

Medical Malpractice as a Separate Criminal Offense: a Higher Degree of Patient Protection or Merely a Sword Above the Doctors' Heads? The Example of the Croatian Legislative Model and the Experiences of its Implementation

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Abstract A comparative overview of the criminalisation of medical errors in Europe shows that this in principle is approached in two ways. Under the first approach, such errors are incriminated through the general regime for criminal offenses, such as bodily injury or causing death by negligence. The second approach, adopted in a smaller number of countries, prescribes it as a separate criminal offense (as medical malpractice). Croatian law is a typical example of the second model, which has given rise to discussions in Croatian scholarly circles about the abandonment of such a model. The author analyses the Croatian legislative solution and its realisation in judicial practice, and based on this analysis, through the presentation of noteworthy case law, provides conclusions on whether or not the Croatian legislative solution indeed provides a higher degree of protection of the health of patients and a higher level of legal certainty.

Keywords: • Doctor • Medical Malpractice • Gross Negligence • Causal Nexus • Rules of the Profession •

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1 Introduction

Medicine is one of the professions which face daily and large risks in the occurrence of harmful consequences to human life and health. The nature of the work, the handling of severely ill and vulnerable persons, creates a work environment in which a doctor must be ready to face possible human losses and to potentially bear legal responsibility for such events. In the legal sense, such responsibility can also imply criminal liability, as the *ultima ratio* of the protection of the health of patients and society as a whole (Fletcher & Ohlin, 2005: 541; Jescheck & Weigend, 1996: 2 – 8; McHale, 2003: 135; Martin-Casals et al, 2003: 153 - 175). Considering the special working conditions of medical staff and the largely humanistic nature of their work, certain legal systems give precedence to civil law protection. This is particularly notable in countries where healthcare is largely privatised. A typical example is the USA, where medical errors are almost never treated under criminal law protection, but are dealt with in civil litigation for the compensation of damages. Medical errors are mostly resolved through a developed settlement system (Di Landro, 2012: 222).

On the other side of the spectrum, in countries where healthcare is mostly administered by the public sector, the criminal prosecution of doctors for medical errors is much more prevalent. This is particularly true for the countries of continental Europe. A comparative overview of the criminal codes of the majority of European countries shows that there are two main approaches to regulating medical errors: through general criminal offenses against life and body (which is typical for Western European countries) or prescribing separate criminal offenses called medical malpractice which are designed for the work of doctors (which is typical for Eastern European countries, such as the countries of former Yugoslavia¹ and Ukraine²).

Croatian legislation is an example of legislation that dedicates significant attention to the protection of patient health. The Croatian Criminal Code (hereinafter: the CC) contains a separate chapter (Chapter XIX) with the title “Criminal offenses against the health of people” and contains 14 criminal offenses that protect patient health from different kinds of harm and attack. One of the most prominent criminal offenses in this category is the criminal offense of medical malpractice (Article 181), which aims to protect the health of people (in this case the health of patients) from all types of medical procedures which

¹ E. g. Art. 179 of Slovenian Criminal Code, Art. 126 of Serbian Criminal Code, Art. 290 of the Criminal Code of Monte Negro.

² Art. 140 of Criminal Code of Ukraine.

were not conducted in accordance with the norms of the profession (*lege artis*). This regulation has been subject to criticism in medical circles in Croatia, especially from the Croatian Medical Chamber, as the main professional physicians' association. The Chamber's position is that the majority of countries do not have such a separate criminal offense and that sufficient protection can be achieved through the general criminal offenses of physical injury and death by negligence, and that this approach puts additional pressure on doctors (thereby contributing to the unwanted phenomenon of defensive medicine), without improving the protection of patients' health. Thus, there is momentum towards abolishing this particular criminal offense and for instead processing medical errors under general criminal offenses against life and health, which is the case in the legal systems of the majority of the Member States of the European Union.³

This paper aims to determine whether or not the existing legal solution in Croatia brings any added value to the protection of the health of patients, i.e. whether this legal framework contributes to increased levels of legal certainty, or if it actually creates legal uncertainty. Considering the fact that legislation which is not followed by an adequate practice is merely dry ink on paper, a deeper analysis of the relevant judicial practice is necessary in order to find substantive answers to the existing questions. In this sense, the paper is structured in the following manner: The first section contains a brief description of the *actus reus* and *mens rea* of the criminal offense of medical malpractice the way it was provided in Article 181 of the CC. Section 2 analyses the available judicial practice which will highlight the four main difficulties in both interpreting and proving the liability related to this criminal offense. The third section provides an assessment of the existing framework in the context of protecting the health of patients and legal certainty.

³ An ardent proponent of the abolition of medical malpractice as a separate criminal offense was the newly elected president of the Croatian Chamber of Physicians, dr. Krešimir Luetić. For more details, see <http://www.kresimirluetic.com.hr/vijesti> (29 May 2019).

