Artificial Intelligence in Medicine

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Summary

If one posed a question on how ready is the Republic of Croatia, for use of artificial intelligence in legal and legislative terms in medicine, the answer at this point would be – it is not. The fact is that processes in medicine involve the application of state-of-the-art technologies, as is artificial intelligence, but it is also a controversial fact that the health legislative system does not develop seemingly, in the direction in which it is assumed, according to standards that exist in other developed countries of Europe and the world.
Our society awaits many challenges due to the use of ever more ubiquitous applications of artificial intelligence and state-of-the-art, sophisticated technologies and technological processes in treatment, which will need regulation through the prescribed cognitive legal norm. Regulation of the medical treatment process driven by artificial intelligence, must be in place through the norm because the area is too important to be left to technological progress without legal control and adequate legal regulation. In this regard, medicine and all treatment processes, diagnostics and therapies in the health care system must be carried out with one single clear goal, which is the protection and preservation of human health and life.

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Introduction

Artificial intelligence, machine or mechanism as a replacement for humans, some time ago was unreal and unimaginable in Croatia. Now it is coming to be an evident reality and a daily routine. Artificial intelligence in health care raises several questions, primarily the question of necessity of using these products in diagnostic and therapeutic processes, and on the other hand the expediency and efficiency of the same. When we find and establish a straightforward answer to these questions, it will be clear why the system has the need to use artificial intelligence in medical practice [1].

Like "Ars Medica," medicine is perception and accepted throughout history as the art of treatment. Only members of the selected profession were able to engage in this activity, so individuals who dealt with the treatment teamed up with the echoes, which we later know as chambers, first and foremost to control the standards of the profession and professionally perform health activities. The Republic of Croatia and in today's modern times has professional associations that have special regulation as legal persons to whom the state has transferred state public powers.

Physicians and other healthcare professionals, such as nurses or radiological technologists, in order to be able to engage independently in their profession, must meet the specific criteria. This entails education in health institutions, the standards of training and professional development, and the acquisition and renewal of the license, i.e. authorisations for independent work. Only a healthcare professional who meets all the above criteria has the possibility to work as a medical professional.

Progressive technological advances in science, both theoretical and experiential fields, have contributed to the fact that all the healthcare professionals, as well as many other experts in their work have started to apply various mechanisms and technical means in their vocational activities. In such new circumstances, the standards of treatment in diagnostics and therapy had to be adjusted, and the healthcare professionals have begun to use numerous related features as equipment and techniques for the purpose of delivery of health services. Extensive technological developments in medicine have resulted in what was once an auxiliary agent, the so-called facility has now become a relevant factor in medical procedures and treatment. These facilities, called medical equipment or means, have been so perfected

and sophisticated that they have replaced humans in many ways. Mechanisms, inventions and products such as novel MRI, dialysis machine, mechanical heart and so forth, are evident elements and visible appearances of how human work is enhanced and even replaced. It is proof that what was once done by humans – that is, the work of healthcare professionals, is now being done by a machine [2].

If we therefore ask ourselves whether the process of introducing artificial intelligence and robotization into the medical system is necessary, it is clear that the answer is affirmative. For it is evident that through highly sophisticated technological processes we can discover and do so much more than the confined mind of humans actually can alone. The machine can read and analytically process a multitude of data that humans themselves, in quality and quantity cannot and are not able to do. So, it is indisputable that the machine has and must have its place in medicine, in two forms either as a substitute or as an element of improving certain standard forms of treatment. Technology can largely improve all conventional ways of diagnostics and therapy, i.e. treatment as a whole, while the number of individuals who want to engage autonomous in a health profession is getting less and less every day.

The question arises as can the outcome of such a technological treatment process, with the help of a machine or artificial intelligence, be somewhat the same or better than the conventional, traditional treatment. A mechanism or means that exclusively serves a healthcare professional in the acquisition and implementation of certain procedures or treatments and which are used with the purposeful goal of improving treatment is very necessary and already well proven. A machine that fully undertakes certain actions and treatments instead of humans themselves can prove to be more efficient, precise and safer. Work of artificial intelligence or machine should be dosed and framed to well-known elements, so as not to cause an obstacle and a problem that cannot be solved.

With clear control and management of the mechanism, there should be no major problems in the realization of the treatment process. It is highly likely that the results of such work will be more effective. It is for simple reasons that the machine is not projected and is therefore not burdened and determined by emotional stimuli, it cannot be tired, and it is very important that the machine has no fear of the negative consequences of a potential medical error. All of this in theoretical terms may represent increased productivity and efficiency in treatment and the results of treatment.

However, on the other hand the fundamental problem of such emotionless action of the machine is its focus, working on the same unitised principle for each patient without difference in the specific needs, difficulties or peculiarities that can differ from man to man.

