ORIGINAL ARTICLE
PRACA ORYGINALNA

RISK IN THE PERFORMANCE OF MEDICAL ACTIVITIES: MEDICO-LEGAL OVERVIEW

DOI: 10.36740/WLek201912203

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ABSTRACT

Introduction: The article analyzes the medical and legal analysis of the professional right to justified medical risk and the grounds for exclusion of their responsibility for the occurrence of negative consequences as a result.

The aim:of the article is to review the legal regulation of medical risk at the international level and, based on that analysis, to define the concept of justified medical risk and to analyze its main features.

Materials and methods: International acts, legislation of European states, scientific developments, jurisprudence were analyzed, building on dialectical, comparative, analytical, formally logical, statistical, complex methods of scientific research and sociological method (questionnaire).

Results: The survey found that most physicians understand some of the actions that a doctor takes to improve a patient's health, and believe that the risk begins with the identification of circumstances that may endanger the patient's life and health. The results made it possible to confirm that the medical risk is present in the practical activity of each of the doctors, and the main purpose is to save the life and health of the patient.

The analysis of court convictions shows that due to insufficient regulation of risk, its onset and basic features, most of the concepts are evaluative, which leads to a lack of uniformity of jurisprudence on medical risk issues and the unlawful prosecution of doctors.

Conclusions: Based on the analysis of key signs of medical risk, it has been formulated that justified medical risk is the risky action of a doctor within the framework of normative acts on treatment, which are performed in order to protect the life and health of the patient, if the stated goal cannot be achieved by risk-free actions. The study also revealed trends in the use of justifiable risk by physicians in practice.

KEY WORDS: right to life and health, treatment, medical risk, justified medical risk

Wiad Lek 2019, 72, 12 cz. II, 2410-2415

INTRODUCTION

Turning to health providers for patient's diagnosis, prevention and treatment, there's always the possibility for serious unexpected effects. Although the standards of modern treatment allow us to choose such methods that will be beneficial for the patient's recovery, but individual specific features of a patient's organism and other factors might have an impact on the usual course of treatment and compel a doctor to risky methods. Being allowed to take risks, physicians should be aware of the state's obligation to exclude their liability in case of the adverse effects of risky treatment. In order to protect the fundamental rights and freedoms of the patient from medical errors during the treatment process, as well as to guarantee the professional right of the physician to take risks, it is necessary to be aware of the reasons for its justification in each particular situation, the commencement of the risky action, its motivation and objectives, with an assessment of which often arise difficulties. Therefore, it is important to regulate medical risks in the treatment properly, while taking into account the interests of both patients and physicians at taking risks. Clarification of the outlined issues is possible on the basis of international experience.

THE AIM

To find out the state of regulation of medical risk at the international level and in the legislation of the individual European countries, to formulate the concept of justified medical risk, to analyze the basic signs of medical risk as a basis for effective protection of the doctors' rights in their practical activity.

MATERIALS AND METHODS

International Acts of the World Medical Association (hereinafter - WMA), legislation of certain European countries (Poland, Germany, France Italy), scientific works, judgments of the European Court of Human Rights (hereinafter - ECHR), 96 sentences of national courts of Ukraine under art. 140 of the Criminal Code (hereinafter referred to as the Criminal Code) of Ukraine for the «Inadequate delivery of professional duties by a medical or pharmaceutical worker», the results of a survey among 92 medical specialist.

This article is based on dialectical, comparative, analytical, formal-logical, statistical and complex methods of scientific research and sociological method (questionnaire).

RESULTS AND DISCUSSION

According to researcher Z. Gladun, the basis for regulating the relationship between the patient and the doctor or other medical workers is the norms of morality and ethics, which over time have developed into a separate area of knowledge, called medical ethics. From his point of view, the relations between the patient and the doctor or other health care workers are regulated by both legal and moral and ethical standards, which in this sphere of relations acquire the character of medical-ethical, deontological norms [1, p. 9-10].