2 Part I: Main Characteristics of Art. 181 of the Croatian CC

2.1 General Remarks

In comparative law, the criminalization of medical malpractice is usually accomplished by one of the two possible legislative techniques. One approach is to treat every medical procedure as a type of bodily injury and therefore to qualify cases of medical malpractice as a criminal offense of causing bodily harm to a patient. As a typical example of such legislative approach, one can point to German law, which considers the cases of medical malpractice under the § 223 which regulates the general crime of causing bodily harm (Germ. *Körperverletzung*) (Schönke & Schröder, 2001: 1803). The practical consequence of such an approach is that every medical procedure partially constitutes *actus reus* (Germ. *Tatbestand*) of the criminal offence unless the defendant proves the existence of grounds for the exclusion of that *actus reus* (Germ. *Rechtfertigungsgrund*) (Hilgendorf, 2016: 13–18). This approach is common in European countries. However, it can lead to significant practical difficulties in cases involving medical procedures that are not medically necessary (e. g. plastic surgery) (Schroth, 2010).

Another possible approach for certain legislator is to prescribe medical malpractice as a separate crime (in a separate chapter of the criminal code). This kind of regulation allows the specification of the details of medical malpractice, the legal grounds of criminal liability and the appropriate penalty. The practical consequence of this model is that not every medical procedure constitutes *actus reus* of criminal offence, but only those characterized by special circumstances (e.g. only the ones deviating from medical standards). Therefore, the criminal zone is narrower than in the first model. One typical example of such an approach is Slovenia, since the Slovenian Criminal Code provides for a special offence of negligent treatment (Art. 179) (Šepec, 2018: 48).

The Croatian legislator has chosen the second approach. The CC contains a special chapter for criminal offences against the health of people (in Croatian: *kaznena djela protiv zdravlja ljudi*). Within this chapter, Art. 181 is titled “*Medical Malpractice*” (in Croatian: *nesavjesno liječenje*) and it is devoted to the criminalisation of medical errors with consequences for patients’ health or life. The *actus reus* and *mens rea* of this offence will be discussed in the following sections.

2.2 Actus Reus

This criminal offense is regulated as *delictum proprium*, which means that only the person who has certain qualifications can be a perpetrator. According to Art. 181/1 of the CC, the perpetrator has to be a doctor of medicine, a doctor of dental medicine, or other healthcare professional.⁴ He or she has to act in rendering medical services, which means that there will be no criminal liability if he or she is acting outside of duty (e.g. during free time, holiday, etc.). Healthcare is considered a public profession, which can have further consequences in the context of crimes connected with corruption.⁵ Other persons who do not qualify as a perpetrator can only be charged as aiders or abettors. Unlike the perpetration of this crime that is punishable if committed both intentionally and with negligence (see the following section), aiding and abetting is punishable only if committed intentionally. Croatian criminal law also provides for the criminal liability of legal entities, which means that hospitals and other healthcare institutions can also be charged, prosecuted and convicted as perpetrators of medical malpractice. However, there have been no such proceedings yet in Croatian jurisprudence.

The perpetrator, to be held liable, must apply medical procedures that are contrary to the accepted norms and standards of medical practice. Art. 181 lists four modalities of such activities or omissions. The breach of any one of these modalities is sufficient to lead to liability. Breach of more than one of the modalities is treated as an aggravating circumstance. These modalities are:

- a) application of obviously inadequate remedy of treatment;
- b) application of obviously inadequate method of treatment;
- c) obvious deviation from accepted medical standards; or
- d) obvious (Roksandić Vidlička in Cvitanović et al, 2018: 230) careless acting.

In each case, it is essential that act or omission is *obvious* which means that it has to significantly deviate from accepted standards.

⁴ According to the Croatian Healthcare Act (Art. 124/1), a health worker is every person who has at least minimum degree of specialized health education and performs healthcare services as his or her occupation.

⁵ This means that a healthcare worker has the status of an *official* and therefore falls under stricter regime than other persons. See decision of the Supreme Court of the Republic of Croatia, III Kr 81/2013 of 21 January 2014.

The Supreme Court emphasises that carelessness has to be “*clearly visible*”, which has to be proven beyond a reasonable doubt (Supreme Court of the Republic of Croatia, IV Kž-103/03 of 29 January 2004). The criterion is the consciousness of an “*average person with the same qualifications and experience as the defendant*” (Supreme Court of the Republic of Croatia, IV Kž-244/02 of 26 June 2003). To prove this circumstance, the court must engage a professional expert. An overview of jurisprudence shows that the majority of errors are caused by careless diagnoses that lead to the wrong treatment. For example, a doctor was convicted because he had failed to diagnose leukaemia on time, as he did not order additional blood tests even though such procedure was part of the accepted standards of oncologic practice due to the obvious febrile state of the patient (Supreme Court of the Republic of Croatia, IV Kž-120/91 of 18 December 1991). Another doctor was convicted because she performed only a superficial examination and therefore failed to diagnose sepsis which resulted in the patient’s death a few hours later (Supreme Court of Croatia, Rev 1180/08 of 26 October 2011).

Errors in diagnosis and therapy are necessary conditions of criminal liability. However, if they are proven, it is still not sufficient for conviction. The prosecutor must prove two further requirements of liability: the occurrence of consequences and a causal nexus between the errors in treatment and consequences. The consequence consists of either the aggravation of the disease, the deterioration of health, the termination of a pregnancy or the death of the patient.