Taking in account the benefits on one side and machine deficiencies on the other, it is clear that only a combination of machine and human work, with clearly defined processes and roles, can indisputably contribute to improving the treatment process.

Legal aspects

Legal aspects and perception of the machine as a relevant subject, i.e. the work and action of something that consequently affects a patient's life and health, can be overseen through a legal-theoretical analysis of the provisions of the law and other legal regulations in this respect. Article 49 in the Republic of Croatia Constitution entrenches entrepreneurial freedom, and the same article states that the State encourages economic progress, while it is embedded in Article 59 of the Constitution that each individual is entitled to health care. By analysing and interpreting these provisions, it is clear that we do not read concrete determination from the very constitutional principles that would directly address the issue of artificial intelligence, robots and issues bordering on their status [3].

In general, if we consider the broader interpretation of the provision that states encourage economic progress, we can also cover the issue of development and stimulation of artificial intelligence in medicine in this segment of the fundamental principles. Therefore, the objective of state power and key factors in the health authority system should be to foster all modern technologies, including robotics and artificial intelligence, especially in the health care system as an element that practically improves the economic aspect of society. Considering the second constitutional principle that guarantees everyone the right to health care, artificial intelligence in the health care system is a potential element of improving the treatment process and in an indirect way, it indicates the obligation to plan such processes by the state towards the health system.

Consequently, it is undeniable that artificial intelligence has the justification to exist in the health care system in the necessary segments of treatment if such mechanical use and operation in the treatment process will result in improved, more efficient care and ultimately result in providing the cure for every individual.

The Health Care Act as a basic law governing the way of performing health care in the Republic of Croatia does not mention robotics as one of the possibilities and ways of providing health services. The Health Care Act regulates and standardises issues of health workers who perform health care activities, equipment, and means that are in disposal to health institutions [4].

The law establishes the necessity of continuous professional development of healthcare professionals in accordance with the latest developments in medicine, and the need to monitor technological progress, modernization and new standards in medicine.

In this regard, the application of artificial intelligence as an important part of the professional development of healthcare professionals is also associated, assuming that information technology and robotics are a necessary part of the process of developing technological methods in medical delivery.

The legal regulations regulating minimum standards regarding premises, workers and medical and technical equipment for the performance of health activities, which must be met by the health institutions, institutes, private healthcare professionals engaged in health activities in private practice and companies engaged in health activities, do not project direct use of artificial intelligence as an element and possibility in the health system.

The State insurer, the Croatian Institute for Health Insurance, which allows its policy holders – all Croatian citizens access to health service and care, and provides the means to provide the same through salaries to healthcare workers, did not regulate in general internal acts the possibility to cover the costs of some of the health services performed with the help of artificial intelligence.

Professional instances in the process and distribution of expertise and guidelines in the field of individual activities and specialities of healthcare professionals do not mention or regulate the use of artificial intelligence and robotics.

This segment has nominally been integrated in the Telemedicine system, which can represent the beginnings of regulation of artificial intelligence, and assumes the basis for the development of telesurgery i.e. robotics-guided surgery. Other procedures can be implemented in such similar way in the system of providing health services and healthcare. Telemedicine is carried out by providing remote health services, using information and communication technologies, in cases where healthcare worker and patient or two healthcare workers are not in the same location. Telemedicine includes remote medical monitoring of patients, consulting health services, preventive activity in healthcare, data-based diagnostic and therapeutic procedures available through the information-communication system, as well as information sharing for the continued lifelong professional development of healthcare professionals.

Telemedicine activity is performed through a network of telemedical centres. Through the network of telemedical centres, required number of health facilities, healthcare companies and private health workers with approval for the work is determined. [5].

Telesurgery as part of telemedicine developed primarily from laparoscopy. The surgeon is not looking directly into the operating area, but looking at the monitor. The image is transmitted in real time where it is necessary for the physician to consult with other specialists who are not at the very place of surgery. Telemedicine and laparoscopy are a prerequisite for the use of robotics in medicine. Telemedicine services in neurosurgery include the transfer of imaging materials (CT, MRI) and other forms of diagnostic findings from telemedicine access centres to telemedicine specialist centres, which enables neurosurgical consultation in institutions that do not have neurosurgical activity. By applying telemedicine services in neurosurgery, it is possible to make an accurate diagnosis in the shortest time and allow for further rapid and expedient treatment, which is especially important in emergency cases.

The use of telemedicine services in neurosurgery avoids unnecessary diagnostic and therapeutic procedures and reduces the patient's stay in the institution as part of the telemedicine access centre. The Ministry of Health has adopted the Ordinance on the manner of performing telemedicine, which defines telemedicine centres and services in the Republic of Croatia. Healthcare institutions, healthcare professionals, health care companies and private healthcare professionals engaged in telemedicine activities in the Republic of Croatia must be authorised to operate as a telemedicine centre and must be included in the network of telemedicine centres. Therefore, it would be possible to regulate the use of artificial intelligence and robotics through the integration of telemedicine and legislation on this subject.

