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Introducing No-Fault Compensation in Slovenian Medical Tort Law

Wprowadzenie systemu kompensacji no-fault w słoweńskim deliktowym prawie medycznym

ABSTRACT

The National Strategy for Quality and Safety in Healthcare 2022–2031, drafted in November 2021 from the Slovenian Ministry of Health, sets out, i.a., the basic foundations of a no-fault compensation model for medical errors. No-fault compensation is a new concept in Slovenian (medical) tort law. Therefore, the purpose of this paper is to determine whether a no-fault compensation regime, as set out in the Strategy, is at all necessary and reasonable in the light of the existing tort law regime and, in particular, whether such a regime would actually improve the patient's position in tort legal relationships due to medical errors and facilitate their options. By our findings, the Strategy does not provide a sufficiently compelling rationale for intervening in the existing compensation legal regime. The Slovenian case law has already established measures to compensate for the disturbed parity between the legal positions of the patient and the healthcare organization in the assessment of medical errors.

Keywords: no-fault compensation; medical error; tort law; healthcare; safety

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INTRODUCTION

After cancer and heart disease, professional medical error is ranked as the third leading cause of death in the United States.[1] There is no comparable data available for Slovenia. A. Robida estimates at least 1,000 deaths per year in Slovenian hospitals due to medical errors.[2] In recent years, Slovenian case law has seen an increase in the number of claims for compensation for damages due to medical errors.[3]

The Slovenian Ministry of Health is preparing the National Strategy for Quality and Safety in Healthcare 2022–2031 (hereinafter: the Strategy),[4] which aims to improve the quality of healthcare and patient safety, as part of the Support for improving the quality of healthcare and patient safety in Slovenia[5] project. The Strategy, drafted in November 2021, sets out, i.a., the basic foundations of a no-fault compensation model for medical errors.

No-fault compensation is a new concept in Slovenian (medical) tort law. Therefore, the purpose of this paper is to determine whether a no-fault compensation regime, as set out in the Strategy, is at all necessary and reasonable in the light of the existing tort law regime and, in particular, whether such a regime would actually improve the patient's position in tort legal relationships due to medical errors and facilitate their options. To this end, the model of no-fault compensation as set out in the Strategy is presented first, followed by a discussion and analysis of the specific substantive and procedural legal aspects thereof, in particular the advantages and disadvantages of such a proposed regime in relation to the existing medical tort law regime. The findings are summarised in the concluding chapter, which also provides a starting point for improving the model of no-fault compensation as set out in the Strategy.

[1] M.A. Makary, M. Daniel, Daniel M., *Medical Error – The Third Leading Cause of Death in the US*, "BMJ" 2016, no. 353, i2139.

[2] A. Robida, *Tudi sam sem ga kdaj lomil*, 11.6.2016, https://www.dnevnik.si/1042740716/slovenija/andrej-robida-tudi-sam-sem-ga-kdaj-lomil (access: 10.8.2022).

[3] Of course, this in itself does not mean that the number of medical errors is growing.

[4] Phase 6, Support for improving the quality of healthcare and patient safety in Slovenia, RFS REFORM/SC2020/021, AARC – Consortium.

[5] The aforementioned project is carried out under the auspices of the European Commission's Structural Reform Support Service.

RESEARCH AND RESULTS

1. Key features of the no-fault compensation model from the draft of the National Strategy for Quality and Safety in Healthcare 2022–2031

In section 10.4, the Strategy sets out the fundamental orientations of the no-fault compensation regime in the field of medical tort law. Thus, it is envisaged to introduce a system of no-fault compensation as a mandatory first step in the process of claiming financial compensation for an error occurring during medical treatment.[6] In cases of medical error, a civil law compensation claim is intended to be a subsidiary procedure.[7]

The Strategy emphasizes the principle of universal inclusion in the regulation of no-fault compensation, which means that all healthcare providers in Slovenia, as well as all the patients they treat, would be bound by the no-fault compensation regime.[8] As regards the funding of monetary compensation, it is envisaged that this would be split between several different sources, as the usual no-fault compensation scheme covers a wide range of injuries ranging through a variety of fields and practices, both by medical and other staff.[9] Thus, it is proposed to develop a model involving one or more of the following sources: health insurance contributions, contributions from the revenue of healthcare providers, general or special taxation sources, or sources of insured persons.

In accordance with the starting points of the Strategy, claims for no-fault compensation should be decided by a special, independent, and autonomous body, created in a multidisciplinary manner, namely including representatives from the legal, medical, economic, and other disciplines. If the members of the decision-making body lack expertise in a particular field, an expert can be brought in. The members of the Board should be held liable for compensation for work within their remit, in particular for the uniform application of standards and recommendations on awarding of compensation.[10]

In relation to the issue of what constitutes legally recognized damage that justifies the payment of no-fault compensation for medical errors, the Strategy states that compensation is awarded in the following cases: medical error or a failure to exercise due care in the course of treatment, defective or inadequate medical

[6] See item 2.1 of the Strategy.

[7] See item 2.2 of the Strategy.

[8] See item 4 of the Strategy.

[9] See item 5 of the Strategy. The system of compulsory liability insurance for doctors and other healthcare professionals, implemented under the Medical Services Act, should remain applicable, though is to be adjusted to accommodate the reduced number of claims resulting from the enforcement of no-fault compensation.