These requirements are proven by the analysis of court-appointed medical experts (chosen by the court from a list of medical experts based on their experience and competence in a certain field). Unlike other countries, where the determination of at least two experts is required (Bajanowski, Rabl & Fracasso, 2013: 120), one assessment is sufficient in Croatia. Additional determinations by the same or different medical experts are warranted only in situations where the initial determination is unclear or contradictory. Criminal liability will be excluded if there is a disruption of the causality, such as in the example of surgeons who unnecessarily removed healthy tissue during kidney surgery, but where the medical expert determination showed that the death of the patient was caused by a rare congenital anomaly which was not detected during the standard diagnostic examinations (County Court in Zagreb, KIR-3578/10 of 26 February 2011). However, if the act of omission of the doctor was at least one of the contributing factors, the criminal liability will remain, unless if it significantly increased the risk of the occurrence of the consequence (Mrčela & Vuletić, 2019: 18). Thus, the courts released two doctors from liability for making several errors in the diagnosis and treatment of a patient, because the

court determined that the patient's death was caused by multi-organ failure which was a consequence of generally poor health and a pre-existing pathology (kidney inflammation and dislocation of the stomach into the left thoracic) (Municipal Court in Osijek, 32. K-402/2015 of 5 May 2016).

2.3 Mens Rea

Croatian criminal law has traditionally been strongly influenced by the Germanic legal systems, especially the Swiss and German systems. As a consequence, Croatian law adopted the German concept of the criminal offense as a unity of four elements: the act, the body, unlawfulness, and guilt (Germ. *Handlung, Tatbestand, Rechtswidrigkeit, Schuld*). There are two types of guilt. One is intentional conduct and the other is conduct that rises to the level of negligence. These further branch out into sub-types, and thus intent can be direct (*dolus directus*) and indirect (*dolus eventualis*). Direct intent exists if the perpetrator wants to commit the criminal offense (for example, shooting the victim in the head in order to kill him or her), and indirect intent exists if the perpetrator is aware of the possibility of committing the criminal offense and accepts this risk (for example, a burglar attempting to escape the police pushes a policeman over the rails of a bridge, thereby accepting the possibility that the policeman could drown in the river). Negligence can be conscious/intentional (*luxuria*) or unconscious/unwitting (*negligentia*). Negligence is intentional if the perpetrator is aware of the possibility that a crime could be committed but disregards this fact or assumes that he will be able to prevent the consequences (for example, driving fast and assuming that he will be able to brake in time), while unwitting negligence exists when the perpetrator was unaware of the danger but should and could have been aware (for example, a hunter who fires a shot at something making noise in the bushes and kills another hunter, thinking he shot a wild animal) (Novoselec, 2016: 221 – 233).

According to Article 181 of the CC, medical malpractice can be committed both with intent and through negligence. Therefore, it is important to emphasise that intent (direct or indirect) is possible only for the element of inappropriate conduct (i.e. the application of inadequate medical treatment), while negligence is always necessary with regard to the consequences. If the consequences were also covered by the intent then there would be a more severe criminal offense (such as murder) (Mrčela & Vuletić, 2019: 20). Thus, in theory, an intentional form of medical malpractice would exist when a doctor intentionally violated the rules of the profession in order to make a procedure quicker or simpler (for example, performing laparoscopic surgery in a situation which merits the

classical opening of the stomach of the patient), without the intention of causing the consequence.

However, such situations have not yet occurred in judicial practice, and most of the cases include negligence. Negligence will exist when the doctor is either unaware that the applied medical treatment is inadequate or fails to foresee any possible consequence in a certain situation (i.e. fails to notice a certain danger). Courts found that negligence existed, for example, in the case of a doctor who failed to order additional blood tests on a pregnant woman with a fever, which prevented the timely discovery of developing sepsis, ultimately causing her death, which could have been prevented (County Court in Osijek, Kž-241/2012 of 18 April 2012). Courts also found a paediatrician guilty of negligence for leaving a child with a fever unattended with a thermometer in its rectum, which caused the death of the child. The court determined that the physician recklessly thought that she would be able to return shortly to attend to the child and that no adverse consequences could occur in such a short period of time (Cvitanović et al, 2018: 264).

It should also be noted that there is no standardised test for determining intent and negligence under Croatian law, such as the one that exists under English law (*R. v. Adomako*) (Quick, 2006: 425 – 426). Consequently, the criteria are mostly determined on a case-by-case basis and the practice varies in this respect (more on this will be elaborated in the next chapter). In principle, it can be said that determining the type of guilt in practice will also always require expert determinations, because only a court medical expert will be able to assess with competence whether or not a certain consequence was foreseeable (or should have been foreseeable) to a doctor in a given situation, or if the doctor was aware (or should have been aware) of the inadequacy of a certain diagnostic or therapeutic procedure.

