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EDITORIAL

Dear Readers,

You have opened the Theme Issue devoted to Doctors' and Patients' Rights and Obligations.

The topic is indeed "ever-green." Nowadays, however, it has got a new coloration. Medical and legal professions are to find responses to both the challenges appearing with respect to technological advances and the ones resulted from the COVID-19 pandemic.

Has the scope of those rights and obligations been changing? What connotations did the new times bring?

The human rights to life and health start to be perceived as the right to survive not only with respect to children but also concerning any human person. The rights of children, the elderly, and other vulnerable groups, which have always been in focus, become of even greater concern. The authors contributed to the Theme Issue share their observation and ideas as to the ways of improving national and international protection of such rights.

The countries that tackle the recently emerged problems while conducting drastic healthcare reforms face special difficulties. What is essential for the successful design and implementation of a healthcare reform? I hope that the reading of the relevant input will give you new insights and stimulate discussion.

Despite the new "distancing realities," often resulted in the reduced possibility of full-fledged communication between doctors and their patients, physicians still manage to express compassion and account for patients' personal values, thus maintaining the relationship of trust.

Will it remain that after the introduction of robotic medicine and artificial intelligence in the routine practice of Medicine? The authors of the Theme Issue share their concerns and hopes substantiating the need to rethink the informed consent doctrine.

Informed consent is known as one of the most significant manifestations of the patient's autonomy. And what about the doctor's autonomy? Shall one

take doctors' personal values into account? And, if yes, what would the best way of doing that be? In the paper devoted to the conscience clause, the reader will find the reflections on reconciling physician's autonomy with the rights of the patient.

Now more than ever, it is important to look for a balance between the doctors' and patients' rights and obligations; to use the best foreign practices finding the "common legal denominator"; and to boost confidence in healthcare professionals and public institutions responsible for healthcare and welfare.

I want to believe that the discussion contained in the following pages will contribute to the said goals and will be continued as there are so many topics that are worth covering: vaccination and human rights, medical triage, physicians' liability and its limits, etc. … . You may continue this list to be written with professional experience and a caring heart of every author and reader.

I hope that the reading of the Theme Issue will be of use to you, dear colleagues, providing you with new insights and giving you an impulse for further research.

Stay safe and read the Journal!

With my warmest regards,

Ass. Prof. Dr. **Radmyla Hrevtsova,** Adv.,
Governor of the World Association for Medical Law (Ukraine),
Guest Editor

March 2021

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CHANCE TO SURVIVE: THE HUMAN RIGHT TO LIFE AND HEALTH IN THE COVID-19 PANDEMIC

Bohdana Ostrovska*

Abstract: The outbreak of the COVID-19 pandemic has actualized many bioethical issues related to medicine and human rights. In particular, they concern the rights and responsibilities not only of a doctor and a patient but of a state and a citizen, which is reflected in the need to study the decisions of state bodies on the validity of restrictions on human rights in time of emergency or the state of emergency and their compliance with international law. In general, the spread of SARS-CoV-2 has been a challenge for each state to respect human rights in a pandemic, especially the right to life and health of citizens under their jurisdiction, as the obligation to protect them is a positive obligation of each state.

Against the background of the escalation of the pandemic, there was a significant derogation - the exemption of states from their obligations to respect human rights and freedoms in time of emergency or the state of emergency, defined in international documents. International organizations such as the United Nations, WHO, UNESCO, UNDP, the International Committee of the Red Cross, the Council of Europe and others play an important role in the field of human rights protection in the context of the COVID-19 pandemic.

The issue of global biosafety currently requires a fundamental revision. At present, coordinated action by the international community to prophylaxis, prevention of spreading and treatment of diseases and their consequences must play an important role. International legal regulation of these issues, taking into account bioethical aspects,

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should remain on the agenda of the international community for early prediction and prevention of new future threats to humanity and biological threats in particular.

Keywords: Human Right to Life; Right to Health; International Law; Pandemic COVID-19; Bioethics; Biosafety.

In the current conditions of innovative biomedical technologies development, the chance of each person for a qualitative improvement in health, preservation and extension of life increases, especially in the field of reproductive technologies, transplantation, etc. The development of innovative biomedical technologies, in particular in genetics, embryology, cytology, and transplantology, has significantly influenced the preservation and prolongation of human life. At the same time, the biomedical technologies for human cloning, cryopreservation of cells, tissues, organs, and human embryos, production of human embryonic stem cells, genetic diagnostics, genetic engineering, etc., have generated a lot of bioethical problems. National governments try to regulate these problems at the level of national legislation. However, their solution is possible only based on international cooperation, especially within the framework of international organizations, namely, the United Nations, the Council of Europe, and the European Union.[1]

Along with this, the outbreak of the COVID-19 pandemic has actualized a lot of other bioethical problems related to fundamental human rights, primarily the right to life and health, namely: restrictions on the provision of medical services, including routine examination and treatment, as well as surgical intervention, which makes it impossible for all citizens, who need it in connection with other diseases, to have equal access to health care; medical triage, which takes place in prioritizing of medical care provision of medical care and actually manifests itself in the decision of doctors to the question "who will live", which contradicts to the principle of non-discrimination of a person on the provision of necessary (previously urgent) medical care; lack of reliable scientific data about the SARS-CoV-2 virus, which leads to experimental treatment in the absence of treatment protocols (based on experimental protocols) and gives rise to the prescription of drugs "of label"

1 Ostrovska BV. International legal aspects of human life protection in the process of application of innovative biomedical technologies. [Internet]. Science and innovations. [cited 2021 Febr.]. 2018;14(5):25-33. Available from: http://scinn-eng.org.ua/sites/default/files/pdf/2018/N5/Ostrovska.pdf

(that is, not according to the indications specified in the instructions), antibiotic resistance etc.; the ratio of experimental treatment for coronavirus with the right to appeal against unlawful decisions and actions of health care institutions' employees, as well as to compensation for harm caused to health; the ratio of compulsory vaccination in compliance with the principles of personal autonomy and voluntary informed consent of a person to medical intervention; the safety of the new vaccine; legal consequences of refusal of vaccination and treatment; the priority of vaccination for certain categories of people (doctors, the elderly, etc.); ensuring proper conditions for transportation and storage of the vaccine and responsibility for their observance; violation of confidentiality of personal data; restriction of freedom of movement et al. These issues need clear regulation in the legal field of states, but first of all their solution will be facilitated by unification at the level of international law.

The problem of discrimination in society for certain categories of people belonging to vulnerable groups has also increased, what is reflected in particular in restriction of access to medical care for children deprived of parental care; lonely elderly people or living in social institutions; people with disabilities; people suffering from concomitant diseases (HIV/AIDS, diabetes, etc.); homeless people, deprived of possibility for self-isolation; refugees; stateless; internally displaced persons; migrants; persons in prison (overcrowding in such places is an additional risk factor for the spread of disease); representatives of certain ethnic groups (in particular the Roma); as well as people suffering from mental illness and being in appropriate institutions. According to the United Nations Population Fund (UNFPA), during the pandemic period, quarantine and self-isolation have increased the number of cases of domestic violence, the victims of which are usually women[2] and children, constitutes an additional threat to their life and health.

The severity of the circumstances required the consolidation of states' efforts, first of all, the convening of an international conference on threats of coronavirus spread for a joint resolution of urgent and controversial issues. Instead, against the background of the aggravation of the pandemic, there was a massive derogation of states from their obligations to respect human rights

2 Impact of the COVID-19 Pandemic on Family Planning and Ending Gender-based Violence, Female Genital Mutilation and Child Marriage. Pandemic threatens achievement of the Transformative Results committed to by UNFPA. UNFPA. 27 April 2020. Available from: https://www.unfpa.org/sites/default/files/resource-pdf/COVID-19_impact_brief_for_UNFPA_24_April_2020_1.pdf

and freedoms in time of emergency or state of emergency, defined in a number of international instruments, in particular in:

- The International Covenant on Civil and Political Rights (1966), which in Art. 4 contains a provision that "the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin", emphasizing the impossibility of derogation from a number of articles of this Covenant, in particular Art. 6, which provides for the human right to life and Art. 7, including the part "no one shall be subjected without his free consent to medical or scientific experimentation".[3] Such warnings remain relevant during a pandemic.

- The Convention for the Protection of Human Rights and Fundamental Freedoms (1950) (hereinafter - European Convention on Human Rights), Art. 15 of which provides for a derogation in time of emergency "within the limits required by the severity of the situation, and provided that such measures do not conflict with other obligations under international law".[4] This Convention also contains restrictions on derogations from Art. 2 and Art. 3, which establish similar human rights pacts.

- The American Convention on Human Rights (Pact of San Jose) (1969)[5], which in Art. 27 provides for the suspension of guarantees in the event of an emergency in a State in the form of a measure by which it withdraws from its obligations under this Convention.

However, even if the conditions for a decision on derogation in an emergency were sufficient. It is necessary to determine whether the restrictions associated with such a derogation are always justified. Syracuse Principles on the Limitation and Derogation of Provisions in the International Covenant on

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3 International Covenant on Civil and Political Rights. Available from: https://treaties.un.org/doc/Treaties/1976/03/19760323%2006-17%20AM/Ch_IV_04.pdf

4 Convention for the Protection of Human Rights and Fundamental Freedoms 4.XI.1950. Available from: https://rm.coe.int/1680063765

5 American Convention on Human Rights. "PACT OF SAN JOSE, COSTA RICA" (B-32). 1969. Available from: https://www.oas.org/dil/treaties_B-32_American_Convention_on_Human_Rights.pdf

Civil and Political Rights (1984)[6] as an authoritative international source for the interpretation of the derogation from the above-mentioned Covenant proclaims that restrictions must comply with the following principles: be provided by law, not interfere with the democratic functioning of society, serve to protect public health, and in case of public emergency when the life of the nation is in danger, apply only to the extent required by the severity of the situation, taking into account the rights from which deviation is not allowed. Currently, these restrictions affect the rights and obligations of not so much as a doctor and a patient, but as a state and a citizen.

In general, the outbreak of COVID-19 has become the test for each state in respect to human rights of citizens in a pandemic, citizens that are under these states' jurisdiction (primarily the right to life and health); the duty to protect them is a positive obligation of the state, which is closely linked to the concept of "due diligence", according to which the state must take all necessary measures to prevent violations and respect for human rights, and respond in a timely manner to such violations, especially in an emergency. Making political decisions "according to the situation", states often transferred legal responsibility to the citizens themselves, which raised the question of the need to study the decisions of public authorities on the validity and proportionality of the restrictions on human rights imposed in an emergency or state of emergency, as well as their legality, primarily in accordance with international law.

However, taking decisions on such restrictions at the level of the domestic law of states requires a study of their constitutionality, since "in countering of a pandemic, the right to life and the right to health are tied the most ... The connection between these constitutional rights means that insufficient, untimely and ineffective state measures in the field of health care in a pandemic may mean a direct encroachment on the right of everyone to life ...; from ill-conceived long-term restrictions - in particular on access to health care or the ability to move outdoors for vulnerable categories of people - threats to life ... can be more acute than directly from COVID-19. Some prohibitions are formulated in a way that violates the very essence (core) of human rights

6 Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights / United Nations, Economic and Social Council, U.N. Sub-Commission on Prevention of Discrimination and Protection of Minorities, Annex, UN Doc E/CN.4/1984/4 (1984). Available from: https://www.icj.org/wp-content/uploads/1984/07/Siracusa-principles-ICCPR-legal-submission-1985-eng.pdf

(human dignity and freedom), which is unacceptable in general, because it is a violation of human rights, not just their restriction" (paragraph 6).[7]

The right of citizens to apply to the European Court of Human Rights (ECtHR) is a guarantee of the principle of inevitability of legal responsibility of states for human rights violations caused by the unreasonableness of the application of restrictive measures, primarily under Art. 2 of the 1950 Convention (right to life), Art. 3 (prohibition of torture), Art. 8 (the right to respect for private and family life), etc. In addition, in order to facilitate the implementation of the European Convention on Human Rights (ECHR) in the framework of the European Program on Human Rights Education for Legal Professionals (HELP), established by the Council of Europe and the European Union, a new online training course "Introduction to the ECHR and ECtHR"[8] has been developed.

The UN General Assembly has adopted a number of important resolutions, which serve as a basis for coordinating the international community's cooperation, identifying priority vectors for an effective fight against coronavirus and minimizing its negative consequences based on the respect of human rights. In particular:

- Resolution A/RES/74/270 "Global Solidarity to Fight the Coronavirus Disease 2019 (COVID-19)"[9] of 2 April 2020, the key issue of which is the need for global cooperation and coordination of their efforts, in particular with the leading role of the United Nations and WHO, to monitor, control the spread and overcome the pandemic and its consequences;

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7 Constitutional Court of Ukraine. [A separate opinion of the judge of the Constitutional Court of Ukraine Lemak VV concerning the Decision of the Constitutional Court of Ukraine in the case on the constitutional petition of the Supreme Court on the constitutionality of certain provisions of the Cabinet of Ministers of Ukraine "On the establishment of quarantine to prevent the spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2 in Ukraine and the stages of mitigation of anti-epidemic measures", the provisions of the first and third paragraph of article 29 of the Law of Ukraine "On State Budget of Ukraine for 2020", the ninth indent of paragraph 2 of section II "Final provisions" of the Law of Ukraine "On Amendments to the Law of Ukraine "On the State Budget of Ukraine for 2020"" of August 28, 2020. № 10-r/2020]. Ukrainian. [cited 2021 Febr.]. Available from: https://zakon.rada.gov.ua/laws/show/nb10d710-20#Text

8 Council of Europe HELP online platform. Available from: http://help.elearning.ext.coe.int/

9 UN General Assembly Resolution A/RES/74/270. Global solidarity to fight the coronavirus disease 2019 (COVID-19). 2 April 2020. Available from: https://undocs.org/pdf?symbol=en/A/RES/74/270

- Resolution A/RES/74/274 "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19"[10] of 20 April 2020, which emphasizes the importance of ensuring fair, transparent and timely access to medical supplies, which is a global priority in combating the spread of COVID-19 and an important condition for the realization of the right to life and health, in particular by ending speculation and illicit stockpiling. Medicines, vaccines, personal protective equipment, medical equipment, which may complicate access to them; strengthening international cooperation in the development of diagnostic, antiviral drugs and a new vaccine to combat COVID-19. Emphasizing the importance of ensuring fair, transparent and timely access to medical supplies, which is a global priority in combating the spread of COVID-19 and an important condition for the realization of the right to life and health, in particular by ending speculation and stockpiling of medicines, vaccines, personal protective equipment, medical equipment, which may complicate access to them; by strengthening international cooperation in the development of diagnostic, antiviral drugs and a new vaccine to combat COVID-19.

The WHO, announcing an outbreak of a new virus in January 2020, and the COVID-19 pandemic on March 11[11], noted an increase in stress and related mental strain on a person, and on March 18, 2020, issued a related document entitled "Mental health and psychosocial considerations during the COVID-19"[12], highlighting the importance of psychosocial wellbeing as well as physical health and access to psychiatric and psychological services to address urgent mental and neurological complaints. It also emphasizes the importance of ensuring the availability of basic psychotropic drugs for people suffering from chronic mental disorders and who require continuous treatment. The issue of protection of vulnerable children's psyche raises separately.

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10 UN General Assembly Resolution A/RES//74/274. International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19. 20 April 2020. Available from: https://undocs.org/en/A/RES/74/274

11 WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. Available from: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

12 Mental health and psychosocial considerations during the COVID-19 outbreak. 18 March 2020. Available from: https://www.who.int/docs/default-source/coronaviruse/mental-health-considerations.pdf

In this context, it should be emphasized that against the background of the pandemic, especially in quarantine restrictions, the bioethical problem of mental health deterioration has become extremely acute, manifested in an increase of mental disorders and suicides cases. In such circumstances, there is a need for more detailed investigation in this period of the admissibility of various forms of euthanasia application (both active and passive) in countries where it is legalized.

On May 18, 2020, the World Health Assembly adopted Resolution "COVID-19 Response"[13] on the implementation by States of the necessary measures in a coronavirus pandemic, including calling on Member States to respect human rights, sanitary standards, the unimpeded delivery of humanitarian assistance and access to necessary medical care in a pandemic, in particular for patients with COVID-19, etc.

The International Committee of the Red Cross, for its part, has also developed the document "COVID-19 and International Humanitarian Law"[14] with the aim of preventing outbreaks of COVID-19 during armed conflicts.

Important support to states during a pandemic crisis is provided by UNDP[15], which helps government agencies to develop and implement an effective emergency response policy to prevent human rights abuses in such settings, contributing to the smooth operation of vital services, fighting against corruption and overcoming misinformation. Corruption schemes significantly affect human rights violations, preventing the receipt of timely and necessary medical care, access to medicines and remedies, creating a mismatch between material and human resources (medical staff) to the needs of patients with COVID-19. To prevent this, when forming state budgets, the need to create reserve funds in case of epidemics/pandemics must be taken into account.

For its part, on April 7, 2020, the Council of Europe prepared and sent to its 47 member states the Information Document "Respecting democracy, rule of law and human rights in the framework of the COVID-19 sanitary crisis. A toolkit for member states"[16], the key issue of which is the need to respect

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13 COVID-19 Response. 73rd World Health Assembly, A73/CONF./1. 18 May 2020. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1-en.pdf

14 COVID-19 and International Humanitarian Law. Available from: www.icrc.org › download › file › covid-19_and_ihl

15 UNDP response. Available from: https://www.undp.org/content/undp/en/home/coronavirus.html

16 Respecting democracy, rule of law and human rights in the framework of the COVID-19 sanitary crisis. A toolkit for member states. Information Documents SG/Inf(2020)11. 7

the proportionality of the measures they introduced during the pandemic with human rights and threats from the spread of the virus.

The document addresses four key issues: derogation from the provisions of the European Convention on Human Rights in time of emergency; adherence to the principles of the rule of law and democracy in emergencies, including restrictions on the scope and duration of emergency measures; basic human rights standards, in particular privacy and protection of personal data, protection of vulnerable groups from discrimination; protection against crime and protection of victims of crime, in particular gender-based violence. The document reiterates that even in an emergency such as the COVID-19 pandemic, States cannot in any way deviate from the fundamental human right to life, the principle of non-torture and inhuman or degrading treatment or punishment, while recalling that the protection of people from deadly diseases and further suffering is a positive obligation of the state. On April 8, 2020, the Council of Europe issued advice on the application of the MEDICRIME Convention[17] in the context of COVID-19[18], concerning the falsification of medical products and other similar crimes that threaten the health and lives of people.

In the context of human rights protection in a pandemic, the role of bioethics is growing, which is based on the concept of human dignity, which is closely intertwined with the right to life and the system of protection of human rights in general. With the rapid increase in the incidence,, there has been an unexpected departure from international obligations and universally accepted bioethical principles, such as respect for human autonomy, non-harm, charity and justice[19], that has become an ethical challenge for the world.

In general, the principles of bioethics related to the regulation of biomedical activities, which are constantly evolving, require a rethinking of the role of ethical norms. These principles significantly affect the promotion and protection of human rights in the field of bioethics, helping to prevent possible violations of human rights and moral norms, which can lead to serious consequences for

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April 2020. Available from: https://rm.coe.int/sg-inf-2020-11-respecting-democracy-rule-of-law-and-human-rights-in-th/16809e1f40

17 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. 28.10.2011. Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168008482f

18 Advice on the Application of the MEDICRIME Convention in the Context of Covid-19. 8 Arpil 2020. Available from: https://rm.coe.int/cop-medicrime-covid-19-e/16809e1e25

19 Beauchamp T., Childress J. Principles of Biomedical Ethics. 7th ed. Oxford University Press; 2013. 480 p.

both individuals and the human race as a whole, helping to form a responsible attitude to the life of future generations.[20(p274-5)]

In an emergency, the role of (bio)ethics committees at the national, regional and international levels in assessing compliance with ethical requirements in decision-making is growing. Since numerous bioethical problems that have against the backdrop of the pandemic are not only local (national, continental), but are common challenges to humanity facing the world community and modern international law, at the level of the UNESCO's International Bioethics Committee and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) on April 6, 2020, a joint "Statement on COVID-19: Ethical Considerations from a Global Perspective"[21] was adopted. It emphasized that the many ethical issues posed by the pandemic required forgetting the differences and pursuing a collective search for ethically acceptable solutions, with a key approach based on bioethics and the ethics of science and technology, as well as respect for human rights.

The COVID-19 pandemic is one of the most significant tests for states' respect for human rights compliance with human rights to life and health in a state of emergency (after the Spanish flu pandemic), which, despite current high-tech advances, were unprepared for new bio-threats, as well as to protect their citizens from them both at the level of medicine and law. Neglect of biosafety (primarily sanitary-epidemiological, environmental norms) can lead to the spread of dangerous viruses and bacteria with the subsequent likelihood of uncontrolled development of morbidity at the level of pandemics, which threatens not only human life and dignity but also the survival of mankind.

The issue of global biosafety is currently in need of a radical overhaul. To this end, coordinated action of the international community to prevent the spread, as well as to treat diseases and to overcome their consequences must play an important role. The importance of conducting modern research in virology and immunology to prevent new diseases in the future should be emphasized. International legal regulation of these issues, taking into account bioethical

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20 Ostrovska BV. [International legal regulation of the human right to life in the context of bioethics: a monograph] Kyiv: Lohos, 2019. 604 s. Ukrainian.

21 Statement on COVID-19: ethical considerations from a global perspective. Statement of the UNESCO International Bioethics Committee (IBC) and the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). SHS/IBC-CO'MEST/COVID-19 REV. 6 April 2020. Available from: https://unesdoc.unesco.org/ark:/48223/pf0000373115

aspects, should remain on the international community's agenda for the early prediction of threats to humanity, including biological ones. Only by uniting the efforts of the entire international community, focusing them on the long term rather than on short-term emergency measures, can be controlled global biosecurity, which is the key to the existence of future generations.

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THE RISE OF ROBOTICS AND ARTIFICIAL INTELLIGENCE IN HEALTHCARE: NEW CHALLENGES FOR THE DOCTRINE OF INFORMED CONSENT

Eduardo Dantas[1] and Rafaella Nogaroli[2]

Abstract: New technologies in the healthcare sector have profoundly impacted the doctrine of informed consent, creating the need for a detailed investigation on the contours and dynamics of this new model of the patient to consent to any treatments or medical interventions. The digital transformation in healthcare was a paramount factor in making it possible to implement artificial intelligence in support of clinical decisions and in the efficiency of medical diagnoses, especially in the early detection of diseases, in view of their ability to process and analyze quickly—and in an efficient and effective way—large amounts of data. In recent years, there has been a significant expansion of artificial intelligence combined with robotics, creating a reality of care robots for use in care and nursing environments or to support independent living for the elderly and those with disabilities. In view of all the current panorama of digitalized medicine and new technologies in the healthcare sector—robotic medicine and artificial intelligence—we were able to conclude, throughout the present work,

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2 Appellate Judge's Advisor at the Court of Justice of the State of Paraná. Master of Laws Candidate by Federal University of Paraná. Specialist in Practical Law by the *Escola da*

that the informed consent of the patient acquires certain peculiarities, considering the diverse random factors and risks inherent to artificial intelligence. The physician needs to disclose to patients that even the best healthcare technologies come with some risks of unpredictable events, inaccuracies, cyberattacks, systematic bias, and a particular type of mismatch between AI's implicit assumptions and an individual patient's background situation. Furthermore, we show that there are three different semantic dimensions of algorithmic opacity which are particularly relevant to medicine: lack of disclosure, epistemic opacity, and explanatory opacity. Reasonable communication between patient and doctor could mitigate this effect, be a precondition for objecting to fully automated processing, and for requiring some form of human involvement in those activities. This would foster ideals of shared decision-making in medicine. In conclusion, we found that the modern dogmatic of informed consent encompasses the idea of an informed choice, since the patient must be in possession of all the information and possible elements for his understanding. In other words, more than a right to information, the patient has a right to explanation and justification in order to consent in a free, informed and clarified manner.

Keywords: New Health Technologies; Artificial Intelligence; Robotic Medicine; Informed Consent; Medical Disclosure

1. INTRODUCTION: From Traditional MedicineTowards the P4-Medicine (Preventive, Predictive, Personalized and Participatory)

New technologies are reshaping the landscape of the healthcare sector, especially in two major areas: digital tools (telemedicine platform services, medical apps for smartphones), and medical robotics (care robots, surgical robots).[3] This new reality is feasible because the amount of collected patient

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3 Degos L. International vision of big data. In: Nordlinger B, Villani, C, Rus, D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020. p. 252.

health data is increasing exponentially worldwide. All these technological approaches are turning medical sciences into a *data-intensive science*.[4] After decades of digitalizing medical records (with growing cloud storage), the healthcare industry has created a huge (and potentially immeasurable) volume of biomedical data. This digitalization was an important factor in making it possible to implement robotics and artificial intelligence (AI).[5]

In 2017, 80% of physicians' records and 100% of hospital records in the United States of America were digitized, facilitating the exchange of information as a result of these digitalized files with biomedical data called electronic health records (EHRs). Some countries, such as Denmark, Estonia, and Hungary, and health insurance companies, such as Kaiser Permanente in the United States and Clalit in Israel, collect, integrate, and structure health data with the aim of using them to improve the way care is provided, changing practices, and facilitating disease prevention.[6] Some countries have more recently embarked on constructing health databases specifically for research. The European Medical Information Framework is a recent European initiative to set up a health data platform for research. Big data on large numbers such as the study of the tumor genome or the study of the genome of patient populations have been collected by international cooperation. For example, the Global Alliance for Genomics and Health (GA4GH) is a network of 400 institutions.[7]

In summary, several types of health databases have been established since the beginning of the digital revolution, and the consequent multiplication of the power of computational analysis, such as electronic medical records, digital administrative data, data collected from medical equipment connected to the internet (Internet of Things in medicine), clinical and pharmaceutical research

4 Holzinger A, Röcker C, Ziefle M. From *smart health* to smart hospitals. In: Holzinger A, Röcker C, Ziefle M. (eds.) Smart health: open problems and future challenges. Cham: Springer; 2015. p. 9.

5 For an analysis of the concept and evolution of artificial intelligence, with an emphasis on the preponderance of algorithms, see Flasiński M. *Introduction to artificial intelligence*. *Cham:* Springer; 2016, passim.

6 Donsa K. et. al. Towards personalization of diabetes therapy using computerized decision support and machine learning: some open problems and challenges. *In*: Holzinger A, Röcker C, Ziefle M. (eds.) *Smart health:* open problems and future challenges. Cham: Springer; 2015. p. 245.

7 Donsa K. et. al. Towards personalization of diabetes therapy using computerized decision support and machine learning: some open problems and challenges. *In*: Holzinger A, Röcker C, Ziefle M. (eds.) *Smart health:* open problems and future challenges. Cham: Springer; 2015. p. 246.

data, genomic data etc.[8] Electronic medical records represent the largest source of health data. They contain the sum of all information about the patient to organize all stages of medical intervention, from anamnesis and medical procedures related to therapy towards the treatment's evolution.[9]

Advances in biomedical informatics and biomedical engineering provide the foundations for our modern and future patient-centered medical and healthcare solutions, biomedical systems, technologies, and techniques. All these advances produce enormous amounts of data, and one of the massive challenges in our networked world is the large and high-dimensional datasets and the massive amounts of unstructured information. To keep pace with these growing amounts of complex data, artificial intelligence algorithms provide important support for clinical decisions, given their ability to process and analyze quickly—and, tendentially, efficiently—large amounts of data.[10]

Jacob Turner defines artificial intelligence (AI) as "the ability of an unnatural entity to make choices through an evaluation process."[11-12] According to the European Parliament, AI refers to "systems that display intelligent behavior by analyzing their environment and taking actions–with some degree of autonomy–to achieve specific goals."[13] Further, AI-based systems can be purely software-based, acting in the virtual world (e.g., voice assistants, image

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8 Grall M. CNIL (Commission Nationale de l'Informatique et des Libertés) and analysis of big data projects in the health sector. *In*: Nordlinger B, Villani C, Rus D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020. p. 236.

9 Degos L. International vision of big data. In: Nordlinger B, Villani C, Rus D. (eds.) *Healthcare and Artificial Intelligence*. Cham: Springer; 2020. p. 241-254.

10 For an analysis of the applications of artificial intelligence in battling Covid-19 and the protection of healthcare data in this scenario, see Colombo C, Engelmann C. Inteligência artificial em favor da saúde: proteção de dados pessoais e critérios de tratamento em tempos de pandemia. In: Pinto HÁ, Guedes JC, César JPC. (eds.) *Inteligência artificial aplicada ao processo de tomada de decisões*. Belo Horizonte: D'Plácido Editora; 2020. p. 225-245.

11 Turner J. *Robot Rules:* Regulating artificial intelligence. London: Palgrave Macmillan; 2019. p. 16.

12 Regarding the classification of artificial intelligence as weak AI and narrow AI, see Turner J. *Robot Rules:* Regulating artificial intelligence. London: Palgrave Macmillan; 2019. p. 6-7. Further, about the different levels of intelligence and autonomy that certain technical artifacts may have and their direct influence on ethical and legal considerations about them, see Medon F. *Inteligência artificial e responsabilidade civil:* autonomia, riscos e solidariedade. Salvador: JusPodivm; 2020. p. 109-135.

13 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe. Available at https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:52018DC0237. Accessed: Jan. 12, 2021.

analysis software, search engines, speech and face recognition systems), or AI can be embedded in hardware devices (e.g., advanced robots, autonomous cars, drones, or Internet of Things applications).

Deep learning[14] has been a game-changer for AI, with a tremendous improvement in performance for specific tasks such as image or speech recognition or machine translation. Training a deep learning algorithm to classify objects works by exposing it to a large number of labelled examples (e.g., images or medical exams) that are correctly categorized. Once trained, algorithms can correctly classify objects that they have never seen, in some cases with accuracies that exceed those of humans. Significant advances in these technologies have been made through the use of large data sets and unprecedented computing power.[15] Thus, the digitization of the healthcare sector was an essential factor to make the implementation of AI possible in the efficiency of medical diagnoses, especially in the detection of early diseases.[16] About this subject, Eric Topol states:

> "In the past few years, several studies relying on deep learning have been published in leading peer-reviewed medical journals. Many in the medical community were frankly surprised by what deep learning could accomplish: studies that claim AI's ability to diagnose some types of skin cancer as well as or perhaps even better than board-certified dermatologists; to identify specific heart-rhythm abnormalities like

14 Deep learning algorithms are "approaches to Machine Learning that use Neural Network models and are particularly useful in complex domains. Neural Networks are loosely inspired by the biology of our brains and consist of many simple, linked units (or neurons). They are, in essence, attempts to simulate the brain, which is why understanding how the brain works can help us discuss the specifics of artificial neural networks. (…) In ML [machine learning], we use the terms that describe these processes in the brain to explain and understand Artificial Neural Networks (ANN), which are also composed of nodes (or neurons) linked by a complex network of connections of different strengths. However, unlike the brain, connections in a neural network are usually uni-directional. An ANN is then organised into input and output nodes connected through a number of in-between layers of nodes, known as the hidden nodes." (Dignum V. *Responsible artificial intelligence*. How to develop and use AI in a responsible way. Cham: Springer; 2019. p. 23-27).

15 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe. Available at https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:52018DC0237. Accessed: Jan. 12, 2021.

16 Shaban-Nejad A, Michalowski M. *Precision health and medicine*. A digital revolution in healthcare. Cham: Springer; 2020. p. 10.

> cardiologists; to interpret medical scans or pathology slides as well as senior, highly qualified radiologists and pathologists, respectively; to diagnose various eye diseases as well as ophthalmologists; and to predict suicide better than mental health professionals. These skills predominantly involve pattern recognition, with machines learning those patterns after training on hundreds of thousands, and soon enough millions, of examples."[17]

During the Covid-19 pandemic, AI also demonstrated its great potential in medical imaging. Due to the rapid increase in number of new and suspected COVID-19 cases, as an alternative to relieve pressure on radiologists and prevent further spread of the disease, AI-based algorithms were developed across the globe that supported these professionals in quickly identifying the pathogen disease by analyzing computed tomography images of symptomatic patients of Covid-19.[18] Besides, in the last years, predictive algorithms have been used to target treatment more effectively toward high-risk patient groups for the prevention of major chronic disease complications. This approach is being applied in other relevant domains to allow for the identification of populations at risk and early identification of impending complications of multiple acute and chronic illnesses.[19] Researchers at an Oxford hospital have developed an AI-based system called Ultromics that can diagnose scans for heart disease and lung cancer. The AI assesses the risk of heart disease and makes clinical recommendations. Using the power of AI, Ultromics aims to improve the accuracy of echocardiogram interpretation to above 90% – substantially better than the 80% currently achieved by human doctors.[20]

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17 Topol E. *Deep medicine:* how artificial intelligence can make healthcare human again. New York: Basic Books; 2019. p. 11-12.