Practical application of Art. 2 of the Convention on Human Rights and Fundamental Freedoms (hereinafter referred to as the Convention), which establishes, in essence, the negative and positive obligations of the State to ensure the right to life. And if a negative obligation means to abstain from the unlawful deprivation of a person's life, then a positive one is to protect a person's right to life through the statutory provisions regarding criminal liability for the unlawful deprivation of a person's life. Besides, as the ECHR notes in the case of «W v. the United Kingdom»1987, the responsibility for the deprivation of life should extend to the actions of individuals as well as those acting on behalf of the state [2, p. 166]. This means that any negligence or carelessness in providing health care services, which leads to negative consequences and violates the human right to life is a ground for liability of the health care provider for violation of Art. 2 of the Convention.

The private life of a person is also under the protection of art. 8 of the Convention which is filled not only with the individual's personal space but also, in the interpretation of the ECHR (Niemitz v. Germany decision 1992), is much broader than the traditional Anglo-American concept of «privacy» and includes both the moral and the physical integrity [2, p. 294-295]. For example, in the case of Csoma v. Romania in 2013, the ECHR held that the violation complainant's right to privacy occurred because she was not included in the choice of medical treatment and the absence of notification of a possible risk during the medical procedure [3].

In order to protect the patient's right to life and health, medical reform has been undertaken in most European countries, the main focus of which is standardization and protocolization of patients' treatments and it allows the doctor to choose the most appropriate treatment option. In practice, there are cases where a physician chooses more risky method of patient's treatment than the others prescribed by appropriate protocols to improve the patient's condition [4, p. 1839]. Therefore, the cornerstone of the issue under consideration is the attitude of the legislator towards physicians who, when applying risky therapies, there is a risk of being prosecuted for the harm caused to the patient's health whose protected rights and freedoms may be violated at risk. Therefore, the study will look one-sided if it focuses only on patients and their right to life and health, without taking into account the professional rights of doctors.

In order to protect the rights of physicians in their medical activities, more attention should be paid to cases in which the physician harms a patient, but it is not related to a medical negligence. One such case is a medical risk. Doctors who exercise the right to risk need additional safeguards and protection in the event of a negative consequences if the risk is justified.

The WMA has adopted a number of acts that regulate general health care issues and, to some extent, regulate medical risk issues. The analysis of international instruments makes it possible to conclude that medical risk is considered in the context of: 1) the patient's right to information about treatment; 2) implementation of medical activities; 3) conducting medical research. This article discusses international instruments that regulate medical risk when performing medical activities.

The right of a doctor to medical risk is enshrined in the International Code of Medical Ethics of the WMA: «A doctor should act only in the best interests of the patient when he or she uses such types of care that may impair the patient's physical or mental state» [5]. This leads to the conclusion that a doctor can apply risky therapies in order to save a patient's life, keep an organ in function, etc., by first comparing the risky action and its potential outcome.

In order to protect the doctor while his medical activity, the WMA adopted a Declaration on the independence and professional freedom of the doctor, which stated that «Doctors should have the professional freedom to provide care to their patients without external influences. The professional prescriptions of the physician, as well as his freedom in making clinical or ethical decisions in treating and assisting patients, should be safeguarded and protected»[6]. Therefore, the doctor may exercise the right to professional freedom , while making decisions and choose a treatment method that is risky, taking into account the condition and features of the patient's illness.

Thus, by analyzing WMA acts, we can conclude that they envisage the doctor's obligation to provide medical care, the doctor's right to medical risk and freedom in making professional decisions, which are interrelated elements. However, the lack of detailed regulation of medical risk, a clear indication of when it starts and ends leads to arbitrariness when considering criminal proceedings and the unlawful prosecution of doctors. C. Rodriguez and other authors in their article point out that the lack of detailed regulation of medicinal risk in the legislation does not contribute to its correct enforcement [7, p.10, 11].

The doctor's right to medical risk is enshrined in the laws of individual European countries. For example, in part 1 of art. 34.1 of the Polish Law on the Profession of the Doctor and the Dentist states that a doctor may perform surgery or apply a method of treatment and diagnosis that creates an increased risk for the patient only after having received the patient's consent [8]. At the same time, paragraph 7 of this article states that a doctor may decide on risky actions without the consent of the patient in the event that delay in obtaining consent may threaten negative consequences.

A similar provision is contained in articles 42 and 43 of the Fundamentals of the Legislation of Ukraine on Health Care [9].