3 Part II: The Main Issues in the Determination of Liability (or Lack Thereof) in Judicial Practice

3.1 General Remarks

In the following sections, we will present the results of the analysis of the available decisions of the Croatian courts reached between 2000 and 2017. The methodological approach is analytical, through the study of concrete cases. The comparative method will be applied at the appropriate junctures, whereby the cases from the Croatian judicial practice will be compared to similar cases from countries which do not treat medical

malpractice as a separate criminal offense, in order to establish whether the courts reach the same or different solutions.

Before turning to the analysis, it should be noted that there is statistical data which shows a relatively small number of verdicts on medical malpractice (especially when compared to the number of criminal reports submitted) in practice. According to the official report of the State Attorney's Office of the Republic of Croatia (SAORC), for the period of 2014 – 2017⁶, there were 321 criminal reports for this criminal offense, where the SAORC conducted investigations for only 70 cases (21.80 percent). In the remaining cases, the SAORC found that the reports were not valid and they were subsequently dismissed. Further, in the same period of time, 47 persons were charged and only four were convicted after complete investigations (investigations can end by termination as well). In other words, only 8.51 percent of the defendants were ultimately convicted. All of the sentences were probationary. If these statistics are taken together, it can be concluded that a large number of these cases are “filtrated” between the report and sentencing which indicates either ample opportunities for initiating proceedings with state authorities (too broad discretion for reports) or the existence of significant difficulties in proving criminal liability. The remainder of this paper then will focus on the difficulties in determining liability, which arise out of the analysed cases.

Considering such statistical data, which indicates a rather small number of verdicts in several years of practice, the author considers the analysed verdicts to be a sufficiently representative sample to provide scientifically sound conclusions. The identified difficulties were categorized into the following four groups: 1) excessive reliance of the court on medical expert testimony; 2) problems in determining (criminal) causality; 3) conduct contrary to the established practice versus conduct in accordance with good practices; 4) the problem of (un)informed consent.

3.2 The Dependence of the Court Decision on the Medical Expert Determinations

Whether criminal liability exists is a purely legal question and its determination and the soundness of the decision is within the competence of the court. In accordance with the *iura novit curia* principle, it is settled Croatian law that the courts know the law the best and do not need interpretative assistance in resolving legal issues. Assistance is necessary

⁶ Available at <http://www.dorh.hr/Default.aspx?sec=645> (30 May 2019).

only in the determination of facts for which the courts do not have expertise, which in these cases implies the mandatory engagement of court medical experts, as previously described. Accordingly, it is important for the court to set clear parameters for the medical expert assessment and to ensure that the relationship between the judge and the medical expert does not cross the line of expert assistance to the court: the medical experts should not *de facto* write the decision for the court through their determination. Therefore, the court must limit the expert's role to providing only the data which is legally relevant for deciding liability (Novoselec, 2016: 220).

In order to fully understand the following analysis, it is important to first understand the functioning of the Croatian criminal justice. Croatia is a country that adheres to the continental legal tradition, where significant emphasis is placed on the principles of legality in theory and practice (*nullum crimen sine lege, nulla poena sine lege*). These principles are strictly interpreted. This means that the courts rule based on the laws, and not upon previous judicial practice (judicial precedents), as is done in the Anglo-American legal systems. Although the previous decisions of the Supreme Court of the Republic of Croatia do have the weight of legal authority, nevertheless they are not legally binding on the lower courts, which instead are only bound by the Constitution of the Republic of Croatia, ratified international treaties, laws and bylaws. In order for the courts to reach a convicting decision, they need to provide a factual description of all the elements of the specific criminal offense and fit them under an existing norm. For example, in a murder conviction, the court will have to describe that A fired a shot at B with the intent to kill, A thereby satisfying the elements of "intentional killing of another person". The same principle applies with regard to medical malpractice, but the situation here is much more complex because the court's judgment additionally needs to describe the elements of malpractice which require a clear violation of the rules of the medical profession. In order to do so, the court relies upon the determinations of medical experts. In the author's opinion, this is where the fundamental issues in determining criminal liability for this offense arise. Namely, the fact that the violation of the rules of the profession is an element of the criminal offense makes the decision on liability excessively dependent on the findings of the medical experts expressed in their determinations. Courts usually just copy the determinations of the medical experts into their decision, and thus the medical experts indirectly help draft the court decision, which is not only inappropriate, but also questionable from the perspective of the constitutional competences of the judiciary. In practice the legal process can take tortuous twists and turns, such as in situations where the courts seesaw between an exoneration and conviction in the same case, based on the changes made in medical experts'

determinations (if several medical expert assessments were ordered in a certain case). Thus, certain trials can be quite lengthy with the injured person dying during the course of a long trial, or with a gynaecologist being tried for malpractice during delivery of a baby, and the injured baby growing up while the trial is still ongoing. One interesting and atypical case from the field of gynaecology will clearly illustrate this state of affairs.