18 The algorithms were programed with thousands of tomography images labeled training images in two general classes: (i) Covid-19 and (ii) Not Covid-19. Images marked as "Not Covid-19" represented cases of patients with healthy lungs. Preliminary studies indicate chest CT has a high sensitivity for detection of COVID-19 lung pathology and several groups have demonstrated the potential for AI-based diagnosis, reporting as high as 95% detection accuracies. Also included were examples of patients with other lung diseases, such as lung cancer, tuberculosis, bronchiectasis, and pneumonia of non-viral etiology. (Harmon SA. et. al. Artificial intelligence for the detection of COVID-19 pneumonia on chest CT using multinational datasets. *Nature Communications*. 2020; 11(1): 4080-4085)

19 Balicer RD, Cohen-Stavi C. Advancing healthcare through data-driven medicine and artificial intelligence. In: Nordlinger B, Villani C, Rus D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020. p. 13-14.

20 The Oxford spinout company using AI to diagnose heart disease. Available at https://www.research.ox.ac.uk/Article/2018-10-15-the-oxford-spinout-company-using-ai-to-diagnose-heart-disease. Accessed: Jan. 10, 2021.

Nowadays, IBM is one of the major companies that creates more technological solutions for the healthcare sector and developed the so-called "Watson for Oncology," a solution powered by information from relevant guidelines, best practices, and medical journals and textbooks. Watson evaluates the information from a patient's medical record, along with medical evidence (scientific papers and clinical studies), thus showing possible treatment options for cancer patients, classified by confidence level. In the end, it will be up to the doctor to analyze the conclusions reached by the AI and decide which is the best treatment option for that specific patient.[21]

With the storage of all this amount of data combined with AI algorithms, the Digital Age of Medicine creates the concept of ***smart health,*** following the transformation phenomenon from traditional medicine towards ***P4-Medicine*** (preventive, predictive, personalized and participatory).[22] In this new scenario, health care is no longer essentially limited to the treatment of pathologies (a task that has never been abandoned, of course) and is now focused on the adoption of measures aimed at preventing diseases (preventive medicine) or making it possible to anticipate the diagnosis (predictive medicine).[23] Regarding personal treatment, the patient is seen in a more individualized way (and less generic, therefore), based on his genetic and health data (personalized medicine). Finally, the doctor-patient relationship ceases to be something punctual and starts to develop in a continuous manner, with the patient's active participation (participatory medicine).[24]

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21 "To date, it has ingested nearly 15 million pages of medical content, including more than 200 medical textbooks and 300 medical journals. By combining MSK's world-renowned cancer expertise with the analytical speed of IBM Watson, the tool has the potential to transform how doctors provide individualized cancer treatment plans and to help improve patient outcomes. In 2015, nearly 44,000 oncology research papers were published in medical journals around the world, or more than 120 new papers each day, outpacing the ability of humans to keep up with the proliferation of medical knowledge." (IBM Healthcare and Life Sciences. The future of health is cognitive. Available at https://www.ibm.com/downloads/cas/LQZ0O1WM. Accessed: Jan. 10, 2021.)

22 Holzinger A, Röcker C, Ziefle M. From smart health to smart hospitals. In: Holzinger A, Röcker C, Ziefle M. (eds.) *Smart health:* open problems and future challenges. Cham: Springer; 2015. p. 1-20.

23 Balicer RD, Cohen-Stavi C. Advancing healthcare through data-driven medicine and artificial intelligence. In: Nordlinger B, Villani C, Rus D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020. p. 9-15.

24 By adding the "participatory" component, P4 medicine "maximizes the effectiveness of systems medicine by expanding its application out from hospitals and clinics into homes, workplaces and eventually schools. With the addition of self-monitoring (activity, weight and calorie intake) and self-assessments in the participatory component, new quantities

This active patient has now assumed the role of "data-gatherer" who sends this trove of information for additional guidance and input to the physician.[25] In 2012, England's National Health Service requested general practitioners to recommend apps to their patients for managing conditions ranging from diabetes to depression in an attempt to give patients more power and reduce visits to doctors. For this initiative, the health secretary, Andrew Lansley, said, "I want to make using apps to track blood pressure, to find the nearest source of support when you need it and to get practical help in staying healthy the norm. With more information at their fingertips, patients can truly be in the driving seat."[26] That is an evident new scenario of participatory medicine.

It should also be noted that, in recent years, there has been a significant expansion of artificial intelligence combined with robotics, creating a reality of intelligent assistance robots for medical care.[27] Robots were first created to free us from the drudgery of repetitive manual labor. The latest generation are increasingly being used to supplement humans caring for lonely seniors.[28] The global rise in life expectancy, added to the growing complexity of medical services, has resulted in a scenario of a drastic increase in health costs worldwide.

Thus, advances in computing applications, combined with sophisticated networks of intelligent sensors, serve as an important solution for this context.[29] Furthermore, as the population is aging around the globe, health systems are under increasing pressure and, therefore, social robots for elderly people serve

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and forms of data will be aggregated and mined to generate new insight into health and disease. These insights will drive the development of new technologies, analytic tools and forms of care" (Flores M, Glusman G, Brogaard K, Price ND, Hood L. P4 medicine: how systems medicine will transform the healthcare sector and society. *Personalized Medicine*. 2013. 10(6): 565-576.

25 About the patient's active participation in the context of virtual hospitals, with artificial intelligence and telemedicine, see Kfouri Neto M, Nogaroli R. (2021). Inteligência artificial nas decisões clínicas e a responsabilidade civil médica por eventos adversos no contexto dos hospitais virtuais. *In*: Barbosa, Mafalda Miranda et. al. (eds.) *Direito digital e Inteligência Artificial:* diálogos entre Brasil e Europa. Indaiatuba, Foco; 2021. To be published.

26 Topol E. *The patient will see you now:* the future of medicine is in your hands. New York: Basic Book; 2015. p. 171.

27 Devillers L. Social and emotional robots: useful artificial intelligence in the absence of consciousness. In: Nordlinger B, Villani, C, Rus, D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020. p. 261.

28 Are robots the answer to elderly loneliness? Available at https://www.aegon.com/newsroom/news/2019/robot-care/. Accessed: Dez. 08, 2020.

29 Holzinger A, Röcker C, Ziefle M. (eds.) From smart health to smart hospitals. *In: Smart health:* open problems and future challenges. Cham: Springer; 2015. p. 1-20.

as a means of relieving this pressure in hospitals and nursing homes, as well as becoming a way to improve health care delivery at home, promoting an independent life for the elderly.[30] The Covid-19 pandemic further boosted the importance of care robots, considering the isolation and loneliness of elderly people because they are often at increased risk from the coronavirus. In 2020, a company launched the Cutii robot and it was placed in about thirty nursing homes for the elderly in France.[31]

Considering the current panorama of digitalized medicine and new technologies in the health area—especially robotics and artificial intelligence—medical disclosure and patients' informed consent[32] acquire certain peculiarities, since various random factors and risks are inherent to the unique and specific characteristics of each technology.

Consequently, the present study aims to analyze the whole dynamics of patients' consent in each type of technology, which involves discussions on several aspects, such as benefits and risks of healthcare technologies, the form and content of the consent term in each technology (which information should be provided) and the way of imputing liability for the breach of the duty to inform. In addition, this paper will seek to answer whether the physician, when applying artificial intelligence in medical diagnostic consultations, for example, needs (or not) to disclose to patients that even the best AI comes with the risks of unpredictable events, inaccuracies, cyberattacks, systematic bias, and the particular type of mismatch. All these issues will be analyzed; however, at first, we will establish a brief historical overview of dogmatic development from the doctrine of informed consent towards a patient's free and informed consent.

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30 Caresses: smart and friendly robots for the elderly. Available at: https://developer.softbankrobotics.com/blog/caresses-smart-and-friendly-robots-elderly. Accessed: Dez. 08, 2020.

31 Cutii has launched, the robot helping seniors stay happy and safe at home. Available at https://www.roboticstomorrow.com/news/2020/01/13/cutii-has-launched-the-robot-helping-seniors-stay-happy-and-safe-at-home/14664/. Accessed: Dez. 08, 2020.

32 Informed consent is the process in which a healthcare provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. Regarding the reform of the physician-patient relationship, particularly toward replacing the "silent world of doctor and patient" with the new model where there is informed patient participation in medical decision-making, see Wear S. *Informed consent:* Patient autonomy and physician beneficence within clinical medicine. Springer Netherlands; 1993, passim.

2. A Brief Historical Overview of the Doctrine of the Patient's Free and Informed Consent.

Currently, the relationship between healthcare provider and the patient established one of its pillars in the duty of information—more precisely, in the obligation of the doctor to provide the patient, or whoever answers on his behalf, with all possible information so that he can exercise his right, supported by one of the most important bioethical principles, that of autonomy, that is, the possibility of disposing of his own destiny, deciding what treatment he will allow, based on clear and precise information about the possible risks and benefits, from his own decision.[33]

The principle of autonomy finds its main foundations in the history of law and philosophy. For its development, the works of John Locke,[34] who fought for the right to protection against non-consented medical interventions, and of the German philosopher Immanuel Kant,[35] for whom the requirement that we consider others free to choose, are fundamental.

Kant's concern with autonomy was to examine what he considered one of the most important aspects of the human being: his will. As long as a person is able to decide what to do or not to do, he is responsible for his actions. Any action motivated by some kind of moral fund must emanate from a duty rather than an inclination. For Kant, autonomy—which means self-regulation—requires taking actions according to one's own convictions, that is, with one's own morals. Being autonomous means not being a slave to instinct or caprice but acting as a rational being. Reason is the faculty that allows action as a thinking individual, and that allows, for example, to choose between right and wrong.[36] At least in appearance, there is little difference between reason and autonomy, between rationality and autonomy.

Beauchamp and McCullough explain that a person's decision is autonomous:

> "When it comes from its own values and beliefs, it is based on adequate information and understanding and is not imposed by internal or

33 Tepedino G. A responsabilidade médica na experiência brasileira contemporânea. *Revista Trimestral de Direito Civil*. 2000. 2(1): 41-75.

34 Locke J. Ensayo sobre el gobierno civil. Madri: Aguilar; 1969. *passim*.

35 Kant I. *Fundamentación de la metafísica de las costumbres*. 7. ed. Mari: Espasa Calpe, 1981, *passim*.

36 KANT. Immanuel. *Fundamentación de la metafísica de las costumbres*. 7. ed. Madri: Espasa Calpe; 1981. passim.

> external constraints, that is, when it brings together three conditions: intentionality, knowledge and the absence of external and internal control. Of these three conditions of the autonomous act, only the first (intentionality) does not admit gradation, while the other two do. From the point of view of knowledge, it must be adequate, so that we can affirm that an action is understood when we are able to understand its nature and, in addition, foresee its consequences. Regarding the absence of external control, we can consider the existence of several levels of gradation, and more especially three: coercion, manipulation and persuasion."[37]

Currently, the modern dogmatic of medical responsibility sees consent as an instrument that allows, in addition to the interests and medical-therapeutic objectives, to increase respect for the sick person, in its holistic dimension.[38] The patient, exercising his right to freedom, will be responsible for determining which treatment, among those presented to him, to choose, or even not to choose any of them. The protection of this physical-psychic sphere, as taught by João Vaz Rodrigues, is under the protection of the general personality right, since informed consent implies "more than the mere faculty of the patient to choose a doctor, or to refuse (dissent about) unwanted medical treatment (of the manifestation of freedom as protection against invasions in the sphere of any human person)."[39]

In Brazil, the principle of autonomy of the will (or self-determination), with a constitutional basis,[40] represents itself as a source of the duty of information and the correlate of the patient's free and informed consent. The Federal Constitution contains, in article 5, XIV, dealing with individual and collective rights, a precept which verbatim mentions that "access to information is

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37 Beauchamp TL, Mccullough LB. Ética médica: las responsabilidades morales de los médicos. Apud Cortés JCG. *Responsabilidad médica y consentimiento informado*. Madri: Civitas; 2001. p. 45. [Translated from the original]

38 Kfouri Neto M. *Responsabilidade civil do médico*. 10. ed. São Paulo: Revista dos Tribunais; 2019. p. 257-282.

39 Rodrigues JV. *O consentimento informado para o acto médico*. Elementos para o Estudo da Manifestação de Vontade do Paciente. Coimbra: Coimbra Editora; 2001, p. 25. [Translated from the original]

40 Luís Roberto Barroso and Letícia Martel identify individual autonomy with the dignity of the human person, an understanding underlying the main human rights declarations of the century. XX, especially of the diverse constitutions promulgated in the Post-war period. (Barroso LR, Martel LCV. A morte como ela é: dignidade e autonomia individual no final da vida. *Revista da EMERJ*. 2010. 13(50): 19-63)

guaranteed to all." Under the infraconstitutional point of view, Law 8.080 / 90, of September 19, 1990, when providing on the conditions of promotion, protection, and recovery of health, ensures in its article 7, V, the "right to information, to assisted people, about their health." Paragraph 3 of the same provision defines as a guideline of the Unified Health System (SUS) the "preservation of people's autonomy in the defense of their physical and moral integrity."

The Consumer Protection Code provides for the obligation to provide information — treated as one of the basic consumer rights provided for therein — in Article 3, III, the right to "adequate and clear information about the different products and services, with correct specification quantity, characteristics, composition, quality and price, as well as on the risks they present," a notion complemented by articles 8[41] and 9[42] of the same Code, applicable here due to the activity provided by the health professional, despite being differentiated and, in particular, legally classified as a service.[43]

When speaking about duty of information, the association with the expression "informed consent" is almost automatic. Certainly, it is common sense in our society that medical intervention must be understood and consented by the patient in order to–among other possibilities — exclude its potential qualification as unethical behavior. However, it was not always like this. To understand the current moment, it is necessary to look at it from a historical perspective.

The first centuries of medical history were marked by a position of superiority among holders of medical knowledge and lay patients. Medical art was seen as something divine, supernatural, and little or no questioning existed in relation to the decisions and determinations of those graced with the gift of knowledge.[45] The idea that the patient had rights related to his condition as a

41 CDC - Article 8: "The products and services placed on the consumer market will not pose risks to the health or safety of consumers, except those considered normal and predictable due to their nature and enjoyment, and suppliers are obliged, in any event, to give necessary and appropriate information about it."

42 CDC - Article 9: "The supplier of products and services that are potentially harmful or dangerous to health or safety must inform, ostensibly and adequately, about their harmfulness or dangerousness, without prejudice to the adoption of other measures applicable in each specific case."

43 Regarding the incidence of the CDC in the provision of medical services, see Dantas E. *Direito médico*. 4. ed. Salvador: JusPodivm; 2019. p. 65-70.

44 Dantas E. *Direito médico*. 4. ed. Salvador: JusPodivm; 2019. p. 107.

45 Dantas E. *Direito médico*. 4. ed. Salvador: JusPodivm; 2019. p. 108.

human being began to take shape after the French and Industrial Revolutions. Gradually, the doctor lost his divine character and took the form of an ordinary professional, subject to failures and questions. At the same time, the massification and depersonalization of care—present in the last decades—once and for all inserted the concepts of ethical, civil, and penal responsibility into health daily, making the concepts inherent to prior consent rooted and established in the doctor-patient relationship.

Miguel Kfouri Neto[46] reports the first historical reference to informed consent: an English trial in the year 1767,[47] concerning the case of a patient who sought two doctors to continue the treatment of bone fractures in his leg. These, in a standard considered normal for the time, did not consult the patient about their opinion, nor did they inform him about the treatment options, removing the bandages and purposely disintegrating the bone callus "with the aim of using a device, not used conventionally, to cause traction during the consolidation process." The inability to deal with the human aspect of the relationship, not seeing the patient, but only the treatment (or the problem), caused the issue to be brought up for discussion in court, on the grounds that the doctors provoked "out of ignorance and malpractice" a new fracture, causing unnecessary damage, in addition to not having informed the patient about the procedure that would be performed.

The two doctors who testified as expert witnesses stated that the equipment used was not in current use and refracting a bone lesion was an exceptional measure, only applicable if it was very poorly consolidated, indicating, further, that they would only adopt this type of procedure with the patient's consent. In fact, the patient in question claimed that he had protested when the procedure started, requesting that it not be carried out. Faced with the analysis of these facts, the court condemned the doctors "for breaking the contract in the care relationship with the patient. (...) In the sentence, it was clear that the judge was concerned with both the lack of consent and the lack of information. It is worth remembering that, at that time, it was the practice of surgeons to inform the patient about the procedures that would be performed due to the need for their collaboration during surgeries, as there was still no anesthesia."[48]

46 Kfouri Neto M. *Culpa médica e ônus da prova*. São Paulo: Revista dos Tribunais; 2002. p. 37-38.
47 *Slater v. Baker and Stapleton,* 2 Wils. K.B. 358 (1767)
48 *Slater v. Baker and Stapleton,* 2 Wils. K.B. 358 (1767)

In French doctrine, one of the first trials to make reference to patients' rights, in 1942, deals—not by accident—with the issue of consent.[49] Most European legislation already recognized the importance of obtaining patient consent, even before the development of the American doctrine on the subject. In France, currently, the concept of ***consentement éclairé*** is widely respected, being inserted in several pieces of legislation, such as the Law of December 20, 1978, which deals with biomedical experiences; Law 94.653, of July 29, 1994, which introduced article 16th, n. 3, in the French Civil Code;[50] and in the French Code of Ethics, 1995, which reinforced the evidence and the need to respect the doctrine of informed consent.

The same doctrinal understanding was used in 1914 in the United States, during the trial of the Schoendorff v. Society of New York Hospitals,[51] which dealt with a similar case, in which the author had undergone, without his prior consent, surgical intervention. The New York Court used the violation of the patient's physical integrity as a basis for the physician's responsibility, even though the treatment had some benefit. The words of the magistrate who presided over the case, Benjamin Cardozo, betting on his sentence, became beacons for the analysis of subsequent cases involving the right to autonomy: "every human being of adult years and sound mind has a right to determine what shall be done with his own body."

The first major ethical-legal response to unauthorized medical interventions was the so-called Nuremberg Code, promulgated in 1948, which resulted from the trial of Nazi doctors before the International Court in Nuremberg, on account of their "scientific research" practices with prisoners of war, still considered examples of unjustifiable barbarism. The very cosmopolitan character and the historical moment of the trial were responsible for giving the Nuremberg Code

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49 In this sense, see Pereira AD. *O consentimento informado na relação médico-paciente*. Coimbra: Coimbra Editora; 2004. p. 61: Cour Cassation, 28-1-1942 (*arrêt* Teyssier): "... attendu que, comme tout chirurgien, le chirurgien d'um service hospitalier est tenu, sauf cas de force majeure, d'obtenir le consentement du malade avant de pratiquer une opération dont il apprécie, en pleine independence, sous la responsabilité, l'utilité, la nature et les risques; qu'en violant cette obligation, imposéé par lê respect de la personne humaine, il commet une atteinte grave aux droits du malade, um manquement à sés devoir proprement médicaux et qui constitue une faute personelle se détachant de l'exercice de sés fonctions."

50 Code Civil, art. 16, n. 3: "Il ne peu être porté atteinte à l'integrité du corps humain qu'en cas de necessite médicale pour la personne. Le consentement de l'interessé doit être recuielli préalablement dans le cas ou son état rend nécessaire une intervention thérapeutique à laquelle il n'est pás à même de consentir."

51 *Schoendorff v. Society of New York Hospital,* 106 N.E. 93 (N.Y. 1914)

an increase in the doctrine of consent, making the most diverse deontological codes and national laws become concerned not only with the content, but also with the quality of the information provided by doctors, and not only those related to research, but especially those pertaining to treatment and surgical interventions. In other words, the patient's merely formal consent was not enough, if not accompanied by the full exercise of his autonomy.

However, informed consent cannot be confused with the effective provision of the obligation to inform, since it is only part of it. Luciana Mendes Roberto defines it this way:

> "Informed consent is the consent given by the patient, based on knowledge of the nature of the procedure to be submitted and the risks, possible complications, benefits and treatment alternatives. That is, it is an agreement in the acceptance of the services to be provided by the health professional in exchange for the payment of the patient or guardian, who is adequately informed of what he is consenting to. [...] Finally, it can be said that, as a legal act in the strict sense, informed consent has its effects limited to the patient's manifestation of will, not generating rights for the health professional. It thus fulfills its social function implicit in art. 104 of the Civil Code, which provides for the forming elements in the legal business, applicable to the legal act according to art. 185 of the same diploma, as well as art. 166, VI, as the legal business is null when it aims to defraud imperative law."[52]

To the patient, it is necessary to be in possession of all the elements possible for his understanding, so that he can, in fact, exercise the faculty of consenting to the proposed treatment or intervention, choosing another of the existing alternatives, although less indicated by the attending professional, or even refusing to be treated. This procedure, which includes informed consent without being confused with it, is called an informed choice.[53] Fernanda Schaefer adds transparency and trust as essential pillars of this relationship:

> "The doctor responds to the trust placed in him by placing his knowledge at the service of the patient, protecting his physical and mental integrity and ensuring his privacy and his clinical data, respecting his autonomy.

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52 Roberto LM. *Responsabilidade civil do profissional de saúde & consentimento informado*. Curitiba: Juruá; 2005. p. 88-96. [Translated from the original]

53 Dantas E. When consent is not enough: the construction and development of the modern concept of autonomy. Medicine and Law. 2011. 30(4): 461-475.

> The patient responds to the doctor's loyalty by revealing whatever is necessary for his diagnosis and treatment, fulfilling the therapeutic determinations and even fighting for his cure. Therefore, there is no doubt that fidelity, transparency and trust are basic principles that guide the doctor-patient relationship and the collection of clinical data, aiming to simplify the conduct, thus imposing a more humanized relationship and the recognition of special condition of the patient (...) Fidelity, transparency and trust are not only generic ethical references, but general clauses that go beyond mere ideals of behavior; they play a harmonizing role and, by assuming different features, impose on the doctor and the patient the duties of loyalty and mutual collaboration to achieve the intended ends, namely treatment and, when possible, cure for the ailments that afflict the sick—functionalized protection of clinical data as a guarantee of human dignity."[54]

Several authors corroborate this position, albeit indirectly, since they treat informed consent as an end in itself.[55] The modern doctrine of informed consent of the patient in the right to self-determination, exercised by a conscious and capable person, after providing the elements of information essential to knowledge and understanding of the health problem or treatment. This notion is a tendency of thought that begins to take shape in jurisdictions around the globe, as can be seen from the words of André Pereira:

> "More recently, some authors have been proposing a more comprehensive concept. Thus, in Anglo-Saxon doctrine the expression *informed consent* is criticized, since information is only one aspect of informed consent ("comprehensive or enlightened consent"). Thus, the use of the expression *informed choice* has been proposed. This concept would have the virtue of covering, among other aspects, information on the consequences of refusal or revocation of consent, therapeutic alternatives, the choice of medicines (which implies changes to the regulation of advertising of medicines), the choice of the health establishment etc. In Portuguese law, we find the right to 'information about existing health services' and the 'right to the free choice of doctors,' as well as the right to 'second opinion.' All aspects which go

54 Schaefer F. *Telemática em saúde e sigilo profissional:* a busca pelo equilíbrio entre privacidade e interesse social. Curitiba: Juruá; 2010. p. 141-142.

55 Concerning this subject, see Pierangeli JH. O consentimento do ofendido: na teoria do delito. 2. ed. São Paulo: Revista dos Tribunais; 1995. *passim*.

> beyond simple consent. They are advanced expressions of the right to informed consent, in its most modern aspect of informed choice: self-determination in healthcare implies not only that the patient consents or refuses a (heteronomously) determined intervention, but that it has all the elements for analysis of possible treatment possibilities in the medical, surgical and pharmaceutical fields."[56]

In other words, even with the obtaining of valid and regular informed consent, if this is not the result of an informed choice, it is subject to the risks arising from the very unpredictability inherent in medical activity. It is necessary to understand that the consent process constitutes, at the same time, a patient's right, and a physician's duty. The patient must be informed, in a way that is comprehensible to his cognitive capacity, regarding his diagnosis, risks, prognosis, and existing alternatives for his treatment. It is important to highlight that the simple act of reading and signing a paper, a document, is not enough to relieve the burden of adequately informing (even if the signature of a document is important to prove diligent conduct). Maria Helena Diniz recognizes the right to autonomy, and the importance of the informed consent process:

> "The patient has the right to oppose a therapy, to choose a more appropriate or less rigorous treatment, to accept or deny a surgical intervention, to change or not a doctor or hospital, etc. The purpose of the principle of informed consent is to increase, as Mark Hall says, the personal autonomy of decisions that affect physical and mental well-being. [...] This right of self-determination gives rise to the duty *erga omnes* to respect it, based on the principle of human dignity. [...] This consent given by the patient after receiving medical information made in understandable terms, that is, in an appropriate and efficient manner, is an indispensable condition of the doctor-patient relationship, as it is a decision that takes into account the objectives, values, preferences, and needs of the patient and taken by him after assessing the risks and benefits."[58]

It should be noted that the modern doctrine of informed consent comprises a consultative role of the doctor, which involves a process of dialogue. The care

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56 Pereira AD. *O consentimento informado na relação médico-paciente*. Coimbra: Coimbra Editora; 2004. p. 74. [Translated from the original]

57 Regarding this topic, see the Brazilian Medical Ethics Code (Resolução CFM nº 2.217/2018), specifically in its provisions 12; 13; 15, §3º; 22; 24; 26; 31; 34; 42; 44; 73; 74; 101 e 110.

58 Diniz MH. *O estado atual do biodireito*. São Paulo: Saraiva; 2001. p. 534-536.

with the duty of information, and the patient's right to autonomy, cannot be exhausted in a procedure as hermetic and flawed as that of obtaining informed consent.[59] Hermetic, as it does not allow the patient (health service user and, ultimately, consumer) to have a more comprehensive view of their condition, restricting their role to the act of consenting or not to the proposed treatment. Precisely for this reason, it fails, since it prevents the exercise of an informed choice, which presupposes the knowledge of all the alternatives and the understanding of what each one of them can represent.

Understanding the consent process as an end in itself does not meet the principles spread across the different legal systems and international human rights documents, under penalty of creating a failure to comply with the duty of information. It is a mistake to think that obtaining simple informed consent, in the terms as it is known and has been practiced, can represent an exclusion of civil liability, or even an example of guilt, in case an unwanted result occurs during the treatment. Even a satisfactory result from a clinical perspective can later be interpreted as flawed if confronted with other possible outcomes expected from other therapeutic methods not informed to the patient.

This lack of information does not necessarily mean a negligent attitude, but rather the expression of the doctor's conviction, based on his own experience or on the specialized literature, that the proposed treatment was the most appropriate for the specific case. It turns out that this is not enough to fully supply the ethical and legal principles that compel him to present all the information available to the patient. Failure to indicate all possible alternatives can be understood, in an eventual disciplinary or even legal procedure, as inducing treatment through omission of information, which contradicts the principles of autonomy and objective good faith.

In a Brazilian context, there is a recent paradigmatic decision by the Superior Court of Justice[60] in the sense that there is an effective fulfillment of the duty of information when clarifications are specifically related to the specific case of the patient—generic information is not sufficient. For this reason, generic consent (blanket consent) will not be considered valid, needing to be clearly individualized. The patient's self-determination is only truly exercised when the information provided is specific, for the specific case of that specific patient, and not generic.[61] Therefore, the duty of information assumed by the

59 Dantas E. *Direito médico*. 4. ed. Salvador: JusPodivm; 2019. p. 130.

60 Superior Court of Justice, Brazil. REsp 1540580/DF. It was judged on August 2, 2018.

61 Farias CC, Braga Netto FP, Rosenvald N. *Novo tratado de responsabilidade civil*. 4. ed. São Paulo: Saraiva; 2019. p. 1318.

doctor will remain fulfilled from the analysis of the "criterion of the concrete patient,"[62] that is, the explanation of the professional must be extensive and adapted to the intellectual and cultural level of the patient.

Felipe Peixoto Braga Netto and Nelson Rosenvald also stand out, explaining that, currently, the physician's contractual duties to inform with loyalty and transparency are strengthened:

> "We are a long way from the time when the autonomy of the will in relation to contracts was absolute, with a religious reverence for the *pacta sunt servanda*. If there is, today, a contract that must be intensively read in the light of its social function, it is that related to the provision of health services. It is not any good that is at stake. It is human health. (...) The duties of reporting with loyalty and transparency are strengthened. It is no longer necessary, as in the past, to keep the patient in a state of ignorance about the state of his health, his choices and possibilities. Only in exceptional cases, properly contextualized, can this occur. (...) The patient, therefore, has the right to a correct and clear diagnosis, as well as to be informed about the risks and objectives of the treatment. Therefore, you must be aware of not only the diagnosis, but also the prognosis. (...) What is expected, more broadly, from doctors—before, during and after surgeries, consultations, or treatments—is that they act based on objective good faith, the duty of care and cooperation. Clear, adequate and sufficient information is expected."[63]

Michael Silva and Roberto Nogueira explain that "transparency determines that a contracting (medical) party with information privilege clarifies, in a clear, precise, ostentatious, detailed, and exhaustive way, that is, through the qualification of the information to be provided, all the elements that be considered by the counterpart (patient) in the decision to consent."[64] In the diagnosis supported by artificial intelligence or in the use of medical

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62 Pereira AD. *O consentimento informado na relação médico-paciente*. Coimbra: Coimbra Editora; 2004. p. 556.

63 Rosenvald N, Braga Netto FP. Responsabilidade civil na área médica. In: BR Braga Netto FP, César Silva M. *Direito privado e contemporaneidade*. *Indaiatuba:* Foco; 2020. p. 62. [Translated from the original]

64 Nogueira RHP, César Silva M. Direito à informação qualificada na relação médico-paciente: estudo das implicações da diferença entre certificado de pós-graduação lato sensu e título de especialista em dermatologia. *Revista da Faculdade Mineira de Direito - PUC Minas*. 2011. 14(27): 71-92.

assistance robots, as well as in any other medical interventions, the duty to inform is a duty of conduct resulting from the physician's objective good faith and his simple non-compliance characterizes contractual default. Marcos Ehrhardt Jr. indicates that the general duty in good faith is fulfilled when "the parties perform their conduct in an honest, loyal and correct manner, avoiding causing harm to the other (duty of protection) and ensuring knowledge of all circumstances relevant to negotiation (duty of information) —behavior that fosters trust between the contractors."[65]

In this context, adequate protection of clinical data and patient privacy are also important issues that need to be addressed, as Fernanda Schaefer points out:

> "In the doctor-patient relationship, the information must be clear and adequate, so that it allows the patient to understand what he is told about his health status and to decide with some certainty. The physician's duty to inform is considered a qualified duty, that is, formal compliance with the provision of information is not enough; it is necessary that this information be given in a way that allows understanding by the patient, so that he can freely make the decisions. (...) the very thing of seeing and informing are attached duties (or lateral / collateral duties) such as: the duty of care, the duty of providence, the duty to be safe and to preserve health, the duty to cooperate and, especially, the duties of clarification and counseling, so important to the doctor-patient relationship. Therefore, due to the resizing of privacy and the new functions recognized in medical information and the confidentiality of clinical data, there is a growing and necessary tendency to release access to anonymous or anonymized health data, sustained by the inevitability of control of some of this information by the community itself (and not just by health authorities), in the search for the realization of the right to health and provided that, obviously, they do not lead to an affront to the dignity of the human person and do not randomly exclude the right to informative self-determination. In contrast, there is a growing concern to protect identified or identifiable medical data whose improper and unauthorized use may lead to forms of discrimination or social exclusion and whose commercialization may pose serious risks to the protection of the human person (considered as an end in itself). In this context, the so-

65 Ehrhardt Júnior M. *Responsabilidade civil pelo inadimplemento da boa-fé*. Belo Horizonte: Fórum; 2013. E-book. [Translated from the original]

> called information security develops as an assumption of all medical data collection (which, by their nature, are considered sensitive). It is information security that will ensure the availability, authenticity, and confidentiality of information."[66]

It is important to consider that there may be an indemnity due for the deprivation suffered by the patient in his self-determination because he was deprived of the opportunity to ponder the risks and advantages of a given treatment, which, in the end, caused him damages that could be avoided, if the procedure is not done per the patient's option.[67] In order to establish the duty to indemnify, it is necessary to verify the causal link between the omission of information and the damage. When medical intervention is correct, but not adequately informed, the blame arises from a lack of information—or from incorrect information.[68] Neglect in treatment is not necessary. The victim must demonstrate that the damage comes from a risk about which he should have been warned in order to decide whether or not to accept treatment.