It is also known that the patient's consent to any manipulation is mandatory, and the violation of this prescription is a ground for compensation for the harm caused to a patient. M. Paszkowska emphasizes that the patient's consent to the use of risky treatment is a guarantee for the protection of both the healthcare provider and the doctor himself from criminal liability [10, p. 1240]. Other researchers believe that the intervention is possible without the consent of the patient, if such intervention is in the best interests of the patient. Consent matters when a patient has received the necessary information about his or her health condition and has been aware of the risks and consequences of medical intervention [11, p. 324].

In order to evaluate the category of medical risk in the doctor's practical activity and to increase the level of protection of their rights, an anonymous survey was conducted among doctors of different specialties from Kiev, Kharkiv, Donetsk, Mariupol, Odessa, Lviv, Uzhhorod, which was conducted from April to September 2019. 92 respondents took part in the survey: 24 of them are dentists, 10 surgeons, 10 ophthalmologists, 6 cardiologists, 7 therapists, 12 neurologists, 2 pediatricians, as well as 3 psychiatrist, 1 otolaryngologist, 1 endocrinologist, 1 endoscopist, 5 dermatologist. Those who took part in the survey, 9% exercise their professions from 5 to 10 years; 30% - from 10 to 20 years; 45% - from 20 to 30 years; 10% - from 30 to 40 years; 6% - 40 years and more.

The questions included in the questionnaire were aimed at clarifying the level of understanding of the concept of medicinal risk, its purpose and the commencement. For each of the questions, doctors were offered several options, one of which provided the opportunity to express their own position.

The first question was aimed at assessing the understanding of medical risk as a phenomenon in practice, namely: «What do you think is medical risk?» And several options were suggested: A) the possibility of adverse effects of treatment over a period of time; B) deviation from the protocol or standard of treatment; C) a specific set of actions taken by the physician at his or her own discretion in the event of a critical condition of the patient, if the course of the disease or medical procedure is atypical and it's impossible to act in accordance with the prescribed rules; D) another option.

Among those interviewed, 43 people (47%) believe that option C most accurately describes «medical risk» as a phenomenon, 37 people chose option A (40%), 7 persons (8%) chose option D and only 5 person chose option B (5%) (Fig. 1).

It is also important to determine when medical risk begins. To clarify this, a question was formulated as follows: «When do you think a medical risk begins?», and the following options: A) from the moment of identification of circumstances that have a potential negative impact on a patient's life and health; B) from the moment of deviation from the protocol or standard of treatment; C) from the onset of adverse effects on the life and health of the patient; D) another option. Of those questioned, 17 people chose option A, 14 people chose option C, 3 people chose option D, 1 person chose option B. 3 people, who chose option D, indicated that determining the commencement of medical risk is a difficult task, as risk always exists (Fig. 2).

In order to confirm or refute the thesis of how often medical risk occurs in the practice, the questionnaire separately revealed whether respondents or their colleagues had to take risks. The survey showed that 82% of doctors had to take risks personally, 16% did not take risks personally, but they did encounter risks in the practice of their own colleagues. 2 of the respondents chose the option «No, I did not encounter cases of risk neither in my own practice nor in the practice of my colleagues», which demonstrates the inalienability of medical risk in the practice of doctors.

To the question: «Are you consciously ready to take a medical risk?» 75% answered that they are ready to take a medical risk in any case, 25% are ready to take a risk only in exceptional cases, and none of the doctors answered that they are not ready to take a medical risk.

The following question was aimed at analyzing the goal of medical risk in the practice and was formulated as follows: «What can make you to take a medical risk?» And the following options were suggested: A) to save the patient's life and health if other ways are ineffective; B) the potential promotion and recognition as a specialist; C) the opportunity to gain experience, even if it is negative; D) all of the above-mentioned.

The survey found that most doctors (88 people) chose option A, i.e. they are ready to take a medical risk in order to save a patient's life and health, only 1 person chose option C (an opportunity to gain experience, though negative), 3 person chose option D (all listed) and none of the respondents chose option B (opportunity to gain experience, although it is negative) (Fig. 3).

When researching the concept of «medical risk» it should be noted that the regulation of treatment methods at international and national levels allows the doctor to choose alternative methods, taking into account the ratio of potential risk of the performed procedure and its results. In each of the methods, there is to varying of degrees specified element of risk (for example, identifying circumstances that were not known to the doctor before the medical manipulation), and therefore it is possible to expect the probability of negative consequences of the performed procedure.