[10] See items 6.1–6.3 of the Strategy.

devices used in the treatment, infections and other accidents for which the health-care institution or hospital is liable.[11] Legally relevant damage occurring due to a medical error or a failure to exercise due care during treatment includes damage arising from any error or failure to exercise due care, whether regarding preventive measures, examinations, diagnoses or at any time during the follow-up treatment process. However, cases will be exempted where an appropriate examination or treatment has been carried out and the damage occurred as a result of a pre-existing medical condition or its predispositions, or a greater propensity for such harm or when there is a known and acceptable risk to the patient.[12] To assess the adequacy of a health professional's or health service provider's conduct, a standard of "good practice" in a particular professional field or conscientious and diligent conduct in the organization of the health service provider's work is required.[13] It is the patient who will have to demonstrate in the claim what damage has been caused to his or her health by the specific medical procedure that was not carried out accordingly.[14] If the treatment was substandard and harm has been caused, the decision-making body will have to decide whether there is more than a 50% probability that there is a causal link between the substandard treatment and the patient's injury or harm.[15]

Compensation could also be justified in cases of an omission of the duty to explain, if it can be stated with certainty that the harm would not have occurred if the duty to explain had been properly performed and the patient would not have opted for a certain medical procedure.[16] This means that only compensation that arose during or as a result of medical treatment is justified, and if the damage could have been prevented or avoided.[17] Compensation claims are not justified in cases when the damage to the patient's health or death results from a significant medical complication, or if the correct diagnosis was made and the correct treatment or intervention was carried out. The damage to the justification of the compensation claim should not arise from a pre-existing disease or from the patient's specific medical condition.[18]

2. Analysis of the material and procedural elements of no-fault compensation

The relationship between a patient and a physician or healthcare organization is a private civil law relationship, characterized by the legal adaptability of the positions of its subjects. Despite the normative recognition of the adaptability of

[11] See item 7.1 of the Strategy.
[12] See item 7.2 of the Strategy.
[13] See item 8.1 of the Strategy.
[14] See item 8.2 of the Strategy.
[15] See item 8.3 of the Strategy.
[16] See item 8.4 of the Strategy.
[17] See item 9.1 of the Strategy.
[18] See item 9.2 of the Strategy.

the positions, the patient is usually in a subordinate role when pursuing claims for medical errors, as they lack medical expertise, often do not have all the necessary medical documentation, are financially weaker than the healthcare institution, etc. In order to compensate for the imparity of the parties to the legal relationship in question, various mechanisms have been developed by legal systems, including, i.a., the concept of no-fault compensation that should aim to ensure that the patient receives compensation for the unavoidable damage caused by the treatment as early, easily and cost-effectively as possible.[19]

Below, the individual (substantive and procedural) legal aspects of no-fault compensation are presented and analyzed in the light of the applicable medical tort law, with a view to determining whether the no-fault compensation regime is as envisaged in the Strategy, in the light of the existing tort law, whether such a regime is at all necessary and reasonable and, in particular, whether it would actually improve the patient's position in medical tort law concerning medical errors and facilitate the patient's chances of obtaining fair financial compensation for damage caused by medical treatment.

3. The basis of the legal commitment to pay compensation for medical errors and on exculpatory grounds

The legal basis of the relationship between the patient and the healthcare organization is usually the healthcare services contract, which provides the fundamental basis for the rights and obligations of the patient and the doctor or healthcare provider.[20] An exception to the contractual principle applies in cases where the physician has to carry out an emergency medical procedure and the patient is in a condition that does not allow him or her to form his or her own will. The physician's behavior in an emergency, when the patient is unable to consent to treatment, is treated as an emergency intervention. The basis for the physician's conduct is the provisions of item 12 of Article 2 and Article 28 of the Patients' Rights Act.[21]

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[19] Other mechanisms to reinforce the patient's unfavourable position include lowering the standard of proof for causation, reversing the burden of proof, etc. See M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (1.)*, "Odvetnik" 2017, no. 83, p. 11.

[20] Cf. *ibidem*; E. Deutsch, A. Spickhoff, *Medizinrecht*, Berlin–Heidelberg 2008, p. 55. Likewise A. Polajnar Pavčnik, *Obligacijski vidik razmerja med bolnikom in zdravnikom. Pravo in medicina*, Ljubljana 1998, pp. 92–98; P. Klarič, *Odštetno pravo*, Zagreb 2003, p. 385; *Obligacijski zakonik s komentarjem*, eds. N. Plavšak, N. Plavšak, M. Juhart, vol. 4, Ljubljana 2004, p. 199; M. Brus, *Podjemna pogodba*, "Pravosodni bilten" 2017, no. 2, p. 97, footnote 21; T.M. Spranger, *Medical Law in Germany*, Kluwer Law International 2011, pp. 71–80; A. Leischner-Lenzhofer, C. Zeinhofer, C. Lindner, C. Kopetzki, *Medical Law in Austria*, Kluwer Law International 2011, p. 78.

[21] Official Gazette of the Republic of Slovenia, no. 15/2008 and 55/2017.

The older legal literature took the view that a healthcare services contract is a work contract.[22] Thus, the Supreme Court of the Republic of Slovenia, referring to the above-mentioned older legal literature, also accepts this definition.[23] As the obligation to endeavor is not a typical consideration in a work contract, more and more authors are now advocating that it is an order contract.[24] Two additional features of the contractual relationship between physician and patient bring it closer to an agency relationship, namely the confidentiality of the relationship and, as a rule, the personal performance of services (as a consequence of the right of free choice of the physician), which are not, as a rule, elements of a work contract. The view that a health service contract is an order contract is also common in foreign case law, e.g., Swiss case law.[25] On the contrary, some theorists argue that, due to its specificities, the health service contract cannot be subordinated to nominative types of contracts, but is instead an innominate or *sui generis* contract that should be regulated as a nominative health service contract.[26]

The aforementioned position of Slovenian case law and theory with regard to the legal nature of the relationship between a healthcare organization and a patient, in terms of the definition of the legal commitment to compensate, means that when a physician fails to act in accordance with professional diligence, which results in professional error, or when they infringe on their duty to explain and the patient suffers damage, this constitutes an infringement of the contractual relationship.

Therefore, since illegality as a precondition for liability for damages for a physician's breach of the aforementioned duty incumbent on them is manifested in the legal fact of an infringement of the contractual obligation to perform the consideration that the physician was obliged to perform in accordance with the health service contract (i.e., to act *lege artis* and to fulfill the duty to explain properly), the rules on commercial liability for damages for the harm caused to the patient by the infringement apply. They exclude the application of the general rule of the

[22] A. Polajnar Pavčnik, *op. cit.*, p. 94; S. Cigoj, *Institucije obligacij*, "Official Journal of the Republic of Slovenia" 1989, p. 108, 147; M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (1.)…*, p. 11; V. Blake, *When Is a Patient-Physician Relationship Established*, "AMA Journal of Ethics. Virtual Mentor" 2012, vol. 14(5).