A gynaecologist was initially convicted of medical malpractice stemming from medical services being provided during the course of delivering a child in 2004. Namely, the gynaecologist in question observed signs of fetal distress in the mother's uterus (with every contraction the heart rate of the fetus slowed down and when the water broke, thick green amniotic fluid gushed out), but failed to deliver the baby earlier through an emergency caesarean section, which is the prescribed practice in the profession. Due to this omission, hypoxic-ischemic brain damage occurred, resulting in a diagnosis of cerebral palsy in the infant. After the case was tried in a criminal proceeding, there was a civil trial for compensation of damages. However, during the trial for compensation of damages, which was conducted several years later, medical experts established that in the meantime there were new scientific findings in the field of gynaecology and obstetrics according to which it was clear that the cause of cerebral palsy occurred during pregnancy and that it had no connection to the birth itself, nor to the gynaecologist's negligence. It was also determined that diagnostic procedures which were available at the implicated time could not have determined the cause. Based on this determination, the gynaecologist requested and was granted a retrial of the criminal proceedings. The new trial lasted another several years and ultimately it was impossible to determine whether or not there was significant medical malpractice, and the court applied the principle *in dubio pro reo* and exonerated the defendant of criminal liability (Municipal Court in Osijek, Kv-96/2015 of 24 February 2015). Considering the fact that fifteen years had passed between the initial indictment and the final acquittal, it is clear that the gynaecologist spent almost half of her professional career under the stigma that she had committed medical malpractice and injured a patient (at the time of the event she was a young resident, and this had impacted her entire career in a very negative way).

This example is being presented not only because it is factually specific and legally interesting, but also because it is a vivid example of how relative, and at times unreliable, the criteria necessary to establish a clear violation of the rules of the profession can be. In addition, this example shows how dependent the decision is on the determination of the medical expert: so much so, that variations in the expert determinations can lead to modifications in the type of decision, from a conviction to an acquittal, or vice versa

depending on the case. This dependence on a medical expert's determination leads us to the next issue, which is the near indemonstrability of the legal standard of criminal causality between a doctor's error and the subsequent consequence for the health or life of a patient. The following section will address this issue.

3.3 Difficulties in Proving Criminal Causality

It is a common occurrence in practice that certain conduct is found to be in obvious violation of the rules of the profession, and yet there is no criminal offense because there is no criminal causality or (more often) because such causality cannot be precisely ascertained. Causality in criminal law in Croatian theory and practice is interpreted more narrowly than in everyday life. Only the conduct (cause) which creates illegal harm to the object is relevant and only to the extent it is actually realised in the consequence from the legal description.

This has created a theoretical foundation which excludes a good number of situations in which several co-causes (contribution of the victim, actions of third persons, unfavourable changes of circumstances, etc.), as well as atypical causes from this term (and thus throwing a rock at a haemophiliac who subsequently bleeds out will not be treated as a relevant cause sufficient for a murder conviction) (Novoselec, 2016: 134 – 143).

The causality issue is particularly notable in the context of the criminal offense of medical malpractice. In determining whether the applicable standard of criminal causality has been violated, just like for the question of an evident violation of the rules of the profession, the courts must rely on the assistance of medical experts. In many decisions, the court accepts the findings of the medical expert, even though they may not seem generally convincing. Consequently, medical experts once again have a decisive impact on the type (and quality) of the verdict. This can be illustrated by the following three examples from the more recent Croatian judicial practice.

In the first example, the defendant was a traumatology surgeon who was on call in a hospital in Bjelovar (a small town in Croatia with a small hospital, which is relevant for the development of the events). He admitted the injured person into the emergency room and suspected a rupture of the aorta. According to the rules of the profession, in such a situation it is obligatory for the doctor to consult a cardio-surgeon or a vascular surgeon and to transport the injured person to one of the larger hospitals where further diagnostics

could be performed and, if necessary, where the patient could undergo surgery. It should be noted that Bjelovar is in the immediate vicinity of the capital of Croatia – Zagreb, which has some of the leading university clinics in the country. Another option was to invite a cardio or vascular surgeon to Bjelovar, if the risk of transporting the patient was deemed too high. However, the defendant chose none of these options, and instead only admitted the injured person for observation. After two days, there was a large haemorrhage and it became evident that the patient indeed had suffered a rupture of the aorta, and the defendant performed surgery, and the patient died. The first expert determination confirmed a violation of the rules of the profession and established that the death rate for patients who underwent surgery for aorta ruptures is 40 percent. For reasons which remain unclear, another expert determination was ordered, which also confirmed a violation of the rules of the profession, but established a death rate of only 14-20 percent, meaning that there was a high probability that the injured person would have survived if he had received the treatment in accordance with the rules of the profession. The court chose to apply the principle of *in dubio pro reo* and accepted the more favourable findings from the first medical expert determination (despite the fact that its ambiguity had prompted the ordering of another expert determination) and acquitted the defendant because “the results of the presented evidence did not indicate with sufficient reliance that the aggravation of the health condition and death were a consequence of an error” of the doctor on call (County Court in Bjelovar, Kž 443/2011 of 16 February 2012). This example clearly demonstrates how determining criminal causality can at times be an inexact science, at best.