Considering this whole historical overview and the modern doctrine of informed consent of the patient presented in this paper, beyond the increasing use of technologies in the health area, especially robotics and artificial intelligence, the duties of informing with loyalty and transparency are inevitably strengthened, implying greater considerations about the patient's free and informed consent. In the next chapter, we will discuss in detail that the current doctrine of informed consent includes an advisory role for the doctor, which involves a dialogue process, the aim of which is to ensure that the patient understands all the circumstances of the proposed treatment and the technology used for that purpose, as well as reasonable therapeutic alternatives, enabling well-informed decision-making.[69]

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66 Schaefer F. *Telemática em saúde e sigilo profissional:* a busca pelo equilíbrio entre privacidade e interesse social. Curitiba: Juruá; 2010. p. 160-161.

67 Kfouri Neto M. A quantificação do dano na ausência de consentimento livre e esclarecido do paciente. *Revista IBERC*. 2019. 2(1): 1-22.

68 Kfouri Neto M. A quantificação do dano na ausência de consentimento livre e esclarecido do paciente. *Revista IBERC*. 2019. 2(1): 1-22.

69 Regarding a more elaborate discussion on this topic, especially on robotic surgery, see Kfouri Neto M, Nogaroli R. Responsabilidade civil pelo inadimplemento do dever de informação na cirurgia robótica e telecirurgia: uma abordagem de direito comparado (Estados Unidos, União Europeia e Brasil). In: Rosenvald N, Menezes JB, Dadalto L. (eds.) *Responsabilidade civil e medicina*. Indaiatuba: Foco; 2020. p. 159-186. Kfouri Neto M, Nogaroli R. Estudo comparatístico da responsabilidade civil do médico, hospital e fabricante na cirurgia assistida por robô. In: Kfouri Neto M, Nogaroli R. (eds.) *Debates contemporâneos em direito médico e da saúde*. São Paulo: Thomson Reuters Brasil; 2020. p. 33-68.

3. Ethical and Legal Challenges of Informed Consent Applying Artificial Intelligence to Support Medical Decision-Making.

The patient's consent in the scope of healthcare robots and diagnosis with AI-based algorithms acquires significant peculiarities. To make it possible to establish limits on the dynamics of consent in these technologies, we will present, at first, the ethical and legal challenges in applying artificial intelligence to support medical decision-making. Although robots and AI can provide great opportunities in medicine, there still may be challenges and pitfalls related to various safety concerns.

In the last few years, unpredictable events and accidents with AI have been widely discussed in various sectors. The first known death caused by a self-driving car was disclosed by Tesla Motors in 2016. In the following year, an autonomous car operated by Uber struck and killed a woman on a street in Tempe, Arizona. It was the first pedestrian death associated with self-driving technology.[70] The likelihood of damage caused by the actions of AI is real. Another example is the escape of the Gaak robot from the Magna Science Centre in England. In 2002, scientists from the England research center ran a project called "Living Robots." Two autonomous robots were released into an arena to simulate a scenario of "predators" and "prey." The experiment had to confirm whether the AI were able to benefit from the gained experience, i.e. to independently come up with new hunting and self-defense techniques. However, during the experiment, one of the robots that was unintentionally left unattended for 15 minutes adopted an unpredictable behavior, found an exit through the arena wall, and went to the street, where it ended up being hit by a car.[71]

The disastrous result of the English experiment and the accidents with autonomous cars reveals the ability of AI to learn and respond to the environment, regardless of the will of the AI developer. The ability to accumulate experience and learn from it, as well as the ability to act independently and make individual decisions, creates preconditions for damages. Another important issue to consider is that while AI holds the promise of delivering valuable insights and knowledge across a multitude of

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70 Self-driving Uber kills Arizona woman in first fatal crash involving pedestrian. Available at: https://www.theguardian.com/technology/2018/mar/19/uber-self-driving-car-kills-woman-arizona-tempe. Accessed: Jan. 10, 2021.

71 Cerka P, Grigien J, Sirbikyt, G. Liability for damages caused by artificial intelligence. *Computer Law & Security Review*. 2015. 31(3): 376-389.

applications, broad adoption of AI systems in healthcare will rely heavily on the ability to trust a decision made by an algorithm. In this sense, how can we trust that the predictions are correct?

> Sameer Singh, assistant professor in the Department of Computer Science at the University of California (UCI), in the United States, reports that one of his students created an algorithm to classify pictures of huskies and wolves.[72] The algorithm could almost perfectly classify the two animals. However, in later cross-analyzes, Singh found that the algorithm was identifying wolves based only on the snow at the bottom of the image, and not on the wolf's own characteristics. Some machine learning techniques, although very successful from the accuracy point of view, are very opaque in terms of understanding how they make decisions. This is the so-called "black box problem" in AI;[73] that is, the algorithms perform certain actions to reach a specific result, but they are not always able to really explain to man how that decision was made.[74] Since many AI systems rely on huge amounts of data to perform properly, it is important to understand how data are influencing the behavior of the AI systems.

Now imagine a poorly-programmed algorithm, or one with some degree of fallibility, in the AI-based system that was used in some countries during the Covid-19 pandemic to diagnose patients infected with the new coronavirus. To program the algorithm, thousands of data from infected patients and their respective chest CT scans were inserted.[75] The AI algorithm was able to distinguish, in a few seconds, between patients infected with the new

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72 Husky or Wolf? Using a Black Box Learning Model to Avoid Adoption Errors. Available at: http://innovation.uci.edu/2017/08/husky-or-wolf-using-a-black-box-learning-model-to-avoid-adoption-errors/. Accessed: Dez. 08, 2020.

73 On the subject, it is essential to refer to Pasquale F. *The black box society:* the secret algorithms that control money and information. Cambridge: Harvard University Press; 2015. *passim*.

74 On the subject, it is essential to refer to Pasquale F. *The black box society:* the secret algorithms that control money and information. Cambridge: Harvard University Press; 2015. passim.
gorithms will help the agent to better judge its decisions and suggestions, thus avoiding simplistic and reductionist views and incurring in the possibility of making humans, to a certain extent, hostages to decisions taken in the 'black box' of the algorithms" (Teffé CS, Medon F. Responsabilidade civil e regulação de novas tecnologias: questões acerca da utilização de inteligência artificial na tomada de decisões empresariais. *Revista Estudos Institucionais*. 2020. 6(1): 301-333. [Translated from the original]).

75 Ping An Launches COVID-19 Smart Image-Reading System to Help Control the Epidemic. Available at: https://www.prnewswire.com/news-releases/ping-an-launches-covid-19-smart-image-reading-system-to-help-control-the-epidemic-301013282.html. Accessed: Dez. 08, 2020.

coronavirus and those with other lung diseases. If wrong data from infected patients were introduced or the algorithm was poorly programmed, the damage would be immeasurable.[76] Healthcare data is the "fuel" of machine learning in medicine and their quality is fundamental for the good performance of AI systems, because the algorithm—which is the calculation of a probability—draws conclusions from the knowledge stored in its bases and the data provided.

In addition, we cannot ignore that, although the software with AI algorithms is efficient in assisting the diagnosis of Covid-19, it will continue to present a significant margin of imprecision.[77] There are studies that show an imprecision rate of around 10%, which can lead to adverse results. Thus, it is always important to keep in mind that AI serves as a support tool for professional decision-making (the concept of AI-as-Tool), that is, the final decision is the doctor's responsibility.[79] The professional will only be held responsible if lack of diligence is demonstrated throughout the diagnostic process.[80]

In the specific scope of healthcare robots, there are some specific risks and ethical implications of AI to be considered. Pepper is a robot designed to

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76 Guia Silva R, Nogaroli R. *Inteligência artificial na análise diagnóstica da Covid-19:* possíveis repercussões sobre a responsabilidade civil do médico. In: Migalhas, 30/03/2020. Available at: https://migalhas.uol.com.br/coluna/migalhas-patrimoniais/322941/inteligencia-artificial-na-analise-diagnostica-da-covid-19--possiveis-repercussoes-sobre-a-responsabilidade-civil-do-medico. Accessed: Jan. 10, 2021.

77 According to Manuel Ortiz Fernández, the situation generated by the Covid-19 pandemic "requires us to reorder the health liability system and, within it, that applicable to the scope of informed consent. In this sense, in order to determine the adequacy of the behavior to the *lex artis ad hoc* it is necessary to reflect on the state of science in order to determine whether knowledge is allowed to act in another direction." (Fernández MO. El estado de la ciencia durante el Covid-19 y el derecho al consentimiento informado. *Pensar - Revista de Ciências Jurídicas*. 2020. 25(4): 1-11)

78 IBM's Watson supercomputer recommended 'unsafe and incorrect' cancer treatments, internal documents show. Available at: https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments/. Accessed: Dez. 08, 2020.

79 About the determination of professional liability for medical error with AI-based system to support medical decision-making, see Nogaroli R, Guia Silva R. Inteligência artificial na análise diagnóstica: benefícios, riscos e responsabilidade do médico. In: Kfouri Neto M, Nogaroli R. (eds.) *Debates contemporâneos em direito médico e da saúde*. São Paulo: Thomson Reuters Brasil; 2020. p. 69-91.

80 Regarding medical malpractice in the scenario of AI to help medical diagnosis of Covid-19, see Guia Silva R, Nogaroli R. *Inteligência artificial na análise diagnóstica da Covid-19*: possíveis repercussões sobre a responsabilidade civil do médico. In: Rosenvald N, Monteiro Filho CER, Densa R. (eds.) Coronavírus e responsabilidade civil: impactos contratuais e extracontratuais. Indaiatuba: Foco; 2020. p. 293-300.

interact with people and, through conversations and its touch screen, recognize facial expressions and "read" emotions.[81] The robot talks to the person and monitors their emotional health, passing on some information to doctors and the healthcare team. Pepper has microphones and a camera with facial recognition, which can identify facial expressions and vocal tones. The AI-powered systems can analyze these data, and the robot sets up a scenario of how the individual feels, reacting to the patient according to this interpretation.[82] Pepper was tested in care homes in the UK and Japan, and researchers found that older adults who used them—up to 18 hours over two weeks—saw a significant improvement in their mental health.[83] The results from this study show that using the Caresses artificial intelligence in robots such as Pepper has real potential benefit to a world that is witnessing more people living longer with fewer people to look after them.

However, considering a scenario that the Pepper robot is also programmed to assist in healthcare routines (e.g., monitoring the schedule of medical appointments and medication administration), there are possible adverse events with ethical and legal implications in the use of a healthcare robot, which are highlighted in the lessons of Nalin and Nogaroli:

> "If an elderly woman, diagnosed with Alzheimer's and diabetes, is assisted by a healthcare robot, but on a certain day, the robot does not bring to her the injection with insulin, causing, consequently, serious damage to her health, important ethical and legal discussions arise from this hypothetical situation. The possibility of artificial intelligence causing unpredictable damage—due to the improvement of machine learning—in addition to the problem of lack of transparency in data processing and reliability of the algorithms, are factors that directly reflect in the discussion about legal liability. In addition, it brings the bioethical debate about autonomy and consent for the person to be cared for by a robot and other ethical principles that must be followed by the developers of these technologies becomes of paramount

81 Pepper. A robot designed to interact with humans. Available at: https://www.softbankrobotics.com/emea/en/Pepper. Accessed: Dez. 08, 2020.

82 Pandey AK, Gelin R. Pepper: The First Machine of Its Kind. A Mass-Produced Sociable Humanoid Robot. *IEEE Robotics and Automation Magazine*. 2018. 25(3): p. 40-48.

83 Robots like Pepper could be used in UK care homes to improve elderly people's mental health and reduce loneliness, study suggests. Available at https://www.dailymail.co.uk/sciencetech/article-8707603/Robots-improve-mental-health-loneliness-older-people-study.html. Accessed: Dez. 08, 2020.

> importance. Therefore, the brief statement of these examples of the incorporation of AI and robotics in healthcare illustrate some of the various benefits that this technology can provide. Such potential benefits are accompanied, however, by important ethical and legal questions, with particular emphasis on the ethical principles applicable to artificial intelligence, as well as the way of determining civil liability for adverse events in the context of robot care."[84]

Furthermore, Nalin and Nogaroli present a possible adverse event with the healthcare called Robobear. It is a robot that can help in the care of debilitated patients. The robot can lift a person who is standing or lying down, transfer him to a wheelchair, transport him from one place to another, or even turn him from a position on the bed. Thus, the authors present a scenario in which Robobear, when transferring a debilitated patient from the bed to a wheelchair, ends up dropping him on the floor.[85] It is clearly observed that robots can be a way of caring for our aging populations in the near future. However, the ways in which robots care for older people could impact their autonomy and dignity. It is important to take this into consideration because of the risk of developing robotic solutions to the problems of aging that result in a reduced rather than in an improved quality of life for older people.

In view of the possibility of AI causing unpredictable damage due to the machine learning processes, in addition to the problem of reliability and validity of AI algorithms, it is of utmost importance to investigate the ethical principles that must be followed by its developers. According to Eduardo Magrani, when dealing with artificial intelligence, it is "essential for the research community and academia to promote an extensive debate about the ethical guidelines that should guide the construction of these intelligent machines."[86]

In 2019, The European Union High-Level Expert Group on Artificial Intelligence presented "Ethics guidelines for trustworthy AI."[87] According to

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84 Nalin P, Nogaroli R. Perspectivas sobre ética e responsabilidade civil no contexto dos robôs inteligentes de assistência à saúde. In: Campos AF, Berlini LF. *Temas Contemporâneos de Responsabilidade Civil:* teoria e prática. Belo Horizonte: D'Plácido; 2020. p. 61-94. [Translated from the original]

85 Nalin P, Nogaroli R. Perspectivas sobre ética e responsabilidade civil no contexto dos robôs inteligentes de assistência à saúde. In: Campos AF, Berlini LF. *Temas Contemporâneos de Responsabilidade Civil:* teoria e prática. Belo Horizonte: D'Plácido; 2020. p. 61-94.

86 Magrani E. New perspectives on ethics and the laws of artificial intelligence. *Internet Policy Review - Journal on internet regulation*. 2019. 8(3): 1-19.

87 High-Level Expert Group on AI. Ethics guidelines for trustworthy AI. Brussels: European

the guidelines, trustworthy AI should be: (1) *lawful*: respecting all applicable laws and regulations; (2) *ethical*: respecting ethical principles and values; (3) *robust*: both from a technical perspective as well as taking into account its social environment. In addition, developing, deploying and using AI systems must occur in a way that adheres to the ethical principles of respect for human autonomy, prevention of harm, fairness and explicability.

Respect for human autonomy is the first ethical imperative that professionals in the field of AI must always seek to respect, in order for technology to be developed, deployed and used in a reliable manner. This means that human beings' full and effective self-determination needs to be maintained when interacting with AI. According to Paula Boddington, "autonomy is not just a core value in contemporary society, not just a core value underlying many codes of professional ethics, such as codes of medical ethics — it's of particular concern to us as a key to AI which is developing autonomous systems and machines."[88] AI-based systems must be created to increase, complement and enable the cognitive, social and cultural competences of human beings, always ensuring the human supervision and control of AI.

Respect for the individual's autonomy is a core value in codes of medical ethics, expressed in various ways and articulated via concern for issues such as confidentiality and free and informed patient consent. The history of medical ethics over the last century or so can be read in no small way as the history of how patient autonomy has been granted greater and greater emphasis, as opposed to the "doctor knows best" model. According to Maria de Fátima Freire Sá and Bruno Torquato de Oliveira Naves, for the patient to make his clinical decision, he must be informed of as much information as possible, which must be presented in a clear and comprehensive manner. Information must be constructed dialogically and not unilaterally. Thus, it is not enough for the professional to report facts, but he must evaluate the patient's level of awareness and education to make each decision.[90]

Commission; 2019. Available at: https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai. Similar to this well-grounded initiative, many countries, companies and professional communities are publishing guidelines for AI, with analogous values and principles, intending to ensure the positive aspects and diminish the risks involved in AI development. Available at https://policyreview.info/pdf/policyreview-2019-3-1420.pdf.

88 Boddington P. *Towards a code of ethics for artificial intelligence*. Cham: Springer; 2017. p. 41.

89 Sá MFF, Naves BTO. *Bioética e biodireito*. 4. ed. Belo Horizonte: Del Rey; 2018. p. 101-114.

90 Sá MFF, *Naves BTO*. *Bioética e biodireito*. 4. ed. Belo Horizonte: Del Rey; 2018. p. 108.

91 Ferreira AE, Pereira AD. Uma ética para a medicina pós-humana: propostas ético-jurídicas

Regarding human autonomy and patient consent in the context of healthcare robots, André Dias Pereira and Ana Elisabete Ferreira explain that the respect of the refusal to be treated by a robot is "a fundamental claim of the technological transition in healthcare."[91] About the topic, the European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics states that informed consent "should be pursued and obtained prior to any man-machine interaction. As such, robotics designers have a responsibility to develop and follow procedures for valid consent, confidentiality, anonymity, fair treatment and due process."[92] In addition, considering the possible adverse events previously reported in the context of the healthcare robots Pepper or Robobear, Nogaroli e Kfouri state that:

> "(...) there is the fundamental investigation into the required elements of informed consent. On the one hand, the patient's right to consent and, on the other, the doctor's duty to inform. Will the professional who indicates to an elderly patient the use of the Pepper robot fulfill this duty to inform if he only transmits some general information about the advantages of the robot in providing a more independent life to the patient in his daily care? Certainly, there is a need to also transmit the information about the possibility of specific risks of artificial intelligence algorithms, such as the lack of transparency in the way AI processes information and unpredictable behaviors resulting from machine learning. It is also necessary to consider that the robot collects sensitive data about the healthcare condition of the subject under its care, passing it on to the doctor (...)"[93]

It is also important to consider the specifics and dynamics of informed consent in the context of medical diagnosis and prognosis using AI-based systems. As we mentioned before, the Watson for Oncology platform is a cognitive computing system that helps oncologists make treatment decisions for individual patients. It analyzes, in a few seconds, numerous clinical attributes from each patient

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para a mediação das relações entre humanos e robôs na saúde. *In*: Rosenvald N, Menezes JB, Dadalto L. (eds.) *Responsabilidade civil e medicina*. Indaiatuba: Foco; 2020. p. 13.

92 European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics. Available at https://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html. Accessed: Jan. 18, 2021.

93 Kfouri Neto M, Nogaroli R. O consentimento do paciente no admirável mundo novo de robôs de assistência à saúde e algoritmos de inteligência artificial para diagnóstico médico. In: Tepedino G, Guia Silva R. (eds.) *O direito civil na era da inteligência artificial*. São Paulo: Revista dos Tribunais; 2020. p. 139-164. [Translated from the original]

and runs through a medical database (with medical guidelines, clinical studies, medical journals, textbooks, and papers) to return a recommendation to the physician on whether the standard treatment should be followed, considered, or abandoned. In this context, to respect the autonomy and self-determination of a patient, it is necessary to clarify to him that the technology has a degree of fallibility and, in the end, it will always be up to the doctor to decide. As remarkable as AI is in the analysis of numbers and the processing of data, it cannot be ignored that it makes mistakes. There are studies that revealed that in 10% of cases, Watson for Oncology made different treatment decision from the physicians.[94] Therefore, it is justified that AI should be used as a support for medical decision-making (the concept of AI-as-Tool need be here), without the intention of replacing the doctor.[95]

According to the European Parliament's guidelines mentioned above, the principle of explicability is also crucial for maintaining a trustworthy AI.[96] This means that the capabilities, purposes, and decision-making processes of AI systems need to be transparent, making it feasible–to the extent possible–to explain an outcome (or decision) to those directly and indirectly affected by the technology. Considering the black box problem, an explanation as to why a model has generated a particular output or decision (and what combination of input factors contributed to that) is not always possible. In these cases, the European guidelines present other explicability measures (e.g., traceability, auditability, and transparent communication on system capabilities).

In order to provide traceability and increase in transparency, "the data sets and the processes that yield the AI system's decision, including those of data gathering and data labelling as well as the algorithms used, should be

94 IBM Watson agrees with cancer docs on treatment options 90% of the time. Available at https://www.fiercebiotech.com/medical-devices/study-ibm-watson-agrees-cancer-docs-treatment-options-90-time. Accessed: Jan. 18, 2021.

95 Nalin P, Nogaroli R. Cirurgias assistidas por robôs e análise diagnóstica com inteligência artificial: novos desafios sobre os princípios contratuais e o equacionamento da responsabilidade civil médica. *In*: Ehrhardt Júnior M, Catalan M, Malheiros P. (eds.) *Direito Civil e tecnologia*. Belo Horizonte: Fórum; 2020. p. 649-670.

96 Nalin P, Nogaroli R. Cirurgias assistidas por robôs e análise diagnóstica com inteligência artificial: novos desafios sobre os princípios contratuais e o equacionamento da responsabilidade civil médica. In: Ehrhardt Júnior M, Catalan M, Malheiros P. (eds.) Direito Civil e tecnologia. Belo Horizonte: Fórum; 2020. p. 649-670.

97 High-Level Expert Group on AI (HLEG AI). (2019). Ethics guidelines for trustworthy AI [Report / Study]. Brussels: European Commission. Retrieved from: https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai.

documented to the best possible standard."[97] Thus, whenever an AI system has a significant impact on people's lives, it should be possible to demand a suitable explanation of the AI system's decision-making process. Finally, humans have the right to be informed that they are interacting with an AI system, considering that "the option to decide against this interaction in favor of human interaction should be provided where needed to ensure compliance with fundamental rights. Beyond this, the AI system's capabilities and limitations should be communicated to AI practitioners or end-users in a manner appropriate to the use case at hand."[98]

Medical disclosure in AI is also based on the idea of transparency and there is a higher degree to which explicability is needed. This is incredibly important to consider because of the severity of the consequences if that output is erroneous or otherwise inaccurate. Processes and data sets used must be tested and documented at each step, such as planning, training, testing, and deployment. It is essential to allow the maximum traceability and, consequently, transparency of the AI, when it is necessary to investigate why a decision was made in an erroneous way.

The difficulty of humans to understand and explain how these systems work is also called "opacity of artificial intelligence systems." Nicholson Price explains that one of the biggest fears for the healthcare sector in times of artificial intelligence is the unpredictable events resulting from machine learning and the so-called "black box medicine," given the obscurity in the way information is processed by the algorithms.[99] Agata Ferretti, Manuel Schneider and Alessandro Blasimme observed that there are three different semantic dimensions of opacity particularly relevant to medicine: (i) lack of disclosure; (ii) epistemic opacity; and (iii) explanatory opacity. According to the authors:

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98 High-Level Expert Group on AI (HLEG AI). (2019). Ethics guidelines for trustworthy AI [Report / Study]. Brussels: European Commission. Retrieved from: https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai.

99 On the other hand, Price indicates some benefits associated with black box medicine: "a black-box model might, for instance, identify the specific genes that predict who will develop a disease or condition; or it might tell physicians, earlier than they could otherwise tell, which of two similar diseases a patient has. Some of these benefits can be obtained through other means; others unique to black-box medicine. But even when other means are available, black-box algorithms could significantly reduce health-care costs by eliminating the need to perform other, costly tests or to waste time on ineffective treatments. And they could lead to better health outcomes as inappropriate treatments or dangerous side effects are avoided." (Ford RA, Price WN. Privacy and accountability in black-box medicine. *Michigan Telecommunications & Technology Law Review*. 2016. 23(1): 5-7).

"From a general point of view, *lack of disclosure refers* to the fact that data subjects are unaware that automated decision-making and profiling activities about them are being carried out. This type of opacity does not depend on intrinsic technical characteristics of AI systems, but derives from the way automated data processing and profiling activities are conducted. In principle, any type of data processing activity could be conducted without the data subjects being aware of it (…) Epistemic opacity occurs when it is not possible to have access to or there is not sufficient understanding of the rules an AI system is applying to make predictions, classifications and decisions. Epistemic opacity is therefore related to the question of how an AI system provides a specific outcome. (…) Explanatory opacity relates to the question of why an AI system provides a specific outcome. What an ML system is designed to do is to discover patterns between huge numbers of variables in a training dataset, and to leverage these patterns to make classifications, predictions and decisions regarding new input data. The output, in other words, is the result of patterns that the ML system has generalised from training examples. In the field of medicine, for example, an ML system could learn that certain geometrical properties of a histology slide correlate with a bad prognosis. (…) An alternative to providing in-depth information about an AI system and a way to overcome the implications of explanatory opacity lies in counterfactually examining the outcomes provided by the AI system. Wachter, Mittelstadt and Russellhave argued that 'counterfactuals describe a dependency on the external facts that led to that decision' and that more than one counter factual might exist. Counterfactuals can illustrate how even a small change in an input variable can result in a different outcome. Input variables can therefore be systematically varied and corresponding outcomes can be compared to the original, in order to gain deeper insight into the relationship between input variables and the computed outcomes. This opens up the possibility to infer a reason why the original outcome was produced. The explanation provided based on a specific case might not result in an exhaustive description of the entire AI system, but it would contribute significantly to the perspective of human understanding."[100]

100 Ferretti A, Schneider M, Blasimme A. Machine learning in medicine: opening the new data protection black box. *European Data Protection Law Review*. 2018. 4(3): 320-332.

In conclusion, opacity is a polysemic concept. In the specific domain of healthcare, the amount and type of information provided to patients has long been a topic of discussion due to its practical and ethical implications. More research is needed to understand patients' and physicians' attitudes towards opacity in AI systems. Anyways, it is important to consider that patients may feel undermined from the point of view of their decisional autonomy and capacity to influence healthcare provision practices about themselves.

Across the globe, tens of thousands of hospitalized patients have already had their discharge planning decisions with help from an artificial intelligence model. However, few of those patients has any idea about the AI involved in their care.[101] At a growing number of prominent hospitals and clinics around the United States, clinicians are turning to AI-powered decision support tools—many of them unproven—to help predict whether hospitalized patients are likely to develop complications or deteriorate, whether they are at risk of readmission, and whether they're likely to die soon. But these patients and their family members are often not informed about or asked to consent to the use of these tools in their care. Some doctors could defend a paternalistic discourse that they dominate the profession's *legis artis,* which is why they would not need to inform the patient about all the resources they use in the clinical decision-making process. According to Glenn Cohen, a Harvard Law School professor, hospitals and clinicians "are operating under the assumption that you do not disclose, and that's not really something that has been defended or really thought about."[102]

Despite this scenario, medical disclosure and the explainability of such systems, and the obligations relative to the information about their use in patients' care, are especially important and likely to affect the patient-doctor relationship. Reasonable communication could mitigate this negative effect, be a precondition for objecting to fully automated processing, and for requiring some form of human involvement in those activities. This would foster ideals of *shared decision-making in medicine*. Thus, the patient who is somehow affected by AI during the clinical decision process does not only have a right to information. It is not enough for the doctor, after any damage resulting

101 An invisible hand: Patients aren't being told about the AI systems advising their care. Available at: https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals/. Accessed: Jan. 18, 2021.

102 An invisible hand: Patients aren't being told about the AI systems advising their care. Available at: https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals/. Accessed: Jan. 18, 2021.

from an erroneous diagnosis supported by AI, to simply say "I'm sorry, the algorithm did it" —that is, the algorithm produced this erroneous result from the patient's clinical condition. As far as possible, medical disclosure is required and manifested by the need for a broad explanation and justification prior to the clinical decision.[103]

Additionally, there is a relevant discussion about the fact that the opacity of an AI system can make it difficult for healthcare professionals to ascertain how the system came up with a specific decision and how an error might occur. For this reason, physicians who use machine learning systems need to become more educated about the general panorama of their construction, the data sets they are built on, as well as their limitations. Remaining ignorant about the construction of AI systems in medicine or allowing them to be freely constructed as black boxes could lead to ethically problematic outcomes. Moreover, professional societies such as American Medical Association are recommending that AI systems must be "transparent," and it is important to "encourage education for patients, physicians, medical students, other healthcare professionals, and health administrators to promote greater understanding of the promise and limitations of healthcare AI."[104]

Considering the entire context presented, the two principles of the European guidelines mentioned above—human autonomy and explicability—directly impact the creation of a new model of informed consent for patients in the context of robotics and AI-based systems. Another essential issue to be discussed in the scenario of AI in medicine is the patient's privacy. Protocols must be adopted to inform how the personal data will be processed, who will have access to them and under what specific circumstances (finality). About this topic, the European guidelines for trustworthy AI state:

> "AI systems must guarantee privacy and data protection throughout a system's entire lifecycle. This includes the information initially provided by the user, as well as the information generated about the user over the course of their interaction with the system (e.g. outputs

103 In this sense, see Pasquale F. Toward a fourth law of robotics: preserving attribution, responsibility, and explainability in an algorithmic society. y. Ohio State Law Journal. 2017. University of Maryland Francis King Carey School Of Law legal studies research paper, n. 2017-21. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3002546. Accessed: Jan. 18, 2021.

104 American Medical Association. Augmented intelligence in health care H-480.940. Available at https://policysearch.ama-assn.org/policyfinder/detail/augmented%20intelligence?uri=%2FAMADoc%2FHOD.xml-H-480.940.xml. Accessed: Jan. 12, 2021.

> that the AI system generated for specific users or how users responded to particular recommendations). Digital records of human behaviour may allow AI systems to infer not only individuals' preferences, but also their sexual orientation, age, gender, religious or political views. To allow individuals to trust the data gathering process, it must be ensured that data collected about them will not be used to unlawfully or unfairly discriminate against them."[105]

Regarding the duty of medical disclosure and informed consent about healthcare data in the context of new technologies, Flaviana Rampazzo Soares asserts:

> "With technological development, it will become increasingly common to use computer systems that will present patient's healthcare data. In this case, it will be essential to pass through a later non-automated stage with technical follow-up (...) for the conference regarding the content of the information received, the necessary clarifications, as well as the recipient's understanding and apprehension, so that this step can be considered admissible and appropriate."[106]

Nowadays, there has been a profound change in the understanding of the protection of personal data. These data integrate personal privacy, which, in turn, is linked to the individual's personality and development. In the last few years, the Network Society[108] is experiencing a worldwide phenomenon of "digitization of the body,"[109] as proposed by Rodotà, in the sense that, in postmodern society, the "constitutionalization of the person" is revealed not only by the protection of the "physical body" (right to the integrity of the person), as well as the "electronic body" (right to the protection of personal data), characterized as the sum of a set of rights that configure the "citizenship in the new millennium."[110] The essential effect of this paradigm shift has

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105 High-Level Expert Group on AI. Ethics guidelines for trustworthy AI. Brussels: European Commission; 2019. Available at: https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai

106 Soares FR. *Consentimento do paciente no direito médico: validade, interpretação e responsabilidade*. Indaiatuba: Foco; 2021. p. 160. [Translated from the original]

107 In this sense, see Doneda D. *Da privacidade à proteção de dados pessoais*: elementos da formação da Lei Geral de Proteção de Dados Pessoais. 2. ed. São Paulo: Revista dos Tribunais; 2019. passim.

108 Dijk JV. The network society. 2. ed. London: Sage Publications; 2006. p. 253-254.

109 Basan AP, Faleiros Júnior JLM. A tutela do corpo eletrônico como direito básico do consumidor. Revista dos Tribunais. 2020. 1021(1): 133-168.

