared with the abstract conduct required by the professional standard in the matter.

In one case, a surgeon was found guilty of culpable conduct when, while performing an orchidectomy operation on the injured party, he mistakenly removed his healthy right testicle instead of his left testicle, which was affected by a tumor, thereby causing him disability. It is clear from the evidence in the case that, at the end of the operation, while recording the activities carried out in the medical documents, the defendant stated to the entire medical team that 'I excised the healthy testicle'. In this case, it is possible to identify a failure to comply with professional standards, given that the doctor was obliged to check the documents and to locate the organ to be excised topographically correctly[7].

In another case brought before the Brasov Court of Appeal, it was found that the injured person went to the UPU where he was examined by the defendant who wrote him a prescription and sent him home because he did not consider it necessary to admit him. On the same day, his health condition deteriorated, and he was brought back to hospital and diagnosed with hemorrhagic stroke. The injured person was finally classified as severely impaired. What is interesting in this case are the contradictory findings of the forensic experts. In the first forensic report drawn up in the case, it is stated that the approach was in accordance with the approach of a doctor serving a health unit intended to deal strictly with emergency cases given that the general condition of the patient at that time did not suggest a medical emergency requiring the initiation of special treatment and hospitalization measures. The second forensic report drawn up by the National Institute of Forensic Medicine shows that at the time of the patient's presentation to the UPU, a minimum of laboratory investigations, hospitalization and emergency initiation of specific treatment were required. In this context, the court of judicial review ordered the conviction of the defendant, finding that there had been a breach of professional standards[8].

In a similar case, the defendant was charged with the fact that he did not request a post-operative neurological consultation which would have been useful both to verify the existence of a neurological lesion, which resulted in paresis and therefore permanent physical disability. The court, on the grounds of the forensic expert opinion, held that the defendant had complied with the recommended medical standards, making a correct and complete diagnosis in a context in which a neurological consultation, although useful, was not mandatory. At the same time, it was also stated that, due to the type of surgery, the patient was subject to a significant risk that cannot be ignored, while the witnesses heard in the case did not confirm the existence of any incident during the surgery or the use of an aggressive surgical technique by the defendant[9].

III. Permissible risk and the offenxe of culpable homicide under article 192 para. 2 of the Romanian Criminal Code

Similarly to the offence of culpable bodily harm, according to Art. 192 para. (2) of the Criminal Code, the offence of culpable homicide will be considered aggravated if it

[7] Decision no. 143/2023 of 24.02.2023 ruled by the Court of Miercurea Ciuc, available on rejust.ro.
[8] Decision no. 508/2019 of 25.06.2019 ruled by the Court of Appeal Brasov, available on rejust.ro.
[9] Decision no. 735/2020 of 30.07.2020 ruled by the Bucharest Court of Appeal, available on rejust.ro.

is committed "as a result of failure to comply with legal provisions or measures for the exercise of a profession or trade or the performance of an activity".

In another interesting case, a nurse on the ICU ward was convicted for wrongly determining the patient's blood group by performing a single method pretransfusion test, which determined that the victim had blood group AII, although in fact she had blood group B, after which she was given two units of blood group AII, resulting in death[10].

The present case is relevant because the causal link was argued by the court by direct reference to the concept of non-permissible risk. Thus, the perpetrator's conduct which led to the typical result was from the beginning a dangerous one, i.e. one which created a certain likelihood of producing an injury or endangering the protected social value. At the same time, the wrong determination of the blood group endangered the victim's life, given the victim's pre-existing pathologies, and the death was not directly caused by any other cause unrelated to the defendants' activity.

Also, in a case involving the offence of culpable homicide, a surgeon was charged with failing to recognize the complication of necrotizing fasciitis following surgery on a patient, labelling the symptoms as caused by alcohol withdrawal and belatedly making the diagnosis due to misinterpretation of clinical signs. In the present case, the court analyzed the legal obligations imposed on the doctor to carry out his activity and found that no obligation had been breached by him[11].

Although the court's decision is basically correct, the arguments are more in the direction of the lack of guilt from the perspective of the intellective component than in the direction of the lack of objective typicality in relation to the causal link. Thus, it is stated that "like any form of guilt, fault – including professional fault – must be proved". This sentence continues, in our view, in a critical manner, along the lines of causality, stating that "no causal link can be established between the activity of culpable homicide and the result produced, the death of the victim".

Despite this slightly confusing situation, the court correctly analyzed the standard of practice in relation to which the doctor's conduct could be assessed as improper. Thus, an overall analysis of the factual situation was carried out, concluding that no violation of medical rules could be identified and that the defendants did not fail to comply with medical protocols, leading to an acquittal.