In another example, defendant, a gastroenterologist, in treating a person injured as a result of an automobile accident, failed to perform an examination required under the standard procedure and thus failed to detect an injury of the intestine. The failure to perform the standard examination led to the development of sepsis and subsequent death. The medical expert found that there was an error and that the death had been caused by the sepsis, but that it did not develop solely due to the intestinal injury, but also partially due to injury of the thorax and the stomach, which should be viewed collectively. Based solely upon this expert’s determination, and without conducting an independent, and more comprehensive analysis of the contribution of the omission of the defendant on the causal chain which led to the death, the court took the easier path and acquitted the defendant (Supreme Court of the Republic of Croatia, IV Kž 146/2000 of 22 January 2002).

The most recent example of this kind dates back to 2018, when three doctors were criminally charged with medical malpractice because they disregarded obvious symptoms which indicated the need for additional diagnostic and radiological examinations of the patient in a larger hospital. This case received broad media attention, because journalists were contacted by a witness who was in the hospital bed next to the injured patient and who told them the course of events. The patient was a man in his mid-forties who was severely overweight (weighed 180 kg). He was admitted in the surgery ward of the hospital in Vinkovci. Vinkovci is a small town with a small hospital, but it is near the city of Osijek, which is the regional center, with a large university hospital. Even at the moment of admission, the patient complained about sharp abdominal pain, but the medical staff just left him on the hospital bed. According to the description of the witness, his wailing and moaning lasted six hours, after which he fell into shock and died. The medical expert determination found that professional errors were made, but that, considering the poor health condition and obesity of the patient, it could not be determined whether a timely diagnosis would have saved his life. Therefore, the State Attorney issued a decision on the rejection of the criminal charge, and the case never reached the courts (Municipal State Prosecutor in Vukovar, K-DO 644/2018, KPO-DO 14/2018 of & November 2018).

One significant conclusion from this analysis is that Croatian judiciary authorities sometimes accept the determinations of medical experts too easily and without their own, independent critical assessment. Moreover, by their broad interpretation of the procedural principle of *in dubio pro reo*, the courts (and at times the State Attorney's Office) make their own jobs easier but simultaneously lose sight of the *ratio legis* behind medical malpractice, which is the increased protection of the health of patients. Namely, there are many situations in which causality cannot be proven with 100 percent certainty (or complete probability), but does this mean that there can be no criminal liability? If so, then it is unclear why the legislator would even prescribe medical malpractice as a separate criminal offense.

This issue is also manifested in practice through a very specific legal standard: acting in accordance with the established practice, which at times deviates from the good practices and rules of the profession. This will be the topic of discussion in the following section.

3.4 When Established Practice Deviates From Good Practice

In different branches of medicine, there are established (written or non-written) protocols of conduct, which define what is known as good practice. This practice also has to be taken into consideration by the courts when determining whether or not the rules of the profession were violated. This is a very sensitive area in Croatian law, precisely because to be held in breach of these rules requires an obvious violation of the rules of the profession. However, doctors can then claim that they acted in accordance with the established practice, which means that their violation of the rules of the profession was not as obvious as it was required by law. This is a particularly sensitive issue due to the fact that the infrastructural deficiencies of the Croatian healthcare system sometimes make it impossible or at least economically unfeasible for doctors to always follow all of the protocols verbatim. This is why doctors often face the daily pressure of choosing either the safest or the least expensive methods. This is especially notable in the field of diagnostics, where some examinations are expensive and they expand the waiting lists, and it is therefore more economically convenient to avoid them. The next example is the best illustration of this conundrum.

Three doctors – gynaecologists at the University Hospital in Osijek – were criminally charged because they admitted a woman in her 19th week of pregnancy, whose waters had broken and who needed to undergo an abortion. The doctors were so focused on securing the woman's consent for the abortion that they failed to order the control lab blood tests. If they had done so, they would have detected the development of disseminated intravascular coagulation (DIC), which ultimately led to sepsis and death. The entire event took place over the course of 48 hours, during which the three charged doctors attended to the patient, but none of them complied with the protocol until it was too late. Two criminal proceedings were conducted, which resulted in acquittals for two out of the three doctors (only the youngest resident doctor was convicted) because the court accepted the defence which was based on the determination of the medical expert, according to which “the conduct was contrary to the rules of the profession, but most doctors would have acted the same way as the defendants, because the clinical image was atypical and this was the established procedure in Croatian hospitals” (Mrčela & Vuletić, 2017).

This case can be compared to a case from the Austrian judicial practice, where there was a clear deviation of the established practice from the good practice, but the Austrian court did not give it the same significance as the Croatian court. The defendant was a resident in the paediatric oncology ward of an Austrian hospital, where he was treating a ten-month-old baby on cytostatic therapy. He received explicit instructions from a senior doctor to give the child the antibiotic Cotrim-Kugh orally through a syringe (in order to ensure maximum precision). Due to a fever, two other antibiotics were prescribed – Refobacin and Fortum, which were to be given through IV. The senior doctor told the resident to draw a blood sample and to administer Refobacin 30 minutes later, and then to draw another blood sample after 30 minutes. During the drawing of the blood sample, a nurse brought an unmarked syringe with the Cotrim-K medicine and said that she had brought the “oral medicine”, to which the resident did not reply in any way. When the nurse left the room, the resident gave this medicine via IV instead of the Refobacin (although he thought that this was what he was administering).

