

CHALLENGES OF TECHNOLOGICAL DYNAMISM FOR LAW IN THE AREA OF HEALTH

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Abstract. Technologies, overcoming the limitations of human factors, acquire distinctive expression forms and trends in human society through mutual human and technè integration. The impact of dynamism of technologies, as an object of legal regulation in the area of health law, is explored in this article as a degree of turmoil in social relationships and as the issues of resultant legal regulation rather than from the perspective of state-of-the-art research and development in the area of technologies. Hence, the impact of the new technologies in the area of health, as an object of legal regulation, implies changes with external features and attributes, with individual, variable, and accidental nature that law should, on the principle level, foresee, plan, and bring together by determinant and coordinating links into an integrated system of interacting elements.

Keywords: health law, new technologies, information and communication technologies (ICT).

JEL Classification: K30, K32.

Introduction

On the one hand, the impact of new technologies, as human creative potential, brings along hopes of a more effective health system that enables to overcome the limitations relating to the human factor and, on the other hand, raises concerns over the issues of adaptation, increasing exclusion, appropriate data control, and the protection of fundamental human rights.

The object of the article is the impact of technological dynamism as an issue for health law. It aims to provide a differentiated summary of the impacts of new technologies in the health sector as the phenomena of change where their management is the most important problematic effect. This objective is implemented through the following tasks: to reveal multiple meanings and polysemy of the concept of technologies; identify the systematic features of the impact of new technologies characteristic of the health area; distinguish ensuing problematic areas of health law.

Therefore, the issues of the impact of new technologies on the area of health should be primarily tackled on the level of notions and principles established in legal acts, which are conceptual instruments, methods for the stability of legal power, and for a mature legal

framework to enable an acceptable balance between risks and benefit.

Considering the work of scholars around the world on this issue, it is important to note that it is unanimously questioned whether the transfer of responsibility (both of doctors and patients) to a machine in the healthcare process can give rise to doubts about the humanistic foundations of the healthcare act (Gueydier et al., 2018).

It is regrettable that there is still a dearth of research on the difference between the patient's choice in the face of illness and the mere possibility of illness. The risks posed by the availability of information and the emergence of the right not to know in the field of genetic technology also concern algorithms, which means that technologies are increasingly influencing the regulation of health law, and we dare a hypothesis that this influence will inevitably become stronger in the future.

The integration of different web generations in the health system is manifest in the importance of information and its dissemination, in the need for an interoperable and collaborative health system, the changing boundaries of telecare and personalised care, more objective data for health promotion and prevention, and in the increasing autonomy of the patient, which eliminates the paternalistic

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healthcare model. The health system is steered towards giving more autonomy to artificial intelligence, which brings along the need for an appropriate balance between human competence and the legal regulation of technology use. Such impacts of new technologies, first of all, imply their disruptive effects, i.e., the health system finds itself *de facto* against technologies (Bauman, 2011). These changes are not isolated in individual segments of a large health system, but continue to transform the system as a whole. Therefore, on the one hand, such impacts, such as human creative potential, bring along hopes of a more effective health system that allows us to overcome the limitations related to the human factor and, on the other hand, raise concerns about adaptation, increasing exclusion, appropriate data control, and the protection of fundamental human rights. Therefore, the genesis of the integration issue of new technologies into the health system should, first of all, be addressed at the level of the notion of health and the principles of health law. They are conceptual instruments for the stability of legal power and the mature legal framework that enable an acceptable balance between risk and benefit.

1. Ambivalence of the term “technology”

The Greek word *technè* means efficient use of existing elements (materials). *Technè* is the opposite of *phusis* (nature), since nature creates objects that are intrinsic to it and *technè* refers to a planned and creative act (Frogneux, 2013). However, both terms refer to purposeful activity in accordance with certain principles and laws. The relationship between *phusis* and *technè* is complex and paradoxical in its mutual advantage: *technè*, by partially imitating *phusis*, complements and completes what it is incapable of doing (Aristotel', 1937).