By an order No. ACZ 1329-1317 dated 11 April 2018 of the Appeals Court of Civil Affairs in Poznan, it was stated that even if the medical service or treatment was carried out with proper adherence of professional duties, regulations and medical knowledge, the possibility of occurrence negative consequences for the life and health of the patient can't be excluded. In this case, it is a medical risk [13].

However, the onset of adverse effects is preceded by the physician's choice of a treatment or modalities for the implementation of medical procedure that may cause such

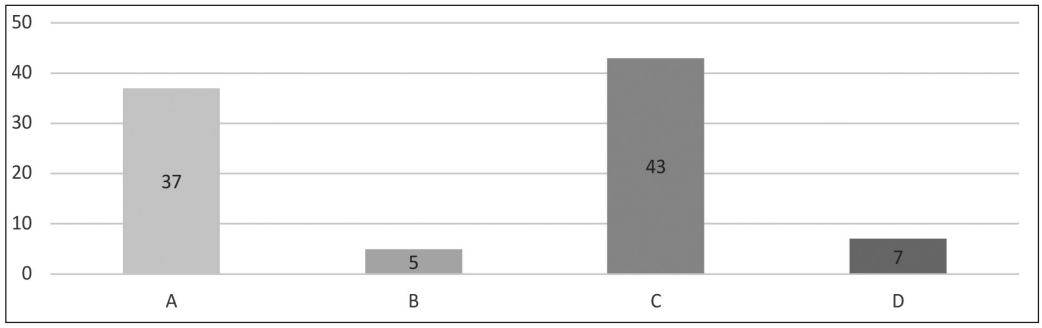

Fig 1. Definitions of medical risk
A. the possibility of adverse effects of treatment over a period of time
B. deviation from the protocol or standard of treatment
C. a specific set of actions taken by the physician at his or her own discretion
D. another option

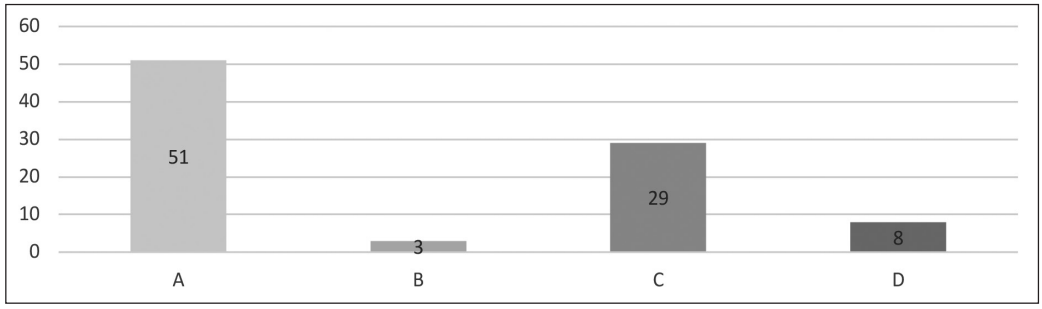

Fig 2. Medical risk start
A. from the moment of identification potential negative impact for patient
B. from the moment of deviation from the protocol or standard of treatment
C. from the onset of adverse effects on the life and health
D. another option

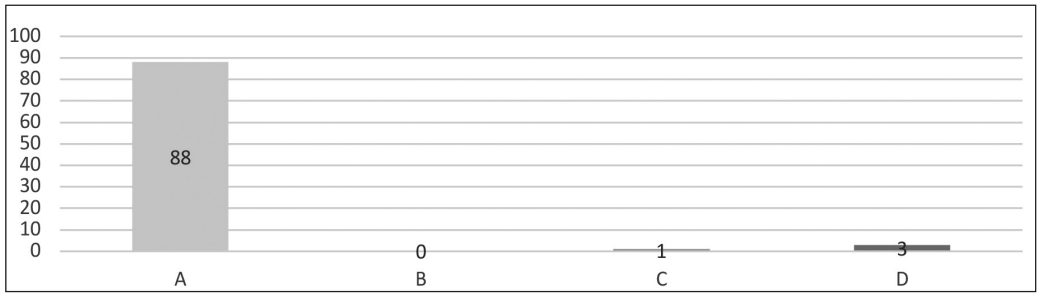

Fig 3. Goal of medical risk
A. to save the patient's life and health if other ways are ineffective
B. the potential promotion and recognition as a specialist
C. the opportunity to gain experience, even if it is negative
D. all of the above-mentioned

effects. This means that the most accurate characterization of the concept of risk was given by the 47% of the interviewed doctors, who said that the medical risk is a certain set of actions that the doctor does at his own discretion in the critical condition of the patient, if the disease or medical procedure is atypical and it is impossible to act according to the rules provided.