It should be concluded that there are no clear or precise provisions in the legal regulations that would directly regulate the use or operation of artificial intelligence in the health care system in the Republic of Croatia.

Acts that exist can only assume or enable future construction of a system for use of artificial intelligence in the Republic of Croatia, but they cannot possibly satisfy the form of existence of a complete act that would define this area.

None of the above means that there is no daily work in practice with aspects of artificial intelligence, i.e. the use of robots and machine mechanisms in the provision of health care in diagnostic and therapeutic procedures. If we exclude machines in radiology that record even the smallest parts of the human body, or machines in anaesthesiology that practically uphold or sustain the human life, the significance of use of artificial intelligence is evident, above all in surgery.

The use of artificial intelligence, robots in surgery has application on two levels: assistant, whereby the robot does not perform surgery, but only functions that are associated with surgery; and the second – an independent level, in which the robot directly performs surgery.

Today, a robot, presumed under the supervision of surgeons, performs surgeries proposed by a surgeon. Surgery requires precision that humans cannot always perform. That is why there is work is progress, on systems that join surgical knowledge and computer precision. Surgeries are done with minimal invasion, i.e. without opening the patient. In addition to robots in surgery, the so-called "robot" is extremely significant for servicing, i.e. to help immovable persons or for physical therapy. For example, the so-called "Lokomat" – a sophisticated robot designed to restore the functionality of lower extremities for adult patients and children who have partial or complete loss of this function [6,7,8].

Legal and ethical dilemmas

Elementary legal and ethical dilemmas that surround the use of artificial intelligence, robotics and the use of machines in medicine are questions of subjectivity, personality of robots and artificial intelligence, and the question of responsibility in the processes of work, i.e. treatment. This is particularly significant in systems such as the health care system where the responsibility of a health professional for medical error is exponentiated to the level of a range of responsibilities, from criminal, civil, disciplinary, misdemeanour and moral. The term medical error is defined as a violation of the commonly known rules or standards of the treatment due to lack of due care or caution. The term covers not only errors in treatment, but also errors in diagnosis, prophylaxis and subsequent care. It could also be formulated that medical error covers all errors in prophylaxis, diagnostics, treatment and subsequent care due to neglect or deviation from medical standards and medical science. A medical error should be distinguished from a complication, which in its nature is a consequence of the unpredictable course of the disease, injury or condition of the patient, despite all the *lege*

artis activities, medical procedures that were undertaken, proper equipment, medical protocols and medicines that were used and appropriate implementation of the health service.

Our legislation does not recognise the concept of a medical error or a similar term associated with it. The name medical error in itself indicates a mistake made by a medical practitioner in his profession. In principle, from the point of view of applicable laws and regulations, a health worker who does not comply with the rules of the health profession and its moral and ethical principles when providing health care makes the error. Therefore, if there are widely known rules of medical science rooted in his profession, the physician is obliged to apply them. When choosing diagnostic and therapeutic methods, he is obliged to act in accordance with scientific knowledge and professionally proven methods, and if in doubt, he is obliged to stick to the principle of a safe path. In this regard, mistake will be made in case a method or procedure that is not recognized in medicine is chosen in the course of health care delivery.

Physicians and healthcare professionals in general are just ordinary and fallible people with special knowledge and abilities, who are under extreme burden of the possibility of making an error. The peculiarity of the medical profession is manifested in the sensitivity of the consequences of medical errors and other unplanned or unforeseen complications, since any medical complication or error carries with it a violation of the highest human value, life and health of the individual. In addition, the fact is that if the health worker does not comply with the rules of his/her profession, he/she can cause fatal consequences for the individual. Given the nature of the medical occupation, any form of unprofessionalism can affect unspecified number of other persons, and as it can be directed against the health of an indeterminate number of people, not just an individual, it has a general dangerous character. If medical practitioner fails to comply with the prescribed obligations, it is a subject of liability. Depending on the type and severity of the infringements of the rules under which the health activity is carried out, such errors of healthcare professionals, can be: criminal, civil, misdemeanour and will call for disciplinary action.

Regarding medical error and criminal responsibility, the legislator singled out special crimes against human health in Title 19 of the Criminal Code of the Republic of Croatia, such as the spread and transmission of an infectious disease, unconscionable treatment, unauthorized taking and transplantation of parts of the human body, failure to provide medical assistance in emergency conditions, etc. It should be noted that a medical error constitutes a criminal offence only in the case where the gross breach of professional duty has been identified, which constitutes a significant deviation from the generally accepted and adopted rules of the medical profession.