Hence, *technè* can be interpreted as a rational and structured activity, and in healthcare, according to Aristotle, it expresses the intertwined relationship between experience, art, and science (981a–981b). The ability to transmit knowledge is an indication of competence in a particular field (Aristote, 1974). Plato emphasizes the activities that bring knowledge into being because it is important that knowledge brings benefits. Therefore, the aim of *technè* is to transmit knowledge and, thereby, make it useful. Thus, the ancient Greek words τέχνη (art, craft) and λογία (science), which make up the term technology, refer to the practical realization of resources as the process of purposeful transformation of a theory or a set of resources into required techniques, products, services, etc.

The distinction between τέχνη and λογία has led to different meanings of the term technology. The social, economic and technological changes resultant from the application of the means of economic development (industrialisation) have led to a renaissance in the epistemic dimension of the concept of technology and triggered a confusion in the meanings of these terms (Platon, 1990). The Anglo-Saxon *technology* has been transposed into other languages, irrespective of the meaning this word had acquired in those languages (Platon, 1990, p. 181). The

Anglo-Saxon notion of technology refers to useful transfer of knowledge (Gilbert, 2008, p. 3) i.e. putting scientific knowledge into practice. Science can be used as a tool to achieve efficient technological outcomes (Kuhn, 1972, p. 192) but technology is closely linked to the application of knowledge in the material world (production methods, tools, etc.). According to the European notion of technology, “technology” can be science, ie designate a scientific study as such on the use of knowledge. The study of human activity, which includes goals, planning, process, and results, means technology as the science of techniques.

The researchers of the Lithuanian Institute of Hygiene note the plurality of interpretations of the definition of technologies by different international institutions in their analysis of this definition in the health field, however, they state that “the content of the concepts is similar and they are not mutually conflicting”. However, the ambivalence of the term “technology” mentioned above is also apparent in the health law. On the one hand, it refers to technical means. *The Law on the Health System of the Republic of Lithuania* defines technology as medicines, medical devices or therapeutic and surgical procedures, as well as means for the prevention, diagnosis, or treatment of diseases used in the provision of healthcare services. The executive branch understands technologies as the procedures, equipment, and medicines used in the provision of healthcare services (Order No. V-642 of 14 September 2004 of the Minister of Health of the Republic of Lithuania). In EU law, that means medicines, medical devices, medical or surgical procedures (Directive 2011/24/EU, Article 3). On the other hand, it is also noted that technologies include any intervention used to improve the prevention, diagnosis and treatment of diseases, rehabilitation, and long-term care; that covers methods and methodologies used in the provision of healthcare services; as well as all assistive technologies for the provision and organisation of health services (Health Technology Assessment (HTA) glossary), and the WHO places emphasis on innovation by defining technologies as the application of knowledge and skills in the form of the technical instruments mentioned above in order to tackle healthcare problems and improve the quality of life.

Health law thus uses a broad concept of technology that encompasses both Anglo-Saxon and European meanings. The definition of technology in the *Law on Technology and Innovation of the Republic of Lithuania* should be considered a reference model as it combines cognitive, teleological and practical aspects in the concept of technology which calls for scientific investigation of social problems and application of the knowledge obtained in practice to achieve a targeted approach to solving those problems.

2. Impact of dynamic technological developments on the area of health: challenges for legal regulation

The first paragraph of Article 168(1) TFEU, which actually matches the second sentence of Article 35 of the Charter, provides that “a high level of human health protection