110 RODOTÀ, Stefano. *A vida na sociedade da vigilância:* a privacidade hoje. Rio de Janeiro: Renovar; 2008, passim.

been noticed recently, as it is a period characterized by the celebration of innovation, which awakens new reflections about classic legal institutes, as well as the functions performed by the institution of civil liability in the face of damages, especially those caused by personal data breaches.[111]

Electronic body concepts such as those brought by Stefano Rodotà (*corpo elettronico*)[112] or Roger Clarke (*digital persona*)[113] have a direct impact on any assessment of ethical and legal impacts—especially in matters of civil liability for breach of the duty to inform the patient—in view of the new risks that arise in the context of artificial intelligence systems in the health sector. According to Matthieu Grall, when it comes to the processing of personal health data, among the main risks are the irregular treatment of data (especially in relation to privacy), automated decisions in data processing and the lack of information or consent on how data were collected, processed and shared.[114]

In 2016, protected health information breaches in the United States affected over 113 million individuals. Four of the fifty-one hacking incidents in 2015 involved electronic medical records (EMR). One hacking incident affected 3.9 million individuals' health information.[115] A ransomware attack on the Florida Orthopedic Institute in 2020 potentially breached the data of about 640,000 patients.[116] Hacking incidents topped the list as the main cause of healthcare data breaches.

The UK's National Health Service had 16 breaches that exposed 1.8 million health records during the 12-month period ending in July 2012.[117] During 2019, 67% of UK healthcare organizations experienced some kind of cybersecurity incident. Research found that almost half (48%) of these incidents occurred as

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111 A personal data breach means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data. This includes breaches that are the result of both accidental and deliberate causes.

112 RODOTÀ, Stefano. *Intervista su privacy e libertà*. Bari: Laterza; 2005. p. 121-122

113 Clarke R. The digital persona and its application to data surveillance. *The Information Society*. 1994. 10(2): 77-92.

114 GRALL, Matthieu. CNIL (Commission Nationale de l'Informatique et des Libertés) and Analysis of Big Data Projects in the Health Sector. In: Nordlinger B, Villani, C, Rus, D. (eds.) *Healthcare and artificial intelligence*. Cham: Springer; 2020, p. 235.

115 Healthcare Data Breaches: Insights and Implications. Available at: dashboard.healthit.gov/quickstats/pages/breaches-protected-health-information.php. Accessed: Jan. 12, 2021.

116 The 10 Biggest Healthcare Data Breaches of 2020. Available at https://healthitsecurity.com/news/the-10-biggest-healthcare-data-breaches-of-2020-so-far. Accessed: Jan. 12, 2021.

117 UK Health Records Breached: 1.8 Million. Available at https://www.databreachtoday.co.uk/uk-health-records-breached-18-million-a-5261. Accessed: Jan. 12, 2021.

a result of the introduction of viruses or malware from third-party devices—including IoT devices and USB sticks.[118] Almost 20 hospitals across the United Kingdom experienced a huge cyberattack, which resulted in the need to cancel routine appointments and divert ambulances to neighboring hospitals.[119] In 2020, a patient's death was linked directly to a cyberattack in Germany. Police have launched a "negligent homicide" investigation after ransomware disrupted emergency care at Düsseldorf University Hospital.[120] The patient arrived at the hospital's emergency department in serious health condition, but she could not be attended because the cyberattack targeted the computer information system. When Düsseldorf could no longer provide care, she was transferred 19 miles (30 kilometers) away to another hospital, but the patient didn't survive.

Cyberattacks are targeting healthcare organizations around the globe, due to the lack of security in the transmission of information, little care or the lack of access keys, different permissiveness of systems, and applications that weaken the storage and exchange of information. This whole problematic scenario has a direct reflection on the need to inform the patient about the possibility of illicit access to their sensitive data by third parties. Another important point to consider is that there are some massive security incidents involving the improper disposal of patient records, such as the episode in 2020 with the healthcare provider now known as Elite Emergency Physicians. In total, the records of 550,00 patients were exposed as a result of the improper disposal incident.[121]

The growing incidence of cyberattacks and misuse of personal data has resulted in a slew of data privacy protection regulations by various governments across countries. In the case of irregular processing of sensitive patient data or illicit access by third parties, there are specific rules in several countries to

118 67% of healthcare organisations suffered a cyber security incident in the last 12 months. Available at https://uktechnews.co.uk/2020/01/16/67-of-healthcare-organisations-suffered-a-cyber-security-incident-in-the-last-12-months/. Accessed: Jan. 12, 2021.

119 NHS hack: Cyber attack takes 16 hospitals offline as patients are turned away. Available at https://www.independent.co.uk/news/uk/home-news/nhs-cyber-attack-hack-hospitals-16-patients-turned-away-wanna-decryptor-a7733196.html. Accessed: Jan. 12, 2021.

120 A patient has died after ransomware hackers hit a German hospital. Available at https://www.technologyreview.com/2020/09/18/1008582/a-patient-has-died-after-ransomware-hackers-hit-a-german-hospital/. Accessed: Jan. 12, 2021.

121 Business Associate Incidents Added to Breach Tally. Available at https://www.databreachtoday.com/business-associate-incidents-added-to-breach-tally-a-14456. Accessed: Jan. 12, 2021.

determine responsibility for the breach of sensitive health data.[122] For example, in European Union countries, there is the General Data Protection Regulation (GDPR),[123] and the "Lei Geral de Proteção de Dados Pessoais" (LGPD) in Brazil.[124] The GDPR sets out seven key principles relating to the processing of personal data: lawfulness, fairness and transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality (security), and accountability. The LGPD establishes ten principles: purpose, adequacy, necessity, free access, quality, transparency, security, prevention, non-discrimination, responsibility and accountability.

Both legislations present a series of principles that seek to conform, precisely, to the idea that the holder of personal data must be empowered with the control of his personal information and, above all, in his autonomy of the will. Informed consent to processing personal data must be done for specific, legitimate, explicit, and informed purposes. It is important to remember that healthcare technologies such as Watson for Oncology platform uses patients' sensitive data, in order to obtain a prognosis with treatment options for them. Thus, the way of processing health data—both the description of its purpose and the subjects who will have access to this information—is a point of relevant importance to be informed to the patient.

On the other hand, there are some academic discussions about patients' consent to process sensitive data in the context of healthcare. We developed some studies[125] in the context of the LGPD and have concluded that, despite

122 About the healthcare data protection in telemedicine in Brazil, see Faleiros Junior JLM, Nogaroli R, Cavet AM. Telemedicina e proteção de dados: reflexões sobre a pandemia da covid-19 e os impactos jurídicos da tecnologia aplicada à saúde. Revista dos Tribunais. 2020. 1015(1): 327-362.

123 In Portugal, Centro Hospitalar Barreiro Montijo has been fined 400,000 euros for violating the GDPR. There was a violation of the minimization principle–by allowing indiscriminate access to an excessive number of users–and a violation of integrity and confidentiality–as a result of non-application of technical and organizational measures to prevent unlawful access to personal data. The hospital didn't have the capacity to ensure the continued confidentiality, integrity, availability and resilience of treatment systems and services, as well as the non-implementation of the technical and organizational measures to ensure a level of security adequate to the risk. (Available at https://iapp.org/news/a/first-gdpr-fine-in-portugal-issued-against-hospital-for-three-violations/. Accessed: Jan. 12, 2021.)

124 On the subject, see Dresch RFV, Faleiros Junior JLM. Reflexões sobre a responsabilidade civil na Lei Geral de Proteção de Dados (Lei nº 13.709/2018). In: Rosenvald N, Dresch RFV, Wesendonck T. (eds.) Responsabilidade civil: novos riscos. Indaiatuba: Foco; 2019. p. 65-89.

125 See generally Dantas E, Nogaroli R. Consentimento informado do paciente frente às novas tecnologias da saúde (telemedicina, cirurgia robótica e inteligência artificial). *Lex*

Brazilian law including provisions for unnecessary consent for certain exceptional purposes–such as "protection of the life or physical safety of the holder or third party" (art. 11, II, "e," LGPD) and "protection of health, exclusively, in a procedure carried out by health professionals, health services or health authority" (art. 11, II," f ")–the LGPD expressly establishes the need for personal data processing activities to observe good faith and the principle of transparency (art. 6, caput, and VI, LGPD). Taking these into consideration, it seems to impose the recognition of the physician's duty to disclosure information to the patient about the treatment of his data, both regarding the purpose (e.g., insertion in Watson for Oncology) and the conservation of his (anonymized)[126] health data in cognitive technology after the end of the original treatment. This is the standard of conduct imposed on the professional, even in exceptional cases of unnecessary consent.

Therefore, given the scenario presented, there are two characteristic risks the physician needs to disclose to patients in the context of robotics and AI: the risk of a cyber-attack and the risk of a mismatch. In this sense, Flaviana Rampazzo Soares explains that the risks associated with new technologies must be disclosed to the patient.[127] The physician needs to disclose to patients that even the best healthcare technologies come with some risks of unpredictable events, inaccuracies, cyberattacks, systematic bias, and a particular type of mismatch between AI's implicit assumptions and an individual patient's background situation.

The current of technological advancements in health care, on one hand, can generate great benefits for the patient. On the other hand, it imposes new challenges related to the individual's human rights that should not be underestimated or neglected.[128] Consequently, the great challenge is to

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Medicinae - Revista Portuguesa de Direito da Saúde. 2020. 33 (1): 25-63. Kfouri Neto M, Guia Silva R, Nogaroli R. Inteligência artificial e big data no diagnóstico e tratamento da Covid-19 na América Latina: novos desafios à proteção de dados pessoais. *Direitos Fundamentais & Justiça*. 2020. [special edition]. 14(1): 149-178.

126 Anonymization is defined as data that must be processed in such a way that it can no longer possible to identify a natural person. Data anonymization is the process of de-identifying sensitive data while preserving its format and data type. (Raghunathan B. The complete book of data anonymization: from planning to implementation. Florida: Taylor & Francis Group; 2013. p. 4.

127 Soares FR. *Consentimento do paciente no direito médico: validade, interpretação e responsabilidade*. Indaiatuba: Foco; 2021. p. 175.

128 Magrani E. *Entre dados e robôs:* ética e privacidade na era da hiperconectividade. 2. ed. Porto Alegre: Arquipélago Editorial; 2019. p. 263

maintain all advances and impletions of new technologies in the healthcare sector without compromising its ethical and human side, reinforcing codes of medical ethics and data protection and privacy legislation in order to guarantee protection of patient privacy and self-determination.[129]

4. CONCLUDING NOTES: The New Model of Informed Consent in the AI-Driven Era of P4-Medicine

Scientific developments in robotics and artificial intelligence in medicine have revolutionized the healthcare sector. In this paper, we presented the great benefits of the AI-driven era of P4-Medicine (preventive, predictive, personalized and participatory). However, it was also possible to identify that new technologies do not eliminate the factor of unpredictability in medical treatment; on the contrary, advances in medicine can sometimes make diagnosis and therapy even more random. In this context, the patient's informed consent (read: free and clarified) acquires certain peculiarities, in view of the various specific factors and risks inherent to each technology. The current doctrine of informed consent demonstrates the importance of a dialogue process to ensure that the patient understands all the circumstances of the proposed treatment and the AI-based system used.

The physician needs to disclose to patients that even the best healthcare technologies come with some risks of cyberattacks, systematic bias, and a particular type of mismatch between AI's implicit assumptions and an individual patient's background situation. Furthermore, we hold that there are three different semantic dimensions of algorithmic opacity particularly relevant to medicine: (i) lack of disclosure; (ii) epistemic opacity; and (iii) explanatory opacity. Reasonable communication could mitigate this effect and be a precondition for objecting to fully automated processing and for requiring some form of human involvement in those activities. This would foster ideals of shared decision-making in medicine.

It is worth mentioning that it was not intended to establish in this paper that this whole process of dialogue—obtaining informed consent from the patient—is an easy task. Certainly, it is important to consider that some healthcare systems have a lot of problems: daily setbacks, medical professionals' lack of time, the inadequate capacity of the physical facilities of healthcare services, the inability of illiterate patients to understand the information or even want to receive it,

129 Doneda D. *Da privacidade à proteção de dados pessoais:* elementos da formação da Lei Geral de Proteção de Dados Pessoais. 2. ed. São Paulo: Revista dos Tribunais; 2019. p. 128-129.

the high demand for medical services, and the small number of professionals available. These are all factors that seem to justify and put in second (or third) place the adequate, transparent, and complete transmission of the information necessary to obtain consent through an *informed and clarified choice*.

However, to diminish the importance of this act—or rather, of this *process of obtaining consent*—is to expose doctors to too much unnecessary legal risk. It is necessary to be aware that the legal precepts regarding the duty to provide correct, complete, and adequate information. The patient's autonomy must be observed and respected. Ironically, after choosing the principle of autonomy as a pillar of informed consent, we realize that this alone is not enough to face a legal system that fails to promote the patient's personal values of individuality. To protect self-determination, we need to establish a system that allows patients to access information that is relevant to their personal values and beliefs, in order to allow them to make an informed and clarified decision.

In conclusion, we observed in this paper the need to review the current system of obtaining patients' informed consent, converting it truly into an *informed choice process*. It is necessary to counterbalance concepts that are apparently seemingly incompatible, such as the patient's right to autonomy and the prevalence of opinion and medical expertise. This is the first of many challenges nowadays. There is another challenge arising from the evolution of new technologies in the healthcare sector: doctors need to understand that the patient's right to receive complete information coverage (which corresponds to their duty to inform) also includes specific consent for the use of new technologies. This consent will be informed and clarified if it is based on patients' knowledge of AI-systems' particularities, such as their operation, objectives, advantages, costs, risks and alternatives. It is also a process of "informed conviction," much more laborious, but also much safer from the legal point of view, since it establishes not an act, but a process, which results in the concept of *shared responsibilities* between patient and doctor.

One of the greatest opportunities offered by AI is to restore the precious and time-honored connection and trust—*the human touch*—between patients and doctors. Eric Topol states that "not only would we have more time to come together, enabling far deeper communication and compassion, but also we would be able to revamp how we select and train doctors."[130] Even if AI

130 Topol E. Deep medicine: how artificial intelligence can make healthcare human again. New York: Basic Books; 2019. p. 18.

fulfills its promise of increasing efficiency and treatment personalization, it might not lead to improvements in the patient-clinician relationship. The link between successful implementation of AI in healthcare and maintaining or improving the patient-clinician relationship relies on several assumptions.

A healing patient-doctor relationship is formed by mutual trust, respect, and commitment. Maintaining these relationships is also essential in the context of AI-based systems. Without the trust that emanates from a healing relationship, patients can experience anxiety, frustration, and second-guessing. Given the importance of building and maintaining these relationships, the integration of emerging technologies into medical care should aim to promote rather than diminish the relationships between clinicians and patients.

These brief final reflections should be closed with the following thoughts of Bernard Nordlinger e Cédric Villani:

> "The road ahead is full of challenges, but the journey is worth it. The 'mechanical' medical doctor (MD) is certainly not for tomorrow and certainly not desirable. The doctor of the future should be 'augmented,' better equipped, and well informed to prevent, analyze, decide, and treat disease with empathy and the human touch. The aim will be to improve diagnoses, observations, therapeutic choices, and outcomes."[131]

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THE PHYSICIAN'S RIGHTS IN PARENTAL REFUSAL AS SURROGATE CONSENT TO PEDIATRIC PATIENT

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Abstract: Children are special legal subjects who need help from others to protect and defend their rights, including in the field of health care. Referring to the health legal system in Indonesia, a child who is under 18 years of age does not have the legal competence to give informed consent or informed refusal for the medical treatment that will be given to him or her. The authority to express the consent is transferred to the parents or family, the consent of which is called surrogate. However, there are still many cases in Indonesia where the surrogate consent statement does not cater for medical needs of the child, which in turn causes the death of or inflicts harm to the pediatric patient. This creates ethical and legal dilemmas for doctors who provide health services. Doctors have a legal obligation to respect the patient's autonomy rights through the mechanisms of informed consent and informed refusal. But on the other hand, doctors are also obliged to provide health services according to medical needs. These two obligations are not only recognized as legal obligations which, if violated, lead to legal consequences, but also as ethical ones that are bound to the medical profession. Based on the above facts, this study aims at searching for a philosophical ground for the need to limit the right to surrogate consent in interventions on children's health rights by strengthening the right of doctors in making medical decisions based on the child's best interest principle. Another aim of the study is the substantiation of the need for institutional protection of children

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health rights from the power of parents whenever it stands in conflict with the pediatric patient's medical needs. The final objective of this study is exploring legal ways to allow doctors to ignore the parents' informed consent / informed refusal based on the consideration of the pediatric patient's medical needs.

Keywords: Pediatric Patient; Doctor; Surrogate Consent; Informed Refusal; Medically Needs

I. INTRODUCTION

Indonesia is a constitutional state[1], and in a constitutional state, human rights are protected[2]. Health is part of human rights[3] and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in the Pancasila and the Preamble of the 1945 Constitution. Health is the basic right of every individual and citizen, as guaranteed in the 1945 Constitution which must be realized by efforts to improve the highest level of public health.

Recognition and protection of the right to health as part of human rights such as the above provides recognition of the right to health care as part of the rights of Indonesian citizens, whereas human rights, the right to health services must be protected and fulfilled by the State as stated in the 1945 Constitution.

Support for patient autonomy has led to a fundamental change in the pattern of relationships between doctors and patients in health care, from doctor-focused to patient-focused health services[4]. Abstract

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1 See The 1945 Constitution of the Republic of Indonesia and The Constitutional Court Act 2003 (Jakarta: Secretariat General, 2003). See Majda El Muhtaj,Hak Asasi Manusia dalam Konstitusi Indonesia (dari UUD 1945 sampai dengan Perubahaan UUD 1945 Tahun 2002), Jakarta : Kencana, p.17-18,2005.

2 Bahder Johan Nasution, Negara Hukum dan Hak Asasi Manusia,(Rules of Law and Human Rights); Mandar Maju, Bandung, p.10,2012.

3 Arrie Budhiartie, Disertasi Doktor : "Eksistensi Asas Kesetaraan Fungsi Dalam Pengembangan Figur Hukum Keperawatan, Upaya Mewujudkan Perawat sebagai Tenaga Kesehatan Profesional dalam Menyelenggarakan Pelayanan Keperawatan Altruistik yang Berkeadilan Profetik", (Disertation : The Existance of Function Equality Principle in Palembang : Universitas Sriwijaya,p.3-4,2017.

4 Dionisius Felenditi, Paternalisme dalam Tindakan Medis, Jurnal Biomedik, volume 2, number 3, p. 162-168, November 2010.

One manifestation of patient-focused care is a belief that the results of service to patients will be better if the right patient and family or those who are entitled to make decisions are involved in making service decisions and processes that are in line with expectations, values and culture. One of many attempts to get patients involved in decision making in the care process is by giving consent[5].

A patient must receive an explanation of the factors related to the care plan to be given before deciding to give his consent. This is called informed consent. The patient has the right to decide whether to give consent or refusal of a treatment. The patient's decision must be respected regardless of the doctor's belief that the treatment is appropriate and important for the patient concerned[6].

Protection to the patient's rights, especially for informed consent and informed refusal in Indonesia, is outlined in the trilogy of legislation in the health sector[7]. Protection of the rights of recipients of health services is regulated in the Medical Practice Act 2004, which states that patients in receiving services in medical practice, have the right to refuse medical treatment; the Health Act 2009, in the case that every person has the right to accept or refuse part or all of the relief measures that will be given to him after receiving and understanding information about such actions in full. The Hospital Act 2009 also regulates the patient's right to give consent or refuse actions to be taken by health provider for their illnesses; this informed consent is absolutely necessary because medical actions carried out without the patient's permission can be classified as battery. Furthermore, a medical action carried out by a doctor without the patient's permission, the doctor can blamed and prosecuted on the basis of a lawsuit[8].

The legal relationship between providers and recipients of health services also raises the obligations of service providers, as regulated in the Medical Practice Act 2004, which states that doctors or dentists in carrying out medical practices have an obligation to provide medical services in accordance with professional standards and operational procedure standards as well as the patient's medical

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5 Sutoto, Standar Nasional Akreditasi Rumah Sakit edisi 1, Komisi Akreditasi Rumah Sakit, Jakarta,2017,p.97.

6 Puteri Nemie Jahn Kassim, Law and Ethics relating to medical profession,3rd printed,International Law Book Services,Selangor Darul Ehsan,p.19,2016.

7 The trilogy of legislation in the health sector in Indonesia, namely Medical Practice Act 2004, Health Act 2009, Hospital Act 2009.

8 Rivian Yuris Ardani, "Pertanggungjawaban Perdata Dokter mengenai Tindakan Medis tanpa Informed Consent", Jurnal Hukum Fakultas Hukum Universitas Indonesia, Depok,2014.

needs. Likewise, the Health Act 2009 states that health providers who are authorized to administer health services must meet the provisions of the code of ethics, professional standards, the rights of health receiver, health service standards, and operational procedure standards. The obligation to administer health services in accordance with the standards and professional code of ethics and protection of the rights of patients, especially the right to consent or refuse to act against the disease to be carried out by health provider often cause conflicts of interest in daily practice.

Problems arise when the patient is incompetent and represented by his family. Is the principle of autonomy delegated to parents or guardians of incompetent patients also unlimited? A case of a 2-year-old child experiencing respiratory failure due to aspiration pneumonia (inflammation of the lung parenchyma, distal to the terminal bronchus, which includes respiratory bronchioles, and alveoli, as well as causing lung tissue consolidation and disruption of local gas exchange caused by foreign body aspiration both from inside the body and from outside the patient's body)[9] where the parents (after being given information about the patient's condition and medical action plan) refuse to do an intubation action (Endotracheal intubation is the act of inserting a tracheal tube into the trachea through the rhyme glottides by developing a cuff so that the distal tip is approximately in the middle of the trachea between the vocal cords and tracheal bifurcation)[10] for the safety of his life, but the refusal brings death to the patient. Many cases are found that medically require certain medical procedures which if performed medical measures it is believed (based on science) will bring improvement or healing to the patient, but the proposal is refused by the family, which then the rejection is fatal (disability or death). Decision making by family on these incompetent patients is possible because it is regulated in the Approval of Medical Action Regulation 2008 which states that the approval is given by competent patients or the closest family. This also confirmed the statement issued by the Indonesian Medical Association, that is, if the patient's age is less than 18 years, must obtain the approval of parents or guardians[11]. In reality in the field, doctors may not dare to do medical actions without the patient's permission (in this case, delegated family) because the

9 Marik.E.P.Aspiration Pneumonitis and Aspiration Pneumonia.N Engl J Med, vol 334, No.9.Texas tech University Health Science Center ; Massacussetts,p.94,2001.

10 See pasca anestesia, dalam petunjuk praktis anestesiologi, edisi kedua, bagian anastesiologi dan terapi intensif, FKUI, Jakarta, p.253-6,2002.

11 Dionisius Felenditi, Penegakan Otonomi Pasien melalui Persetujuan Tindakan Medis (Informed Consent), Jurnal Biomedik, Volume 1, Number 1, p. 29-40,2009.

act without permission is included in the category of battery that is included in the criminal sphere. In civil terms, the adagium "volenti non fit inura", which means that someone who already knows the risks and will also be willing to bear them if they arise, cannot then file another lawsuit, cause doctors and hospitals to feel safe and do not want to dispute the informed refusal, despite knowing that the informed refusal will cause the patient to experience disability and even death. This action actually violates the Human Rights Act, which states that every child has the right to obtain proper health services according to his physical and mental spiritual needs. Every child has the right to be raised, nurtured, cared for, be guided by the life of his parents or guardians until adulthood. The child's rights at the same time give birth to obligations for each parent or guardian to carry out obligations as a real parent.

A desire to protect and respect the patient's autonomous rights often negates the patient's autonomous rights by surrendering fully without limitations to the family. Any decision to be imposed on the patient is entirely in the hands of his family. This is precisely different from what is applied in western countries. European countries such as France and Italy[12], in the case of refusing blood transfusions caused by reasons of the belief of the Jehovah's witnesses for example, does not necessarily follow the wishes of a family, especially in child patients. It is said that children over 12 years of age can give consent for their own medical treatment without the help of a parent or guardian. On the other hand, for children under 12 years old, parents or guardians may not refuse blood transfusions that will be given to their children only for reasons of belief or religion, unless they can show an alternative that is acceptable to the medical[13].

The problem of informed refusal taken by the surrogate or proxy consent as a manifestation of the patient's autonomy rights that cause disability or death of the patient actually brings a conflict between legally and empirical facts. At the normative level, there is a mismatch between the applied of legal norms with the applied of medical ethics principles, are the application of the principle of unlimited autonomy by family (be as surrogate consent) with the principle of therapeutic goals (the principle of beneficence). On one hand Article 23 of the

12 Carlo Petrini, Ethical and legal aspects of refusal of blood transfusions by Jehovah's Witnesses, with particular reference to Italy, NCBI, USA, 12 januari 2014.

13 Nicola Caine. "The challenges of treating Jehovah's witnesses",2014.[Online] Available : https://www.medicalprotection.org/southafrica/casebook/casebook-may-2014/the-challenges-of-treating-jehovah's-witnesses.

Health Act 2009 requires aspects of patient safety as a benchmark for health services by prioritizing medical and non-discriminatory indications in the best interests of patients and in accordance with medical indications, Article 24 of the Health Act 2009 and Article 51 of the Medical Practice Act 2004 also state that health provider (including doctors) must meet the provisions of the code of ethics, professional standards, the rights of users of health services, service standards and standard operating procedures. But on the other hand, Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in which regulates the patient's right (without limits) to give consent or refuse actions to be taken against him, including the rights of parents or guardians to patients who are not competent, this often creates conflict in the practice of health services in hospitals.

There are no restrictions on the rights of patients in Indonesia as stipulated in Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in giving consent or refusing actions to be taken against him, including when those rights are delegated to parents and guardians due to incompetent patients (for example because the age is less than 18 years) causes a lot of disability and deaths that can actually be prevented. The responsibility of the Indonesian state as a constitutional state which is obliged to protect the rights of its citizens to health as mandated in Article 28 of the 1945 Constitution. Recognition that the right to health is part of universal human rights stated in the general explanation of the Health Act 2009 has given the responsibility of the government/state to realize this[14]. This unrestricted right has the potential to violate the human rights of others. The patient's autonomy rights (including by family) should be limited in accordance with human rights arrangements in Indonesia that every human rights of a person creates a basic obligation and responsibility to respect the rights of others reciprocally, and it is the duty of the government to respect, protect, uphold and promote it.

There is a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle) and the conflict between the value of individual freedom and the value of benefits (social) at the level of values, as well as the existence of vague norms, especially in regulating the patient's consent-refusal rights (including family) require comprehensive and integrated legal study. The right of child to health and the right to health care service create the obligation for parents, doctors and the state to protect those rights.

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14 Arrie Budhiartie and Elizabeth Siregar,Perlindungan Hukum Hak-Hak Pasien dalam Transaksi Terapeutik, Majalah Hukum Forum Akademika, p. 178.

In the therapeutic relationship between the doctor and the child as a patient represented by the parent, the basic rights of the child give rise to the doctor's right to struggle for the child's rights when there is a disagreement between the parent and the doctor that has the potential to endanger the child's safety.

Based on the descriptions above and challenges that might be hold, encourage this scientific writing with the title: The Physician's Rights in Parental Refusal as Surrogate Consent to Pediatric Patient

RESEARCH METHOD

This legal research had used a statutory approach that is supported by a conceptual and comparative approach with the United Kingdom and the Netherlands in the application of Informed Refusal involving the paediatric patient in medical care. As legal research, it will describe the ambiguous norms that have the potential to cause multiple interpretations and cause legal problems in the practice of medical services.

There are no restrictions on rights as stipulated in Hospital Act 2009, in giving approval or refusing actions to be taken against him, including when those rights are delegated to parents and guardians because of incompetent patients causes a lot of disability, and deaths can be prevented. This unrestricted right has the potential to violate children's rights as regulated in the Human Rights Act and the Child Protection Act.

FINDINGS AND DISCUSSION

It is well established in Indonesian health law system that a doctor must get informed consent from the patient or the other party who get the authority on it, A competent person has a constitutionally protected right in refusing unwanted medical treatment. The right to refuse treatment and grant informed consent does not disappear for individuals who are incompetent. Rather the right is one that must be exercised for them[15]. Under Indonesia law, minors are generally considered incompetent to provide legally binding consent regarding their parents were generally empowered to make those decisions on their behalf, and the law has respected those decisions.

15 Cruzan v. Director, Missouri Department of Health, US 497: 261 (1990).

Article 13 of the Approval of Medical Treatment Regulation as a follow-up to the Medical Practice Act and Article 37 of the Hospital Act gives the patient or surrogate equal status as the party who has the authority to exercise patient autonomy in the form of refusal or approval of proposed medical interventions. The use of the word "or" in the second formulation of the article means that the family can replace the patient in making decisions in medical care. The two regulations never stipulate what qualifications must be met before the family can be involved in making the decision. This was also confirmed by a statement issued by the Executive Board of the Indonesian Doctors Association that is, if the patient is less than 18 years old, he must obtain the approval of a parent or guardian. Without a qualification regarding the terms of involvement of the family in making medical decisions, this has the potential to violate the patient's autonomy itself (in this case, pediatric patients). Specifically, the Approval of Medical Action regulation regulates the refusal of medical measures, including: "Refusal of medical action can be done by the patient and/or his immediate family after receiving an explanation of the medical action to be performed".

Regulation in Indonesia has not created a balance against efforts to protect patient autonomy when patients lack competence yet. Legal efforts to protect the interests of pediatric patients in upholding the principle of autonomy become important when there is a conflict between the will of the family with the proposed medical treatment from the health service provider. There is no regulation of which party is responsible for supervising medical decisions made by parents/family when the medical decisions are detrimental to pediatric patients. Indonesian health law system does not provide an opportunity for doctors to be involved in overseeing the use of the principle of autonomy for parties outside the patient in the event that the outside party makes a medical decision that does not reflect the patient's best interests or is contrary to the provision of good medical services.

Role of family in Decision Making Process in Indonesia

The discourse of human rights and bioethics in Asia, establishes the family as the central unit of autonomous rationality. The family plays a greater role in Asian contexts (including Indonesia) than would be found, for example, in Northern Europe[16]. The Asian values discourse is ideologically tied to an

16 Addlakha, Renu, et all. *Family Autonomy and Patient Rights to Healthcare in an 'Asian Values' Context*, Folk: Journal of Danish Ethnographic Society,vol.45, p.87-104,2003.

outdated notion of culture as essence, tied to place and determining action. In the triangle of physician, patient and relative, the patient is usually the weakest, whereas the dynamic power structure between the other two actors is intensely negotiated to determine the course of action. In this process, the role of the family is important.

The family remains factually important because it more often than not has to find the resources to pay for medicine and medical investigations, and because the patient is dependent on family support before, during and after treatment. There are several good reasons for this presumption to respect parental autonomy and family privacy[17]. First, because most parents care about their children, they will usually be better situated than others to understand the unique needs of their children, desire what is best for their children, and make decisions that are beneficial to their children. Second, the interests of family members may sometimes conflict, and some family members may be subject to harms as a consequence of certain decisions. Parents are often better situated than others outside of the family to weigh the competing interests of family members in making a final decision. Third, parents should be permitted to raise their children according to their own chosen standards and values and to transmit those to their children. Finally, in order for family relationships to flourish, the family must have sufficient space and freedom from intrusion by others.

For all of these reasons, one must begin with the assumption that parents are the party best suited and most inclined to act in the best interests of their children[18], and that in most cases, they will do so[19]. In most situations, parents are given wide latitude in terms of the decisions they make on behalf of their children[20].

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17 Joseph Goldstein, "Medical Care for the Child at Risk: On State Supervision of Parental Autonomy," in Who Speaks for the Child: The Problems ofProxy Consent, eds. Willard Gaylin and Ruth Macklin (New York: Plenum Press, 1982),pp. 153–190, here pp. 158–162.

18 Kenneth A. DeVille and Loretta M. Kopelman, "Fetal Protection in Wisconsin's Revised Child Abuse Law: Right Goal, Wrong Remedy," Journal ofLaw, Medicine,and Ethics 27 (1999): 335.

19 Christine M. Hanisco, "Acknowledging the Hypocrisy: Granting Minors the Right to Choose Their Medical Treatment," New York Law School Journal of Human Rights 16 (2000): 904.

20 Ibid., see also Newmark v. Williams, Del Super Ct 588: A.2d 1108 (1991).

The intrinsically Western notion and promotion of the individual as the center of decision-making, which is the basis for the concept of patient autonomy, is not necessarily universally meaningful, possible or desirable, and that grounded explorations are required to guide a bioethics discourse that is often naïvely ethnocentric, but the straightforward acceptance of family autonomy as a normative bioethical principle may be repressive, dangerous and against the interests of the patient.