If a physician chooses a method of treatment, diagnosis or surgery that carries an increased level of risk, he or she may use the right to medical risk, which is a form of action related to the risk provided under art. 42 of the Criminal Code of Ukraine [12].

From the point of view of justified medical risk, the following can be traced in the criminal codes of individual countries as a circumstance that excludes criminal liability for harm to a patient. For example, the general concept of justified risk is established in Part 1 of art. 42 of the Criminal Code of Ukraine: «Risk is considered justified if the goal that was set could not be achieved by this action (or omission), which is not connected with risk, and the person who permits the risk reasonably expected that the measures that he or she had taken were sufficient to prevent harm to the patient's legally protected interests» [12]. Similarly, in most European countries, justified risk is recognized as a circumstance that excludes criminal liability. Something similar is the way of defining the risk in art. 33 of the Criminal Code of Latvia and in art. 34 of the Criminal Code of the Republic of Lithuania [14].

In proving the existence of justified medical risk, the criminal liability of the doctor is excluded due to the absence in his or her actions of a sign of the illegality of his or her behaviour. The basis of a medical risk is its justification, which is determined by three elements, the presence of which in conjunction is the basis for the mandatory exclusion of criminal liability for the harm caused to the patient.

Firstly, it is the existence of an objective situation that necessitates the achievement of a significant socially useful purpose and which may present a risk. The most frequently in medical practice the objective situation is the risk of a patient's death, a declining health, the likelihood of organ loss, or other serious health effects.

Secondly, the inability to achieve the goal of preserving a patient's life, significantly improving his or her health and so on by risk-free actions. For example, an atypical disease course or unforeseen worsening of a patient's health condition is the basis for choosing more risky treatment because the less risky methods and procedure will not lead to the desired results and the patient's life

must be preserved. However, if it is established that the physician had and was aware of a real possibility to apply non-risky methods, but he or she decided to apply, on the contrary, risky methods of treatment, then he or she could be held liable on a general basis for the harm caused to the patient.

As an example, it can be used the court sentence No. 0110/1844/2012 of 1 October 2012, Kirovsky District Court of the Autonomous Republic of Crimea, where the surgeon was found guilty of committing crime under part 1 of art. 140 of the Criminal Code of Ukraine, for improper performance of professional duties by a medical professional. The surgeon, as the doctor on duty, decided to puncture the soft tissue of the upper third of the left shoulder and further surgical procedure for the patient who was in treatment. As the result of these actions, it caused damage to the patient's left axillary artery, which led to external bleeding, resulting in death. The investigation revealed that the doctor did not examine the patient and was not convinced of the ineffectiveness of other treatments that were less risky than surgery [15].

Thirdly, the implementation of the necessary measures by a doctor, which gave him sufficient reason to reasonably expect to prevent harm to the patient's legally protected interests. This means that those risky actions that either do not cause or although do harm to the patient are considered justified, but this harm is due to other factors that could not have been foreseen at the time of the risky intervention. At the same time, if the inevitability of causing harm is known to the physician in advance, then the justification of the risk is excluded and he or she is liable on a general basis. A. Nafsika and R. Allison emphasize that before making a decision on risk, it is necessary to consider all possible options for the course of events taking into account a specific situation [16, p. 146].

As already mentioned, in case where there are all three of the above-mentioned elements of risk justification exist, the physician has grounds to exercise the right to a medical risk, which in turn is characterized by the following features. The first indication is the socially useful goal of risky action, which in medical risk cases is to save the patient's life and (or) significantly improve his or her health condition. It is this purpose that legitimate the risky action, regardless of whether it has been achieved. According to an anonymous survey, the driving force for a doctor's decision to exercise the right to risk is to preserve the patient's life and health.