shall be ensured in the definition and implementation of all Union policies and activities”. Article 114(3) TFEU states that a high level of health protection means such protection which “takes account in particular of any new developments based on scientific facts”. The importance of the dissemination of health information as set out in the TFEU has been developed in the objectives of the Lisbon Strategy adopted by the European Council, in the strategic initiative for growth and employment i2010 adopted by the European Commission, and in the EU’s research and innovation programme Horizon 2020 adopted by the European Commission. These EU documents see information and communication technologies (ICTs) as an area of strategic importance, development, growth, and expansion. The impact of ICTs is considered by many scholars to be of particular importance in the world of modern technology. This is also the view of the WHO. Therefore, considering the importance of information dissemination for public health as set out in EU law and in the instruments implementing these provisions all over the Union, it should be stated it is the dissemination of information and the technologies chosen for this purpose that should be the basis of the targeted process of management in the public health area in order to enable the fight against the “diseases that most of all endanger health”. The impacts of new technologies can be both purposefully planned to achieve the desired results and random, i.e. phenomena. The following sections provide a differentiated summary of the impacts of new technologies on the health sector as phenomena of change. Their external features and attributes, individual, variable, and random nature, must be foreseen, planned, and brought together by law through determinant and coordinating links into an integrated system of interacting elements in the area of health.

2.1. Challenges of technological innovation and change for health law

The National Audit Office of the Republic of Lithuania pointed out in its 2017 State Audit Report that the e-health record system has only been partially developed and implemented, even though ICT has been used for decades. Therefore, innovation is a relative phenomenon (Aydalot & Keeble, 2018, p. 3). Technologies can be introduced by adopting them from another field and applying for health processes. Such relative nature of technological innovation is an indication of complicated integration of innovations into the societal technical complex. The health sector is characterised by its resilience to the disruptive effects of new technologies.

Technological innovation can also mean a lack of scientific certainty. Application without complete investigation, based only on hypothetical risks that do not allow full prediction of consequences, and the need to take decisions without all the answers in place is, *inter alia*, a characteristic of new technologies. Examples include the technologies of genetically modified organisms (GMOs) or brain-computer interaction (BCI) (Klein, 2016, p. 1311).

The impact of technological innovation on law is an indication of the lack of effectiveness in law-making. In health law, this has led to the introduction of new principles of precaution and trust. The National Audit Office of the Republic of Lithuania noted its 2018 National Audit Report on the law-making process that “it is often only after the adoption of a law that gaps in legislation and the negative consequences of legal regulation become visible” (vkontrole, 2018). And the WHO points out that innovation implies impossibility to rely on a single narrative about the future because “there is no single perfect model of a health system since context is key”. Thus, technologies evolve rapidly, while legal regulation is slow. Consequently, health law is exposed to the phenomenon of technological innovation as a challenge to the stability of law as such.

With a diminishing ability to accurately predict the future in relation to the impact of technologies on health, it is necessary to anticipate the phenomenon of innovation and change as a technological context for law. The ability to adapt has therefore become important in all spheres of social activity. For institutions, this means being able to renew; for legal regulation – specification of the general principles of law in the contexts of changing technologies. Static, vertical organisational structures and one-off solutions are more and more at odds with the context of technological progress. For example, the National Audit Office of the Republic of Lithuania notes in its National Audit Report on the law-making process that “The legislative process does not adequately involve the societal groups affected by the legal regulation, and therefore does not get their views on the envisaged legal regulation, ways of solving problems and expectations. The law-making process lacks openness and transparency”.

In 2019, the Constitutional Court of the Republic of Lithuania ruled that, in order to ensure the quality of enacted laws, as well as the consistency and internal coherence of the legal framework, the legislative process, in particular the deliberation stage, must be regulated so “as to enable the content and effects of the legal regulation envisaged in the draft laws to be properly assessed during their deliberation”. In 2018, the National Audit Office of the Republic of Lithuania noted that draft legislation is overly abundant and that urgency or special urgency procedures are too often used in the legislative process. This reduces the time necessary to consider the draft legislation. This also leads to a lack of the conditions necessary for law-making, which hinders “the transparency and publicity of the legislative process, as not all the stages of the normal procedure for legislative consideration are applied, and the possibility for stakeholders to participate in law-making is reduced” (vkontrole, 2018). However, scholars draw attention to speed as an attribute of modern technological innovation and change (Thimbleby, 2013, p. 161).

Human resources (competences, qualifications, labour sharing arrangements, etc.) change slowly (Griškevičius & Kizlaitis, 2012, p. 17). This brings about adaptation challenges relating to a systemic redistribution of functions that would be optimal for the context and capacities.