Beneficence versus Autonomy Principles in Informed Refusal by Surrogate Consent

There is a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle) and the conflict between the value of individual freedom and the value of benefits (social) at the level of value in the application of unlimited informed refusal by a family in pediatric patients requiring ontological, epistemological and axiological studies of the existence of informed refusal by the parent or guardian of the pediatric patient. What is the true nature and purpose of the existence of informed refusal by parents or guardians in pediatric patients? Why does the existence of unlimited refusal informed by the family have the potential to violate the rights of the child concerned?

Informed refusal exists because of the realization of the patient's autonomy rights. The term autonomy comes from Greek, which is "autos" which means self and "nomos" which means rule, governance, or law[21]. Jhon Stuart Mill defines autonomy as liberty, that is, the sovereignty of the individual over his body and mind[22]. According to Ruth R.Faden and Tom L. Beauchamps, autonomy is rooted in a liberal western tradition that emphasizes the importance of individual freedom and freedom of choice[23]. In the context of legal rights, Ruth R.Faden and Tom L. Beauchamps categorize patient autonomy as a personal right that respects aspects of self-determination. In the world of health services, patient autonomy which is also often referred to as the right to self-determination (The Right of Self Determination) is a basic right or primary right in the health sector. The autonomy rights of these patients come from

21 Tom L.Beauchamp and James F.Childress, *Principle of Biomedical Ethics*, Fourth Editio, Oxford University Press,Oxford,p.120,1994.

22 Jhon Stuart Mills, On Liberty dalam buku Bio Ethics An Anthology Second edition, edited by Helga Kuhse and Peter Singer, Blackwell Publishing,p.621.

23 Ruth R.Faden and Tom L.Beauchamps *in collaboration with* Nancy M.P.King, *A History and Theory of Informed Consent,* Oxford University Press, New York,p.7, 1986.

human rights, which then give birth to the right to informed consent and the right to Informed Refusal. Patient autonomy is the main goal of explaining the doctrine of informed consent.

The fact that the practice of health services that promotes the principle of patient autonomy as part of human rights and is even seen as part of justice raises the question of which principle of autonomy will be applied? In situations where the patient does not have the competence because he is a child, it requires the will of the family or person who supervises the child. The problem of informed refusal in pediatric patients by surrogate consent as a manifestation of the patient's autonomy rights that cause disability or death of the pediatric patient brings a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle). Beauchamps associates this beneficence element with non-maleficence elements, namely the obligation to perform the best medical action in the best interests of patients. The benefit element is also seen as a form of obligation for doctors / medical service providers in order to maintain and respect human dignity (patients). On the one hand, The Health Act 2009 requires patient safety aspects as a benchmark for health services by prioritizing medical and non-discriminatory indications in the best interests of patients and in accordance with medical indications, Health Act 2009 and Medical Practice Act 2004 also states that health provider (including doctors) must meet the provisions of the code ethics, professional standards, user rights for health services, service standards and operational procedure standards. But on the other hand, Hospital Act 2009, in which regulates the patient's right (without limits) to give consent or refuse actions to be taken against him, including the rights of parents or guardians to patients who are not competent. This often creates conflict in the practice of health services in hospitals. The desire to protect and respect the patient's autonomous rights that occur at this time often actually negates the patient's autonomous rights by surrendering completely without restrictions to the family, every decision to be imposed on the patient is entirely in the hands of the family.

From the perspective of utilitarianism, where the moral value of an action is determined by the consequences of that action, it can be analyzed that unlimited informed refusal by a family that has the potential to endanger lives or cause disability violates the moral rules. Perspective Deontology, where the moral quality of an action is determined by the right or duty, actually the duty of the family to protect (and not just replace) the autonomy rights of the child patient. Likewise, with doctors, who have the task of reducing suffering or prolonging the lives of their patients (as a manifestation of the principle of beneficence.

The medical profession has its own autonomous nature, which has a certain value system that binds the behavior of doctors, both fellow colleagues and members of the community. The value system had brought to medical ethics up. The basic ethics of the medical profession are derived from the time of Hippocrates: "The health of the sufferer will always be my priority" (The health of my patient will be my first consideration) remains a principle that has never changed, and is a series of words that unites the doctors in the world[24]. In relation to patient consent, Besides the principle of respecting patient autonomy, doctors are also bound by the principle of beneficence (The Principle of Beneficence means that all actions taken by a doctor against a patient must benefit the patient in order to reduce suffering or prolong his life) and the principle of justice (The principle of Justice means that doctors must act fairly, do not look at position, do not look at wealth and are impartial in treating patients). Under certain conditions, the two principles serve as a philosophical basis for helping patients, such as in emergencies and unconscious patients, doctors do not need to wait for informed consent to immediately take action that is necessary for the safety of the patient's life (saving life). The basis of the consideration is that medical measures are taken because they are solely to help the soul. Saving the patient's life is of higher importance than the issue of informed consent. This shows how the doctor in deciding patients who are unconscious and in a state of danger (for example, the patient has severe and unconscious bleeding), it is important for him to question and consider whether the patient will agree with actions to be taken if he is conscious (e.g. giving a blood transfusion). If there is a reason for this, then this fact becomes important in justifying such actions (giving blood transfusions to patients with severe bleeding) even when patients later, perhaps for reasons of belief and religion, blame and prosecute doctors for having performed the blood transfusion procedure[25].

Efforts to protect the interests of patients in upholding the principle of autonomy become important when there is a disagreement between parents or guardians of children and the medical team that treats these patients. The principle of beneficence in medical practice, one of which is manifested in the evidence-based medicine approach (Evidence based medicine (EBM)[26] is the integration

24 R.hariadi. *Dasar-Dasar Etik Kedokteran. Dalam* : *Sajid Darmadipura.ed. Kajian Bioetik 2005*.Unit Bioetik Fakultas Kedokteran Universitas Airlangga, Surabaya,p.6,2005.

25 Ronald Dworkin, *Taking Rights Seriously*, Harvard University Press, Cambridge, Massachusetts, p 152,1978.

26 Sackett,D, *Evidence-Based Medicine:How to Practice and Teach EBM*, 2nd edition, Churcill Livingstone, 2000.

of scientific evidence in the form of the best research results with the clinical ability of doctors and patient preferences in the decision-making process of medical services) in providing medical care to evidence-based patients (Evidence-based health care is health care for an individual by using the best current evidence in making clinical decisions. The best current evidence is to update information from valid and relevant research on the effects of sharing forms of health care)[27]. The application of EBM that results in evidence-based medical care is an effort to fulfill the principle of beneficence to patients. In application in the field, often the principle of beneficence is difficult to apply because it is prevented from an informed refusal conducted by parents or guardians as the implementation of unlimited delegation of authority to parents or guardians in making the decision on the pediatric patient. The principle of beneficence in pediatric patient health services is prioritized, not as an effort to kill the principle of respecting the autonomy of the pediatric patient, but the principle of beneficence is put forward to restore and maintain the autonomy rights of pediatric patients that have not yet had the competence until the child reaches maturity and has the right of full autonomy to be able to make his own decisions as part of the right to determine his own destiny[28]. If a child dies or has a disability due to medical treatment in accordance with his best interests cannot be given due to barrier of his parents' or guardian's refusal, then the child's death or disability has wasted the child's opportunity to have full autonomy rights as a competent individual in later. The principle of beneficence must be present to restore and maintain the autonomy of these pediatric patients so that the child may be able to grow and develop as they should reach competent and autonomous adult individuals.

The application of unlimited refusal informed by parents or guardians in pediatric patients has also violated the principle of justice, where children cannot get access to quality health services as obtained by adult patients. The law must be present to provide protection for the rights of children who have been harmed by another party as a form of legal protection[29].

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27 see Evidence based Medicine and Practice. http://www.omicsonline.org/evidence-based-medicine-practice.php

28 Marc Stauch dan Kay Wheat, *Text, Cases and Materials on Medical Law and Ethics*, sixth edition, London : Routledge, p. 33, 2019.

29 Zahir Rusyad, *.Hukum Perlindungan Pasien-Konsep Perlindungan Hukum terhadap Pasien dalam Pemenuhan Hak Kesehatan oleh Dokter dan Rumah Sakit*.Malang : Setara Press.2018.

Comparison of Informed Refusal Regulation in Pediatric Patients between Indonesia and Netherland (Civil Law System)

N.B.W. regulates qualification terms and conditions related to enforcement of patient autonomy between ages before 12 years, 12 to 16 years, and 16 years and above. Based on Article 7: 465 par. 5 and Article 7: 450 par. 2 N.B.W, from the age of 12 to the age of 16, patients can be considered competent. Competence at that age is limited to that age and is considered to have competence as long as it is able to properly consider and appreciate its interests. The basis used is to assess competence at that age is the suitability of the actions of patients at that age with the standard of providing good medical services. If a patient of that age commits an action that is contrary to the provision of good medical services, the medical service provider can represent the patient in carrying out his competence[30]. Based on the arrangement in N.B.W., patients who are 16 years old are essentially competent in order to declare their will in medical care. Every adult has the capacity to determine his destiny.

In situations where the patient does not have the competence because he is a child, it requires the will of the family or person who supervises the child. This need is not absolute if the will of the family or the person supervising is contrary to the provision of good medical services or to prevent more serious consequences for the patient, the medical service provider can perform medical treatment without the consent of the family or supervisor. This can only be done by a medical service provider if medical treatment for the child is intended to prevent serious consequences for the patient. In addition, medical service providers can also ignore the will of the patient's family, who is not yet old enough if the will of the family or the child's supervisor is against the provision of good medical services. This was also used by the Netherland in arranging medical care contracts in hospitals as regulated in Article 7: 465 par. 4 N.B.W.

In patients who have limited competence (N.B.W. applies to patients who are aged 12 to less than 16 years), medical care for patients also requires the will of the family or supervisor of the child. This is not absolute. In patients like this, medical service providers must also involve the patient in making decisions. If the patient's will is contrary to the will of the family or the supervisor, the medical service provider can ignore the will of the family and follow the patient's will for several reasons. First, the actions of medical service

30 Eko Pujiono, *Keadilan dalam Perawatan Medis (Penerapan Prinsip Otonomi Pasien : Teori Hukum & Praktik di Pengadilan,* Penerbit PT Citra Aditya Bakti, Bandung,p.78,2017.

providers in order to prevent serious consequences for patients. Second, the patient wants medical treatment, and his decision does not conflict with the provision of good medical services. Third, the patient does not have the ability to appropriately appreciate the best interests, while the family has stated its will, which is contrary to the provision of good medical services. This can be seen from the arrangements in Article 7: 465 par.2 jo.par.4 and Article 7: 450 par.2 N.B.W.

In the Netherlands, based on Article 7: 450 par. 2 N.B.W., the position of parents does not absolutely replace the autonomy rights of children aged between 12 and before 16 years. The rights of these parents depend on the best interests of the patient. The doctor also has a legal interest to determine the patient at that age. That is part of good medical practice. In patients who have reached the age of 12 years and have not reached 16 years, there is an obligation to also involve the patient in making decisions as much as possible. However, at that age, there are some people who can represent their legal interests, namely their parents or those who legally guard it (regulated in article 7: 450 par. 2 N.B.W.). In addition, the party representing them can also be the party whose support or person is appointed as their advisor in relation to their autonomy in medical care, as formulated in Article 7: 465 par. 2 N.B.W. The authority to represent is not absolute. The medical service provider may waive their legal authority to declare their will if there are serious consequences that will arise if not handled or medical refusal from the party concerned will bring serious consequences to patients and their actions are contrary to the provision of good medical services, as stipulated in Article 7: 465 par. 6 N.B.W, Article 7: 450 par. 2 N.B.W and Article 7: 450 par. 4 N.B.W.

In the Netherlands, in pediatric patients aged 0 to before 12 years, there is no involvement of the child's role in decision making. The person responsible for representing his legal interests is the parent who is responsible for the child or the person who looks after the child. This is confirmed in Article 7: 465 par. 1 N.B.W. The rights of these people are not absolute. There are situations in which medical service providers do not need to ask the will of the parents or the person looking after the child, which is to prevent serious pain in the patient. In pediatric patients aged 0 to less than 16 years, medical service providers can be legal representatives in making decisions and ignore the wishes of the child's parents or their representatives if the actions carried out by parents or their representatives are contrary to the standards of providing good medical services. , as affirmed Article 7: 465 par. 4 N.B.W. In pediatric patients aged 0 to less than 12 years, it is not necessary to involve the child in making medical decisions, as regulated in Article 7: 465 par. 5 N.B.W.

Comparison of Informed Refusal Law in Pediatric Patients with United Kingdom Law (Common Law System)

According to the Family Law (Reform) Act 1969 states that children are anyone under the age of 18 years. The law effectively divides pediatric patients into 3 main categories when deciding whether they meet the capacity requirements to provide legal approval, namely Children 16-18 years old, Children under 16 who are Gillick-competent, Children under 16 years who are not Gillick-competent[31].

Children aged 16-18 years: In England and Wales, the 8th Family Law (Reform) Act of 1969 states that:

'8(1) – The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian[32].

Thus, pediatric patients older than 16 years but younger than 18 years are considered to have sufficient capacity to provide treatment approval. Children under the age of 16 who are not Gillick-competent (in children who do not have sufficient maturity, intelligence and understanding), they cannot give legal approval.

In the case of Re R (a minor) [1993] 2 FLR 757, a child aged ten months was suffering from B-cell lymphoblastic leukemia. Her doctors considered that she needed treatment over the next two years, which could involve blood transfusions at any time. Her parents were practicing Jehovah's Witnesses with their beliefs preventing them from consenting to such treatment. An application by the local authority was obtained to authorise the use of blood products against the parents' wishes. The parents were concerned that any order made should not give the doctors blanket authority to act without consulting them. The court held that the child's need for blood was so overwhelming that for her welfare, the parents' wishes had to be overridden, and the use of blood products authorized. To overcome the parents' fear, the court phrased the order that in imminently life-threatening situations, the child should be given

31 Family Law (Reform) Act 1969 sect 1.
32 Law Reform Act 1969 sect 8 (1).

blood products without the consent of the parents, but otherwise, the doctors should consult with the parents and consider other options only if there was no reasonable alternative should the doctors be at liberty to administer blood products without the parents' consent following the above Re R case, you may proceed with blood transfusion only if you believe there are no other reasonable alternative to save the child's life[33].

Handling of pediatric patients where there is a disagreement between parents and the medical team: in the United Kingdom as stipulated in the case of Re B (A Minor) (Wardship: Medical Treatment) [1990] 3 All ER 92, the court's decision considers the welfare of children as the most important consideration, although the wishes of parents are taken into consideration. The court puts forward the best interests of the child[34].

Limitation of Informed Refusal by Surrogate Consent in Pediatric Patient

State intervention is justified not only when a parental refusal is contrary to a child's best interest, but also when the parental refusal places the child at significant risk of serious preventable harm. This article takes as its point of departure the best interest (positively), and harm principles (negatively) concomitantly provides a stronger and comprehensive basis as a threshold for state intervention.

Threshold for Intervention: Best Interest

Parental authority is not absolute, however, and when a parent acts contrary to the best interest of a child, the state may intervene[35]. The doctrine of parens patriae holds that the state may act as ''surrogate parent'' when necessary to protect the life and health of those who cannot take care of themselves, including children[36,37].

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33 Catherine Tay and Leslie Tay, *Medico-Legal and Ethical Issues in Cardiology and General Medicine : Case Scenarios,* McGraw-Hill Education (Asia),p.39-41,2010.

34 Claudia Carr, *Unlocking Medical Law and Ethics 2nd* Edition,Routledge, New York, p.184, 2015.

35 Lainie Friedman Ross, Children, Families, and Health Care Decision-Making (New York: Oxford University Press), p. 135, 1998.

36 Yolanda V. Vorys, ''The Outer Limits of Parental Autonomy: Withholding Medical Treatment from Children,'' Ohio State Law Journal 42 : 815–816, 1981.

37 Kathleen Knepper, ''Withholding Medical Treatment from Infants: When Is It Child Neglect?'' University of Louisville Journal of Family Law 33: 1–2,1994.

Brock and Buchanan define best interest as ‘‘acting so as to pro-mote maximally the good of the individual.’’[38] Beauchamp and Childress define the best interest standard as one in which ‘‘.. .a surrogate decision maker must determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs.’’[39] the standard requires the surrogate to act so as to always make the decision most favorable to the child.

In pediatric patients, autonomy does not automatically become an absolute right of parents. Vivienne Harpwood believes that the basis for making medical decisions in order to represent pediatric patients must be based on the child’s best interests[40]. Irresponsible medical decisions on the part of parents who consciously ignore the child’s medical needs are a form of crime. In the Common Law system, this is reflected in the judge’s decision in the case R v. Sheppard[41] (In the case of R c. Sheppard, parents of 16-month-old babies who die from hypothermia with malnutrition. The basis of the accusation, in that case, was the negligence committed by Sheppard which resulted in the baby-Martin Sheppard- becoming a victim and suffering. Under the law, their actions take the form of negligence (omission), which is failing to provide something appropriate for the baby’s needs) and Gillick v. West Norfolk and Wisbech Area Health Authority [1986]. Parental status carries the consequences of parental responsibility for the children under their authority. The act of representing the child patient is part of the responsibility of being a parent to the child for the child’s benefit. In the case of R v. Sheppard, F v. West Berkshire Health Authority, R v. Harris and another, and Gillick v West Norfolk and Wisbech AHA and another, the position of the doctor representing the child in making medical decisions should not be understood as an attempt to take over the responsibilities of parents and children’s affairs. In principle, parents and doctors have the right to protect the best interests of the child patient.

The nature of interests is frequently complex. Although medical considerations are important, a child’s interests will also be affected by emotional and physical accompaniments of the chosen course. Best interests, all too often, may be

38 Allen E. Buchanan and Dan W. Brock, Deciding for Others: The Ethics of Sur- rogate Decision-Making (New York: Cambridge University Press),pp.88, 1990.

39 Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 5th edition (New York: Oxford), pp. 102,2001.

40 Vivienne Harpwood, Vivienne Harpwood. *Legal Issues in Obstetrics*.USA : Darmouth Brookfield, p.88, 1996.

41 Jo.Bridgeman, *Parental Responsibility, Young Children and Health care Law*, Cambridge University Press, New York, p. 86-7,2007.

reduced to objective medical interests alone[42]. According to Jo Bridgeman, to assess the best interests of patients is not based solely on medical measures but also combines medical interests, emotions and other aspects of well-being, namely whether the proposed medical treatment brings benefits to children emotionally, psychologically, and socially. Such construction can be used to control good medical decision making in pediatric patients. The best interests in the child's medical care should not overlap with the parents' legal responsibilities to the child. The position of parents or guardians cannot replace the patient's right to autonomy.

Circumstances where the family refuse an action and the hospital and the care giver feel safe and do not make an issue of informed refusal to the pediatric patient may provide teleological or consequentialist justification. Justification that bases on the results it brings benefits or kindness to as many people as possible (the greatest good for the greatest number of people) but sacrifices the best interests of the child. This is unacceptable for a deontologist who holds that the devolution of authority to parents or guardian in pediatric patients is not to sacrifice the best interests of patients, it is the obligation of the parent or guardian of the child to protect and ensure that the best interests of patients should be the main consideration. This view requires all parties to play a role in ensuring that children get their rights to get health services best. Parents or guardians protect the best interests of children through the delegation of authority given, the care giver oversees the decision given by the parent or guardian whether it is in the best interests of the child, so this is in accordance with the pattern of service focusing on patients, not other parties.

The application of informed consent and informed refusal as the implementation of the patient's autonomy rights is very closely related to how the concept of Human Rights is the basis. The view of the Indonesian nation about human rights that human beings as God's creatures bear the aspects of individuality and aspects of sociality should animate the formation and implementation of Informed Refusal related to children in Indonesia. In its application in the Pancasila-based country of Indonesia, the autonomy rights of patients contained in the Informed Refusal by the family when the patient is not competent, must continue to recognize and respect human rights but must also be limited and adjusted to the values contained in Pancasila.

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42 Douglas S. Diekema, *Parental Refusals Of Medical Treatment: The Harm Principle As Threshold For State Intervention*, Teoretical Medicine Journal, pp.243-264.2004.

Threshold for Intervention: Harm Principle

State intervention is justified not only because a decision is contrary to the child's best interest but also because it places the child at significant risk of serious harm. In the medical setting, courts have frequently placed a high burden on the state to show that medical treatment is necessary before compelling treatment over parental objections, and the state is most likely to interfere with a parent's decision when the child is suffering from a serious and potentially life-threatening illness or injury that can be readily managed with medical treatment. The state must establish that parental choices endanger the child and thus fall below the acceptable threshold[43]. In these cases, the state acts in loco parentis, in the place of the parents.

In general, courts have gone against parents when the life of a child is endangered but have typically given great discretion to parents in situations that are not imminently life-threatening[44]. Having identified the harm principle as a basis for state action, the next step is to further define the harm threshold by identifying the level of harm to be tolerated in parental decisions. It seems clear that not all harms should trigger state intervention. Several of these have further refined the definition of serious harm to include loss of life, loss of health, loss of some other major interest, and the deprivation of basic needs[45].

Defines the harm threshold for state intervention:

First, the parental decision to deny treatment will place the child at significant risk of serious preventable harm[46].

Second, the harm standard requires that the harm be imminent, requiring immediate action to prevent it.[47] When a parental refusal does not place a child imminently at significant risk of serious harm, state intervention should be postponed and attempts made to work with the child's parents or guardians in a

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43 H.D. Krause, Family Law in a Nutshell, 2nd edition, (St. Paul, Minnesota: West Publishing Co, 1986).

44 Angela Holder, "Circumstances Warranting Court-Ordered Medical Treatmentof Minors," 24 POF 2d : 175–177,1980.

45 Richard B. Miller, Children, Ethics, and Modern Medicine (Bloomington, IN: Indiana University Press), pp. 118–145,2003.

46 F.M. Hodges, J.S. Svoboda, and R.S. Van Howe, "Prophylactic Interventions on Children: Balancing Human Rights with Public Health," Journal of Medical Ethics 28: 10,2002.

47 Ferdinand Schoeman, "Parental Discretion and Children's Rights: Background and Implications for Medical Decision-Making," The Journal of Medicine and Phi-losophy 10: 32, 1985.

non-confrontative manner to resolve the issue. Rather, state intervention should require that there be expert consensus, ideally supported by sound evidence, that interference with the parental decision and the provision of treatment has a high probability of being successful [48].

Third, For state action to be justifiable, interference with the parental decision must offer net benefit to the child.[49] The harm prevented must be more substantial than the harm that will result by interfering with parental choice.

Fourth, the extent of state intervention and the treatment allowed under the authority of the state should represent the least intrusive alternative that will reduce harm to the child and minimize the impact on parental authority. Most of the time, removal of the child from the home will not be necessary and should not be contemplated unless every other possibility has been considered.

Fifth, the pursuit of state intervention must be generalizable and impartial in the sense that all similar cases would also result in state intervention. The decision to seek state intervention should not be influenced by morally irrelevant considerations (i.e., the religious nature of the decision). For example, state intervention in the case of refusal to consent to a blood transfusion is justified not because the parental refusal has a religious basis but because the parents are refusing a potentially life-saving therapy that meets the conditions above. A parent's reason for the decision should not be a factor in whether state intervention is sought. Rather, the likely outcome of their decision is the only relevant factor: is it likely to result in serious harm to a child.

Physicians' Rights in Parental Refusal in Pediatric Patients

The doctor-patient relationship is an engagement called a therapeutic agreement. The definition of a therapeutic agreement is an agreement between a doctor and a patient, which places the patient as the party that gives authority to the doctor to make health service efforts based on the expertise and skills possessed by the doctor. There are specificities in the therapeutic agreement when compared to the agreement in general, including the object of the therapeutic agreement in the form of professional medical action characterized by the provision of assistance; and The purpose of the agreement is an effort

48 Joseph Goldstein, Anna Freud, and Albert J. Solnit, Before the Best Interests of the Child (New York: Free Press, 1979).

49 Sanford Leikin, "A Proposal Concerning Decisions to Forgo Life-Sustaining Treatment for Young People," The Journal of Pediatrics 115: 18, 1989.

to maintain and improve health which includes activities to improve health (promotive), prevention (preventive), healing (curative), and recovery (rehabilitative). Theoretically conceptually, between professional groups and the general public, there is a social contract, which gives the professional group the right to self-regulate (professional autonomy) with the obligation to guarantee that the practicing professionals are only competent professionals and who carry out their professional practices according to standards[50].

In providing services to children as incompetent patients, consent to medical action is left to the parents with the assumption that parents are the persons best suited and most inclined to act in the best interests of their children. But when there is a disagreement between the parents and the doctor regarding the medical action to be given to the child, where the parental refusal has the potential to endanger the child's life or cause disability, then The right to health and the right to health care for child patients, creates an obligation for parents, doctors and the state to protect it. In the therapeutic relationship between the doctor and the child patient represented by the parent, the basic rights of the child give rise to the doctor's right to fight for the child's rights. Doctors can be given the right to supervise the application of consent to pediatric patients' medical actions by their parents. Are medical decisions made in the best interests of the child and fulfill the harm principle? If not, then the doctor has the right to submit a proposal to the court for permission to perform medical procedures without parental consent in the best interest of the child.

II. CONCLUSION

The problem of informed refusal in pediatric patients by Surrogate Consent as a manifestation of the patient's autonomy rights that cause disability or death of the pediatric patient brings a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle). Efforts to protect the interests of patients in upholding the principle of autonomy become important when there is a disagreement between the parents or guardians of children and the medical team that handles these patients. however, the principle of beneficence is prioritized to restore and maintain the autonomy of these pediatric patients, so that the child may be able to grow and develop as they should reach competent and autonomous adult individuals. The position of the parent or guardian does not replace the patient's right to autonomy but

50 Cruess SR et.al., MJA 2002 177 (4) : 208-211.

ensures and safeguards that the child will get services based on the child's best interests as part of the parents' responsibility towards the child.

The rule of law in Indonesia also has not yet created a balance against efforts to protect patient autonomy when the patient lacks competence. Changes are needed in legislation (Health Act, Hospital Act, Medical Practice Act) which regulates the position of third parties in the principle of autonomy of pediatric patients to create a balance against efforts to protect patient autonomy when the patient has no competence. Reconstruction of regulation regarding the limitation of family authority on pediatric patients based on the right to health and the right to health care for child patients creates an obligation for parents, doctors and the state to protect it. In the therapeutic relationship between the doctor and the child patient represented by the parent, the basic rights of the child give rise to the doctor's right to fight for the child's rights based on two important principles, namely positively health care must respect the best interests of patients, and negatively health services must avoid situations that endanger the safety (harm principles) of pediatric patients as an effort to fulfill human rights to health services guaranteed by the Indonesian Constitution.

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CONSCIENCE CLAUSE IN THE POLISH LEGAL SYSTEM ON THE EXAMPLE OF THE LEGAL ACT GOVERNING THE MEDICAL PROFESSION

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Abstract: The paper introduces the issue of the conscience clause, primarily in the context of Polish practice and legislation. Undoubtedly, the consciences clause institution is used in many countries, including member states of the European Union. However, national legislation displays considerable differences in the formation of this institution. Therefore, comparative legal research in this area seems to be justified. The study begins with the analysis of the concept and sources of the conscience clause, in particular the principle of freedom of conscience expressed in the acts of international law and the Polish Constitution. The following parts are devoted to the examination of the evolution of the conscience clause in Polish legislation and practice, especially the impact of the judgement of the Constitutional Court of 7 October 2015. In the end, the current provisions on this issue are studied, and various problems in interpretation when applying the law are shown.

Keywords: Conscience Clause in Polish Legislation; Freedom of Conscience; Right of Medical Doctors to Object; Polish Act on the Profession of Doctor and Dental Practitioner; Refusal to Perform Medical Treatment

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The Concept and Sources of Conscience Clause

The issue of conscience clause, which has already an over forty-years-long history,[1] is undoubtedly an important matter, primarily when it comes to Polish medical law. Nevertheless, its basis consists of a non-legal problem. Moreover, from the very outset, a strictly mechanical legal approach to this matter is doomed to failure, as it leads to the omission of the real reasons for the establishment of an institution of conscience clause, which stem from religion, ethics or even mentality of individual societies. As aptly pointed out by A. Zoll, "the problem of conscience clause, in the context of a statutory law, requires referencing to the relationship between two sets of standards: a set of standards of conduct consisting of a statutory law system and a system of ethical standards."[2] Correspondingly ethical standards, which do not constitute a legal system, have developed and still continue to evolve under the influence of factors the majority of which are of non-legal nature. These factors, especially the influence of the ethics, religions or, for example, the perception of good and evil, evoke extreme emotions in society, as they touch the moral beliefs of each individual. Abandonment of such beliefs, or behaviour contrary to them, is often seen as a denial of oneself, a betrayal of life ideas or a sin understood as a violation of the divine commandments, etc. Moreover, the name of the clause itself includes the concept of "conscience", which can be defined in different ways (both subjective and objective) and by its nature is not a strict legal category.

On the other hand, it is obvious that freedom of conscience is a protected category in Polish legal order, not least because of international obligations. Article 9, paragraph 1 of the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms states that "everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief and freedom, either alone or in community with others and in public or private, to manifest his religion or belief, in

1 Nawrot O. Klauzula sumienia w zawodach medycznych w świetle standardów Rady Europy. In: Zeszyty Prawnicze Biura Analiz Sejmowych Kancelarii Sejmu, no. 3 (35) 2012, p. 18. (Polish) The author sees the Resolution of the Parliamentary Assembly of the Council of Europe 337 of 1967 on the right of conscientious objection, which recognized the possibility of exercising conscience clause as one of human rights, as the legal origins of the issue of the conscience clause.

2 Zoll A. Klauzula sumienia. In: P. Stanisz, J. Pawlikowski, M. Ordon (eds). Sprzeciw sumienia w praktyce medycznej – aspekty etyczne i prawne. Lublin; 2014, p. 77. (Polish)

worship, teaching, practice and observance."[3] In addition, in the current Polish Constitution of 2 April 1997, Article 31, paragraph 1 provides for a general standard stating that "freedom of the person shall receive legal protection." The above-mentioned standard is developed further by pointing out that "freedom of conscience and religion shall be ensured to everyone" (Article 52, paragraph 1 of the Constitution of the RP) and "freedom of religion shall include the freedom to profess or to accept a religion by personal choice as well as to manifest such religion, either individually or collectively, publicly or privately, by worshipping, praying, participating in ceremonies, performing of rites or teaching. Freedom of religion shall also include possession of sanctuaries and other places of worship for the satisfaction of the needs of believers as well as the right of individuals, wherever they may be, to benefit from religious services" (Article 52, paragraph 2 of the Constitution of the RP). In other words, the conscience clause is a legal instrument that allows the protection of the freedom of conscience in situations where a person could be forced to behave contrary to their worldview. This legal instrument is at the lowest, though not the least important, level of law enforcement practice. "Clause of conscience can be considered from many points of view, but its substance remains the same. It is the emanation of freedom of conscience and its legal guarantees."[4] Unlike general declarations and legal guarantees, be it international or constitutional, concerning both *internum* and *externum* that is the intimate sphere which cannot be regulated at all by a legislator as well as expression of external manifestation, the conscience clause undoubtedly concerns the external manifestation of own convictions. A pluralistic society, consisting of individuals with different views on various socially sensitive issues, should seek to develop legal mechanisms that eliminate situations where, with full consent of the law, a person is forced to act against their conscience. "In practice, this means that a healthcare provider must not be forced to engage in activities contrary to their system of beliefs."[5] In Polish doctrine, the application of conscience clause is considered not only in the medical field but in others too. For example, criminal law, labour law, and

3 European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, OJ 1993 No 61, item 284, rev.

4 Zalewski W. Klauzula sumienia w prawie karnym. In: Nawrot O. (ed). Klauzula sumienia w państwie prawa, 1st ed. Sopot; 2015, p. 57. (Polish)

5 Nawrot O. Klauzula sumienia w zawodach medycznych w świetle standardów Rady Europy. In: Zeszyty Prawnicze Biura Analiz Sejmowych Kancelarii Sejmu, no. 3 (35) 2012, p. 15. (Polish)

contract law may be at stake here.[6] This, however, is not the topic of the study discussed in this paper.