[23] Cf. judgments of the Supreme Court of the Republic of Slovenia: II Ips 342/2014 and II Ips 207/2015.

[24] N. Plavšak, [in:] *Obligacijski zakonik…*, vol. 4, p. 199; M. Brus, *op. cit.*, p. 97, footnote 21; M. Ovčak Kos, *Civilnopravna odgovornost zdravnikov*, [in:] M. Ovčak Kos, S. Senčar, V. Đekić, *Civilnopravna odgovornost zdravnikov, zavarovanje odgovornosti ter etične in moralne kršitve v zdravniški praksi, zbornik*, Ljubljana, March 2017, p. 4.

[25] See, i.a., decisions BGE 117 Ib 197 and BGE 116 II 519; F. Wenzel, *Handbuch des Fachanwalts Medizinrecht*, Köln 2007, p. 1493; Y. Unver, *The Legal Nature of Doctor-Patient Relationship in Turkish Medical Law*, "Medicine, Law & Society" 2016, vol. 19(1), p. 60.

[26] P. Klarić, *Odštetno pravo*, Zagreb 2003, p. 385; M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (1.)…*, p. 11.

first paragraph of Article 131 of the Obligations Code[27] (hereinafter: the OZ) that governs the presumptions of general non-business liability for damages. Since the basis of the legal relationship between the patient and the physician in the case of emergency acts is not commercial, it is clear that the physicians in such cases can only be held liable in tort (Article 131 of the OZ).

A physician is exonerated from liability for non-contractual damage under the rules of liability for faults if they prove that they were not at fault for the harm, and from liability for contractual damage if they prove that they were unable to perform the contract or that they were delayed in performance due to circumstances arising after the conclusion of the contract and that they could not have prevented, remedied or avoided. The basis of the liability for assessing the exculpation of a physician or healthcare organization will not normally be decisive in terms of the burden of proof; in both tort and contractual liability for damages, the allegations and evidence that the medical staff did not commit professional misconduct and that there is no causal link between the tortious conduct and the damage will be crucial to exonerate the liability. The position of the Supreme Court of the Republic of Slovenia in case II Ips 207/2015, which is that a physician is exonerated of their liability under the provisions of Articles 239 and 240 of the OZ by proof of due diligence, but they must also prove that there were circumstances that made it impossible for them to (properly) perform the contract, which were insurmountable or unavoidable for them, requires further consideration. As already pointed out, the law defines exculpatory grounds differently for a tort than for an infringement of contract. For both cases, it regulates them comprehensively. The judgment commented on, however, cumulates the prerequisites for the exculpation of a physician under both bases of liability for damages: the proof of due diligence challenges the assessment of the unlawful conduct of the physician, which is one of the constitutive elements of a tort and excludes the infringement of contract, whereas the circumstances referred to in Article 240 of the OZ can only become relevant in the case of an infringement of contract by the physician.

In light of the above, it can be concluded that a medical error in the strict sense does not constitute negligent conduct but an infringement of contract. The healthcare institution cannot exonerate itself of liability by proving due diligence, but must prove that there were circumstances preventing it from (properly) performing the contract and that they were insurmountable or unavoidable.[28]

Therefore, since Slovenian case law has already taken steps to balance the positions of the patient and the healthcare organization in the assessment of medical errors, and has withdrawn from the concept of tort, before introducing no-fault compensation, in our view, it would be necessary to identify the actual weaknesses

[27] Official Gazette of the Republic of Slovenia, no. 97/07 and 64/16.

[28] M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (1.)…*, p. 11.

of the current regime under the OZ in the pursuit of such compensation claims and how they can be overcome and improved by the new concept of no-fault compensation. In this respect, the Strategy highlights the exclusion of establishing negligence or fault as the most important contribution of the introduction of no-fault compensation.[29] As stated above, fault is not, as a rule, a prerequisite for a legal commitment to compensate in this type of claims, as it is a contractual damage, and in our view this does not, in itself, improve the position of the patient in medical tort law concerning medical error. Therefore, the Strategy should provide a professionally supported rationale to justify the introduction of no-fault compensation.

Accepting the concept of no-fault compensation also requires a clear definition of no-fault compensation towards the OZ in this type of legal relationships and a clear definition of the assumptions of no-fault compensation, which cannot be inferred from the Strategy.

4. The understanding of no-fault compensation and the definition of medical error

There is no definition of medical error or malpractice in Slovenian healthcare regulations. In fact, this would also be difficult to imagine, as such a definition would require the establishment of a rule on the correctness of treatment, which depends on the circumstances of each case.[30] The concept of professional error in the treatment process as a medical error has been developed through legal theory, which was followed by case law. It is therefore a purely legal concept that is not specifically supported in medical doctrine or in the science of patient safety.[31] Given the fact that the concept of treatment should be understood broadly, so that (with a broad concept of health) it covers all the activities of physician-patient interaction, whether curative or preventive, and that a range of persons may be involved in treatment, not exclusively physicians but also other healthcare professionals. Therefore, it would probably be more terminologically appropriate to refer to a professional error occurring during the treatment process[32] as a medical error.

The case law of the Supreme Court of the Republic of Slovenia clarifies that a professional error committed by a physician, a physician's assistant, or medical personnel is assessed when their conduct is not in accordance with the requirements

[29] Strategy 1.6, objective 2.

[30] The Patients' Rights Act uses phrases such as inappropriate treatment and inappropriate conduct by a healthcare professional, suggesting that medical error is conduct that does not comply with the rules of the profession.

[31] Cf. A. Robida, *Zdravniki nimamo zdravniških možganov, imamo samo človeške, zdravniki ne delamo zdravniških napak, ampak samo človeške, tako kot vsi drugi ljudje*, "Revija ISIS" 2015 (November), p. 32.