IV. Compliance with professional standards – evidential value of forensic expertise

In practice, forensic expertise is ordered from the outset of criminal proceedings and is one of the most important and complex evidentiary procedures in cases of medical malpractice. There are a number of standard aims specific to cases of culpable bodily injury, i.e. wrongful death, committed by a doctor, which are directly related to the risk involved.

Therefore, among the common aims encountered in practice, we can list the existence of errors in medical technique and conduct during hospitalization, their identification, who committed them and what consequences they produced, respectively

[10] Decision no. 397/2022 of 10.06.2022 ruled by the Court of Sector 1 Bucharest, available on rejust.ro.
[11] Decision no. 32/2023 of 13.02.2023 ruled by the Court of Curtea de Argeș, available on rejust.ro.

whether there is a causal link between the errors in medical technique and the injury or death. At the same time, it must also be pointed out that the practice often resorts to a forensic finding, with the same objectives as the expertise. What is dangerous in such situations is the possibility that this forensic finding can be excluded in pre-trial proceedings.

Reading Article 172 para. (9) of the Criminal Procedure Code, it is clear that three alternative conditions must be met in order for the prosecution to use this evidentiary procedure: (i) when there is a danger of disappearance of evidence; (ii) when there is a danger of a change in factual situations or (iii) when it is necessary to clarify urgently certain facts or circumstances of the case.

It is true that the use of a forensic finding rather than an expertise is a matter of opportunity rather than legality, and in the criminal prosecution phase, the prosecution body is the only authority entitled to use a particular evidentiary procedure or a particular means of evidence or another.

However, whether the prosecutor or, as the case may be, the criminal investigation body complies with the conditions prescribed by law when opting for an evidentiary procedure or means of proof is a matter of the legality of the acts of criminal prosecution and is a matter for the preliminary chamber or pre-trial proceedings.

In other words, the preliminary chamber judge does not have the legal authority to examine the opportunity to dispose of an evidentiary procedure or the use of evidence during the criminal proceedings, but he has the legal authority to examine whether the prosecuting authority has complied with the law when deciding to use that evidentiary procedure or evidence.

The rulings of the Constitutional Court are also relevant in these matters, the Constitutional Court stating that "the order to make a finding will always be the exception, and it can only be made if the conditions laid down in Article 172 para. (9) of the Code of Criminal Procedure[12].

Although in cases of medical malpractice, urgency can be presumed, given that time can lead to a healing of the injuries (if we are talking about days of medical care in the case of the offence of culpable bodily injury), the performance of the forensic finding should be treated as the exception, as it is a non-contradictory procedure and thus offers less guarantees than the expertise[13].

V. The relationship between the surgeon and the anestethist – grounds for establishing theit liability

As has been pointed out recently in the literature, the anesthetist was initially held liable not only for harm resulting from the way in which anesthesia itself was carried out or from other therapeutic interventions of his specialty (e.g. interventions in intensive care or resuscitation work), but also for harm resulting from the way in which he fulfilled his duty to supervise the patient[14].

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[12] Decision of the Constitutional Court No 460 of 5 July 2018, published in Official Monitor of Romania, Part I, No 979 of 20 November 2018, para. 51.

[13] According to Article 172 para. (8) of the Criminal Procedure Code, authorized experts may participate in the expert's report at the request of the parties.

[14] I. Kuglay, *Răspunderea penală pentru malpraxisul medical*, Ed. C.H. Beck, Bucureşti, 2021, p. 55.

In this respect, the anesthetist is responsible for his acts during the pre-operative, operative and post-operative period, and from the moment the surgeon has left the operating room, the patient is under the responsibility of the anesthetist[15].

In another common law approach, the surgeon is considered to control and supervise the actions of the anesthetist. In Chalmers-Francis v. Nelson, the Supreme Court held that "the surgeon has the power and therefore the duty to direct the participants and their actions during the operation"[16].

In this context, the doctrine advocated the idea of the anesthesiologist as a "legal servant" of the surgeon, the arguments revolving around this being rather anachronistic and based on the idea of the patient's trust in the surgeon and the supposedly secondary role that the anesthesiologist plays[17].

A few ideas worth discussing were set out by the Supreme Court in the famous *Hillyer* case, where during surgery, while the patient was under anesthesia, his hands hung over the sides of the operating table, and one limb ended up being burnt by the hot water canister, while another suffered permanent nerve damage as a result of being pressed against the table. Although legal action was taken against the anesthetist and the hospital, it failed. The court ruled that the surgeon rather than the hospital or the anesthetist was the "legal master" of the hospital employees in the operating theatre[18].