Nevertheless, the use of a conscience clause in the medical sphere seems to be the most controversial. It is not just about social emotions that accompany cases of this type in Poland, but, above all, it is about the need to protect the rights of the patients, whose interests must certainly also be taken into account. There will be no exaggeration to say that in casu this is really about the health of the patient and even the threat to their life. Moral beliefs of the person providing the health care, if carried out without properly obeying the patient's rights, might threaten life. There is no doubt that one is touching here absolutely existential aspects of life of both the physician and the patient. It is, therefore, appropriate to state that "the conscience clause is the strongest privilege of a health care provider. For patients, the risks associated with this privilege are correlated with its abuse resulting from overly superficial interpretation."[7] The statement that the essence of the medical profession is to assist the patient, who should not be turned down, ought to be considered a truism. The conscience clause allows for a legal and legitimate refusal to perform a procedure and renders the possibility of not assisting a patient.

The Conscience Clause in the Modern Law of the Republic of Poland Prior to the Constitutional Court Judgement of 7 October 2015

The scope of this paper does not allow the full history of the evolution of the provisions on conscience clause in Polish law to be shown in detail, so I would only like to address the most important stages of this legislation concerning medical doctors. This will facilitate understanding of the current provisions. Following the departure from the socialist system in Poland and the beginning of the democratic transition in 1989, from the standpoint of this study, the most important piece of legislation to introduce conscience clauses was the Act of 5 December 1996 on the profession of medical doctor[8] (now under the name of "the profession of doctor and dental practitioner"). Although this is outside the scope of the paper, I would like to mention that a conscience clause was also introduced in the Act of 15 July 2011 on nurse and midwife

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6 Cf. e.g. collected texts concerning various fields where conscience clause might be applied: Nawrot O. (ed). Klauzula sumienia w państwie prawa. 1st ed. Sopot; 2015, pp. 1-161. (Polish)

7 Boratyńska M. *Wolny wybór. Gwarancje i granice prawa pacjenta do samodecydowania*, 1st ed. Warsaw; 2012, p. 348. (Polish)

8 Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza, Dz. U. 1997 nr 28 poz. 152. (Polish)

professions.[9] In the original version, article 39 of the Act of 5 December 1996 on the profession of medical doctor stated that "a doctor may refuse to carry out a medical service discordant with his/her conscience, subject to article 30, nevertheless s/he is obliged to indicate real possibilities of obtaining the service from another doctor, or in another medical institution and justify his/her decision and mention about the refusal in the medical documentation.

Additionally, a doctor who carries out his/her profession on the basis of an employment relationship or within the service is required to give prior written notice to the supervisor."[10] The conscience clause and effectively the autonomy of medical doctor decision-making based on their convictions was limited by the wording of Article 30 of this Act. It states that "a doctor must provide medical assistance whenever delay in giving it could cause a threat of loss of life, serious injury or grave disturbance of health, and in other cases of urgency." The legal norm from Article 30 seems to be primary and thus it cannot be waived with the use of the conscience clause. Without discussing in detail this no longer binding legal situation, it should be pointed out that the legislator's approach was welcomed with fairly varied reception even at a theoretical level, not to mention different interpretations concerning individual actual situations. On the one hand, part of the doctrine emphasized the importance of the obligation to indicate the real possibility of obtaining from another physician the assistance, which the former doctor refuses to grant. "It is not a guarantee, as this would be unrealistic; however, the refusing doctor is obliged to know who of his/her colleagues does not refuse such insistence and to direct the patient there."[11] Another part of the doctrine indicated that

9 Ustawa z dnia 15 lipca 2011 roku o zawodach pielęgniarki i położnej, Dz. U. 2011 nr 174 poz. 1039. (Polish) At the time of the adoption of the Act, Article 12, paragraph 1 stated that "a nurse and midwife is required, in accordance with their professional qualifications, to provide assistance whenever delay in the provision thereof could result in an immediate threat to human health." In turn, the conscience clause was expressed in Article 12, paragraph 2 of that Act: "A nurse and midwife may refuse to perform a medical commission and to perform any other health care assistance not in accordance with their conscience or with the scope of their qualifications, stating without delay the reason for refusal in writing to the supervisor or the contracting person, unless the circumstances referred to in paragraph 1 apply." In addition, Article 12 paragraph 3 provides for a solution similar to the one to be found in the Act on the profession of medical doctor: "In the case referred to in paragraph 2, the nurse and midwife is required to immediately inform the patient, or his legal representative or actual guardian, about such refusal and to indicate the real possibility of obtaining this assistance from another nurse, midwife or healthcare institution."

10 Ustawa z dnia 5 grudnia 1996 roku o zawodzie lekarza, Dz. U. 1997 nr 28 poz. 152. (Polish)

11 Boratyńska M. *Wolny wybór. Gwarancje i granice prawa pacjenta do samodecydowania*, 1st ed. Warsaw; 2012, p. 362. (Polish)

the responsibility to protect health lies primarily with the public authority, which results from Article 68 of the Constitution of the Republic of Poland. "The obligation placed on a doctor to indicate the real possibility of obtaining assistance from another doctor or medical institution thus seems to be of constitutional concern"[12]. I presented here only one of the many doubts about the compatibility of the institution of the conscious clause with the Constitution of the Republic of Poland, which ultimately brought this matter to the Polish Constitutional Court, as will be discussed later in the text.

It should be clarified immediately that, in the light of international standards for the protection of human rights, the very possibility of introducing conscience clause in the Polish legal order has not yet been called into question, although this issue has often been considered as a kind of a side concern. The high-profile case of A. Tysiąc versus Poland[13] should be mentioned here. It is often referred to as an example of the fact that the Polish conscience clause is in line with international standards. Thus, in Polish literature of the subject, there is often a belief that this confirms the Polish conscience clause compliance with international standards[14]. Such a standpoint can only be partially correct, as the issue of the conscience clause was not the most important one in this particular case. In the case in question, the applicant alleged that it was made impossible to carry out an abortion procedure legally. However, it was not a refusal made under the conscience clause but the result of issuing of a medical opinion against which the applicant disagreed. Therefore, the use of the conscience clause was not the main cause of conflict between the medical practitioners and the applicant, hence only the indirect mention of this institution in the judgement by the formation of the court: "The intervener further argued that under the 1997 Ordinance the determination of the conditions in which abortion on medical grounds could be performed was left to medical professionals. Circumstances indicating that pregnancy constituted a threat to a woman's life or health had to be attested by a consultant specialising in the field of medicine relevant to the woman's condition. However, a gynaecologist could refuse to perform an abortion on grounds of conscience. Therefore, a patient could not

12 Szczucki K. In: Safian M. Bosek L. (eds). System prawa medycznego, Instytucje prawa medycznego, vol. 1. Warsaw; 2018, p. 889. (Polish)

13 Judgment of the European Court of Human Rights of 20 March 2007 in Case Tysiąc v Poland, complaint No 5410/03; available at: http://hudoc.exec.coe.int/ENG?i=004-20592

14 Cf. e.g. K. Szczucki [in]: System prawa medycznego, Instytucje prawa medycznego, vol. 1, eds. M. Safjana, L. Boska, Warsaw 2018, p. 886, O. Nawrot, Sprzeciw sumienia a prawa człowieka i ich filozofia, [in]: Klauzula sumienia w państwie prawa, ed. O. Nawrot, I Edition, Sopot 2015, p. 27. (Polish)

bring a doctor to justice for refusing to perform an abortion and hold him or her responsible for a deterioration in her health after the delivery"[15]. A more comprehensive analysis of the Polish regulation of conscience clause was carried out in the case of R.R. versus Poland[16], which concerned the illegal prevention of access to genetic tests, which ultimately led to the impossibility of carrying out an abortion. In particular, "the applicant submitted that the violation of her rights had originated also in the unregulated practice of conscientious objection. The refusal of the Kraków University Hospital to provide certain services on grounds of conscientious objection constituted a failure to ensure the availability and accessibility of reproductive health services. The public health care institutions, being public entities, had a duty to provide legal health services to the public. The State had a duty to ensure that the laws governing conscientious objection were complemented by implementing regulations or guidelines balancing the medical staff's right to object against the patient's rights to obtain access to lawful medical services."[17] However, despite the judgement in favour of the applicant, the mere fact of the legality of inclusion of the conscience clause in Polish legislation was not questioned. A separate case was the infringement of the provisions regarding this clause by several doctors, which was primarily confirmed by Polish national courts before the ECHR judgement was issued.

The Judgement of the Constitutional Court of the Republic of Poland of 7 October 2015

One of the most important statutory changes to the conscience clause resulted from the judgement of the Constitutional Court of 7 October 2015[18]. The judgement raised a rather considerable controversy, also among the adjudication panel of the Court, as four separate sentences have been submitted to it, which is a relatively large number, considering that the case was adjudicated by 14 judges. In the discussed case the Supreme Medical Council was the applicant claiming a non-compliance of certain legislative

15 Judgment of the European Court of Human Rights of 20 March 2007 in Case Tysiąc v Poland, complaint No 5410/03 available at: http://hudoc.exec.coe.int/ENG?i=004-20592; No 100.

16 Judgment of the European Court of Human Rights of 26 may 2011 in Case R.R. v Poland, complaint No 27617/04; available at: http://hudoc.echr.coe.int/fre?i=001-104911

17 Judgment of the European Court of Human Rights of 26 may 2011 in Case R.R. v Poland, complaint No 27617/04; available at: http://hudoc.echr.coe.int/fre?i=001-104911; No 173.

18 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish)

measures with the constitution. The judgement of the Court, irrespective of its relevance, is very well-founded, counts multiple pages, and even contains a lot of historical topics concerning the development of the institution of the conscience clause. I would only like to mention a few aspects that are most important when it comes to the currently applicable legislation. As I indicated above, Article 30 of the Act of 5 December 1996 on the profession of medical doctor states that "a doctor must provide medical assistance whenever delay in giving it could cause a threat of loss of life, serious injury or grave disturbance of health, and **in other cases of urgency."** In other words, the doctor could not exercise the right to refuse to provide health care in situations of real danger to life or in other, not further specified in the act, urgent situations. The Supreme Medical Council stated in its appeal that "'other cases of urgency' referred to in the contested norm should not have 'a priority over' the right of a doctor to exercise freedom of conscience. In particular, this is supported by the fact that the term applies to both medical and non-medical services. In the case of the latter services, since they do not serve to preserve, save, restore and improve the health of the patient, the doctor should absolutely retain the right to refuse to perform them in the situation where this does not endanger the life of the patient or cause serious injury or grave disturbance of health."[19] Furthermore, one of the main accusation of the Supreme Medical Council against the conscience clause in force at the time was that "the obligation imposed on a doctor, exercising his/her right to use the conscience clause, to indicate the real possibility of receiving services from another doctor or another health institution is, in fact, a legal obligation to aid in the performance of a service considered by that doctor to be unconscientious. This provision forces the doctor to give active, specific and real help in obtaining a service which is incompatible with his/her conscience."[20] The following should be indicated as the most important reasoning in the judgement given by the Polish Constitutional Court that reveals the adopted standpoint:

- the adjudication panel recognised that, in the light of the Polish Constitution, the right of conscientious objection should be recognized as a primary right towards its limitations;

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19 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish); available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001633

20 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish); available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001633

- the right of the doctor to invoke the conscience clause arises not from the provisions of the law governing medical activities but directly from constitutional provisions and international law. The Court, therefore, considers that there is no basis for defining a separate right to the "conscience clause" and consequently there is no doubt that the legislator cannot freely define or abolish this "privilege", but must respect the constitutional conditions for the establishment of limitations on both human and citizen rights and freedom (Articles 30 and 31, paragraph 3 of the Constitution);[21]

- the freedom of conscience may be limited while respecting the principle of proportionality as set out in Article 31, paragraph 3 of the Constitution;

Consequently, the Constitutional Court stated that the reference made in the first sentence of Article 39 of the Law on the profession of medical doctor to another provision, i.e. Article 30 of the Act, containing vague wording, leads to unresolvable doubts as to the extent to which the legislator restricts the freedom of conscience of medical doctors. It is, therefore, justified to claim the infringement of the principle of proper legislation derived from Article 2 of the Constitution[22]. Also, the imprecise phrasing in the act does not provide grounds to indicate in the sake of what constitutional value the physician is to concede their conscience. Besides, the Constitutional Court establishes that the restriction of the freedom of conscience of a medical doctor, by requiring them to inform the patient of the possibility of obtaining a service which is contrary to their moral principles, does not pass the proportionality test. Apart from ethical doubts, a doctor who refuses to provide a specific service (e.g. abortion) in reality does not have the knowledge which doctor will be able to provide such service. Hence it is not a disincentive to indicate such a person, but an actual lack of knowledge. Moreover, it is questionable that this obligation to inform is imposed on a particular doctor and not on a healthcare institution. Therefore, the Constitutional Court concludes that "the contested provision,

21 In accordance with Article 31, paragraph 3 of the Constitution of the Republic of Poland "Any limitation upon the exercise of constitutional freedoms and rights may be imposed only by statute, and only when necessary in a democratic state for the protection of its security or public order, or to protect the natural environment, health or public morals, or the freedoms and rights of other persons. Such limitations shall not violate the essence of freedoms and rights."

22 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish); available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001633

in so far as it imposes on a doctor who refrains from providing health care services which are incompatible with his or her conscience the obligation to indicate the real possibility of obtaining such a service from another doctor or another health care institution, is incompatible with Article 53, paragraph 1 in conjunction with Article 31, paragraph 3 of the Constitution."[23]

The above-mentioned views of the Constitutional Court, although far from being comprehensive, clearly show that the position of the doctor and its effective legal autonomy in deciding whether or not to provide a medical service are strengthened. In many respects, the Court dealt with technical matters, as hitherto the relevant provisions had been imprecise. Perhaps the most exuberant example consists of the obligation under Article 39 of the Act of 5 December 1996 on the profession of medical doctor that stated "[…] In addition, a doctor who carries out his or her profession on the basis of an employment relationship or within the service is required to give prior written notice to the supervisor."[24] As the Constitutional Court pointed out it was not clear whether it refers to a declaration provided on the establishment of an employment relationship, i.e. general and applying for the entire time of employment, or a notification on a case-by-case basis concerning a specific procedure. This shows a relatively high degree of abstraction, rather unacceptable in the context of such ethical sensitive issues. Consequently, it was considered, with great caution, that "it is rather a priori notification in principle addressed to the supervisor at the time of the establishment of employment or service, possibly during it, when the doctor, as the result of a change of world-views, wishes to refrain from providing services, which he or she was previously ready to carry out in accordance with his or her conscience."[25] Polish legislator was possibly trying to make the obtaining of certain services more real (for patients), but in fact, a number of obligations have been imposed which, in practice, do not render a positive effect.

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23 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish); available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001633

24 Ustawa z dnia 5 grudnia 1996 roku o zawodzie lekarza, Dz. U. 1997 nr 28 poz. 152. (Polish)

25 Wyrok Trybunału Konstytucyjnego z dnia 7 października 2015 r., K 12/14, Dz.U. 2015 poz. 1633. (Polish); available at: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001633

The Conscience Clause Following the Statutory Changes in the Current Polish Law

At present, the legal framework of the conscience clause set out in Article 39 of the currently applicable version of the Act of 5 December 1996 on the profession of doctor and dental practitioner states as follows: "a medical doctor may refrain from providing health services which are incompatible with his or her conscience, subject to Article 30, provided that he or she is obliged to record this fact in the medical record. In addition, a doctor who carries out his or her profession on the basis of an employment relationship or within the service is required to give prior written notice to the supervisor."[26] It should be pointed out right away that, despite continued lack of accuracy, the above-mentioned provision requires the doctor to give prior notice that he or she will not carry out certain treatments during his professional activities in a particular hospital, which should help the employer with a rational redirection of patients. In the case of establishing an efficient and functional hospital registration system, there will be no confrontation between the patient and physician. It may also be the case that, considering the submitted declarations, it is known in advance that no personnel in the particular hospital can perform a medical abortion.[27] As it seems, such information should be made public as widely as possible to avoid pointless efforts to receive certain treatment, albeit lawful, since a particular health care institution does not have adequate staff to perform it. In turn, the obligation to record in the medical record does not apply to a general declaration, but merely to an indication made on a one-to-one basis that the service was not provided. At the same time, the medical doctor is not obliged to provide detailed reasons for their decision either to the patient or in the medical records. Both in the previous legal situation and in the present one,

26 Ustawa z dnia 5 grudnia 1996 roku o zawodach lekarza i lekarza dentysty, Tekst jednolity Dz. U. 2020, poz. 514 z dalszymi zmianami (Polish)

27 Literally a few days before this paper was submitted to the editorial office, after the conflict lasting several months and having street demonstrations in the background, the Judgement of the Constitutional Court of 22 October 2020, ref. K 1/20, was published in the Journal of Laws 2021, item 175. The judgement concluded that a part of the premises which served previously as the grounds for conducting medical abortion are non-constitutional. Without examining the judgement itself, which could be a subject of a separate study, I would only like to point out that medical abortion will probably no longer exemplify medical treatment in the case of which physicians will be most often exercising the conscience clause. As the matter of fact, the Constitutional Court has eliminated most of the cases that can occur in real life situation, thus effectively removing any decision-making in this regard from doctors.

when assessing the legal acceptability of the use of the conscience clause, the ethical motivation itself is not subject to scrutiny, and the decision itself is sovereign[28]. It is legally irrelevant whether the doctor is guided by religious beliefs or ethical considerations that do not have religious grounds.

Moreover, a physician is not obliged to indicate another hospital, advise another doctor or assist the patient in any other way. The use of the conscience clause is limited only by the obligation resulting from Article 30 of the Act on the profession of doctor and dental practitioner: "a doctor must provide medical assistance whenever delay in giving it could cause a threat of loss of life, serious injury or grave disturbance of health." The current system is relatively coherent from a technical and legal point of view, however, the problem of qualification of the medical condition and thus a possible dispute between the patient and the doctor remains relevant. Also, the act continues to use the concept of "medical services", which can be understood in a variety of different ways. The individual acts contain definitions or examples of medical services, but it is questionable whether they can be transposed to the context of the conscience clause. It should be agreed that the right to information is essentially ethically neutral, so basic examination, diagnosis, etc. cannot be refused[29] by referencing to the conscience clauses. However, it is questionable whether a conscience clause can be exercised in the case of the so-called non-medical activities, for example, to refuse to prescribe contraceptives that are not compatible with the conscience of the doctor[30]. This is just an example of a number of situations where individual qualification of service, one way or the other, may lead to a refusal to provide the service by invoking the conscience clause.

Polish legislation has definitely abandoned the legacy of the 1990s and has clarified the framework on the application of the conscience clause. It can be safely said that obvious technical and legal flaws and lack of legal precision have been partially removed. In my personal opinion, the instruments of classical law have been exhausted at this time. The vast majority of the proposals and discussions currently underway, such as regarding greater access to abortion, persistent therapy, contraception, etc., are clearly of

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28 Dyszlewska-Tarnawska A. In: Ogiegło L. (ed). Ustawa o zawodach lekarza i lekarza dentysty. Komentarz. 2nd ed. Warsaw; 2015, commentary on Article 39. (Polish)

29 Cf. e.g. Boratyńska M. *Wolny wybór. Gwarancje i granice prawa pacjenta do samodecydowania,* 1st ed. Warsaw; 2012, p. 356. (Polish)

30 In this respect cf. e.g.: Szczucki K. In: Safian M. Bosek L. (eds). System prawa medycznego, Instytucje prawa medycznego, vol. 1. Warsaw; 2018, pp. 891-2. (Polish)

ideological nature or even philosophical and religious one. The practice of exercising the right is extremely dependant on the conscience of individuals applying the conscience clauses. The processes taking place in society, such as secularisation or clericalization, have an extremely strong influence on the process of not only interpreting the law but on the shape of the legislation itself. Medical legislation (perhaps in addition to family law) is the first victim of the ongoing public debate. Lawyers can offer their arguments, but in fact, the will of the majority is shaping the values that are then brought to a constitutional level. One would not like to use the Marxist postulate about the base and the superstructure, but in this case, the law is definitely a superstructure dependant on social processes. At present, Polish society is in the course of an extremely turbulent discussion about values, human anthropology, and the position of religion. The outcome of this debate may support or dismantle the current shape of the conscience clause, which strongly protects the rights and the autonomy of medical doctors. The process of reconciling this autonomy with the rights of the patient has proved to be a very difficult task for Polish society.

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THE CONSTITUTIONAL WEAKNESS OF UKRAINE'S HEALTH CARE REFORM

Roman Kovalenko*, and Olha Kytaika**

Abstract: The constitutional bases for Ukraine's health policy partly explain the country's poor health outcomes. The constitution – and particular article 49 – contain self-contradictory provisions that run right through the rest of Ukraine's health laws. The constitution gives citizens and others the right to free health care, and burdens the government with many ancillary obligations related to health policy. Yet, nothing in Ukraine's law – or its constitutional jurisprudence so far – has limited that right. Since the founding of the new republic, lawmakers have struggled with their understanding of such a right.

The first contradiction - everyone has the right to health protection, with state funding serving as the mechanism for providing such a right. The second contradiction – the state must basically provide for effective and accessible medical service. The third contradiction – if everyone has the right to medical insurance, and if the state must provide health care for free, it, therefore, follows that the state must provide such insurance for free (which it does not). The fourth contradiction – the state must provide conditions for effective, accessible medical service and promote the development of privately owned medical institutions, partly through funding socio-economic programs and physical culture and sports. Yet, how can state-funding help the development of privately owned institutions and the larger development of a market system?

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This article describes the jurisprudence of constitutional law in the health sector for a developing market economy – and shows just how a seemingly innocuous provision, nestled deep in its constitution, could reverberate into the wider economy-building arena. The authors argue that the constitutional provision on free health care needs amendments as it does not reflect neither the reality nor the goal of the health care reform (the goal of the reform is the transition to the state solidarity health insurance system).

Keywords: Health Care Reform; Ukrainian Health Care Reform; Constitutional Basis for the Health Care; Ukrainian Medical Law Axiology

Introduction

In June 2020, the Ukrainian news agencies announced that the EU experts would assist with the health care system reform. This reform is an ongoing process since the country gained independence, and for now, the results are not very impressive. One of the reasons is because recent reforms conflict with this constitution promise of free care, the legal basis for these reforms remains as shaky as ever. The constitutional underpinnings of Ukraine's health care law direly need reforming.

In this short article, we review the constitutionality of recent lawmaking in the Ukraine related to health care reform. We show the inherent contradiction between legislation – following international best practice – which attempts to install free market principles into Ukraine's health system, and a legal heritage based on the old Semashko system.[1]

First, we describe the constitutional bases of Ukraine's health system – analyzing the contradictory provisions in Ukraine's constitution, and we look at recent legislation, which contradicts its mixed-up constitutional basis. Rather than healing the problems in Ukraine's constitutional law, though, the new law exacerbates them.

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1 The Semashko model of financing and organizing health care emerged in the 1920s in the Soviet Union. Named after Nicolai Semashko, the USSR's health minister from 1918 to 1930, the model represents a particular type of socialised medicine, in which the government controls and operates health care facilities and provides such services without payment at time of service. For more on this system, see Michael Borowitz and Rifat Atun, The Unfinished Journey from Semashko to Bismarck: Health Reform in Central Asia from 1991 to 2006, Central Asian Survey 25(4), 2006.

Secondly, we describe the two major Constitutional Court decisions related to Ukraine's health-related constitutional provisions. The Constitutional Court meekly avoided defining any of the contentious issues in the law, leaving the matter unresolved to today.

Thirdly, we give an overview of the current stage of the Ukrainian health care reform and conclude how it can be grounded in the relevant constitutional foundation. One more case of the Constitutional Court is mentioned – the one about the health care reform, that has not been decided since 2018.

Overview of the Current Problems in the Ukrainian Health Care: Facts

On July 23, 2020, the Grand Chamber of the Constitutional Court of Ukraine continued consideration of the case upon the constitutional petition of 59 People's Deputies of Ukraine on the constitutionality of the Law of Ukraine *On State Financial Guarantees of Public Health Care* 2017[2]. The Ukrainian body of constitutional jurisdiction had not been able to pass the decision of this case for more than two years. This fact shows that there is a constitutional conflict around the current stage of health care reform.

Health care reform in Ukraine is a permanent process since the country gained its independence. In 2010 V. Lekhan, V. Rudiy and E. Richardson have pointed out that the Ukrainian system preserves the Soviet Semashko system while simultaneously trying to introduce market competition throughout the broader economy.[3] Health facilities remain subordinate to the Ministry of Health but accountable to regional and local governments. As a result, health facilities do not receive the funding they need, as shown by Ukraine's very low health spending. Worse still, evidence shows that Ukrainian health care institutions have not increased their productivity, thus burdening the government budget further.[4] Yet, such expenditure comes nowhere near to providing unlimited health care – as promised by Ukraine's constitution. Worse still, despite this

2 The Constitutional Court of Ukraine considered the case on the constitutionality of the law on state financial guarantees of medical care. July, 23, 2020, available from: http://www.ccu.gov.ua/en/novina/ccu-considered-case-constitutionality-law-state-financial-guarantees-medical-care

3 See Valery Lekhan, Volodymyr Rudiy and Erica Richardson, Ukraine: Health System Review, Health Systems in Transition 12(8), 2010.

4 See Anatoly Pilyavsky and Matthias Staat, Efficiency and Productivity Change in Ukrainian Health Care, Journal of Productivity Analysis 29(2), 2008.

constitutional promise, the availability and cost of health care make such care unattainable for many citizens.[5]

In 2015 the results of the study "*(Non) free medicine*", conducted as part of the USAID project, showed that 'every second patient in Ukraine refuses treatment or postpones it due to lack of funds. The main problem for 94% of patients who participated in focus groups is the high cost of medicines. At the same time, 48% of patients complain of counterfeits and poor quality of medicines. And the percentage of those who resort to self-medication reaches almost 70%'[6].

The authors of *National Strategy on Health Reform* claimed that:

- 75% of Ukrainian hospital beds have extremely low capacity to provide services, as they are located in small facilities - city and district hospitals, specialized (tuberculosis, venereology) hospitals, dispensaries and rural hospitals, some of which are in a dilapidated condition. Due to lack of investment and other constraints, very few facilities are able to provide modern comprehensive medical care (for example, modern cardiac surgery or cancer treatment);

- Ukraine has an excessive number of specialized medical professionals (more than 100 medical specialties) who conduct reception in 8,300 polyclinics, district and city hospitals and specialized dispensaries for one disease (tuberculosis, HIV / AIDS, etc.). Initially, they were intended for referral services from medical centers, outpatient clinics and polyclinics allocated and / or attached to district and rural hospitals that provided primary health care on a district basis. Primary care facilities are usually staffed by a doctor and nurse (in rural areas, a paramedic and / or midwife), who provide limited services in the absence of the necessary equipment and have no incentives to maintain quality, and their professional competence deteriorates over time. As a result, most patients seek medical care directly from specialists, who are usually happy to provide assistance in exchange for a semi-official or informal payment[7].

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5 Dina Balabanova, Bayard Roberts, Erica Richardson, Christian Haerpfer and Martin McKee, Health Care Reform in the Former Soviet Union: Beyond the Transition, Health Services Research 47(2), 2012.

6 (Non) Free Medicine, available from: https://moz.gov.ua/article/statistic/rezultati-doslidzhennja-bezkoshtovna-medicina

7 National Strategy for Health Care Reform in Ukraine for the Period 2015-2020, available from: https://moz.gov.ua/strategija

In 2016 the Ukrainian Government approved the *Concepts on Health Care Financing Reform* and revealed more of the sad statistics about the national health care situation. According to the Cabinet of Ministers' information, 'the total (sum of public and private) expenditures on health care in Ukraine in 2014 was 7.4 percent of gross domestic product. This is lower than the EU average (9.5 percent of gross domestic product in 2013). As a result, about 3.8 percent of households in Ukraine (or 640,000 families) suffer from catastrophic medical expenditures, and 92 percent are afraid of financial difficulties in the event of illness[8].

This Concept announced that Ukraine aims to build the model of state solidarity health insurance, which takes into account the best modern practices and experience of transformation of health care systems in the world, in particular in Central and Eastern Europe. The main source of funding for the renewed health care system is the State Budget, and payments for an individual's treatment are not tied to their individual contributions. Budget funds for medical financing will be distributed through a new, modern mechanism of strategic procurement of medical services.

Ukraine's Mixed-Up Constitutional Stance on Health Care Law

Many of the provisions in Ukraine's constitution seem at odds with the market economy. The constitution's very first article proclaims the country a "social...state."[9] A subsequent article further affirms that "an individual, his life and *health*...shall be recognised in Ukraine as the highest *social value*" (underlining ours).[10] These provisions clearly place health policy – and thus a health care system – at the summit of Ukrainian state policy. As if to remove all doubt, the constitution further clarifies that "the State shall be responsible to the individual for its activities."[11] These basic provisions set the stage of Ukraine's health care policy – and its accountability to the electorate for such policy. Regarding the state's specific legal requirements vis-a-vis this 'highest

8 On approval of the Concept of Health Care Financing Reform: Order of the Cabinet of Ministers of Ukraine of November 30, 2016 № 1013-r, available from: https://zakon.rada.gov.ua/laws/show/1013-2016-p

9 Specifically, "a sovereign and independent, democratic, social, law-based state." In this context, we infer that 'social' refers to the economic system, as 'democratic' refers to the political system. See Constitution of Ukraine 1996, at art. 1, available from: https://www.justice.gov/sites/default/files/eoir/legacy/2013/11/08/constitution_14.pdf

10 Id. at art. 3.

11 Id.

social value', the constitution states explicitly – and in no uncertain terms – that "Everyone shall have the right to health protection, medical care and medical insurance."[12] The specifics of the constitution's promises to provide health care require a bit more analysis.

The Ukrainian constitution's promise to provide universal health care rings hallow, even before considering other provisions in law. First, the relevant constitutional provision gives "everyone...the right" to three things: "to health protection, medical care and medical insurance."[13] At first glance then, the Ukrainian constitution joins the community of other constitutions – many of the former Soviet Union – promising free, universal health care.[14] The constitution does not define health "protection" (which ostensibly refers to preventative medicine), "care" or "insurance."[15] Second, state funding "shall be ensured" for such 'health protection,' specifically by funding "the relevant socio-economic, medical and sanitary, health improvement and prevention programmes."[16] Such a mandate thus requires spending, not only on medical programmes (already a stretch given Ukraine's past health care spending), but also on prevention and even social and economic programmes impacting on the general population's health.[17] Such a blank check then leaves the government open to fund any programme, as long as any proponent of the proposed programme can argue some plausible "relevant" link with health policy.[18]

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12 Id at art. 49, para. 1.

13 Id.

14 The international standard refers to (variously) "standard of living adequate for the health and well-being of himself and of his family" and the "highest attainable standard of physical and mental health" rather than free, universal healthcare. See Universal Declaration of Human Rights, 1948, at art. 25(1) and Constitution of the World Health Organization (WHO), 1946, at preamble. For more on this right in constitutional law, see Jody Heymann, Adèle Cassola, Amy Raub and Lipi Mishra, Constitutional Rights to Health, Public Health and Medical Care: The Status of Health Protections in 191 Countries, Global Public Health 8(6), 2013.

15 While Ukraine's Constitutional Court and/or members of its parliament can not consult other countries' definitions of these terms, other post-Soviet countries have made inroads in creating viable constitution doctrine around terms like 'health protection.' For a recent analysis, see Ants Nomper and Taavi Annus, The Right to Health Protection in the Estonian Constitution, 7 Juridica International 1, 2002.

16 Constitution of Ukraine 1996, at art. 49, para 2.

17 Despite the expansive wording of this constitution, like most others, both governments and courts have taken a much more restrictive approach to such a right. For a fuller description, see Lawrence Gostin, Public Health Theory and Practice in the Constitutional Design, 11 Health Matrix 265, 2001.