That is a challenge in ensuring the human right to health, which, if not addressed, leads to inadequate accessibility of health services, to information barriers, untapped potential of professionals to optimise the number of visits, operations, etc., to inadequate redistribution of functions among doctors, nurses and other staff, and diminishes the reserves for increasing the efficiency of medical equipment (Beliūnienė et al., 2014, p. 225).

The need to adapt thus poses challenges of legal consistency and lack of internal coherence, since, on the one hand, the system needs flexibility in such a context, but on the other hand, in the words of John Finnis, “the famous ‘rigidity’ of law” is equally important (Finnis, 2014, p. 400).

The speed of technological innovation and change has highlighted the need to reinforce simplicity (comprehensibility) at the level of legal principles as a means to facilitate the integration of technologies into the health system. The growing importance of this principle, *inter alia*, in the health field, is reflected in the increasing importance of visuality, simplicity (comprehensibility) of processes, and transparency. This is illustrated by technological innovations such as insta story or RPA (robotic process automation).

It is, therefore, important that law does not unduly restrict technological progress, but gives effect to the human right to benefit from its results as enshrined in the UDHR. However, the rapid pace of technological progress is a challenge to the consistency and internal coherence of law. It brings along the risk of inadequate legislative effectiveness and the necessity to take decisions in the absence of scientific certainty. The principles of caution and trust are therefore gaining a foothold in health law. The challenges of adapting to a changing technological environment have brought the principle of simplicity into focus.

2.2. Challenges of the technology market for health law

Healthcare is part of the EU’s overall policy of economic integration and, therefore, requires to ensure the free movement of goods, services and people. This means that “healthcare has been transformed into an economic service sector” *with the potential for profit and reinvestment as the driving factor for its development*. The patient is one of many factors here, but not the only one. This brings along challenges to ensure that technological progress actually serves the human right to better health. *Researchers state that the lack of holistic policies makes individual progressive initiatives ineffective*. The law must strike a balance between the development of the health market and its positive impact on the pursuit of better health.

The market rule that “the ultimate goal of all goods sold is to be consumed by customers” implies that technological development is driven by the reduction of production costs, inputs, efforts, resources necessary, etc., in order to maximise profits, but not by the benefit to the patient. Similarly, the fact that “buyers will wish to obtain commodities for consumption if and only if consuming them promises gratification of their desires” (Bauman, 2011, p. 24) means that, alongside the innovations necessary

for healthcare, technological development can become a tool for manipulating consumer preferences. Therefore, it is necessary to assess such risks using the process and criteria of the health technology assessment (HTA) and distinguishing between possible subjective preferences and objective health benefits (Thimbleby, 2013, p. 166).

The preferences of healthcare consumers (purchasers) can become an object of technology marketing and can expose patients or clinical trial participants to the risk of unreasonable expectations. Researchers have identified that new technologies pose risks of such nature for the institute of free and informed consent. Attention to the subjective factors involved in the perception of information in the legal framework of free and informed consent, as well as health literacy education, can help to prevent such risks.

The market is entered and retained by players who focus in their supply not on long-term but on short-term fragmented solutions that promote higher consumption. For example, *SaaS* (software as a service). This trend shows that service providers prefer continuous and predictable, although lower, income rather than one-off and higher gain. The aim is to bind the consumer to the producer’s products in the long term. *However, this may lead to the lack of legal principles such as justice, equity and solidarity in the area of health*.

The impact of economic trends encourages the privatisation of health services, which can bring along the risk of inequality in access to healthcare services. These risks are inherent in the ability of algorithms to segment patients in order to distribute the most expensive resources in a way that violates the principle of human equality. It is likely that the primary level of healthcare services will increasingly involve lower-skilled professionals and their functions will be performed by means of algorithms to support decisions *in corpore*. This will make it more expensive to provide healthcare by specialists who have skilled competence of integrated knowledge and the ability to respond to individual patients’ needs. Access to such care is likely to be based on algorithms that take into account variables of other nature (not only health related). This exposes patients to the risk of being classified (ranked).