[32] This is also suggested by A. Robida (*ibidem*).

of medical doctrine;[33] that a medical error represents a deviation from professional standards of professional action, care and attentiveness that may result in any deterioration of health[34] or that a physician has committed a professional error if they fail to act with the utmost care in accordance with the rules of medical science and the profession and with normal conduct, and if they fail to prevent harm to the patient or cause the patient's health to deteriorate, whereby the first part concerns the legal standard of diligence of a good professional, as defined in the OZ.[35]

Conduct *contra legem artis*, which completes the meaning of medical error, is therefore conduct or omissions thereof contrary to the professional, occupational standards of conduct and behavior in force in the field of medicine at the time of the harmful event. The completing of the legal standard of due (required) expert (professional) care depends on the circumstances of the particular case and on the standards of conduct and behavior that have been developed, which are so varied and substantively interdependent with the changing factual circumstances that they cannot be defined in any relatively definite way. In the case of the medical attentiveness of the physician, they refer to the professional, occupational standards of conduct and behavior in force in the field of medicine. The court, with the help of an expert, defines the content of this legal standard and determines what the modern medical doctrine, professional standards, and norms require in a specific case in the light of the development of the healthcare system in the Republic of Slovenia, and how the physician should have acted. On the basis of the information provided by the expert and the circumstances of the particular case, a judgment is made as to whether the physician's conduct in a particular case meets or departs from the legal standard of care and diligence.[36]

It can therefore be concluded that a physician has properly fulfilled his or her contractual obligation if their (specific) conduct meets the standard of due care, namely due professional care.[37] The criterion for fulfillment or the normative concrete terms of the legal standard of due care of a physician is abstract, namely the typical, normal conduct of the average professional in a given medical field. The

[33] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 384/2009, 19.5.2011, ECLI:SI:VSRS:2011:II.IPS.384.2009.

[34] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 80/2011, 29.3.2012, ECLI:SI:VSRS:2012:II.IPS.80.2011.

[35] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 302/2011, 26.4.2012, ECLI:SI:VSRS:2012:II.IPS.302.2011.

[36] Cf. *ibidem*; M. Ovčak Kos, A., Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (2.)*, "Odvetnik" 2018, no. 84, p. 10; A. Božič Penko, *Nekatera pravna vprašanja v zvezi z odgovornostjo za zdravniško napako v sodni praksi*, "Pravni letopis Inštituta za primerialno parvo" 2017, pp. 69–88.

[37] Otherwise, it applies when the physician's obligation is a result of obligation. In such a case, the end result of the service rendered is the criterion for assessing whether the service obligation has been properly fulfilled.

hypothetical medical professional is not a brilliant, but an average individual, but they act with greater care. The rules and knowledge of medical science and experience, which are necessary to achieve the goals of treatment and that have been tested in practice, tell how the average professional in a given medical field should act. This criterion is also used to judge the behavior of physicians with less experience (e.g., junior physicians). Determining what is *lege artis* conduct in a particular case is always an *ad hoc* and *ex post* determination. The assessment of care is tied to the moment at which the physician made the decision; any subsequent medical discoveries are not legally relevant. For example, if a certain item of information on the mode of action of a particular pharmaceutical product during treatment is only available in one paper published in an inaccessible peer-reviewed journal, which was validated years later, a duly diligent physician cannot be required to know it.

In light of the above, it is legally irrelevant whether the physician or healthcare professional in question possessed the appropriate knowledge or did the best they could in the particular case, given the stressful situation and circumstances and their abilities.[38] Therefore, it is not judged what should be done in a specific case for the treatment to be successful, it is only legally decisive whether, in a specific case in the given circumstances, what was performed met what is dictated by modern (world) medical doctrine, professional standards, and norms, taking into account the development of the Slovenian healthcare system and the current treatment capacity in Slovenia.

Conduct contrary to the rules of the profession constitutes an infringement of the health service contract by the healthcare provider and is a key prerequisite for liability for damages resulting from a medical error, regardless of whether liability is considered in a non-contractual or contractual manner.[39] A complication occurring in treatment is not a medical error, therefore the liability for damages for medical error is excluded in such a case.[40] However, liability for damages caused by the complication in the event of an infringement of the duty to explain is not excluded in such a case.

The essence of the concept of no-fault compensation for medical errors, as emphasized in the literature, is to provide the patient with adequate financial compensation for the harm suffered quickly and with the least possible cost, without the burden of proving negligence on the part of the healthcare professional. As a rule, damage that is legally recognized is damage that was unavoidable in the course of the treatment.

[38] A. Robida highlights these circumstances as important. See A. Robida, *op. cit.*, pp. 33–34.

[39] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 302/2011.

[40] Cf. judgments of the Supreme Court of the Republic of Slovenia: II Ips 506/1992; II Ips 385/2006, 21.11.2008, ECLI:SI:VSRS:2008:II.IPS.385.2006; II Ips 1145/2008, 28.1.2010, ECLI:SI:VSRS:2010:II.IPS.1145.2008; II Ips 80/2011.

It is clear from the Strategy (item 7.1) that no-fault compensation should be awarded for medical error resulting from a failure to exercise due care. The failure to exercise due care is an element of fault (negligence), which suggests that the fault of the healthcare professional should also be established in these proceedings. However, this contradicts the very concept and objectives of introducing no-fault compensation. The Strategy (item 9.1), which talks about damage that could be prevented or avoided, further adds to the confusion. Thus, the criteria for defining a medical error are not entirely clear – only in terms of harm resulting from negligent conduct, or harm that could have been prevented or avoided, or a combination of these conditions. I believe that a clear definition is needed here, which leaves no room for doubt. It should also be clearly defined whether the compensation is only for medical errors in the strict sense or also for an infringement of the duty to explain, as set out in the Strategy (item 8.4).

5. Regarding legally recognized damage, with particular reference to non-pecuniary damage

Only those consequences of professional medical errors that harm the injured party's physical and mental integrity, as defined in Article 179 of the OZ, may be relevant as regards the merits of monetary compensation. It is a well-established and uniform position of the case law of the Supreme Court of the Republic of Slovenia that the circle of forms of non-pecuniary damage is closed and that the legislator has excluded the possibility of claiming pecuniary damages in respect of other more or less similar non-pecuniary damages. Therefore, those non-pecuniary damages that they have not legally recognized cannot be compensated, even by analogy with the rules on compensation for legally recognized forms of non-pecuniary damage.[41] This is not a legal gap, but a deliberate arrangement under which monetary compensation can only be claimed for certain non-pecuniary damages.