In addition, in order for a medical error to be a criminal offence, other assumptions are required, e.g. there are consequences of exacerbating disease or impairing one's health. Ultimately, in order to find the health worker guilty of committing a criminal offence against human health, one must act intentionally or out of negligence, conscious or indebted and able to be aware that his work is prohibited. In the case of direct intent, the perpetrator is aware of the characteristics of the offence and will or is certain of their consequence. In the event of direct intent, the perpetrator is aware that he or she can be charged for matters with the characteristics of the crime and yet agrees to do so, therefore the perpetrator in this case does not seek to avoid the consequence of prohibition, but accepts the realistic possibility of the consequences and despite the known risk does not give up his actions. As for conscious negligence, the perpetrators act with insipience, being aware that they can ascertain the characteristics of the crime, but recklessly considering that this will not happen or that they will be able to prevent it. They therefore act carelessly even though they foresee the possibility of committing an act. In contrast, the perpetrators act with unconscious negligence when they are unaware that their action can portray the characteristics of a criminal offence, even though they could and should be aware of this possibility based on the deeds. Therefore, the perpetrator may have not paid sufficient attention to the dangerous situation and hence did not link the known danger to the danger of his proceedings.

The responsibility of physicians is classified as one of the professional responsibilities in the society, and its fundamental characteristics are that it is personal and subjective, proportional to the scope of their duties and it has its limits. Further important characteristics of the criminal process are the presumption of innocence, the prosecutor must prove the defendant's (physician's) guilt, and the defence attorney in this case is the defendant's process assistant (not the representative!) who, with his knowledge and process skill, will help the defence.

In connection with civil liability, in accordance with the Law on the Protection of Patient's Rights as well as the Convention on Human Rights and Biomedicine (Oviedo 1997, ratified in the Republic of Croatia in 2003), the patient is entitled to compensation in accordance with the general regulations of mandatory law, i.e. he is guaranteed the right to compensation for damages caused by medical intervention. Liability for damages is such a mandatory relationship in which one party is obliged to repair, i.e. compensate for damage caused to the other party and the other party is authorised to claim such compensation. In order for this obligation to exist, the following assumptions must be cumulatively fulfilled: there must be entities of liability for damages, harmful acts, damages, causal link between harmful acts, damages and unlawfulness of the harmful action. The responsibility of the physician, i.e. guilt due to a medical procedure that leads to a harmful consequence, is determined by the court in this case. The form of guilt in civil proceedings is different from the one in criminal proceedings.

In civil proceedings, the limits of medical responsibility are much broader and unlike criminal proceedings where guilt has to be proven, in civil proceedings the guilt of health workers is remedied. In the civil case for damages, i.e. a medical error, in principle the employer is liable, i.e. healthcare facility where the medical practitioner was working at the time of causing the damage. Therefore, the employer is liable for a medical error on the principle of presumed guilt. This means that hospital must prove that it acted in the manner prescribed by the rules of the medical profession, that the provision of a health service was handled with lege artis and that the damage was not due to the ordinary negligence of the health worker who carried out the procedure (it is up to the medical institution / practitioner to prove that it was acted according to the rules of the medical profession). In the case is that

healthcare professional caused the damage intentionally or out of gross negligence, the employer has the right to require the employee to reimburse the costs of making for the damage (so-called recourse action).

The disciplinary responsibility of a healthcare professional is only one type of liability aimed at ensuring professional and lawful medical activity. Namely, healthcare professionals, precisely because of the social importance of the activities they carry out, can, except for damages due to a medical error [9].

The disciplinary responsibility of a doctor/healthcare professional is only one type of liability aimed at ensuring professional and lawful medical activity. Namely, healthcare professionals, precisely because of the social importance of the activities they carry out, can be liable for not only criminal offences and misdemeanours, but for disciplinary breaches as well, committed during the performance of medical activity.

Disciplinary liability prejudges disciplinary violations that manifest themselves most often as the unprofessional pursuit of the medical profession or the non-compliance with the provisions of the professional code. Most importantly, it is the fact that the procedure for these violations is carried out by members of the profession, namely in front of a professional chamber, of which the health worker charged with a certain disciplinary injury is a member. Disciplinary responsibility can be defined as the health worker's responsibility for braking of legal rules and obligations of the profession, for which a certain penalty is given by the competent authorities.

A healthcare professional is disciplinarily liable if he violates the provisions of professional laws, violates the Code of Medical Ethics and Deontology, performs an unprofessional deed, acts unprofessionally towards a patient, another healthcare professional or third party, injures the reputation of the profession, does not comply with the Statute or other general act of a particular member's obligation to the Chamber or commits a criminal offence that makes it unworthy to carry out the activity. It should be highlighted here that criminal and misdemeanour liability or responsibility in a health facility, company or other legal person performing a health activity does not exclude the disciplinary responsibility.