Thus, the inert development of new technologies based on economic benefit and on the factor of benefit for the majority can be incompatible with the human right to seek the best possible health. The health system should not deviate from its principles in its harmonious interaction with the market economy because “the traditional medical ethics, which is based on the ideas of selflessness and service to patients, is contrary to the ideology of the market economy”. Given the plurality of interests involved in the development of *technology*, it would be difficult to expect *technology to develop in optimal harmony with the concept and principles of health*. It is therefore relevant to question the perspective of interests as a starting point for reflecting on the future of the health system: the patient, the healthcare professional, the developers, the producers or the sellers of technologies? Economic models should structure

the behaviour of all actors in the health system around a vision to implement the concept of positive health and around the principles of health law which would be based on and verified not by performance indicators, but by the achievement of human health outcomes in the long term and holistic perspective. Such outcomes will, in the context of the influence of market factors, increasingly depend on the quality of coordination among all actors involved in the health system.

2.3. Challenges for legal regulation of the integration of ICT in the health area

The processes of information, data and knowledge management and the resulting changes in social relations, collaborative infrastructure and organisational space to be regulated by health law are one of the major challenges posed by new technologies. The economic potential of the “information society has made it a political aspiration” (Žilinskaitė-Vytienė et al., 2016, p. 99) and the development of ICTs is being promoted on the level of political institutions – national governments and supranational organisations. E-health is the “use of information and communications technologies in support of health and health-related fields, including healthcare services, health surveillance, health education, knowledge and health research”. For the different degrees of integration of these technologies in the health domain, a web generation classification of 1.0, 2.0, 3.0 and 4.0 is applied by analogy, indicating better technological solutions for health. This classification provides a systematic definition of the web evolution and allows the identification of the characteristic features of its interventions in the health field. In this context, the main expressions of the changed relationship with information in the health field and their implications for legal regulation should be discussed.

Health 1.0 signifies the web of products, services, search engines, and healthcare institutions. It is a static *www* with the primary function to disseminate information (read only). Health 1.0 has brought about a change in the relationship with information so that it no longer remains the prerogative limited to a narrow range of professionals. “Information society” as a phenomenon has begun to spread in healthcare as new ways of accessing personal health data, leading to new possibilities for patient monitoring, prevention and intervention. This generation of technologies has brought along the challenges for legal regulation in the health area in terms of protection, reliability, innovative and effective use of information in virtual environments and health literacy. Health 1.0 has thus contributed to the minimisation of the paternalistic model of healthcare in law, to patient participation changes, the shift in the concept from disease to health, and the interoperability of actors and data of the health system.

The paternalistic paradigm of healthcare is likely to erode even further in the next decade as the patient seeks to become a full equivalent actor in any experience of his or her health. The changing role of the patient in health law implies changing rights and obligations in areas such

as data security, the procedure for free and informed consent, the mutual duty of information between the doctor and the patient, etc. The importance of transparency, simplicity, reasoned and comprehensible explanations and the need to ensure this at the level of law are growing accordingly.

Health 3.0 means new challenges for health law in the areas of equality, solidarity and access to healthcare. International systemic harmonisation is essential as the diversity and incompatibility of options on different platforms is an obstacle to the development of Web 3.0 in health. Many of the technologies of this generation, in addition to being a real aid or the prevention, diagnosis and treatment of patients, also mean a growing and increasingly uncontrolled investment in their development. In the context of the development of private services, the challenge for health law is to ensure the principle of solidarity as social exclusion grows: two services at two different speeds (expensive, continuous monitoring *versus* cheap periodic consultations) (Allaert & Mazen, 2016, p. 29). In the Health 3.0 technology generation, data are becoming an asset that enables the dynamism of any activity, and data management, processing and interoperability are the objects requiring more extensive legal regulation. Consequently, opportunities for targeted health supply are growing with increasing access to data. Researchers believe that pooling large amounts of data to identify patient needs more accurately could lead to more efficient and cost-effective treatments, even if this means creating new needs (Gueydir et al., 2018, p. 15).