The foregoing does not mean that the case law cannot respond to societal changes, changes in values, and new forms of damage without changing the law of obligations. The manifestation of new consequences of harm to the physical and mental integrity of the injured parties may pave the way for the existing closed system of legally recognized non-pecuniary damage (physical pain, mental anguish, and fear) through interpreting them broadly and by a broad interpretation of the legally limited sources of mental pain (diminution of enjoyment of life, malformation, infringement of personality rights, etc.). The OZ defines both in distinctly abstract

[41] Cf. judgments of the Supreme Court of the Republic of Slovenia: II Ips 591/2008, 24.6.2010, ECLI:SI:VSRS:2009:II.IPS.591.2008; II Ips 470/2009, 8.7.2009, ECLI:SI:VSRS:2009:II.IPS.470.2009; II Ips 99/2013, 5.11.2015, ECLI:SI:VSRS:2015:II.IPS.99.2013.

terms,[42] as legal standards.[43] For example, it has long been established in the case law that inconvenience during treatment, medical examinations, the administration of medicinal products and the like are considered physical pain; in a more recent judgment, the Supreme Court awarded compensation for inconvenience related to treatment for an injured party who, due to a permanent hormonal disorder resulting from a concussion, will be placed on hormone therapy for life, the abandonment of which would put his life at risk.[44] The Supreme Court considered mental anguish to be a disturbance of mental balance, psychological discomfort, and tension.[45] In both cases, the feelings or conditions are not generally understood to be physical or mental pain.

Most personal injury claims are based on physical pain though, on rarer occasions, physical suffering is caused by mental trauma. However, the law does not make the right to compensation for physical pain conditional on its origin, only on the fact of its occurrence. It is different in the case of emotional pain. For these, the law makes the right to compensation conditional on one of the exhaustively listed causes: diminution of the enjoyment of life, malformation, defamation of reputation and honour, curtailment of liberty, infringement of personality rights and bereavement. These sources of mental anguish are also defined in abstract terms or as legal standards. Some of these have already been interpreted very broadly by case law; for example, the loss of a school year has been considered a diminution of the enjoyment of life.

In the area of the origins of mental anguish, there is considerable room for interpretation in the field of the infringement of personality rights; many interferences with a person can be defined as such, including those that constitute new forms of harm. It does not define personality rights as the origin of mental anguish under Article 179 of the OZ. That may be an advantage. Article 35 of the Slovenian Constitution guarantees the inviolability of a person's physical and mental integrity, privacy and personality rights. Unlike human rights that protect people from state interference in legally protected spheres, the latter also protect each individual in

[42] D. Možina, *Nepremoženjska škoda zaradi izgube počitnic: Leitner pri nas doma*, "Podjetje in delo" 2014, no. 1, p. 41 ff.

[43] A. Božič Penko, *Razmislek in sodna praksa Vrhovnega sodišča o nekaterih aktualnih vprašanjih odškodninskega prava v zvezi z nepremoženjsko škodo*, "Pravni letopis Inštituta za primerjalno parvo" 2016, p. 69.

[44] See judgment of the Supreme Court of the Republic of Slovenia, II Ips 133/2016, 21.1.2016, ECLI:SI:VSRS:2017:II.IPS.133.2016. They clarified that substitution therapies should be considered as a nuisance in relation to treatment, in the same way as the administration of medicines, because of the closed circle of non-pecuniary damage. See M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (2.)…*, p. 10.

[45] For example, see judgments of the Supreme Court of the Republic of Slovenia: II Ips 409/2009, 18.2.2010, ECLI:SI:VSRS:2010:II.IPS.409.2009; II Ips 576/2008, 7.4.2011, ECLI:SI:VSRS:2011:II.IPS.576.2008.

relation to other individuals.[46] The scope and forms of their civil law protection are governed by the OZ. Since neither this (nor the Constitution) provides a list of personality rights,[47] it is left to the case law to decide whether, in the light of the development of a society's culture, value system and legal consciousness, there arose a need for the legal protection of a particular non-pecuniary personal good.[48]

On the topic discussed in this article, the Supreme Court of the Republic of Slovenia has, in recent case law, upheld the plaintiff's claim that she is entitled to compensation for mental anguish due to the infringement of her personality right because, despite taking contraceptive pills, she became pregnant, as other drugs reduced their effectiveness and the methods of treatment used indicated an abortion; the personality right violated is her right to freely decide on the birth of her child.[49] Otherwise, when the plaintiff decided on an abortion, but the abortion was not "successful" because it was performed incorrectly, and she gave birth to a healthy child, the Court held that the birth of a healthy child did not constitute damage; the medical error (only) resulted in damage in the form of expenses for the child's subsistence.[50]

The Strategy does not make it clear what constitutes legally recognized damage. Therefore, it is unclear whether it refers only to non-pecuniary damage or also to compensation for pecuniary damage. In our view, a catalog of forms of non-pecuniary damage should also be defined.

6. The strategic objective that the damage justifying a compensation claim should not arise from a pre-existing disease or from the patient's specific medical condition

The Strategy (in item 9. 2) states that the damage to the justification of the compensation claim should not arise from a pre-existing disease or from the patient's specific medical condition. In our view, the Strategy thus advocates a complete discharge from liability for damage caused to a patient as a result of his or her medical condition, i.e., as a result of a personal trait of the patient that contributed to the damage.

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[46] L. Toplak, [in:] *Komentar Ustave Republike Slovenije*, ed. L. Šturm, Fakulteta za podiplomske in evropske študije 2002, p. 369.

[47] On the "indetermination" of personality rights, see, for example, judgment of the Supreme Court of the Republic of Slovenia, II Ips 919/2007, 17.9.2009, ECLI:SI:VSRS:2009:II.IPS.919.2007.

[48] P. Klarić, [in:] *Odgovornost za neimovinsku štetu zbog povrede prava osobnosti u vezi s radom*, eds. I. Crnić, P. Klarić, Zagreb 2007, p. 16; M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (2.)…*, p. 10.