Disciplinary measures that can be issued for disciplinary harms are a note, a fine, reprimand, a public reprimand, a temporary or permanent confiscation of authorised work, a temporary or permanent limit on the scope of authorised work, and a disciplinary measure of additional education.

Provisions of health and professional laws that state behaviours that are considered misdemeanours and for which penalties are prescribed regulate misdemeanour liability. Regulations of the conduct of healthcare professionals when performing their profession and other rights and duties include misdemeanour provisions, and fines are usually prescribed for offences. A healthcare worker, for example, may be held accountable and punished with a fine for violations prescribed by professional laws in cases where he / she performs activities outside the scope of the authorised work (license), withholds medical assistance, does not comply with the commitment to keep a secret, does not carry out a reporting commitment, does not keep medical records and fails to comply with the obligation to inform another healthcare professional [10].

The concept of a healthcare professional

A healthcare professional as a term is clearly defined in the provisions of the legal regulations of the Republic of Croatia governing the field of health care.

Thus, the basic health law, the Health Care Act defines a healthcare professional as a person who has completed a health educational programme, and a person who after completing basic health care education has completed a internship and passed the professional / state exam. In addition to these basic determinations, a healthcare professional in order to perform his activity independently must be licensed, therefore has to be registered by his professional organization (Chamber) and have obtained approval for independent work (license) from the competent professional organization (Chamber). In order to renew the license, health workers have to be continuously educated and permanently professionally improved. These elements form the fundamental, formally legal characteristics of a healthcare professional.

A healthcare professional in the Republic of Croatia acquires his basic education at several health institutions organized within the University or College. In principle, doctors of medicine are educated at medical faculties. By introducing the Bologna process and amending the criteria of education in accordance with the European acquis, other health workers have been given the opportunity to actively participate in all further higher education. In the Republic of Croatia, secondary vocational schools that educate individual healthcare professionals continue to exist and they are recognized in the health system as such. However, the tendency to incorporate the European qualifications framework relating the education of healthcare professionals requires active harmonisation of adopted common standards, which will ultimately lead to all healthcare professionals who will carry out a health activity having to meet a minimum educational standard that includes having a bachelor's degree in the profession.

Healthcare professionals have a duty after their basic undergraduate or graduate education, in order to allow for the performance of health activities and their profession, to complete the internship and pass the professional / state exam. Internships are performed in health institutions at different organisational units in order to acquire primary conditions of qualification for work. The traineeship element is known either as a separate element of professional qualification in duration of one year, or as an integral element incorporated into the study program of formal education. As a segment of the study programme, it is recognized in integrated health studies, and as such is present in most European health systems. In its legislation, Croatia has also implemented the standard of internships through study programmes and it is expected for it to take place in all health professions in due course.

After passing the professional / state exam, the healthcare professional is obliged to obtain approval for independent work (license) as a prerequisite for the possibility of work in his / her profession. The authorisation for independent work (licence) is the basis for the recognition of the healthcare professional and his or her affiliation within the specific health profession. Without authorisation for independent work, healthcare professionals are not able

to carry out the duties of their profession in the course of performing a health activity. There are healthcare professionals, i.e. persons who have completed health studies – formal health education but do not have authorisations to work independently, because they perform their jobs outside the profession, i.e. outside the framework of the health activity, i.e. the health profession.

The approval for independent work – license is issued by the competent organizations (Chambers) of Health Workers. They regulate the conditions for obtaining, renewing and revoking licenses by law. The general conditions prescribed in all health chambers for issuing of approval are the completed formal health education of certain level, the internship performed and the professional exam passed (or the internship under the integrated study programme) and either Croatian citizenship or knowledge of Croatian language in foreigners who also have the opportunity and authorisation to carry out the activity of their profession within the framework of the health care under specially prescribed additional conditions (procedures for the recognition of foreign professional qualifications).

The certificate / authorisation for independent work (license) is a formal document that proves in its content that its owner is authorized and in charge of independently performing the work. The license to healthcare practice means that the healthcare professional is certified and obliged to perform the duties of his health profession independently. There are eleven standardized health professions in the health care system in Croatia. These professions have earned their status based on clearly established and set standards that need to be met in order for a particular person to be able to engage in the activity of such a profession. Members of health professions must be educated at health institutions, professionally trained to carry out the work in this matter, obtain a license for independent work, and continuously professionally improve themselves. Therefore, the product of such preconditions is being a part of the profession. The legislator as well, who, by law, prescribed fundamental determinations of the same professions and established the authorities to protect the interests thereof and pursue public authority on behalf of the State gives the importance of health professions. One of the main factors of pointing out the importance of health professions and performing the tasks and activities of individual professions is the license. License is a formal public document, and with its content, it represents much more.