As data flows increase, efficient data assimilation through algorithms becomes increasingly important. If Health 2.0 was a collaboration between healthcare institutions and doctors, Health 4.0 is already a collaboration with algorithms and implies the issues of legal regulation relating to the growing dependence on them. Algorithms are at the core of functioning of all the digital objects which keep growing unstoppably in modern society and which have gradually taken root, *inter alia*, as new elements in the structure of public policy. Artificial intelligence leads to the replacement of human decisions by algorithmic ones, or at least to the support of human decisions by means of verification. The machine learning ability of algorithms makes them artificial intelligence. The algorithms used in virtual platforms also have a normative impact and for law this means that algorithms are becoming sources of law and creators of norms. This has enabled the emergence of legal-techs. Technological progress in law, as in other areas, reveals the limiting influence of the human factor on the professional functioning of the system. Researchers, therefore, predict an increase in the integration of technology into law. A decision supported by mathematical calculations and logical numerical operations is *a priori* more objective and thus superior to subjective human decisions. Therefore, in the context of representative democracy, the algorithm seems to be a more efficient and objective solution for regulating legal relations. The algorithmic law replaces the vertical law with the immanent normativity

derived from technologies. In short, law is no longer based on normative causation but on practical correlation (Baby, 2016, p. 311), which means the robotisation of law, since algorithmic normativity is the standards and norms dictated by automated data processing. Conventional legal reasoning is replaced by findings based on data flows. Such (algorithm-supported) law-making becomes an advantage over all the immanent, spontaneous and non-standard situations that are normally less taken into account by general legislation. However, it is necessary to address the inherent risks of hacking or the threats of unintentional discrimination. The latter may arise because artificial intelligence operates on the basis of databases, which means that the algorithm can reproduce and amplify errors in these databases as it processes them. This means exposure to the risk of unintentional discrimination.

The development of algorithms is driven, *inter alia*, by the trust of the public in the objectivity and neutrality of technologies. However, such neutrality is an appearance that can obscure political and ideological interests (Barraud, 2018, p. 37). A technical tool is neutral, however, the criteria, parameters and data by which the algorithm achieves its results are determined by people. In facilitation of efficiency and productivity, algorithms at the same time guide people's decisions through the results they are given. That is why scholars speak of "invisible auto-propaganda" (Katyal, 2014, p. 1685) as the dictatorship of algorithms, the normative consequences of which can be contrary to the idea of democracy. In order to avoid this threat, people should be aware of the use of algorithms (especially in public authority structures): what is the purpose, degree and manner of such use, its contribution to decision-making, what data are processed, how and where they were obtained, and what processing parameters and operations are used. In the opposite case, the continuous and rapidly advancing chain of technology that overcomes human autonomy can more and more "bypass" political, ethical and legal choices. Thus, the impacts of web 4.0 generation technologies highlight the vulnerability of the sovereignty of the human community over technologies. The law must, therefore, protect society from fully automated decisions by imposing requirements on the transparency of algorithms.

The patient, in turn, must be well informed and have the possibility to opt in or out of treatment. Algorithms, however, are increasingly automating services. As human labour and competences become more expensive and as functions that do not require such competences are handed over to automated platforms, it is reasonable to expect new circumstances for the legal regulation of the principle of patient's autonomy. It can be expected that auto-responders or platforms ensuring services under the FAQ principle will be used for diagnosing the most basic symptoms and prescribing treatment. Such models of healthcare would be adequate to the potential of technologies and for more efficient use of human resources (Gueydier et al., 2018, p. 13). The intervention of algorithms in healthcare brings to the fore changes in the legal

concept of information as an integral part of the healthcare process. On the one hand, it is necessary to address the growing bureaucratic burden, but on the other, the nuances of appropriate patient information are becoming more complex, the range of situations and risks requiring information is changing and finding the right balance between accessibility of services, reduction of bureaucracy and guaranteeing the autonomy of the patient is becoming more and more difficult. In addition to the issues raised, it is also appropriate to consider the impact of the information provided by a technical tool (machine) on the patient's ability to make a decision.