[49] See judgment of the Supreme Court of the Republic of Slovenia, II Ips 736/2005, 24.5.2007, ECLI:SI:VSRS:2007:II.IPS.736.2005.

[50] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 185/2016, 1.9.2016, ECLI:SI:VSRS:2016:II.IPS.185.2016.

The legal question is whether the person who caused the damage – the provider of a healthcare service who failed to provide the service in a proper manner and who, as a result, caused the deterioration of the patient's state of health or even death – is also liable for damage the occurrence of which or a greater extent of the damage was contributed to by the personal traits and condition of the injured party (the patient). It is a question of legally recognized causation and of deciding which natural cause of the damage, when there are several possible causes, should be given decisive importance. In general, establishing legally recognized causation is one of the most complex issues in traditional tort law. According to the theory of adequate causation that is accepted in our law and is the most widely used, among the several circumstances that are relevant to the occurrence of damage, only those that, i.e., foreseeably, in the ordinary course of things, lead to the same result, are considered to be the cause of the damage. It is therefore not (more importantly) the "eggshell theory", according to which the injured party is also liable for any unforeseeable consequences of their conduct or consequences that are difficult to foresee that arise from the particular characteristics and delicate conditions of the injured party.

In the light of the Strategy (item 9.2), this would be, e.g., the case:

- for competing medical error and disease (whether the cause of the deterioration in the patient's condition is a failure in hip or spinal surgery, or a previous degenerative change; according to case law, degenerative changes are not generally a legally relevant cause until they are manifest – only the healthcare provider is liable for the damage and the patient is not partly liable to suffer it themselves),
- for competing errors and conditions from previous injuries (whether the deterioration in the health is due to spinal surgery that was not performed *lege artis* due to an error in screw fixation and new surgery was needed, or to the patient's condition after a previous injury that left the spine unstable),
- for competing errors and specific patient sensitivities.

In the case law, all of these circumstances are characterized as personal traits of the injured party and do not constitute a basis for excluding the liability of the person who caused the damage for the damage that occurred and for any greater extent of the damage (also) resulting from these circumstances. However, shared causation (resulting in shared responsibility) is not always excluded. The assessment always depends on the factual findings in each individual case, and the assessment of what those facts are cannot be arbitrary.

The Strategy does not follow these premises that would be particularly problematic if it is impossible to seek full compensation outside the concept of no-fault compensation (out-of-court settlement or in litigation against the tortfeasor or his insurer). In my view, there are no compelling reasons for such a departure from the normal tort law regime.

7. The circle of recipients of no-fault compensation

The death or serious disability of the direct victim as a result of a medical error leads to compensation for mental anguish suffered by his/her relatives.[51] The number of monetary damages awarded by the case law to indirect victims is, as already mentioned, extremely low and demonstrates the inadequate placement of the protected non-pecuniary value in the system of values protected by tort law.

As a general rule, an injured party is only the person who has suffered direct damage within the meaning of the OZ. In the case of non-pecuniary damage, Article 180 of the OZ expressly stipulates otherwise: as a result of the death or particularly serious disability of the direct victim, compensation is (also[52]) due to the victim's close relatives – the indirect victims – for the mental anguish they suffer as a result.[53] The same provision also defines the beneficiaries entitled to compensation: immediate family members – spouse, children and parents, and, subject to the condition of a more permanent living relationship, siblings and a cohabiting partner.[54] However, is the circle of close family members referred to in the first and second paragraphs closed and limited to the indirect victims listed? In theory, views on this were divided at the time the Law of Obligations[55] was in force. The case law since then and since the entry into force of the OZ has considered the beneficiaries to be exhaustively listed, but has nevertheless partially opened up the allegedly closed circle by considering as members of the immediate family, as mentioned in the law, other persons who had a relationship with the deceased or severely disabled person that can be identified in substance with a relationship with a spouse, parent or child. Thus, in a case where a deceased grandchild lived in the same household as his grandparents before his death, and the grandmother was a substitute for the working mother, the Supreme Court took the legal view that, in addition to the spouse, children and parents, the immediate family may also include the grandparents, if the particular circumstances warrant it.[56] The Croatian

[51] See Article 180 of the OZ.

[52] In the case of a particularly serious disability, both the direct and indirect injured party is entitled to compensation.

[53] The provision expands beyond the existing limits the legally relevant causation and thus the scope of the harm for which the perpetrator is liable: although the indirect injured parties suffer from the condition of the direct injured party, their close relative, the legally relevant cause of their suffering is the conduct of the person who caused that condition. See also I. Crnić, *Utvrđivanje iznosa novčane naknade neimovinske štete*, Zagreb 2013.

[54] The OZ retained the full circle of beneficiaries from the Law of Obligations, but extended it to siblings in the case of a particularly serious disability of the direct injured party, provided that there was a more permanent life partnership between them and the direct injured party.

[55] Official Gazette of the Republic of SFRJ, no. 29/78, 39/85, 2/89, 45/89, 57/89.

[56] Legal opinion of the plenary session of the Supreme Court of the Republic of Slovenia of 21–22 December 1992, VSS Report 2/92.

case law at the time the Law of Obligations was in force granted compensation to a grandchild for the death of his grandmother, who in every respect replaced his parents, living elsewhere, to children for the death of their stepfather, who had replaced their father in everything, and to a stepmother for the death of their stepchild, because the relationship between them was comparable to that between mother and child.[57]

It is not clear from the Strategy whether only the patient as a direct victim is entitled to no-fault compensation or also their relatives as indirect victims if the patient dies or becomes particularly severely disabled. In my view, there are no reasons that would preclude no-fault compensation to indirect victims as provided for in the OZ.