18 Most scholars find, unsurprisingly, that such socio-economic rights aren't worth the paper

Other aspects of Ukraine's constitutional provision for healthcare also create impossible obligations on the state (and unenforceable law). Besides guaranteeing such health protection and funding for such protection, the constitution further requires "the State...[to] create conditions for effective medical service accessible to all citizens."[19] The provision does not require the state to provide 'effective' and 'accessible' access for all citizens. The state only "shall create conditions for" such access.[20] Yet, the constitution forestalls any free market interpretation of this provision by requiring that, "state and communal health protection institutions shall render medical care free of charge."[21] Most modern constitutional law scholars consider such provisions aspirational rather than binding statements of rights and obligations.[22] Both recognising the strategic nature of policymakers and closing the door toward market-driven health facilities, the provision also requires that "the existing network of such institutions shall not be reduced." Such a restriction ignores need, quality, and invites corruption by guaranteeing legacy health institutions their continued survival despite performance.[23] Constitutional protections for existing state health facilities, guarantees of free health care, and the right to effective/accessible care represent conflicting constitutional rights, even before considering the impossible economics underlying such provisions.[24]

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they are printed on. For more, see Dennis Davis, Socioeconomic rights: Do they deliver the goods?, International Journal of Constitutional Law 6 (3-4), 2008.

19 Constitution of Ukraine 1996, at art. 49, para. 3.

20 Critics of the Semashko approach may argue that fomenting market institutions for health care similarly 'creates conditions' for such access, as a population earning good incomes does not need free medicine in order to access such medicine. Indeed, the Chinese have adopted such an approach. Future legislators may keep this in mind when thinking about whether to delete the constitutional right to "free" medicine. For more on the Chinese interpretation, see David Blumenthal and William Hsiao, Lessons from the East — China's Rapidly Evolving Health Care System, 372 New England Journal of Medicine 1281, 2015.

21 Constitution of Ukraine 1996, art. 49, para 3, line 2. Such a provision cover both state and communal levels, leaving nothing outside the net of free health care provision (except private institutions to the extent allowed by law).

22 Indeed, many scholars see these statements in context, envisioning the state's commitment to free healthcare along a continuum. See Eleanor Kinney and Brian Clark, Provisions for Health and Health Care in the Constitutions of the Countries of the World, 37 Cornell Int'l L.J. 285, 2004.

23 Indeed, the provision directly contradicts the delivery of free health care. Imagine how long a free health care system can survive when its hospitals and clinics waste resources and have no accountability? For a historical review of this hard lesson, see Joseph White, The Challenge of Budgeting for Healthcare Programmes, OECD journal on Budgeting, 2014(1), 2014.

24 EU law illustrates the impossible contradiction better than most – with constitutional

Two other provisions related to health care pose seemingly insurmountable legal problems for the constitutional jurist. Rather incongruously, the "State shall provide for the development of physical culture and sports, and ensure sanitary-epidemic welfare," mixing sports and plague.[25] Ignoring the law related to physical culture and sports, the constitutional issues around ensuring sanitary-epidemic welfare bring in issues of international law, cross-country budgeting and represent powers extending very far behind simple health policy.[26] The final *coup de contradiction* comes from the provision requiring that, "the State shall promote the development of medical institutions under all forms of ownership."[27] As we have just argued, the protection of state health facilities necessarily implies the disfavoring of private health facilities. Moreover, if government policy aims at free market reforms, why would the state 'promote' state ownership?

The constitutional contradictions contained in just that one provision (article 49) illustrate the shaky foundations of Ukraine's health law. The first contradiction - everyone has the right to health protection, with state funding serving as the mechanism for providing such a right. Yet, the state must provide for the development of medical institutions 'under all forms of ownership.' The guarantee of public funding necessarily privileges state medical bodies. The second contradiction – the state must basically provide for effective and accessible medical service. Yet, the state (when it provides such healthcare) must provide it for free. The freer health care the state provides the less resources available to ensure quality health care.[29] Contradiction three – if

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courts accepting the constitutional trade-offs between negative and positive social medical rights. See Tamara Hervey and Bart Vanhercke, Healthcare and the EU: the Law and Policy Patchwork. In E. Mossialos, R. Baeten, R. and T. Hervey (Eds.), Health System Governance in Europe: the Role of EU Law and Policy. Cambridge: Cambridge University Press, 2009.

25 Constitution of Ukraine 1996, art. 49, para 4.

26 For the way these difficulties have impacted on US constitutional law, see Joseph Barbera, Anthony Macintyre, Larry Gostin, and others, Large-Scale Quarantine Following Biological Terrorism in the United States Scientific Examination, Logistic and Legal Limits, and Possible Consequences, Special communication of the American Medical Association, available at: https://jamanetwork.com/journals/jama/article-abstract/194439

27 Constitution of Ukraine 1996, art. 49, para 3, line 2.

28 Economists call this 'crowding out.' For evidence, see Jonathan Gruber and Kosali Simon, Crowd-out 10 years later: Have recent public insurance expansions crowded out private health insurance?, Journal of Health Economics 27(2), 2008.

29 Even more worryingly, such state support represents the 'soft budget constraints' which local governments use to extract money from the central government. Evidence from Italy, for example, shows how government budget support encourages local governments and hospitals

everyone has the right to medical insurance, and if the state must provide health care for free, it, therefore, follows that the state must provide such insurance for free (which it does not).[30] Contradiction four – the state must provide conditions for effective, accessible medical service and promote the development of privately owned medical institutions, partly through funding socio-economic programs and physical culture and sports. Yet, how can state-funding help the development of privately owned institutions and the larger development of a market system?[31]

Ukrainian Health Care Reform: First Steps

The constitutional basis of the Ukrainian Health Care reform was always unclear, especially in terms of its financing. All of the three cases on this reform this Court faced were about the financial issued.

In 1998, Ukraine's Constitutional Court held hearing to decide on the constitutionality of the Cabinet of Ministers Decree *On the Approval of the List of Paid Services*.[32] The Court squashed the Decree. Yet, the Court's reasoning opened the way for further contests to the right to free health care. The Court decided to divide the constitutional issue into a procedural one and substantive one. The procedural issue – do the items on the list guarantee the 'right to health' – with nothing less and nothing more? The substantive issue – how much latitude does the Cabinet of Ministers (and the Ministry of Health) right to conduct health policy (as stipulated in that self-same article 49)?

The Court contributed to limits on a 'right to health' by restricting the administrative sets of activities, programs, services and goods, which contribute to such a right. The Court acknowledged that any items on list benefiting from the constitutional right must, "cover only those types of medical work, without which the patient's health does not exist."[33] The Court found that "only a small

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to run up large losses. See Rosella Levaggi and Francesco Menoncin, Soft budget constraints in health care: Evidence from Italy, The European Journal of Health Economics 14(5), 2012.

30 Health contributions are taken from workers salaries. For more, see Bernd Rechel and Martin McKee, Health reform in central and Eastern Europe and the former Soviet Union, The Lancet 374(9696), 2009.

31 Little evidence – even from places like China - supports the idea that general government spending on health contributes to broader economic growth and development. See Xiao-peng Zhang, Yu-qi Xiong, Jing Ye, Zhao-hua Deng and Xin-ping Zhang, Analysis of government investment in primary healthcare institutions to promote equity during the three-year health reform program in China, BMC Health Services Research 313:114, 2013.

32 Supra at note 44.

33 Id at point 2, para. 5.

part of the provisions of the List can be considered services rendered free of charge in state health care facilities [which] cannot be taken by the state."[34] They cannot be taken (paid) because they do not constitute "medical care" under a reasonable definition, which leads to health.[35] Other parts of the List completely fell outside the required definition of any service providing for health.[36] These admissions point to limits on items and services which the state can reasonably pay for – reining in this expensive right somewhat – by imposing procedural limits and safeguards.

The substantive reasons the Court gives to allow private fees and payments though really strain at incredulity. First, the Court acknowledged the government's right to develop and implement "national social and other programs."[37] As long as health care provision represents a social program or policy, the government can set fees and payments, just like with any policy.

Second, the Court also acknowledged patients' rights to provide "voluntary donations to health care" as a way to both all patients to pay – and for them to remain free.[38] Namely, if patients 'donated' the cost of their services and medicines to the relevant medical establishment or relevant state body responsible for the treatment, such a donation would not comprise a payment – thus, the service remains officially free. Third, the government still has the power to impose "taxes and fees."[39] If the Cabinet of Ministers and Verhovna Rada pass a law-imposing medical "taxes," could medical bodies might conceivably collect payments in this way? The Court was not ready to go this far – striking down a similar piece of administrative law – before finally striking down the Decree.[40]

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34 Id at point 2, para 9.

35 Noting the lack of any definition for 'medical care', the Court uses the rest of point 2 to describe why any such definiton much lead to the outcome of health as envisioned by the constitution.

36 Specifically those in Part III of the List. See Id. at point 2, para. 10.

37 Id at point 2, para. 12. The Court specifically cited such rights in accordance with the constitutional provisions assigning such powers to the Cabinet of Ministers (art. 116, para. 4) and the Verkhovna Rada (art. 85, para. 6).

38 Id at point 3, para. 3.

39 Id at point 4, para. 2. Again the Court cites art. 116 (clause 3) for such a power.

40 The Court specifically squashed a parliamentary resolution to the Ministry of Health, asking the Cabinet of Ministers to quickly approve the order allowing for paid health care services and the sneakily labeled "voluntary compensation" from patients. See Resolution of the Verkhovna Rada, On the State of Ukraine's Health Protection System and Prospects for Development" (496/97-BP) from 18 July 1997, No. 496. See also The Regulation on the Ministry of Health of Ukraine, approved by the Decree of the President of Ukraine of August 17, 1998 No. 884 (884/98).

The Court's decision left an important legacy, in light of "the critical situation of budget financing of healthcare."[41] As part of its holding, the Court opined that "not in the introduction of a virtually unlimited list of paid medical services, but...in accordance with...the Constitution... conceptual approaches to solving problems related to ensuring constitutional rights to medical care [require the government] to develop, approve and implement relevant national programs that clearly define State guarantees (including state financing), the amount of free health care to all citizens in public and communal health care institutions, the introduction of health insurance, etc."[42] One statement in particular, seemed to go the government's way. The "provision of medical care by state institutions...is guaranteed free of charge...within the boundaries of public funding."[43] The government could not use procedural tactics to get around the right. Yet, the government could define programs – with well-defined financial mandates and expenditures – aimed at addressing the issue behind the right.

Parliamentarians did not have long to wait until they received further clarification about the limits of free health care. Another (different) group of members of the Parliament asked Ukraine's Constitutional Court to clarify questions related to free health care.[44] The Court had to interpret the meaning of the constitutional admonition that "health care is provided free of charge."[45] The parliamentarians also asked whether the government could collect revenue for health care through "other solidarity forms, such as sickness funds, credit unions, etc."[46] The question – asked almost 2 years previously – does not even presuppose private payments. Instead, the question only went so far – and we already saw the answer about – as to ask about additional forms of taxation.[47]

This largely incoherent decision argued in circles about the meaning of *gratis* – as somehow a different concept from free. In briefs filed by both the Ministry of Finance and the Ministry of Economy and European Integration, both

41 Id at point 2, para. 13, 1-2 lines.
42 Id at point 2, para 14.
43 Id at point 2, para. 6. In other words, the government's responsibility for free care ends 'within the boundaries' of its means.
44 Decision of the Constitutional Court of Ukraine, On the Case of the Constitutional petition of 53 People's Deputies Regarding the Official interpretation of the Provisions of Article 49.3 of the Constitution of Ukraine, Document v010p710-02, May 29, 2002. Available from: https://zakon.rada.gov.ua/laws/show/v010p710-02/ed20131006
45 Id. at point 1, para 1.
46 Id.
47 We saw the answer because the Court specifically acknowledged the government's constitutional right to assess taxes and fees.

argued that health service users paid for these services in the form of taxes. The disconnect in the time between receiving treatment and the time of paying generally obligatory taxes, as well as the disconnect between the patient and payer, did not necessarily invalidate the fact that citizens and health service users ended up paying anyway.[48] The Court courageously ended up arguing that *gratis* depends on context.[49] Yet, the Court backtracked and clearly stated, "all Article 49 of the Constitution of Ukraine means that an individual who receives such assistance in state and communal services health care institutions should not reimburse its value not in the form of any payments, nor in any form independently from the time of medical care."[50]

From incoherent to contradictory, the Court flip-flopped on even this clearly stated position. After 5 paragraphs describing the etymology of free, medical care and several other words from a wide and random range of sources, the Court then decreed that article 49 encompassed the "right of everyone to health insurance, not obligatory [insurance], but voluntary citizens' medical insurance." After allowing for additional funding from taxes, the Court finally held that:

1. state and communal health care facilities shall be provided free of charge... *regardless of its volume* and without attempts to collect payments in the past, present or future, and

2. The introduction of health insurance, including state and voluntary, to cover medical services *beyond the scope* of medical care, on a fee basis as determined by a list as directed by law.[52]

The Court never reconciled how the state could provide unlimited amounts of "medical care" while simultaneously allowing for (preferably voluntary) payments made to cover excess costs arising from treatment. The Court followed the government's approach to deciding such treatments, services and medicines on the basis of a list...after over-ruling the previous Court's holding

48 We quite liberally interpret the brief's very short summary of these parties' submissions to the court. See Id, at point 2, para. 4 and 5. Point 3 continued summarizing random opinions like the dictionary meaning of words, their synonyms and antonyms.

49 Id at point 4, para. 2.

50 Id.

51 Id at point 4, para. 8.

52 Id at Decision, point 1. We have modified the original to translate the text sensibly into English.

finding such a list-based approach unconstitutional.[53] The Court kicked the can down the proverbial road by dividing care into (necessary for health) "medical care" and other services. Indeed, the Court found that "a holistic legal definition of this concept [medical care], lacking in Ukraine's laws, requires a normative a settlement that goes beyond the powers of [this Court]."[54]

How can private sector agents compete in a health system where the state has a blank check to pay out medical expenses – but only "in public and communal health care facilities"?[55] The Court has failed to define legally coherent limits on healthcare spending. Healthcare related legislation continues to give preferences to state-run entities, even if private ones (theoretically) can receive reimbursements for services provided. The law stubbornly refuses to neatly define the 'right to health' and the 'medical care' that guarantees such a right. No wonder then that any private sector response to demands in Ukraine's health markets remains weak to non-existent. Ukraine's constitutional law is to blame.

The third case is about to be decided for more than 2 years already. The authors of the petition to the Constitutional Court claim that the Law of Ukraine *On State Financial Guarantees of Public Health Care* 2017 does not comply with Articles 22, 49, 64 of the Constitution. Article 49 guarantees free health care in state and municipal medical institutions, while the other two state that constitutional rights and freedoms cannot be revoked or restricted. The Law of Ukraine *On State Financial Guarantees of Public Health Care* introduces changes in direct budget funding of medical institutions and introduces only partial payment for medical services by the state.

The New Health Strategy and the New Law

The Law of Ukraine *On State Financial Guarantees of Public Health Care* 2017 represents the new stage of the health care reform in Ukraine.

The Health Care Strategy 2015 follows on the previous principles and platitudes of government policy – adhering strongly to the constitution's commitment to free health care. In August 2014, Ukraine's Ministry of Health started

53 Specifically, they divided the list into three parts and judged each part separately – with even Part III services (presumably optional procedures) preferably unpaid.

54 Id at point 4, para. 6.

55 The 1998 Decision and 2002 Decision make clear that the provision of these free services only occurs in these institutions (and in contrast with the 2018 Law we reviewed previously).

work on its *National Strategy on Health Reform*. The strategy encompassed five principles, including: a guaranteed package of services available to all, following the national standards of excellence and professionalism, patients [sic] empowerment, collaboration across organisational boundaries in the interest of patients, communities and the wider population, value for money and the most effective, fair and sustainable use of limited resources, and finally accountability to the public, communities and patients that it serves.[56] From this list, only points one and four – with the constitutional commitment to free health care representing an uncomfortable topic in the strategy.[57] Indeed, the attached action plan specific notes that, "a solution needs to be found regarding the Article 49 of the Constitution of Ukraine whose literal interpretation would in fact preclude any health system reform."[58]

The Strategy envisioned several legislative and regulatory amendments aimed at materializing the jargon-ridden, overly optimistic dream contained in the strategy document. The Strategy calls for the revocation of two executive acts, which failed to reform health care financing.[59] The Strategy also calls on the government to adopt three new laws - On Health Care Facilities and Medical Servicing», On Doctors' Self-governance and On Mandatory Social Health Insurance.[60] Beyond that, most of the strategy consists of passing laws and improving systems – with scant mention of concrete ways to improve actual outcomes or describe ways of tackling the funding gap. Such analysis represents a key way forward, given the financing guarantees the government must undertake.

The problems of Ukraine's constitutional approach to health care funding come out most vividly in its first law supporting this strategy. The law, *On State Financial Guarantees of Public Health Care,* describes the financial

56 Ukrainian Ministry of Health, National Health Reform Strategy for Ukraine 2015-2020, sec. 2, p. 16-17, available at: http://healthsag.org.ua/wp-content/uploads/2015/03/Strategiya_Engl_for_inet.pdf

57 The fourth point, referencing international cooperation, could refer to the constitutional commitment to deal with public health emergencies and pandemics.

58 Id, at sec. 4, p. 37, bullet point 4.

59 Id. at sec. 4, p. 37, bullet point 3. For the referred rulemaking, see Cabinet of Ministers Resolution No. 776 of September 18, 2013, On Approval of the Concept for Development of a Health Care Financing System. See also Order No. 33 of Feb. 23, 2000, On Staff Normative and Sample Manning Tables for Health Care Facilities.

60 Id at sec. 4, p. 37, bullet point 13.

guarantees the government will provide for medical services and medicines.[61] Specifically, the Act covers 8 areas where "the state guarantees...full payment from the state budget of Ukraine of necessary medical services and medication" (italics ours).[62] Notice the explicit reference to full payment – covering not only services but medicines as well. To repeat the right, the law stipulates that, "patients are entitled to receive *necessary* medical *services* and medicines...at the expense of the state budget."[63] The law tries to reconcile the constitution's promise of free health care with its promise to all for 'all forms of ownership' by creating something called a "contract on medical care."[64]

These contracts on medical care – in theory – all the market-based provision of health care services, paid by the state. Accordingly, medical providers must apply for licenses, for specific procedures and medicines.[65] The law sets uniform (namely controlled) prices on medical goods and services.[66]

The law refers to these payments as guarantees, rather than payments because of this unique feature. Namely, the medical institution or service/good provider incurs the cost in the first instance. With the production of the right paperwork, the relevant 'Authorised Agency' arranges for the institution's or person's reimbursement (subject to their contract with the scheme). The Law wholeheartedly supports the constitution's commitment to free health care – and another law's commitment to the same - namely the *Fundamentals of Ukrainian Health Law.*

The Fundamentals of Ukrainian Health Law represents mostly a repeat of the constitutional provisions – albeit with more technicalities defined.[67] The Fundamentals repeats the state's commitment to free health and the constitutional

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61 See Law of Ukraine 'On State Financial Guarantees of Public Health Care', Bulletin of the Verkhovna Rada, 2018, No. 5, p.31, available at: https://zakon2.rada.gov.ua/laws/show/2168-19

62 See Id. at art. 4.1. The 8 areas of treatment cover almost every conceivable treatment, specifically emergency medical care, primary health care, secondary (specialised) medical aid, tertiary (highly specialised) medical care, palliative care, medical rehabilitation, medical care for children under 16 years of age (presumably this does not fit under the previous categories for some reason) and medical assistance in connection with pregnancy and childbirth.

63 Id. at art. 6.1.1.

64 See Id at art. 8.1.

65 Id at art. 8 and art. 9.

66 Id at art. 10.

67 See Fundamentals of Ukrainian Health Law, Document 2801-XII, 1993, available at: https://zakon.rada.gov.ua/laws/show/2801-12

construction of a "right to health."[68] Unlike the 'guarantees' provided under the 2018 law, the 1993 law set these guarantees far more expansively as access to "the establishment of an extensive network of health facilities, organization and implementation of...public measures, and financing."[69] The Fundamentals also included internal control of public health facilities, information collection and legal liability.[70] On the surface, the law *On State Financial Guarantees of Public Health Care* looks like just a more specific clarification of one of the bullets in the *Fundamentals*. Yet, with the avowed aim of abolishing the very foundations of the constitutional right to free health care, the Law seems to extend – rather than restrict – free health care.

Current Ukrainian Health Care Reform: Directions and Legislation

The material basis of the current health care reform is created by the main codified Law of Ukraine in this field – by the Fundamentals of the Legislation of Ukraine on Health Care 1992 (with the numerous amendments). Article 8 of this Act states that there are several types of medical care in the country:

- emergency medical care;
- primary medical care;
- secondary (specialized) medical care provided on medical grounds in accordance with the procedure established by the central executive body, which ensures the formation of state policy in the field of health care;
- tertiary (highly specialized) medical care provided on medical grounds in the manner prescribed by the central executive body, which ensures the formation of state policy in the field of health care;
- palliative care[71].

The *palliative care* is practically unreal to get in Ukraine – there are only some private hospices for the huge country. But so far this type of health care was never reformed (to be more precise, the network of the palliative medical institutions should be formed first).

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68 In no uncertain terms, "Everyone has a natural and inalienable right to health." Id, at recitals, first line. See also Art. 7.

69 Id at art. 7(a)-7(c). The Rada revised the financing provision in light of the new 2018 law.

70 Id at arts. 7(d) -7(e bis). What should have been bullet point 7(f) was erroneously labeled as bullet point 7(e) twice.

71 Fundamentals of Ukrainian Health Law, Document 2801-XII, 1993, available at: https://zakon.rada.gov.ua/laws/show/2801-12

The procedural and financial basis of the current health care reform is created by the Law of Ukraine *On State Financial Guarantees of Public Health Care* 2017 gives the legal basis for the reforms of the rest medical care types.

The *emergency medical care reform* is planned for 2018 - 2025.

In 2018, all of the cases that werehandled by this system, were systematized, and the clear algorithms were applied to each group:

- most of the calls are handled without sending the car with the professional – by phone. The patients get advice and directions on what to do;
- some calls are considered emergent (the reanimation car must arrive in 10 minutes);
- some calls are considered urgent (the reanimation car must arrive in 20 minutes);
- some calls are considered serious enough to send the reanimation car only if one is free when the call received. Otherwise, the patient should arrive to the hospital himself or herself.

In 2020 it is already more than 4,5 bln. USD used to continue the reform[72] in the directions as follows:

- buying new equipment;
- buying more medicines and medical goods;
- retraining the personal of the emergency medical care system to get the qualification of the 'emergency medical technician' (new for Ukraine);
- raising the salaries for the personal. The salaries are expected to raise each year gradually, and already if the personnel are involved in cases of COVID-19, they get additional payment.

The reform of emergency medical care is the most impressive in terms of changing the system so far. If before the woman in labor could call for the emergency to go the labor house, nowadays it is impossible. The majority of the population does not approve and support these changes. The articles

72 Більше грошей та ефективності. Як зміниться екстрена допомога? 22.07.2020, available from: https://denzadnem.com.ua/aktualno/61725

about this part of the health care reform usually have provocative titles like 'Emergency Medical Care Reform – This Would Hurt'[73].

The *primary medical care reform* was planned for 2018 - 2025.

Firstly, in 2018 the Ministry of Health Care approved the Regiment of primary medical care. This Regiment states that the services of a primary care physician include preventive examinations of patients from 7 risk groups, 8 basic tests and research, preventive vaccinations, diagnosis and treatment of diseases, injuries, poisonings, pathological conditions, monitoring of uncomplicated pregnancy and support of chronic patients, as well as referrals for diagnosis and treatment at other levels of care if necessary[74].

Secondly, the list of the primary care medical services each person gets for free is revised annually. These free services could be received by the prescription of the family doctor.

Thirdly, in 2019 the E-Health system was introduced. It targets the transfer of the paper medical documentation in the electronic form.

The *secondary (specialized) medical care reform* was planned for 2018 – 2025, and then delayed to be started on April,1, 2020, and now it is mostly paused again. COVID-19 was the official reason to delay the biggest part of the activities within this reform. However, probably the political elites just did not want to stress the population even more in times of pandemic and economic crisis - the medical professional organizations and the outpatient users gave a highly negative respond to the reform. A lot of hospital beds should be cut off, a lot of hospitals should be closed (and some already are).

The main problem this part of the health care reform faces is illustrated by the statistics. Health Index Ukraine – 2019 shows that more than half (62.6%) of outpatient users had costs directly related to their last outpatient visit. 13.2% paid to the charitable fund, 12.6% paid officially at the box office, 11.5% paid informally and 36.1% paid for medical supplies during the visit[75].

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73 Emergency Medical Care Reform – This Would Hurt', available from: https://svidok.info/ru/news/1505

74 Ministry of Health Care of Ukraine, Regiment of Primary Medical Care, Document 504, 2018, available at: https://zakon.rada.gov.ua/laws/show/z0348-18

75 Health Index. Ukraine – 2019. Results of the National Research, available at: http://health-index.com.ua/HI_Report_2019_Preview.pdf

So, many medical professionals prefer to be paid informally – because of the low official salaries. The reform is about to cut this source of income out – and they move either to the Ukrainian private medical institutions or immigrate.

The outpatient users feel the lack of professionals and show a negative attitude to the reform. Some support is shown by the non-medical NGOs. For example, VoxUkraine claims, that 'the goal of the reform is the health of Ukrainians, not the well-being of individual doctors. That is why it needs to be continued'[76].

The *tertial (highly specialized) medical care reform* was planned for 2020 – 2025, but is paused too.

Current Problems in the Ukrainian Health Care Legislation: Summary and Proposals

While many ignore the political and social realities of free healthcare, authors like P.Romaniuk and T.Semigina ignore the legal bases for such a transition.[77] In Ukraine's case – and in most other countries – these legal basis provides more than just a nice supplement to modern and effective hospitals and doctors. These legal bases *determine* the development of the health sector – and a country's transition toward capitalism more generally. Ukraine's health law started on the wrong foot – with Ukraine's constitution choosing Semashko model of health care finance rather than a capitalist one. Such an innocuous decision had wide-ranging consequences that cripples Ukraine's health sector today, and makes it one of the least effective in Europe.[78]

Surely, the constitutionality of medical care – and free care in particular – represents an important issue for many countries. The constitutional bases

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76 Lutsenko E. VoxUkraine Called for Continued Medical Reform, available at: https://hromadske.ua/posts/metoyu-reformi-ye-zdorovya-ukrayinciv-a-ne-dobrobut-okremih-likariv-voxukraine-zaklikav-prodovzhiti-medreformu

77 Their fatuous piece, cheerleading the government, both ignores the policy environment and law. Despite their title, they look at neither the dynamics of health care reform, nor its chances for success toward an end point they do not define. See Piotr Romaniuk and Tetyana Semigina, Ukrainian health care system and its chances for successful transition from Soviet legacies, Global Health 14(116), 2018.

78 We have not provided the usual statistics about Ukraine's health outcomes, given the obvious problems with mortality, morbidity and other problems. For these data in comparative perspective, see Bernd Rechel, Bayard Roberts, Erica Richardson, Sergey Shishkin, Vladimir Shkolnikov, David Leon, Martin Bobak, Marina Karanikolos and Martin McKee, Health and health systems in the Commonwealth of Independent States, The Lancet 381(9872) 2013.

of health care policy touch on so many other rights and values contained in constitutional law.[79] In addition, many other countries, even the US, are debating the constitutionality of reclassifying health care fees as taxes and mandatory insurance requirements.[80] The right to health clearly works in practice – yet not for Ukraine and many other former Soviet Unions to boot.[81] The strongest requirements for free health do not work, though many scholars have not understood why.[82]

The only way to solve the problem of the health care legislation that needs the relevant constitutional basis for Ukraine now – is to change the national Constitution 1996. It is advisable to remove the mention that medical care is free of charge from Article 49.

Firstly, the national health care legislation is too expanded. If Constitution 1996 will be changed, only one article needs amendments – article 49. As for Article 3, which was already mentioned in this paper, – it would be enough for the Constitutional Court of Ukraine to give the new official interpretation of the provisions on the social state.

Secondly, the national health care legislation is (already) mostly based on the reality, not on the constitutional provisions. While the two constitutional articles about the health care represent the Soviet legacy.

If the Article 49 will be modified, the *Fundamentals of the Legislation of Ukraine on Health Care* will need amendments. It is recommended to introduce a new edition of this Law, because now it represents strictly the spirit and the letter of the constitutional provisions about the health care and can be considered the part of the Soviet legacy.

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79 See Wendy Parmet, Public Health and Constitutional Law: Recognizing the Relationship, 10 J. Health Care L. & Pol'y 13, 2007, available at: http://digitalcommons.law.umaryland.edu/jhclp/vol10/iss1/3

80 Kathleen Swendiman, Health Care: Constitutional Rights and Legislative Powers, Congressional Research Service 7-5700, 2010.

81 For proof they clearly work, see Hiroaki Matsuura, The Effect of a Constitutional Right to Health on Population Health in 157 Countries, 1970–2007: the Role of Democratic Governance, PGDA Working Paper No. 106, 2013, available at: http://www.hsph.harvard.edu/pgda/working.htm. For the problems their unique circumstances pose, see Rodica Plugaru. Hospital reform in post-soviet countries: the case of Ukraine and Moldova. 5th ECPR General Conference, Potsdam, Germany. 2009, available at: https://halshs.archives-ouvertes.fr/halshs-00509740/document

82 While a right to health does improve health outcomes, a 'weak' right seems to perform better. See Sungkyoung Choi, Sanghyun Park, and So Yoon Kim, A Comparative Study on

Thirdly, Ukrainian Constitution 1996 is not stable – statistically, its provisions are amended every year and a half. So, it will be less resourceful to change the Basic Law, not the majority of the documents that create the national health care legislation. Right now, the President and his Parliamentary majority are discussing the decentralization reform, that has to be based at the constitutional provisions. The health care reform has at least the same level of importance. So, the necessary amendments can be passed rather quickly (along with the decentralization reform amendments.

Why should the changes be done quickly? Because the health care reform is not as effective and as quick as it might be. In case the reform goes in accordance with the market economy rules, the oppositional politicians run to the Constitutional Court of Ukraine.

So far, the Constitutional Court has done nothing to resolve the muddle.

The first court decision provided many inroads that lawmakers and future courts could have used to move toward private sector provision of health care and removing the albatross of free care from the constitution's neck. The court gave the yellow light to a list of services, which the state would provide for free – a decision later green-lighted by a second decision several years later. The decision opened up the way for voluntary payments – which most countries call private market payments.

The second decision in 2002, though, severely limited the applicability of such payments for financing core health spending. The Court also left an opportunity to tie services to the availability of funding undeveloped. Each of the two decisions contains the same contradictions contained in article 49.

The third case – the problem that is about to be decided for the two years already – was mentioned above. This uncertainty influences the health care legislation a lot.

I.S. Demchenko underlines 'complexity of health care regulation; lack of a clear public health policy and an appropriate strategy for its implementation; inconsistency of current healthcare legislation, and, sometimes, lack of legal regulation at some specific relationships. The classification of healthcare legislation is complicated by objective (first of all, complex nature of healthcare

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the Constitutional Right to Health in the Western Pacific Region Countries, Asia Pacific Journal of Public Health 30(5), 2018.

relations) and subjective (lack of strategic documents that would serve as a basis for the development and improvement of health care legislation) the reasons'[83].

H.M. Sarybaieva argues the 'necessity of forming several "basic" consolidated normative legal acts that would contain administrative rules designed to regulate public relations in the field of health care (regarding the organizational support of public administration in the healthcare, medical activities, pharmaceutical activities)'[84].

R. O. Stefanchuk and others conclude that 'national medical law is not systemic. Obsolete, duplicate and contradictory legal acts of varying legal force, excessive number of subordinate ministerial and departmental acts require the systematization of medical legislation, the creation of a coherent, logical and intra-contradictory system. It is necessary to combine the efforts and knowledge of lawyers and doctors to create an appropriate viable regulatory framework and improve the efficiency and quality of the law-making process'[85].

It seems that the reform is clear and transparent. Though the Ukrainian health care legislation is still partly Soviet, partly from 1990th. The small percent of the modern legal provisions mostly contradicts both the letter and the spirit of the Ukrainian Constitution 1996.

Practically very few constitutional lawyers research this problem. Some of the Ph.D. thesis in the specialty 'Constitutional Law' cover the health care problems.