Conclusions

1. Health law uses a broad concept of technology that encompasses both Anglo-Saxon and European meanings. The definition of technology established in the legal regulation of Lithuania should be considered a reference model as it combines cognitive, teleological, and practical aspects in the concept of technology, which calls for scientific investigation of social problems and application of the knowledge obtained in practice to achieve a targeted approach to solving those problems.

2. Technological impact trends show that data are becoming part of healthcare *per se* at all stages of the healthcare process. Closely linked to this are the issues of their protection, which shape the strategic policy on the use of technologies for health prevention, promotion, patient's responsibility and participation in the healthcare process. The beginning of this century has seen various initiatives, which showed the interest of the national level in the phenomenon of big data in the health field with a view to changing the legal regulation for the wider use of health-related data collected by various institutions. This raises questions about the impact of the data generated by new technologies on privacy paradigm shifts.

3. New technologies have already expanded the notion of information privacy and protectability. By using technologies, people are sacrificing privacy for new opportunities through the use of technologies, however, their identity data lose their valuable price in this way. Similar trade-offs can be expected in the future of healthcare, in particular as the possibilities of data collection and use inevitably distance their controller from the patient as an individual person. Such changes in the privacy paradigm are influenced by the opportunities to personalise care by means of Health 3.0.

4. Security becomes the basis for the effective use of data in the health system, therefore, some legal concepts related to it (e.g. the privacy paradigm) are likely to change. Accordingly, new expressions of the principles of law (e.g. autonomy, free and informed consent, confidentiality), new ways of their application, and new derivative health law principles can become an indicator of legal innovation. On the one hand, it is important to avoid ineffective, excessive, and irrelevant legal regulation; on the other hand, it is necessary to guard against even unforeseeable threats.

This problem necessitates the development of the principles of precaution, trust and proportionality in health law.

5. The intervention of algorithms in healthcare brings to the fore changes in the legal concept of information as an integral part of the healthcare process. On the one hand, it is necessary to address the growing bureaucratic burden, but on the other, the nuances of appropriate patient information are becoming more complex, the range of situations and risks requiring information is changing, and finding the right balance between accessibility of services, reduction of bureaucracy, and guaranteeing the autonomy of the patient is becoming more and more difficult.