In this regard, each license speaks and indicates to an individual healthcare professional, but also to all third parties that this healthcare professional, i.e. the holder of that authorisation, is independent in his / her work, and on that basis is authorized, but also obliged to perform his / her part of the work related to the provision of health care and services to the patient. Therefore, this segment of work cannot and must not be carried out by anyone else but that healthcare professional, regardless of the health activities carried out in the team, in parallel work or independently, i.e. individually. The authorisation for independent work for each healthcare professional is a threshold of his / her obligations and responsibilities in the performance of the profession.

It is very important to stress that this is a matter of job description in the profession to which the healthcare professional belongs, which means that through each license, the independence of the profession and its tasks within and during the provision of health care is reflected. The team should somewhat establish clear limits as to what the job of a particular profession is and what work a particular healthcare professional will actually do in the health team. All the more so because the prefixation of independent performance of tasks is clear.

The authorisation for independent work is determined in its definition by independence, which means that there is no division of tasks, nor the need to interfere with the activities of other professions. It would be clear here that through an element of such established independent tasks, it is also health workers authorisation and responsibility to carry out the above. Authorisation means that this person, the healthcare professional knows what element of work should be done autonomously and independently from others, especially from the members of the team and that this is the job he / she is educated and employed for in the health care system.

On one hand, the license indicates the authority, scope and type of work that can and should be carried out by the healthcare professional, on the other hand, it shows and determines the responsibilities and the obligations of the same healthcare professional. It is clear that a healthcare professional is authorized to do exactly this job of that profession, but he is responsible and obliged to do the same job in relation to other members of the team and in relation to the patient. No one else can and should be held accountable for the element of work for which that healthcare professional is authorised and for which he possesses a formal and recognised certificate. Liability must derive from the authorisation itself, as these are tasks that indicate independence and tasks that are substantially linked to the profession to which the healthcare professional belongs.

Therefore, the responsibility of such a healthcare professional is unquestionable both in terms of content and formal terms. If we are to clearly link the health worker's responsibility to jobs for which they are authorized and obliged to perform as members of the profession in the health team, their responsibility to the patient as a third party, patient as a service user, their employer, society as a whole and social values is clear. By contents, the healthcare professionals responds to everyone for the type and scope of their jobs, which are predefined by the standards and legal norms of the profession itself and the scope of the profession. By form, they are responsible for different types of liabilities as prescribed by the legislator, and as mentioned above (criminal, civil, disciplinary, misdemeanour, disciplinary, moral, etc.). The sequence of such findings would project entirely different dimensions of responsibility process. The same would mean that the healthcare professional is in the sense of process responsible in his subjectivity. All types and ways of procedural responsibilities would be determined with this. Therefore, no one should be held accountable for the work and omissions of a healthcare professional, and all damages should be covered and compensated by the healthcare professional.

However, it common that in the legal process the legislator prescribes, particularly in the segment of civil liability, that the employer has the obligation to compensate if a health worker commits damage in connection with his / her work in health care. Likewise, the legislator prescribes solidary responsibility if healthcare professionals perform

the work together. It is likely that these fundamental principles of procedural liability are non-compliant with the findings arising from the license, nevertheless they represent postulates and criteria for determining and prosecuting liability. Therefore, regardless of the fact that the healthcare professional is licensed to carry out his or her work independently, the employer will be held accountable in the legally processed sense for the damage done by that healthcare professional in the course of his/her work. Healthcare professionals working in the team, if it is determined that the work was done altogether, will be held accountable in solidarity.

Healthcare workers are obliged to use their knowledge, to work and interwork with each other in the process of providing health care, ensuring an appropriate level of health and health protection for all healthcare users. All healthcare professionals must meet the appropriate professional and legal criteria prescribed for all those who, as a professional occupation, are engaged in providing health services. This is not primarily about educational criteria, since it is in itself understandable that professional health care providers can only be people who have completed appropriate education, but it is about the additional conditions set by the legislature as a "*conditio sine qua non*" for providing health care.

The process of continuous training and professional development of healthcare professionals is not a formal procedure. In fact, it is about continuous learning or acquiring new knowledge and skills that arise from ongoing, everyday development of health sciences and technologies. Professional development ensures the quality of work of healthcare professionals, which leads to improved quality of health service provision. Without continuous professional development, healthcare professionals would not be able to carry out their activities, because professional development is a necessity that arises from the unstoppable development of the profession and technologies without which the daily work of health workers would be unthinkable.

The continuous professional development of healthcare professionals is usually carried out through participation in various forms of education such as, for example, professional meetings (courses, congresses, symposia, online education, professional workshops and the like), but it can also be done by acquiring kinds of professional-scientific achievements, such as, for example, defending a doctoral dissertation, acquiring a specialist's or professional master's degree, acquiring the title *primarius*, or completing subspecialty. This is why the legislator introduced a legal obligation of professional development for all health workers and left it to the chambers in health care to write the conditions and manner of professional development more closely with their bylaws.