8. Specific procedural issues in no-fault compensation proceedings

The patient, as the injured party, is usually in a more difficult procedural position in compensation litigation, since, as a lay person, they must allege and prove, against an expert in the relevant medical field who has all the information on the course of treatment and similar, that their health has been impaired or worsened by the physician's detrimental act or omission, and that the physician's detrimental act or omission is the cause of their injury. The Supreme Court of the Republic of Slovenia has also recognized this imparity of positions in the compensation litigation in question and has sought to balance it by relaxing some of the rigorous procedural postulates towards the injured party as a plaintiff. Since the patient, as a layperson, does not know what caused the deterioration of their health (complication or professional error), in such a case, according to the Supreme Court, it is permissible to take indicative evidence from a medical expert, and after obtaining the expert's opinion, it is permissible to supplement the factual allegations (regarding causation), since the patient, as a plaintiff and a layperson themselves, was not necessarily able to make such an assessment beforehand.[58]

The existence of a patterned link between the professional medical error and the damage suffered by the injured party is a difficult gnoseological question for

[57] See judgments of: the Zagreb District Court of 8 May 1984, Gž-3564/84; the Croatian Supreme Court of 4 January 2006, Rev-727/2005; the Croatian Supreme Court of 20 May 1985. Rev-259/87.

[58] Cf. judgment of the Supreme Court of the Republic of Slovenia, II Ips 302/2011. On the contrary, a stricter approach to the assessment of the timeliness of the allegations concerning the infringement of the duty to explain is more appropriate, as it does not impose an excessive burden on the party to argue whether and how much has been explained to them, no special expertise is required, and the facts can be observed and perceived by the party. See M. Ovčak Kos, A. Božič Penko, *Dileme v primerih odškodninskega prava v zvezi z odgovornostjo za medicinsko napako (3.)*, "Odvetnik" 2018, no. 86.

both the court and the parties that justifies the application of a different standard of proof (and argument) – one that does not impose an unresolvable *a priori* burden on the plaintiff, namely the standard of a preponderance of the probabilities.[59] The issue raised is particularly complex in cases of a physician's infringement of due care (e.g., whether the physician could have prevented the patient's natural death by acting differently), as it relates to a hypothetical fact (a fact that actually does not exist). Since we can never know whether or not a particular treatment would have been successful, this kind of conclusion can only ever be made in retrospect, on the basis of a concrete experience (a concrete empirical finding). Therefore, for a hypothetical finding, it must be sufficient if the plaintiff alleges (and proves) that the physician's infringement of due care is of such a nature that it is capable of curing (preventing the death of) patients in a significant (non-negligible) proportion. The likelihood that the physician's failure to act would have prevented the harm (in this case, death) is a professional medical question. Therefore, it shall be answered by experts and is generally empirical (and possibly statistical). At this point, the question of proof (and the application of the rules on the allocation of the burden of proof and the correct content of the standard of proof) ends.[60]

The more flexible approach to assessing and proving causation followed by the recent case law of the Supreme Court of the Republic of Slovenia is also justified in comparative law.[61] The Court of Justice of the European Union has gone one step further in assessing the causal link between the use of a vaccine and the development of a disease in the injured party, stating that even if medical research does not prove or exclude the existence of a link between the use of a vaccine and the development of a disease from which the injured party suffered, the existence of a causal link between the defect attributed to the vaccine and the harm suffered by the injured party shall always be deemed to be established if certain predetermined factual indications of causation are present (in the specific case,

[59] Cf. judgments of the Supreme Court of the Republic of Slovenia: II Ips 671/2008, 20.11.2008, ECLI:SI:VSRS:2008:II.IPS.671.2008; II Ips 183/2015, 3.12.2015, ECLI:SI:VSRS:2015:II.IPS.183.2015; II Ips 17/2015, 29.10.2015, ECLI:SI:VSRS:2015:II.IPS.17.2015. See also C. Hobson, *Williams v the Bermuda Hospitals Board: Pro-Patient, but for Ambiguities Which Remain*, "Medical Law Review" 2017, vol. 25(1); C. Miller, *Case Comment: Williams v. The Bermuda Hospitals Board*, "Law, Probability and Risk" 2017, vol. 16(2–3).

[60] See judgment of the Supreme Court of the Republic of Slovenia, II Ips 183/2015.

[61] For comparative law approaches to causation, for example see the already mentioned case of *Williams vs. the Bermuda Hospitals Board* in the English case law, or judgment of the Croatian Supreme Court, Rev 876/2006.

the coincidence of the vaccination and the onset of the disease and the absence of signs of disease in the personal and family history[62]).[63]

In case of assessing the element of causality, the Strategy is based on the preponderance of probabilities. This means there must be more than a 50% probability that there is a causal link between the substandard treatment and the patient's injury or harm. The Strategy thus follows a more flexible approach in case law to proving causation that undoubtedly facilitates the position of the injured party in proceedings for no-fault compensation. However, the Strategy should also address the issue of expert medical opinions as indicative evidence in no-fault compensation proceedings, as well as the issues of the patient's influence on the choice of expert, disagreement with the expert opinion of the no-fault compensation decision-making body, the possibility for the injured party to obtain an expert opinion in the course of the no-fault compensation decision-making procedure, and the use of the expert opinion from the no-fault compensation procedure in subsequent court proceedings. The Strategy should also provide procedural rules for no-fault compensation procedures that respect fundamental procedural constitutional guarantees (e.g., the right to be heard, etc.).

9. The financing of no-fault compensation

It arises from the Strategy that the financing of compensation schemes would be divided between several different sources and that a model could be developed as an option, which could include one or more of the following sources: health insurance contributions, contributions from the revenue of healthcare providers, general or special taxation sources, or partially sources of insured persons. A bonus/malus model could be developed.

In my opinion, it is not appropriate for compensation for damage caused to patients to be paid from the budget or from special contributions from insured persons. Indeed, this contradicts the very essence of the application of liability for damages. One of its purposes is also prevention – to deter potential perpetrators (intimidated by the prospect of having to pay compensation) from the infringement of duty because they must pay a "penalty" – damages – in the event of harm. As soon as such a heavy burden is no longer borne by the healthcare providers, the

[62] The injured party in case C-621/15 was vaccinated against hepatitis B three times between December 1998 and July 1999 with a vaccine manufactured by Sanofi. In August 1999, he developed various disorders. In November 2000, he was diagnosed with multiple sclerosis. His health gradually deteriorated. At the time of his death on 30 October 2011, he had a functional disability in 90% and required round-the-clock care.