References

- Allaert, F.-A., & Mazen, N.-J. (2016). Évaluation des objets connectés et des applications de santé. *Actualités Pharmaceutiques*, 55(556), 29–32. <https://doi.org/10.1016/j.actpha.2016.03.006>
- Aristotel'. (1937). *Fizika*. Gosudarstvennoe sotsial'no-ekonomicheskoe izdatel'stvo.
- Aristote. (1974). *La métaphysique, tome I*. Nouvelle édition entièrement refondue, avec commentaire par J. Tricot. Librairie philosophique J. Vrin.
- Aydalot, P., & Keeble, D. (2018). *High technology industry and innovative environments: The European experience*. Routledge. <https://doi.org/10.4324/9781315149769>
- Baby, L. (2016). L'algorithme de l'informaticien et le syllogisme du juriste. *Dalloz IP/IT*, 6, 311–312.
- Barraud, B. (2018). Les algorithmes au cœur du droit et de l'État postmoderne. *Revue internationale de droit des données et du numérique*, 4, 37–52.
- Bauman, Z. (2011). *Vartojamas gyvenimas* [Consuming life]. Apostrofa.
- Beliūnienė, L., Ambrazevičiūtė, K., Lankauskas, M., Mauricė, E., Mulevičius, M., Nikartas, S., Mačernytė-Panomariovienė, I., Petrylaitė, V., Kavoliūnaitė-Ragauskienė, E., Šneideris, D., & Zaksaitė, S. (2014). *Aktualiausias žmogaus teisių užtikrinimo Lietuvoje 2008–2013 m. problemos: teisinis tyrimas* [The most relevant problems of ensuring of human rights in Lithuania 2008–2013: Legal research]. Law Institute of Lithuania.
- e-tar. (2018). *Republic of Lithuania Law on Technology and Innovation No. XIII-1414, Register of Legal Acts*. <https://www.e-tar.lt/portal/lt/legalAct/303806a0869411e8af589337bf1eb893/asr>
- e-tar. (1994). *Republic of Lithuania Law on the Health System No. I-552, Register of Legal Acts*. <https://www.e-tar.lt/portal/lt/legalAct/TAR.E2B2957B9182/asr>
- Eur-Lex. (2011). *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the implementation of patients' rights in cross-border healthcare (Article 3)*. <https://eur-lex.europa.eu/legal-content/LT/TXT/?uri=CELEX%3A32011L0024>
- Eur-Lex. (2012). Consolidated version of the Treaty on the Functioning of the European Union C 326/49 (26 October 2012). *Official Journal of the European Union*, C, 326/47. <https://eur-lex.europa.eu/legal-content/LT/TXT/PDF/?uri=CELEX:12012E/TXT&from=lt>
- e-seimas. (2004). *Order No. V-642 of 14 September 2004 of the Minister of Health of the Republic of Lithuania on the approval of the Programme for Ensuring the Quality of Healthcare for 2005–2010*. Seimas of the Republic of Lithuania. <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.242167/asr>
- Finnis, J. (2014). *Prigimtinis įstatymas ir prigimtinės teisės* [Natural law and natural rights]. Aidai.
- Frogneux, N. (2013). Technique. In L. Lemoine, É. Gaziaux, & D. Muller (Eds.), *Dictionnaire encyclopédique d'éthique chrétienne*. Les éditions du Cerf.
- Gilbert, L. (2008). Regards sur les nouvelles technologies. *Al-térités* 5(1).
- Griškevičius, J., & Kizlaitis, R. J. (2012). *Informacinės sistemos medicinoje* [Information systems in medicine]. Technika. <https://doi.org/10.3846/1353-5>
- Gueydir, P., Doat, D., Kohlbrenner, B., Xavier, I. (2018). *Big data et santé prédictive. Prédire le futur de la santé*. Optic Humana Technologia. https://www.academia.edu/35834080/Big_data_et_santé_prédictive_Prédire_le_futur_de_la_santé
- International Network of Agencies for Health Technology Assessment. (2006). *Health Technology Assessment (HTA) glossary*. [http://aaz.hr/resources/pages/55/INAHTA_Health_Technology_Assessment_\(HTA\)_Glossary.pdf](http://aaz.hr/resources/pages/55/INAHTA_Health_Technology_Assessment_(HTA)_Glossary.pdf)
- Katyal, N. (2014). Disruptive technologies and the law. *Georgetown Law Journal*, 102(6), 1685–1690.
- Klein, E. (2016). Informed consent in implantable BCI research: Identifying risks and exploring meaning. *Science and Engineering Ethics*, 22(5), 1299–1317. <https://doi.org/10.1007/s11948-015-9712-7>
- Kuhn, T. S. (1972). *La structure des révolutions scientifiques*. Nouvelle bibliothèque scientifique. Flammarion.
- Platon. (1990). *Sobranie sochinenie v chetyrekh tomakh* (Tom 1, Evidem). Mysl'.
- Thimbleby, H. (2013). Technology and the future of healthcare. *Journal of Public Health Research*, 2(3), 160–167. <https://doi.org/10.4081/jphr.2013.e28>
- vkontrolė. (2018, 16 March). *National Audit Report. Law-Making Process*. National Audit Office. <https://www.valstybeskontrolė.lt/LT/Product/23770/teisėkūros-procesas>
- Žilinskaitė-Vytienė, V., Čiupailaitė, D., & Kirtiklis, K. (2016). *Informacijos visuomenė: pamatinė sąvoka ar madingas raktažodis?* [Information society: A fundamental concept or a trendy keyword]. *Sociologija. Mintis ir veiksmai*, 38(1), 97–116. <https://doi.org/10.15388/SocMintVei.2016.1.10312>