The second sign of a risky act in the case of a medical risk is the nature of such an act, which means that such act outwardly coincides with the crime under the country's criminal code. In Ukraine, this crime (corpus delicti) is covered by Part 1 of art. 140 of the Criminal Code of Ukraine, which establishes responsibility for the non-compliance or improper performance of professional duties by a medical or pharmaceutical worker due to their negligent or careless attitude, if it has caused grave consequences for the patient. By doing so, the doctor threatens or actually harms the patient's life or health. However, due to the lack of wrongful act, the act of the physician is not a crime [12].

To illustrate, we give the following example. The judgment of the Court of Appeal in Szczecin No. I ACa 6/17 of 12 April 2017, the surgeon's actions were recognized as justified medical risk. To stop the degenerative changes and eliminate the cause of cervical instability, it was decided to have surgery that led to dysphonia, which is a frequent occurrence in this type of surgery. The court acknowledged that the surgeon had acted in compliance with the protocol of the operation and the damage caused was far less than the potential threat to the patient's life [17].

The following indication of a risky action is its timeliness, which is that such an act must be committed only during the existence of time of a risk justification. In assessing timeliness, a number of factors should be considered, such as age, condition, underlying and additional diseases, their duration, etc. If a risky act was committed before or after the end of time of a justifiable risk, then the risky act cannot be considered justified.

Particular attention should be paid to the moment when the medical risk status begins. Of those interviewed respondents, 56% chose option A (from the moment of finding circumstances that have a potential negative impact on the life and health of the patient), 32% chose C (since the adverse effects on the life and health of the patient), 9% chose D (other variant), 3% - B (since deviation from protocol or standard of treatment). Choosing option D, 8 doctors stated that determining the onset point of medical risk was a difficult task, as risk always exists. This point of view is not new, and many scientists agree. For example, N. Rahman and others argue that when performing any medical procedure and treatment plan, there are internal risks that may arise from the atypical disease of the patient or when proven treatments do not help [7, p.3]. From the point of view of criminal law, the moment of commencement of a risky act is directly physician's actions or omissions, which are risky, with the purpose of saving patient's life or health.

The Criminal Code of Ukraine does not specify the limits of justifiable risk, which gives grounds to conclude that when the risk is justified the harming is legitimate and covers both the infliction of injures of various severity and causing the death of a patient, but only if it was impossible to use non-risky methods of treatment and the doctor reasonably expected that the measures taken were sufficient to prevent harm to the patient's legally protected interests.

The results has made it possible to see that the medical risk is present in the practical activity of each of the doctors, and the main purpose is to save the life and health of the patient.

The analysis of court judgements shows that due to the insufficient regulation of risk, its onset and basic features of most of the concepts are evaluative, which leads to an absence of uniformity in judicial practice in matters of doctors' risk and the unlawful criminal prosecution of doctors.

When considering a problem of medical risk, we should take into account the object of causing harm, which in the case of risky action advocates the legally protected interests of the person, first of all the life and health of the patient.

CONCLUSIONS

A person and his or her life are the supreme value, and an illegal attempts on one's life and health is a criminal offence. Physicians' actions aimed at protecting and maintaining the patient's life and health, due to the presence of a number of factors (such as weakened immunity, allergic reaction, etc.), make it impossible to apply the treatment to such a patient, even if this treatment has low level of risk. Instead, the use of risky methods often leads to patient's death, deterioration of the health, loss of organs or their dysfunction, etc. However, justifiable medical risk eliminates liability for damage caused to the patient, since justified risky intervention is always done to preserve the life and health of the patient.

The questionnaire of physicians focused on the main aspects of justified medical risk, which made it possible to formulate the concept of justified medical risk, the moment of its initiation and to identify implementation trends of justified risk in practice.

Based on the identification of key features, we can conclude that justified medical risk is the physician's risky action or omission within international and national standards, protocols and instructions for diagnosis, prevention and treatment that are supposed to be done to preserve a patient's life, significantly improve his or her health, keep the organ or organ system in function, if the goal cannot be achieved by other, non-risky actions or omissions, and the doctor reasonably expects that the measures taken by him or her are sufficient to prevent harm to the patient's legally protected interests.

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Conflict of interest:
The Authors declare no conflict of interest.

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Received: 01.09.2019
Accepted: 22.11.2019