[63] Judgment of the CJEU in case C-621/15, *N.W and Others v Sanofi Pasteur MSD SNC and Others*, 21.6.2017, ECLI:EU:C:2017:484.

preventive purpose is difficult to achieve. The payment of such compensation from the health care institution's own resources is also, in our view, a key element in promoting quality in healthcare.

10. The subsidiarity and mandatory nature of no-fault compensation

In my view, the attempt to obtain no-fault compensation should not be obligatory, merely one of the options that a patient could choose in order to seek redress. The injured party must be free to decide how to redress their loss, which is based on the general freedom of action and the right to judicial protection.

Regardless of whether or not the mandatory model applies, the patient should always be able to seek redress up to full compensation in court. Therefore, such a concept of subsidiarity requires clear regulation, in particular of the statute of limitations (e.g., that the statute of limitations is suspended when deciding on no-fault compensation), the procedural rules guaranteeing constitutional law standards, the regulation of expert opinions, in particular the possibility of the patient to influence the choice of expert, to disagree with the opinion, to obtain their own expert opinion, to use the expert opinion in subsequent court proceedings, etc. The subsidiarity of the procedure also requires a clear definition of the prerequisites for obtaining no-fault compensation, in particular the definition of medical error, which has already been highlighted above. It must be clear what the criteria for assessing no-fault compensation were and how they differ, if at all, from the determination of damages in a medical malpractice lawsuit. This is essential for the effective exercise of the right to full compensation. I believe that the method and criteria for assessing compensation and any means of appeal must also be laid down.

11. The composition of the body that will decide on no-fault compensation

The Strategy foresees that no-fault compensation will be decided by an independent body, composed mainly of physicians and lawyers. We believe that the majority of the members of the independent body that would decide on no-fault compensation should be lawyers, experts in tort law. In fact, the assessment of damages is an application of substantive law. The problem may be that the current judges would be part of such a body, as they could face the same issue in a trial. It is true that in such a case, there would be disqualifications, but since the court does not have a specific mechanism to automatically disqualify such cases, the disqualifications would be based on the judge's own discretion, and the judge might forget that he or she had already dealt with a particular case. It would probably make the most sense for such a body to include retired Supreme Court judges, specialists in tort law, and other lawyers who are experts in the field, of course with the participation of a medical expert.

CONCLUSIONS

It can be ascertained that Slovenian case law has already established measures to compensate for the disturbed parity between the legal positions of the patient and the healthcare organization in the assessment of medical errors. Case law has thus departed from the concept of tort, lowered the standard of proof of causation from certainty to a preponderance of probabilities, and allowed indicative evidence by a medical expert in medical malpractice claims. We do not believe that the Strategy that sets out a model of no-fault compensation provides a sufficiently compelling rationale for intervening in the existing compensation legal regime. In this respect, the Strategy emphasizes in particular the exclusion of negligence as a key element in the introduction of no-fault compensation, but as already stated above, fault is not, as a rule, a prerequisite for a legal commitment to compensate in this type of claim, as it is a contractual damage, and in our view, this therefore does not, in itself, improve the position of the patient in medical tort law concerning medical errors. Before introducing no-fault compensation, it would therefore be necessary to identify where the actual weaknesses of the current regime under the OZ for the enforcement of such claims may lie and how they can be overcome and improved by the new concept of no-fault compensation. Accepting the concept of no-fault compensation also requires a clear definition of a possible new law on no-fault compensation towards the OZ in this type of legal relationships and a clear definition of the assumptions of no-fault compensation, which is not apparent from the Strategy. The no-fault compensation model vaguely defines the medical error and its relationship to the complication. It should also be clearly defined whether the no-fault compensation is only for medical errors in the strict sense or also for infringements of the duty to explain, as set out in the Strategy. Moreover, the Strategy also fails to clarify what constitutes legally recognized harm. Therefore, it is unclear whether it only refers to non-pecuniary damage or also to compensation for pecuniary damage. In our view, a catalog of forms of non-pecuniary damage should also be defined. Furthermore, the no-fault compensation model should also address the question of whether only the patient is entitled to compensation as a direct victim or also their relatives as indirect victims if the patient dies or becomes particularly severely disabled. In my view, there are no reasons that would preclude no-fault compensation to indirect victims as provided for in the OZ.

I do not believe that it is appropriate for the non-fault compensation for damage caused to patients to be paid from the budget or from special contributions from insured persons. Indeed, this contradicts the very essence of the application of liability for damages. Regardless of whether or not the mandatory model applies, the patient should always be able to seek redress up to full compensation in court. Therefore, such a concept of subsidiarity requires clear regulation, in particular of the statute of limitations (e.g., that the statute of limitations is suspended when

deciding on no-fault compensation), the procedural rules guaranteeing constitutional law standards, the regulation of expert opinions, in particular the possibility of the patient to influence the choice of an expert, to disagree with the opinion, to obtain their own expert opinion, to use the expert opinion in subsequent court proceedings, etc.

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ABSTRAKT

Narodowa Strategia Jakości i Bezpieczeństwa w Opiece Zdrowotnej na lata 2022–2031, sporządzona w listopadzie 2021 r. przez słoweńskie Ministerstwo Zdrowia, określa m.in. podstawy modelu kompensacji z tytułu błędów medycznych w systemie *no-fault*. Kompensacja *no-fault* jest nowym pojęciem w słoweńskim prawie deliktowym (medycznym). Celem artykułu jest określenie, czy reżim kompensacji *no-fault* wskazany w Strategii jest w ogóle konieczny i uzasadniony w świetle istniejącego systemu prawa deliktowego, a w szczególności czy taki reżim w istocie może poprawić pozycję pacjenta w stosunkach prawa deliktowego wynikających z błędów medycznych i ułatwić mu wybór. Zgodnie z naszymi obserwacjami Strategia nie podaje dostatecznie przekonującego uzasadnienia dla ingerencji w istniejący reżim odszkodowawczy. Słoweńskie orzecznictwo już ustaliło środki zrównoważenia naruszonej równości pozycji prawnej pacjenta i podmiotu opieki zdrowotnej przy ocenie błędów medycznych.

Słowa kluczowe: kompensacja *no-fault*; błąd medyczny; prawo deliktowe; opieka zdrowotna; bezpieczeństwo