The principles of continuous medical training and education are, namely:

- Availability of training and education to all, i.e. inclusion of everyone in the programme of continuous professional development,
- Uniqueness of medical doctrine, which means that medical knowledge must be the property of all who perform health activities at primary, secondary and tertiary level,
- Scientific groundedness and actuality of medical training / education and availability of new information about achievements in the field of medical science
- Competency according to world standards,
- Free choice in the process of medical training and education, i.e. the possibility and right to choose the content and forms of education and training, especially in the area for which the health worker has been granted license,
- Continuous professional development should constantly improve, expand and modernise knowledge and skills in diagnostic, therapeutic and rehabilitation procedures towards patients, which will therefore feel an improvement in the quality of the health services provided.

Constant education, monitoring progress in the profession and personal intellectual development, are the daily need and professional-ethical imperative of each healthcare professional. At the same time, professional development is one of many deontological imperatives that are an integral part of each health profession.

Since medical science is not its own purpose but aims to care for human health, the interaction between healthcare professionals and patients is a specific relationship, the quality of which must constantly improve, maintain and develop to mutual satisfaction. By prescribing professional training and education as a legal obligation, the legislator stressed in particular the importance and necessity of continuous professional development, taking into account the fact that the quality of healthcare can, to the fullest extent, be ensured only by continuous learning, developing and acquiring new skills [11].

Artificial intelligence and medical error

Hereby, the question arises as to how a machine, robot or artificial intelligence can meet the above-described criteria of responsibility and authorization, and who can supervise such work in vocational and professional terms. Given the increasingly indicated elements of licensing and liability, how to answer the question of authorization of the work of machines in the treatment process as well as responsibility for artificial intelligence error.

Artificial intelligence, therefore robots do not have legal prerequisites for the disposal or obtaining of a public document, such as authorisation for independent work, as it still needs to be understood as an objectivity in a legal-process sense. However, the problem arises because the robot, although we assume it is "managed" by individual specialists, performs certain segments in treatment, diagnostics and therapy practically on its own, what is most present in surgery and is increasingly present in radiology.

According to Croatian criminal legislation, only natural persons who reached the age of 14 and were accountable at the time of committing the crime can be held responsible. Thus, for the question of criminal responsibility of

robots in principle, the answer should be undisputed; it simply cannot exist or be applicable.

The robot is not a natural, and neither is a legal person, it has no subjectivity. It can serve as an auxiliary tool, usable for the commission of an act, so it will serve and be valued as an object that was intended or used to commit a crime, so in the criminal process sense, only its confiscation or even destruction can be considered.

Consequently, the responsibility of using artificial intelligence applies exclusively to the person who is in some way related to the operation and control of the machine, i.e. that person has a guaranteed duty to prevent the appearance of damage that a machine can cause to third parties. In practice, it will first be necessary to determine whom the burden of duty falls on and when that burden ceases or passes to another person.

In the process of responsibility can be the manufacturer and the one who manages the machine in the processes of work. Let us suppose the machine as a product is correct, and in the process of treatment with a machine, a mistake occurs [12].

If there is not a "fault" in artificial intelligence, i.e. the robot as a product, but the error occurs in the diagnostic and treatment process itself, e.g. during the surgery, the guaranteed responsibility for such a treatment process would fall to the one who controls or is considered to be operating the artificial intelligence / robot.

In all of the above, the question arises whether and how an individual person, physician or other healthcare professional can manage a robot or any other type of artificial intelligence at all times, when it is known that regardless of the top product and the top educated specialist who manages it, the one who is provided with the service and that is each individual, is the patient with individual needs and all the specifics of his disease that are in no way equal to different people.

In addition, the question arises as to who can, and should manage the machine. Is it always the medical doctor who is authorised as the relevant holder of the health activity to treat persons, or perhaps another healthcare professional in diagnostics and treatment such as a medical radiation technologist, or can it be an IT specialist or a physicist who is either not a healthcare professional, or has no responsibility arising from the license. If it is not a healthcare professional, i.e. if he/ she is not a doctor, a technologist, or other healthcare professional, how to relate to the fact that it is the doctor or healthcare professional who manages the treatment processes and does not manage the robot in the treatment processes.

The question of the complexity of responsibility in AI treatment processes can be concluded by assuming the existence of the objective responsibility of healthcare professionals, because this is *a priori* a dangerous agent or dangerous activity, which further exposes the responsibility and issues of liability in the treatment with the machine.

In legal theory, therefore, there is also the principle of objective liability that determines liability for damages for which the fault of pests, in this case health workers, is not sought. Objective liability arises immediately when these assumptions are fulfilled: harmful action, damage, causal link between harmful action and harm, and unlawfulness of the harmful action. Objective liability rules apply to damages from things and activities from which there is an increased risk of damage to the environment. Whether the performance of the duties of a healthcare professional, i.e. the performance of a health activity, is carried out as a dangerous activity, will be decided by the court in each individual case.