It is true that the surgeon has the obligation to supervise the smooth running of the operation as a whole, but all the obligations of the professionals involved in a team must be taken into account. Thus, in a case brought before the French Court of Cassation, both the surgeon and the anesthetist were held liable, thereby establishing a permanent duty of care and diligence incumbent on the surgeon. In fact, after a tonsillectomy operation, both the surgeon and the anesthetist immediately left the clinic, leaving the patient unattended, the latter dying as a result of cardio-respiratory problems caused by the lack of post-operative anesthetic supervision[19].

Therefore, the surgeon has a duty of supervision, and it is his duty to ensure the smooth running of the operation, both pre-operatively, during the operation and post-operatively, by checking how each member of the team fulfils his or her obligations[20].

VI. Professional standars and forseeability of the criminal provisions

Any regulatory act must meet certain qualitative conditions, including predictability, which means that it must be sufficiently precise and clear to be enforceable[21].

The European Court of Human Rights has ruled that the law must indeed be accessible and foreseeable as to its effects. For the law to satisfy the requirement of foreseeability, it must specify with sufficient clarity the scope and manner of exercise

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[15] *Ibidem.*

[16] Available at https://casetext.com/case/chalmers-francis-v-nelson, accessed on 27.05.2023.

[17] J. Harland, A.. Mewett, *The legal relationship between the surgeon and the anesthetist*, in Springer,Vol. 6, No. 4, 1959, p. 305.

[18] *Ibidem.*

[19] Court of Cassation, Decision No 432 of 30 May 1986, available at https://www.legifrance.gouv.

[20] *Ibidem*.

[21] Decision of the Constitutional Court No 189 of 2 March 2006, published in the Official Monitor of Romania, Part I, No 307 of 5 April 2006.

of the discretion of the authorities in the area concerned, having regard to the legitimate aim pursued, in order to afford the individual adequate protection against arbitrary action[22].

The medical standard is regulated by law in a general manner in Art. 663 para. (1) of the Law No 95/2006 on health care reform, which mentions the obligation of the doctor to provide care to the patient.

At the same time, medical obligations are stipulated in normative acts that are inferior to the law, such as the Code of Medical Ethics or the Protocols of medical units. In this context, even an obligation stipulated in the job description may constitute the source of a professional obligation and, consequently, an instrument for setting the professional standard.

In view of the majority infralegal character of these sources, the constitutionality of the provisions of Article 192 para. (2) and Art. 196 para. (3) of the Criminal Code.

In decision 405/2016 of the Constitutional Court, the Court ruled that the violation of the official's duties can be criminalized only if it constitutes a violation of the law in the narrow sense and not a violation of a normative act of inferior force[23].

The question therefore arises as to whether all the rules governing the conduct of medical activity must be regulated by law or by government emergency ordinances in order for culpable acts committed in the course of such activity to constitute a criminal offence. Along with other authors, we consider that the answer is in the negative, as Decision 405/2016 is not applicable to offences against the person, given the importance of these offences in the axiology of the legal system[24].

VII. The procedural solution

As we have already stated, if the doctor's conduct is within the limit of the permissible risk, i.e. no fault can be identified in the medical act, the discussion will focus on the objective side. Therefore, the correct procedural basis is acquittal under Article 16 par. (1) letter b), first thesis of the Criminal Procedure Code – the act is not provided for by criminal law.

In the past, there was a tendency for the courts to use the basis provided for in Article 16 par. (1) letter b) 2nd thesis of the Criminal Procedure Code – the act is not committed with the form of guilt provided for by law. A change of perspective can now be noted with the adoption of the theory of objective imputation of the result.

However, it has been pointed out in the literature that, although the procedural basis of Thesis I is correct, the substantive correspondence is debatable. Thus, it has been stated that the existence of identity between the actual conduct of the doctor and the ideal conduct leads to the evasion of the essential condition attached to the objective side, the act not being typical in relation to the pattern of the rule in the aggravated form[25].

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[22] Judgment of 4 May 2000, Rotaru v. Romania, para. 52; Judgment of 25 January 2007, Sissanis v. Romania, para. 66.

[23] F. Streteanu, *Considerații privind regimul normelor penale incomplete în lumina jurisprudenței recente a Curții Constituționale*, in CDP No 4/2016, p. 23.

[24] I. Kuglay, *op. cit*., p. 28.

[25] *Ibidem*, p. 63.

VIII. Conclusions

Although it remains a concept not yet established in judicial practice, the permissible risk is nonetheless omnipresent, given that acquittals in the area focus on the non-existence of the dangerous conduct.

Medical activity is essentially a risky activity and any conduct of medical staff must remain within the limits of this risk.

The adoption of a standard that does not conform to the ideal standard entails the assumption that the offence of culpable bodily harm, or culpable homicide in the aggravated form, is typical.

Medical risk is inherent in medical practice and proportional to the degree of scientific development, so that it is impossible for the legislature to anticipate developments that may occur in this area.

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