The baby went into anaphylactic shock because of the IV intake of the oral antibiotic, and died four hours later. In the criminal proceedings, the resident was convicted of manslaughter, because the court found that he should have been aware of his actions, considering the fact that the nurse had warned him of the oral medicine, which she brought in on a platter, while the standard procedure for IV medicine was to bring it in on a special cart. However, in the context of this specific issue, it is interesting that he relied on the defence that the syringe was unmarked, which was contrary to good practice, but it was the established practice in that hospital. The court found that such bad practice cannot exclude criminal liability, but it can serve as a mitigating circumstance at sentencing and ruled accordingly (Amsiejute, 2015: 59 – 60).

The comparison of these two cases shows that Austria, where medical malpractice is not a separate criminal offense, provides a higher level of criminal protection of the rights of patients, because violations of the rules of the profession are interpreted in a more extensive and flexible manner. This is possible precisely because there is no separate criminal offense with a narrower scope which would limit the judge’s decision-making, which is the case with the Croatian CC. It is fair to state that Austrian law provides an extra level of protection for the health of patients (due to the possibility of a more flexible practical implementation) than is the case in the Croatian system, which places more emphasis on this legal good by prescribing a separate criminal offense within a separate chapter.

3.5 The Issue of (Non)informed Consent

At the end of this analysis of judicial practice, the issue of informing the patient prior to diagnostic and therapeutic consequences should also be briefly addressed. Namely, there is an established view in contemporary medicine that a patient can receive treatment only with prior information and a clearly expressed consent by either the patient or the person(s) who are legally authorized to give such consent on the patient's behalf (except in cases of urgency, when this is not possible). This is the so-called concept of doctor-patient cooperation, the purpose of which is not only the protection of the patients, but also the protection of the doctors from subsequent lawsuits and criminal charges (Mrčela & Vuletić, 2019: 25; Kraljić & Kobal, 2018: 457). Informing the patient clearly and in detail on the nature of the procedure and the possible (typical and atypical) risks is the best method to protect the interest of the patient. Thus, doctors must always dedicate enough time and approach the issue of informed consent in a manner which is adapted to the psycho-physical and educational capacities of each individual patient.

Although the Croatian legislature is based on informed consent and the patients are always required to sign consent forms for certain procedures, empirical studies show that this issue is not given much attention in practice. Thus, the standard procedure is to give the patient the consent form on the operating table, right before providing the anesthetic. This practice clearly is not ideal, and the superior practice would be to discuss these issues with the patient during prehospitalization consultations. (Vučemilo, Babić-Bosanac, Altarac & Borovečki, 2014: 105). Therefore, in the court decisions analyzed for this paper, the author could not find even a single situation where the court would determine the existence and scope of informed consent and warning of risks, nor was this issue ever raised.

In this case, just like in the previous chapter, a review of the comparative law shows that the countries which do not have a separate criminal offense of medical malpractice provide a higher level of protection of the rights of patients. Germany is the leader in this respect. Its literature and practice reveal clearly set standards with regard to the duty to inform, as well as the criminal relevance of the failure to inform sufficiently or at all. German jurisprudence automatically binds information deficits with the violation of professional standards and considers it sufficient for a conviction. There are many examples of doctors being convicted precisely for failing to provide patients with sufficient information in different situations. For example, the courts found that there was a breach of the medical professional standards when a physician who was immunizing a

newborn failed to warn the infant's parents of the risk factors of infection (Schöch, 2010: 62). There are many such and similar cases in Germany, while this area is completely disregarded in the Croatian criminal practice with no clearly established standards.

Therefore, it can also be noted here that the practical implementation of a norm is more important than its architecture for the protection of the rights of patients, and that a high-quality practical implementation requires a sufficiently broad and flexible norm. Considering the presented critique, the next chapter will provide the answers to the questions from the introduction, which were set as the topic of the research, which will be followed by proposals *de lege ferenda*.

4 Part III: Does the Croatian Model Provide Satisfactory Levels of Protection of the Patients' Health and What Should be the Direction of Future Developments?

4.1 Does the Croatian Model Provide Satisfactory Levels of Protection of the Patients' Health?

The Croatian legislative solution was previously described, as well as the relevant judicial practice, which shows the practical implication of this solution. Considering the fact that the Croatian legislator provided a separate chapter for the criminal offenses against the health of people, which includes the criminal offense of medical malpractice, it is fair to conclude that the intention was to emphasize the health of the population as one of the highest constitutional objectives and that it should be protected in particular from various types of attacks and harm. But, was this accomplished?