The set legal definition of a dangerous activity or dangerous matter, in its content, does not exclude at all the forms and ways of performing certain tasks in health activities. Surgical procedures, work with ionizing radiation, work with any type of artificial intelligence, robots or general application of robotics, by their basic definition clearly show as dangerous activities or dangerous things. The above would mean that whoever owns the dangerous thing, i.e. operates the dangerous matter, is responsible for it. Therefore, a healthcare worker is directly responsible without determining the element and degree of guilt [13,14].

Dangerous matters are all things that by their purpose, characteristics, position, place and manner of use pose a danger to the environment, therefore they should be monitored with increased attention.

One activity poses an increased danger when, in its regular course, but in its technical nature and way of performing it, the lives and health of people or assets may be at risk, so this endangerment seeks increased attention from those who perform this activity as well as those who come into contact with it. In any case, the work of a healthcare worker with artificial intelligence directly or process in which artificial intelligence needs to be applied is work with dangerous things or dangerous activities.

It is important to indicate that regardless of the application of artificial intelligence, robotics and technological mechanical improvements, the robot cannot replace the individual work of men, i.e. health professionals, individuals and entire teams involved in the health care delivery. Indeed, the robot can and must only serve as an auxiliary tool, but in the structure of responsibility, it must be clearly assumed that managing and coordinating the same at all times and in every segment of treatment and provision of health services is possible. Artificial intelligence or robot should not replace or overcome the human hand and human mind in the first place because of the importance, complexity and demanding of treatment and health activities as it is provided and performed to preserve an individual's health and life.

Conclusion

The Croatian legal system still does not have the legal norm that would define and regulate the work of artificial intelligence and the presence of robotics in diagnostics and treatment, which means that Croatian health legislation has not yet recognized the importance of these technologies in medicine. Artificial intelligence in medicine still comes down to the level of enthusiasm of individuals who are willing, despite the systemic misunderstanding of the importance of artificial intelligence to apply the latest achievements and modern technologies to improve the standards of treatment.

Given the fact that there is no clear determination of state or health authorities in terms of the operation and regulation of the operation and use of robots and AI in medicine, the management of such AI treatment processes

remains legally sketchy, which particularly reflects in the issues of determining authorization and accountability. In this case, it comes down to the facts of legal improvisation, and the use of the principles of legal logic and the established legal standards of responsibility depending on the situation in which artificial intelligence is used. AI and robotics in treatment and diagnostics are not processes that could be classified as other or similar processes of handling a mechanism or a machine, because in the majority of cases where artificial intelligence is used in medicine, the person who manages the machine or information system does not have absolute power and the ability to influence all segments of action taken at all times.

As a result, the assumption of such accountability must not be based on the assumption of absolute responsibility of those who manage or better, co-ordinate the treatment process in which the computer program and / or machine-robot itself participate. For such people, the treatment process may have been eased in the sense that someone else, therefore a machine or program specifically works, but at the same time, the inability to control and manage processes at all times exposes a sense of internal burden, moral and professional responsibility. So as much as artificial intelligence helps in patients' treatment processes, it also potentiates the use of a higher level of expertise and concentration, and therefore the responsibility of the healthcare professional to the patient and the treatment outcomes cannot be overemphasized.

Sažetak

Koliko je Republika Hrvatska spremna za korištenje umjetne inteligencije u pravno-zakonodavnom smislu u medicini, odgovor će u ovom trenutku biti - nije. Činjenica je da procesi u medicini podrazumijevaju primjenu najsuvremenijih tehnologija u liječenju pa tako i umjetne inteligencije, ali isto tako je notorna činjenica da se zdravstveni zakonodavni sustav u regulaciji istog ne razvija u smjeru u kakvom se pretpostavlja i kakvi jesu standardi u drugim modernim državama Europe i svijeta. Naše društvo očekuju brojni izazovi upotrebe sveprisutnih oblika umjetne inteligencije i najmodernijih sofisticiranih tehnologija i tehnoloških procesa u liječenju, a koja će trebati regulaciju kroz propisanu kogentnu pravnu normu. Regulacije procesa liječenja primjenom umjetne inteligencije putem norme mora biti jer je naznačeno područje prevažno da bi se prepustilo tehnološkoj progresiji bez pravne kontrole i adekvatnog pravnog nadzora. Naime medicina i svi procesi liječenja, dijagnostike i terapije u sustavu zdravstvene zaštite i zdravstvene djelatnosti obavljaju se s jednim jedinim jasnim ciljem, a to je zaštita i očuvanje ljudskog zdravlja i života.

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