In the author's judgment, the previous analysis shows that the legislator has overly regulated this area. This is proven by the analysis of the judicial practice, which shows the difficulties in the interpretation of the strict legal requirements. Faced with the difficulties in proving the required standards (serious violations of the rules of the profession and causality), the practice seeks an easy cure. This can be found both in the broad interpretation of the procedural rule of *in dubio pro reo* as well as in choosing to acquit whenever medical experts do not establish causality and foreseeability with overwhelming certainty. In addition to abdicating the adjudicative role to medical experts, which is in and of itself a violation of the judicial legal prerogatives, the judicial practice renders the intent of legislators to provide additional protection to the health of patients null and void. Therefore, it seems justified to pose the question of whether the same or

even a higher level of protection could be achieved even without the existence of a separate criminal offense, i.e. whether this is an unnecessary burden on the legal system? Namely, the practice in countries where these criminal offenses are treated under the framework of bodily injuries and manslaughter (such as Germany, Austria and England to a certain extent) leads to such a conclusion. On the other hand, such a conclusion is supported by the fact that the issue of informed consent is still treated only marginally in Croatian practice. Therefore, the conclusion is that the *ratio legis* of the separate provision on medical malpractice has not been accomplished.

4.2 Does the Croatian System Provide a Higher Level of Legal Certainty?

Since the Croatian model does not provide a higher level of protection of the rights of patients than countries without a separate criminal offense of medical malpractice, does it at least provide a higher level of legal certainty for defendants with respect to what exactly they can and cannot be criminally charged with?

The answer is yes, but with important qualifications. On the one hand, there is no doubt that the provision of precise requirements for criminal liability, which take into consideration the specificities of the medical profession, contribute to legal certainty. It is indeed important for a doctor, as a potential defendant, to know that criminal liability arises only if there was a gross violation of the rules of the profession which caused the legally defined consequences, if there was intent or negligence.

However, legal certainty must extend not only to potential defendants/perpetrators but also to the potential victims. Patients therefore must have clearly articulable rules that establish what is and what is not punishable conduct. Considering the findings made in the analysis of the judicial practice, it can be concluded that Article 181 of the CC sets high standards of legal certainty on the side of potential perpetrators, which creates the risk of it becoming a “shield” from any actual and established criminal liability. In other words, a very specific legal description and the high standards it establishes make the burden of proof very difficult, if not impossible to meet (especially considering the fact that the burden of proof is on the plaintiff). Aside from the presented examples, this is also confirmed by the statistics, which show a very small number of final court decisions (compared to a significantly higher number of criminal reports), as well as the lack of non-probationary sentences in the judicial practice. Therefore, it is also questionable whether the existence of a separate criminal offense (in this form) does more good than harm from the perspective of legal certainty.

4.3 What Should be the Direction of Future Developments?

Finally, there is a question on what direction should be taken in future developments. This question is, naturally, the most important one from the perspective of the Croatian legal system, which is being critically assessed in this instance. It is also relevant for any other system which faces doubts on the regulation of criminal liability for medical malpractice. Therefore, the elaborations presented here should not be limited only to Croatian law.

In this sense, it can be concluded that the provision of a separate criminal offense with narrowly defined elements does not necessarily add value to the protection of the rights of the patients, nor does it increase the level of legal certainty. To the contrary, it is possible that it also has a negative effect on these standards. Therefore, the emphasis should be placed on the development of a unified judicial practice, which, in turn, should rest on two significant postulates: the decreased dependence on the determinations of medical experts and the increased consideration of the will of the patients, which is manifested through their informed consent. This would promote a system which cares for the “best interest” of the patients (Then, 2017).

With this in mind, the Croatian legislature, as well as any other legislature facing the task of regulating this challenging area, should abandon the formalistic criterion of the violation of the rules of the profession (in the narrow sense) and turn to the model which is based on the informed consent of the patients. Criminal law should honor the doctor who will invest enough effort to inform the patient on the specific medical procedure and introduce them to its consequences, in a composed manner. On the other hand, criminal law should not protect the doctor who is unwilling to make such an effort, or who fails to inform the patient at all. This approach should be the foundation for the true protection of the main priority in this area: the health of the patient.

5 Conclusion

The punishment of medical malpractice and medical negligence remains a very controversial issue and many countries have opted to treat these matters under the less repressive branches of law, such as civil and tort law. However, most countries of continental Europe regulate these situations under criminal law. There are two legal models, one according to which such situations are regulated as a separate criminal offense, and the other where they are regulated within the framework of the general criminal offenses of bodily injury, manslaughter, etc. The existence of a separate criminal offense is particularly typical for countries of the former Eastern Bloc, which includes

Croatia (which is an EU member state, and previously a part of the former Yugoslavia).

In this paper, this issue was observed through the prism of the Croatian Criminal Code and its judicial practice, which interprets the standards of criminal liability for medical malpractice very strictly, and which results in a very small number of court decisions in practice. This does not mean that there are no errors or medical malpractice in Croatia, but only that the legislative framework does not fully correspond with the needs of real life.

For these reasons, this paper critically assesses the applicable law and practice, highlights the key issues in the implementation of the law and proposes the affirmation of a new concept *de lege ferenda*. This new concept, which places more emphasis on the informed consent of patients, will translate into a higher level of protection of the health of people in practice. In this sense, the main message of this paper is that insisting on legal formalism and systematisation of the criminal codes does not necessarily achieve a higher level of protection of the rights of the injured persons (victims of the criminal offense).

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