In 2017 V.Vitkova was researching the constitutional right on health care and its legal guarantees in Ukraine. She mostly paid attention to the essence and structure of this human right, and the majority of her conclusions are about the harmonization of the Ukrainian health care law with the European standards (based on the practice of the European Court of Human Rights). She proposed to do some amendments in the constitutional provisions on health care (article

83 Ivan Demchenko, Classification of Health Legislation, Scientific notes of TNU named after V.I. Vernadsky. Series: Legal Sciences. 30 (6), 2019. available from: http://www.juris.vernadskyjournals.in.ua/journals/2019/6_2019/4.pdf

84 Hanna Sarybaieva, Administrative and legal regulation in the sphere of health care: theoretical and legal principles of systematization of normative legal acts. Thesis for obtaining a Doctor's degree in legal sciences. Zaporizhzhia, 2019. P. 11.

85 Ruslan Stefanchuk, Alexey Yanchuk, Mikhailo Stefanchuk, Mykola Stefanchuk, The codification of medical legislation in Ukraine: the question of the formulation of the problem. Pathologia 15 (2), 2018.

49) and concluded that constitutional law should be used more widely when regulating the health care issues[86]. But her Ph.D. thesis does not cover the current stage of the health care reform.

In 2019 Yu.Shvets was researching practically the same issue at the monoghraphy level – his thesis for obtaining a Doctorate's degree in legal sciences 'Realization of the constitutional right of a person to health care: comparative legal study'. According to the author, 'the paper identifies the problems of development of the national constitutional legislation concerning the right of the person to health protection, the degree of importance of the Constitutional Court of Ukraine in protecting the constitutional right of a person to health protection'[87]. Though the author pays attention to the international experience and the constitutional legislation, some of the conclusions are rather general (in the conclusions to the Thesis author lists the articles of Constitution of Ukraine 1996 about the health care, that is very obvious fact and not the result of his scientific research), or lack the proper argumentation (for example, why the Constitutional Court of Ukraine is the court instance, that has a wide range of competence when it comes about the human right to health care[88]). Also, the author do not consider the problem discussed in this article.

The only relevant article appeared in 2020. N.Mishyna and O.Surilova argue that Ukraine's uncodified medical legislation lacks any constitutional basis. The country's parliament – the Verhovnya Rada – has yet to ratify the bill reforming the basic law in this area. The authors conclude that Ukraine needs a medical code incorporating international and European health care standards. Such a code will also further develop the country's medical legislation. Yet the proposed project has many constitutional and administrative weaknesses[89].

86 Valentina Vitkova, Constitutional right on medical assistance and its legal provision in Ukraine. Thesis for obtaining a Candidate's degree in legal sciences. Uzgorod, 2017. P. 180, 182.

87 Yurii Shvets. Realization of the constitutional right of a person to health care: comparative legal study. Extract of the Thesis for obtaining a Candidate's degree in legal sciences. Uzgorod, 2019. P. 38.

88 Yurii Shvets. Realization of the constitutional right of a person to health care: comparative legal study. Thesis for obtaining a Candidate's degree in legal sciences. Uzgorod, 2019. P. 426.

89 Natalia Mishyna, Olena Surilova. Constitutional and Administrative Aspects of the Ukrainian Medical Code. Wiadomosci Lekarskie. 191-195 (1), 2020.

In case the Article 49 of the Ukrainian Constitution will be changed, and the Constitutional Court will have the legal basis to protect the current health care reform.

Conclusion

Ukraine aims to build the health care system based on state solidarity health insurance, like in Central and Eastern Europe. The Law of Ukraine 'On State Financial Guarantees of Medical Care' 2017 changed the principle of financing the medical institutions. They became non-profit communal utilities and stopped receiving funds directly from the budget under the subvention. Funding now depends on the number of services received by a particular patient in a particular institution, this model is called "money follows the patient". Institutions are paid for by the National Health Service (this model is called "money follows the patient").

Yet this attempt lacks the constitutional basis. The Ukrainian Constitution 1996 guarantees free health care. Some main health care laws reflect the spirit and the letter of the Constitution is reflected in (e.g. *Fundamentals of the Legislation of Ukraine on Health Care*), while some do not (e.g. Law *On State Financial Guarantees for Medical Services*). This situation makes the health care reform slower, less effective and cause essential changes in it because of the Constitutional Court's interference.

The Constitutional Court of Ukraine is captured between the promise of the free health care and the realities of the market economy, and it takes years to pass the decisions on the health care cases. Shortly after the adoption of the Constitution and the *Fundamentals of the Legislation of Ukraine on Health Care,* the Cabinet of Ministers had already seemingly turned-face on free health care, approving private payments for certain medical services in public health care institutions and medical schools. Soon after, more 65 deputies of Ukraine's Verhovnaya Rada (Parliament) objected to the executive act. They seized Ukraine's Constitutional Court to decide on the constitutionality of the executive decision. Could the Constitutional Court find a way between private (self) payment for medical services – and the constitutional right to health?

That is why there is a reason to overcome the Soviet socialistic approach to the health care and to amend the Ukrainian Constitution 1996 in terms of the free health care. This provision doesn't reflect neither the reality nor the goal of the health care reform.

Many other constitutional jurists may see Ukraine's experience – and constitutional contradictions of its health policy – mirrored in their own Basic Laws.

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PRIVATE LIABILITY IN MEDICAL PRACTICE: THE BALANCE BETWEEN THE PUBLIC AND PRIVATE INTERESTS

Nataliya Dubytska*

[i]Nowadays, the main aim of protecting human health is fighting against "Covid-19 death". Special attention shall be paid to legal problems and development of the social institutions concerning liability in private law. The paper analyses the legal changes and attempts to meet a critical need in Ukrainian law education and legal practice. This publication combines factual information with a variety of thought-provoking points

A healthcare crisis centered on a single hospital in central Europe (Ukraine, L'viv) has exacerbated the spread of coronavirus in the country, resulting in a city and surrounding area being locked down to contain the threat. The city of Europe and nearby area were placed under quarantine earlier this week, the only part of the country so far put under near-total lockdown.

Abstract: The research of the private liability discussion in the requirements imposed by the nowadays society is one of the important problems which concern equally, the ethical-legal statement of the medical protection, on the other hand also the all world indeed. The original institution of civil responsibility, the key it has been governed by the Ukrainian legislation and then liberalized by the Napoleonic code previously, cannot be applied to new legal situations such as organ donation and triage, telemedicine, assisted medical reproduction, the legal protection of the human being etc. Our purpose of this article is already to present some of the details of a new approach to professional's liability within the medical field, adapted to the problems medicine and law are currently proposed

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Keywords: Private Liability; Medical Negligence; Defective Products; Medical Liability; Risk of Medical Negligence; Doctor's Mistake

Ukraine had 3,183 confirmed cases of coronavirus after lockdown, with over a quarter of those in the state. 116 people have died in Ukraine due to the virus, 36 of those in the city, which has a population of just 100,000[1].

Meanwhile, of the roughly 500 healthcare professionals in Ukraine infected with the virus, at least 200 are from the local county hospital, which has been heavily criticized for lax safety measures, mismanagement and negligence[2].

Nonetheless, there are many new challenges regards the opportunity to protect our society against this disease. In some words, modern vaccines are proposed to all citizens, who need it first of all, especially disabled persons and elderly people.

DISCUSSION

In this research article, a specialty in the legal relationship between a doctor and a patient is discussed. It should be mentioned that most anesthetic activity in a medical practice is very dangerous and also do not usually have patients directly admitted their care. It should be said about special kinds of relations, -- trust relations. Since in regard to Ukrainian legislation: there is a liability for medical negligence, especially for disseminate medical secrecy about patient (Art 145 of Criminal code of Ukraine). Since a patient who has an ischemic arrest on a hospital corridor is owed a duty of care by any doctor who happens to be passing, and provision of assistance in such circumstances would probably be expected and would not be classed as a good act, on the other hand, this scientific research point has not exactly been tested in Ukraine court environmental to our knowledge.

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1 Максим Степанов: Ми суттєво змінимо медичну реформу в Україні, враховуючинаші реалії та вивправши допущені при її плануванні помилки [Електронний ресурс]// Міністерство охорони здоров'я України : [офіційний веб-сайт]. [Maxym Stepanov: We shall substantially change medical reform in Ukraine accounting for realities and correcting the mistakes committed in the course of its planning [Electronic Resource] // Ministry of Health of Ukraine [official website]. URL: https://moz.gov.ua/article/news/maksim-stepanov-mi-suttevo-zminimo-medichnu-reformu-v-ukrainivrahovujuchi-nashi-realii-ta-vipravivshi-dopuscheni-pri-ii-planuvanni-pomilki.

2 Samuel, M., (2020). Over 4,000 care home deaths from Covid-19 in past two weeks. Community Care. Available at: https://www.communitycare.co.uk/2020/04/28/4000-carehome-deaths-covid-19-past-two-weeks-cqc-figures-show/ (Accessed: 11/05/2020)

Legal considerations of negligence require doctors to act to an appropriate standard, usually but not exclusively judges by the standard of their peers, whereas for civil negligence, the standard of practice has no result in serious harm from actions that could be considered to be incompetent or grossly negligent.

The legal discussion of the private liability problem in the conditions imposed by the nowadays society is one of the major issues which concern equally. The original synergetic legal research of medical care, but also the medical world.

The traditional opinion regards civil liability as central to private law, on the other hand, according to Wikipedia data:" Private law is that part of a civil law legal system which is part of the jus commune that involves relationships between individuals, such as the law of contracts and torts (1);[3]

For this practice's purpose, it has been governed to new civil legislation such as medical mistakes and patient informed consent, assisted civil law reproduction, the legal protection of the human being theory and etc. This aims to present some of the details of a new approach to professionals liability within the medical field, adapted to the problems of telemedicine and doctor's mistakes in practice.

Introduction

In Ukraine, there is no special legislation concerning transparency regulation the quarantine measures and lockdown. The lockdown was planned from 12 March previously, and the next part of it is in the winter holidays. Firstly, appearance in public places, without personal protective appearance equipment, moving in groups of more than 10 people and visiting public places were prohibited with special exceptions.

Civil liability may be considered, from a functional point of view, as a technique of indirect market regulation since the risk to incur liability for damages provides an incentive to invest in safety. The idea is that any raise of the stick of civil liability for a given activity would determine a corresponding

3 Bussani, Mauro (18 May 2010). "The Project - Delivered at the first general meeting on July 6, 1995 - The Trento Common Core Project". The Common Core of European Private Law. Turin, Italy: Common Core Organizing Secretariat, The International University College of Turin. Retrieved 8 September 2011. Vértesy, László (2007). "The Place and Theory of Banking Law - Or Arising of a New Branch of Law: Law of Financial Industries". Collega. 2-3. XI. SSRN 3198092..

increase of efforts by firms and professionals operating in the relevant case aimed at reducing the risk or compensation

The main aim of this article is to emphasize the controversial problems of dilemma in balance between public and private interest. That is why we need further development legislation in Ukraine to implement in Ukrainian legislation

On the different "functions" of civil liability, among others, it is very controversial for medical lawyers in the protection of doctor's rights. The current legislation, respectively Law no. 95/ 2006 regarding the healthcare reform, governs in the medical malpractice domain that the medical personnel can be held liable in the medical negligence.

The main obligation of a physician is to act in a prudent and diligent manner. He is not obliged to achieve a specific result; rather, he has to conduct himself with proper care and skill. Deviation from the professional standard will be considered a fault for which a physician can be held liable, even if he regards his action as reasonable.

Informed Consent

A patient has the right to be informed by his physician. The right to receive information and the duty to obtain consent from the patient is laid down in specific legislation concerning patients' rights; article 7 and 8 in the Belgian law on patient's rights 4 and article L. 1111-2 and L. 1111-4 of the French law[4].

Furthermore, a physician needs to inform his patient in due time so that he is able to weigh all aspects of the treatment before consenting to it. With respect to the risks of a treatment, Belgian courts apply the theory of the normal and reasonable foreseeable risks[5]. This means that the physician need not inform the patient about serious but exceptional risks or minor but frequent risks. However, in some cases, it is decided that if the intervention is less necessary or urgent or if the intervention gives a poor result of improvement, the information must be more specific. On the other hand, it has also been argued that a physician needs to inform the patient about the risks that he believes are relevant for a normal person in the same circumstances whether

4 see H. Koziol, Comparative conclusions, in BASIC QUESTIONS OF TORT LAW FROM A COMPARATIVE PERSPECTIVE 746 (H. Koziol ed., Jan Sramek Verlag 2015).

5 Wet betreffende de rechten van de patiënt van 22 augustus 2002.
Loi no 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé.

or not to consent with the treatment (relevant-risk-theory). The latter opinion is supported by article 8 of the Belgian law on patient rights.

In France, the Court de Cassation has recently altered the criterion of which risks the patient has to be more effective for prior to the judgement, courts also adhered to the theory of the normally foreseeable risks[6].

Nowadays, they look at the seriousness of the risk, which means that serious risks have to be communicated to the patient even if those risks are of exceptional occurrence. However, it has been very controversial established that a physician who has not given his patient all the information cannot be held liable for all the consequences of the realization of the risk. Failure to warn has only deprived the victim of a chance to refuse. Recovery is therefore limited to a percentage of the loss suffered (loss of chance, see also §2.6.3.).

The duty of the physician to inform may be limited. In case of emergency, a physician is not obliged to give all necessary information to the patient at the moment of treating him. In addition, when the physician has good reason to withhold information in the best interest of the patient (therapeutic exception), he may withhold information. Whether this was justified has to be proven by the physician.

Finally, a physician does not have to inform the patient if the patient does not want to know. However, if it would seriously harm the patient or third parties, exceptions will be made. Since a patient is properly informed, he has to consent to the treatment, notwithstanding some exceptional situations such as an emergency. The need to obtain consent is based on self-determination and respect for doctor's integrity. Consent can be implied if the patient's will is certain. In order for a physician to start a treatment, the consent of a patient needs to be real and given by a competent person and is only valid for the treatment consented to.

In general, a public hospital is only liable for fault, which means that the patient must show that harm was caused by a fault of an agent of the hospital or by a

6 Cour de Cassation, 7 October 1998, Bulletin Civil I, n° 291 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 105.

fault consisting of a defective organization[7]. In order to establish liability of a public hospital, it is sufficient for a patient to proof mere negligence.[8]

It follows that the patient carries the burden of proof, but in some cases, fault of the public hospital is presumed (e.g. iatrogenic infection)[9]. However, the presumption is very acceptable. In addition, it has also been recognized that a public hospital can be held liable without the existence[10] of a fault for so-called therapeutic risks. Two cases are important in this respect. In one case, a hospital was held strictly liable for the unanticipated side-effects produced by a new medical technique.

The next case concerned ordinary medical techniques. In general, the court accepted strict liability for the exceptional risks and stated that "when a necessary medical test or treatment carries a known but exceptional risk, and when there is no reason to think that it is likely to occur in the circumstances, the public hospital is liable for all the direct damaging consequences of the test or treatment, providing that they are not related with the patient's initial state of health, nor to its foreseeable evolution, and providing that the loss suffered by the patient is extremely serious"[11].

Consequently, if the conditions are fulfilled, and the causal link is established, a patient will be fully compensated for his loss without the need of establishing fault (strict liability).

In general, French private law does not recognize strict liability. However, an exception is made in case of iatrogenic infections. It has been held by the

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7 Conseil d'Etat, 10 April 1992, Recueil Lebon, 1992, 173 and Conseil d'Etat, 20 June 1997, Recueil Lebon, 1997, 254 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 104.

8 https://www.researchgate.net/publication/290832007_Medical_Liability_in_the_Context_of_the_Civil_Liability_Crisis/fulltext/57aa95b008ae3765c3b4f126/290832007_Medical_Liability_in_the_Context_of_the_Civil_Liability_Crisis.pdf

9 G'Sell-Macrez F. Medical malpractice and compensation in France: Part I: the French rules of medical liability since the patients' rights law of march 4, 2002. Chic. Kent. Law Rev. 2011;86:1093. [Google Scholar]

10 Medical liability in the context of civil liability//Lacrima Lidicia Boila//Postmodern opening/2013/ Volume 4/ issue 1march 4 h/ 34-41

11 Cour de Cassation, 7 October 1998, Bulletin Civil I, n° 291 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 105

Court[12] de Cassation that private doctors and hospitals are very dangerous strictly liable for iatrogenic infections contracted by their patients. Whether an iatrogenic infection occurred or not is not defined by the court. However, one can expect that the court will adopt a wide definition by accepting iatrogenic infections as those which had not yet developed when the patient was admitted to the hospital. In case no iatrogenic infection seems to have appeared, the patient must fulfil the conditions of a civil claim[13].

Causal Link[14]

The plaintiff must establish the causal link between the negligent behavior of the physician and the damage suffered. Belgian case law adheres to the theory of equivalence of conditions meaning that any factor that has necessarily contributed to the existence of damage has to be considered as a sine qua non cause of the damage even if there was only an indirect link. In France[15], it is also up to the patient to establish that the physician's fault was a sine qua non for the loss, and in addition, the causal relation needs to be established with certainty.

In cases where the physician had to achieve a specific result, liability will follow for not achieving the result unless he can prove the existence of an unknown cause such as force majeure, fault of a third party or fault of the patient.

Burden of Proof

Since the burden of proof rests upon the injured patient who has to prove the facts of the case, which constitute the physician's fault[16]. Proving fault is not

12 Cour de Cassation, 7 February 1990, Bulletin Civil I, n° 75 cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 105.

13 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779963/Indian J Urol. 2009 Jul-Sep; 25(3): 372–378. doi: 10.4103/0970-1591.56206 PMCID: PMC2779963 PMID: 19881134 Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective

14 Cour administrative d'appel de Lyon, 21 December 1990, JCP II, 1991, 21698 (Gomez) cited in GALANDCARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 104. 10 Conseil d'Etat, 9 April 1993, Recueil Lebon, 1993, 127 (Bianchi) cited in GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 104.

15 Starke J.R., Jackson M.A. When the health care worker is sick: primum non nocere. JAMA Pediatr. 2015;169(9):809–810. [PubMed] [Google Scholar]

16 McDonald B. Legislative intervention in the law of negligence: the common law, statutory interpretation and tort reform in Australia. Syd. Law Rev. 2005;27:443. [Google Scholar]

easy because it is not always clear whether the injury is a consequence of the fault. When it turns out to be impossible to prove fault, the patient must bear the risk of injury and damage. In addition, the patient must also prove damage and causality. It follows that the burden of proof resting upon the patient is heavy. Therefore, the courts have adopted in some cases, the doctrine of res ipsa loquitur. The burden of proof upon the patient differs according to the kind of obligation, that is to say, the obligation to achieve a specific result and the obligation to act with reasonable care and skills. With regard to the former, the patient has to prove that the result was not achieved, while in the latter case, he has to prove that the physician did not act as a normal and prudent physician placed in similar circumstances would have done.

The USA and some European countries introduced a no-fault medical compensation scheme, with concurrent jettisoning of their older medical negligence-based compensation system. Damages are shelled out by an insurer-pool, but the standard of care is overseen by an independent body, thereby dualistic compensation and deterrence. Finland[17] and Denmark followed suit with a scheme funded by a private system. France and Belgium were more circumspect in establishing a more confined and controlled scheme compared to the Scandinavian countries. The United States has medical tort legislation at the state level - States statutes have caps/limitations on damages, liability, attorney-fees and awards from collateral sources. Medical practitioners in the UK and Australia, however, do not have the "luxury" of a no-fault compensation system. They still operate under the Common Law and statute-based negligence system[18].

The Court of Appeal of Liège decided that the burden of proof of informed consent is always on the physician. However, the Belgian Court of Cassation did not yet adopt that view[19].Then in the court motivated its decision by referring to the principle of presumption of innocence in penal cases. Finally,

17 Civil Liability Act 2002 (NSW) 2002. [PubMed] [Google Scholar]

18 Bismark M.M., Gogos A.J., McCombe D., Clark R.B., Gruen R.L., Studdert D.M. Legal disputes over informed consent for cosmetic procedures: a descriptive study of negligence claims and complaints in Australia. J. Plast. Reconstr. Aesthetic Surg. 2012;65(11):1506–1512. [PubMed] [Google Scholar]

19 https://link.springer.com/referenceworkentry/10.1007%2F978-3-642-32338-6_53//Legal and Forensic Medicine pp 691-706| Cite as Understanding Medical Liability

in a civil case[20] whereby a patient starts a claim based on transmission[21], the patient must still prove that all the evidences of the negligence are still present. If the physician refers to a ground for justification, the patient must also prove that this justification does not exist. In a very recent case, the Court of Cassation has confirmed its position[22] (December, 16th, 2004).

Nota bene for doctors: a patient can only recover damages in respect of medical mistake if he has actually suffered all damages. All damages have to be compensated, including moral damages for pain and suffering. Damages will be determined by comparing the real situation with the situation the patient would be in if the fault would not have occurred. Compensation for damages arising out of a breach of contract is limited to what was foreseeable, whereas, in tort liability, there is no limit of compensable damage. In order for damage to be recoverable, it has to be original, acceptable and logical.

However, one patient claims a suit, that's why **we need some affectional changes to be implemented in Ukrainian legislation. They are proposed:**

1) **Firstly:** to establish an institution of medical liability for medical negligence in Civil code and etc.

2) **Secondly:** to promote protection human rights in the vaccination process.

3) **Thirdly:** the protection of doctor's rights is the effective with the instrument of liability under private law. Since, any further investment in safety would cost more than the risk to pay redress to damaged clients and users.

The above technique of indirect market regulation may work only insofar as the risk to compensate damages is allocated onto the same subject called to invest further resources in safety. Therefore, such a paradigm of civil liability invariably requires the identification of a person liable for redress, which is likely to be the producer of a given product of the provider of a given service[23].

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20 Semple S.J., Roughead E.E. Medication safety in acute care in Australia: where are we now? Part 2: a review of strategies and activities for improving medication safety 2002-2008. Aust. N. Z. Health Pol. 2009;6:24. [PMC free article] [PubMed] [Google Scholar]

21 Stapleton J. The gist of negligence Part 1: minimum actionable damage'(1988) Law Q. Rev. 1988;104(Apr):213–238. [Google Scholar]

22 AIHW . Australian Institute of Health and Welfare; Canberra: 2014. Australia's Medical Indemnity Claims 2012-13. [Google Scholar]

23 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779963/Indian J Urol. 2009 Jul-Sep;

Mistake in diagnosis will also not amount to negligence if the required standard of care has been duly observed. In cases where there is some form of doubt on the part of the medical practitioner as to specific diagnosis to make, such a person ought to make a referral to a specialist], failure to do so may however amount to negligence. The standard of care required from alternative medical practitioners appears to be lenient especially where the act is not such that will give rise to liability for criminal negligence. In Shakoor V. Situ, the court held that an alternative medical practitioner could not be judged by standard of an orthodox medical practitioner. In the case of Bolam V. Friern Hospital Management Committee, the court was of the view that it suffices, if a doctor acted in accordance with a practice that was considered acceptable by a responsible body of doctors. The burden is on the claimant to show that no reasonable doctor acting in the same circumstances would have acted in the way the defendant acted. The fact that the culpability of a medical practitioner is largely dependent on the expert evidence of a colleague has been largely argumented on the grounds that the approach seems to be in favour of the medical profession over and above the patient and hence, support from colleagues arguably makes it easy to escape liability for negligence. While this seems like a possibility, the fact that judges have the prerogative to determine the weight to attach to evidence adduced in a suit cannot be overlooked. In essence, where evidence given appears tainted, the judge has a responsibility to disregard such evidence. This was evident in the court's decision in Hucks V Cole[24] where it rightly held that 'the court must be vigilant to see whether the reasons given for putting a patient at risk are valid or whether they stem from a residual adherence to out of date ideas'[25]. In the same vein, the court in Bolitho V. City and Hackney held the view that negligence can be successfully proved even in cases where medical opinion suggests otherwise. The court emphasized the need for the judge to consider the evidence adduced and decide whether the action unnecessarily puts patients at risk. In establishing whether a breach has occurred, the courts can also rely on written guidelines and rules of medical ethics to ascertain standard practices.

25(3): 372–378.doi: 10.4103/0970-1591.56206 PMCID: PMC2779963 PMID: 19881134 Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective M. S. Pandit and Shobha Pandit

24 UN's 2011 Guidelines for Business and Human Rights (Reggie Principles)

25 https://rm.coe.int/1680700281//Strasbourg, 7 March 2005 CDCJ (2005) 3 rev1[cdcj/docs 2005/ cdcj (2005) 3rev1 e]EUROPEAN COMMITTEE ON LEGAL CO-OPERATION (CDCJ) REPORTON MEDICAL LIABILITY IN COUNCIL OF EUROPE MEMBER STATES

Coverage of Doctors and Hospitals under CPA

In the case of the Indian Medical Association vs. V.P. Shanta and Ors., III (1995) CPJ 1 (SC)[26], the Supreme Court finally decided on the issue of coverage of medical profession within the ambit of the Consumer Protection Act, since that all ambiguity on the subject was cleared. With this epoch making decision, doctors and hospitals became aware of the fact that as long as they have paid patients, all patients are consumers even if treatment is given free of charge. The apex court[27] does not favor saddling medical men with ex gratia awards. Similarly, a in a few landmark decisions of the National Commission dealing with hospital death, the National Commission has recognized the possibility of hospital death despite there being no negligence.

According to the majority view in the public international law literature, companies are not, at least not directly bound by human rights. Although numerous international law instruments, including the UN's 2011 Guidelines for Business and Human Rights (Reggie Principles), also address companies, liability for human rights violations is, therefore, a matter of domestic law.

The domestic law applicable to liability for human rights violations must be determined in accordance with the provisions of (European) private international law. Direct recourse to the lex fori, in contrast, is not possible. The legal situation in Europe is, therefore, different from the United States where actions which are brought on the basis of the Alien Tort Claims Act (ATCA) are governed by US-American federal (common) law.

Claims for human rights violations committed abroad will usually be claims in tort. Under (European) private international law it is, therefore, the law of the place where the damage occurs (Article 4(1) Rome II Regulation)[28] and, hence, foreign law which governs these claims. Exceptions apply only within narrow limits, in particular, if domestic laws can be classified as overriding mandatory provisions (Article 16 Rome II Regulation) or if application of foreign law violates the order public (Article 26 Rome II Regulation).

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26 UN's 2011 Guidelines for Business and Human Rights (Reggie Principles)

27 12 GALAND-CARVAL, S., "France" in FAURE, M. and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 113. 14 Court of Appeal Liège, 30 April 1998, T. Gez/rev. Dr. Santé, 1998-1999,139; Court of Appeal Antwerp, 22 June 1998, T. Gez/ Rev. Dr. Santé, 1998-1999, 144 cited in CALLENS, S., "Medical Civil Liability in Belgium. Four Selected Cases", European Journal of Health Law, Volume 10, No. 2, June 2003, 125.6

28 Article 4(1) Rome II Regulation

In addition to tort law, claims for human rights violations may also be based on company law, namely when directors are directly held liable for torts committed by a foreign subsidiary. According to the relevant private international law provisions of the Member States these claims are governed by the law of the (administrative or statutory) seat of the foreign subsidiary. As a consequence, claims in company law are also subject to foreign law. The fact that (European) private international law submits liability for human rights violations to foreign law is very often criticized in the private international law literature. Claiming that foreign law does not sufficiently protect the victims of human rights violations, a number of scholars, therefore, attempt to subject liability claims de lege lata to the domestic law of the (European) parent or Buyer Company.

The medical activity, as a special assumption of liability for damages, in the search of its own identity, is currently experiencing profound changes (*Italian*, 2002/ Trif and Astratostaie/ 2000: Boila, 2009)[29]. Their important analysis proposes his own way in conception and jurisprudence, caused by contemporary social and medical realities. In some words, whenever the patient's condition worsens for reasons other than those strictly related to the diseases he suffers from, for which he requested treatment or surgery, the physician will be forced to pay the damages for the breach of the security obligation, whether or not guilty of the situation created. This requires a legal research of his conduct in relation to the standards set at the current level of the scientific and technical research. Liability under private law for medical accidents is prescribed as liability legitimacy based on the legal links, where the main purpose is the protection of doctors (not only patients) and to ensure their material (not moral) repair.

In this purpose, the renew Civil Code[30] was drafted to reaffirm the idea according to which civil liability is a unique institution with two different legal forms.

In the recent decades, a legal unprecedented situation was signaled in the case of the infringements committed by professionals in the exercise of their duties, which caused harm to other persons, such as injury caused to others due to the breach of security, by medical accidents. The medical field is

29 Cour de Cassation, 29 June 1999, 1999, JCP II, 10138 cited in GALAND-CARVAL, S., "France" in FAURE, M.and KOZIOL, H. (eds.), Cases on Medical Malpractice in a Comparative Perspective, Vienna, Springer-Verlag, 2001, 113.

30 Civil code of Ukraine(new edition)//http://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=en&p_isn=65221&p_country=UKR&p_count=599

characterized by the specific of the diagnostic, prevention, surgery and treatment activities, where the physician acts on the body of the patient to cure or at least to improve the health problems. Ensuring the security of the patient's body is the focus of medical practice; the human being and health are equally guaranteed and protected by law. In performing the medical act, every professional must act solely in the interest and welfare of the patient, social values that should prevail over the interests of science and society.

The current trend of jurisprudence is to establish a more stringent, stricter liability, where the security duty of the physician to his patient is to be recognized as an endeavor of dignity, whose violation should draw the liability as a professional. In other words, whenever the patient's condition worsens for reasons other than those strictly related to the diseases he suffers from, for which he requested treatment or surgery, the physician will be forced to pay the damages for the breach of the security obligation, whether or not guilty of the situation created. This requires an assessment of his conduct in relation to the standards set at the current level of the scientific and medical research. The liability for medical accidents is prefigured as a liability objectively based on the principle of prevail human being (private balance on society), but is harmful for society, where the main objective is the protection of patients and to ensure their compensation.

There is a controversial problem according discussion: what is private liability, is it a special kind of institution or kind of civil liability? It's a dilemma of theory. On the other hand, in civil cases there is a unique practice in Ukraine, according to Civil code: there is moral compensation and material side. Since, this problem on practice need further implementation foreign legislation in Ukraine's laws and court practice.

In this consideration, medical liability is configured as a special case of civil liability for damage caused unjustly to the patients which requires legal regulations and an ethical approach distinct from other cases. In this regard, we note that one of the characteristics of the positive law development is the expansion and diversification of the new regulations of new assumptions of private liability for damages. Thus, facing the danger of increased risks of damage, some of them anonymous, to protect the victims, in some areas, was established by law the obligation of compensation, by designating the responsible persons and the conditions of engaging liability without relying on a particular "form" civil liability.

Since, Nature law in nature obligation for recovering the damage by the person responsible, even in the absence of a risk's contractual basis or the committing with guilt, intentionally or negligently, a "tort action". In the original approach actually, facing this new legal reality, the question emerged: to what extent a "privacy" of the liability assumption as being contractual or delict is required, whereas the law determines the conditions and the effects they produce?

The discussion arises undoubtedly in private liability, an area with a special legal regulation, but which unleashed many interpretations. The current debates from the medical field criticize the approach of the medical act from the perspective of medical negligence, stating that it must be recognized that the medical profession involves certain risks, so that in the event of harming the patient there must be established effective procedures to compensate the victim, either amicably by negotiation, drawing and insurer's liability under the contract of insurance, or by setting up a compensation fund for the victims of medical accidents along with the patterns set by other states. The professional organizations are militating in favor of a new approach to the medical profession in order to stop the blame for the consequences of the physicians, so publicized and which contribute to the defamation of this profession.

There are two main forms of doctor's illegal activity (inaction): medical negligence or doctor's mistake. Taking in this consideration, the medical negligence is clear emphasized in Ukrainian legislation, on the other hand, the doctor's mistake is not enough written in law and in theory without any unique conception

The legal relationship between a doctor and a patient is a uncial special one. Most anesthetist's work in a hospital environment and do not usually have patients directly admitted under their care. When a patient is admitted to hospital, a duty of care relationship is created, which can be applied to any doctor coming into contact with the patient not just the admitting team. Hence, it has been argued by medical law academics that any patient we come across in our professional environment is owed a duty of care, not only by the doctors the patient comes into contact with, but also by those who are employed by the Trust to deliver patient care. For example, a patient who has a cardiac arrest on a hospital corridor is owed a duty of care by any doctor who happens to be passing, and provision of assistance in such circumstances would probably be expected and would not be classed as a 'good Samaritan' act, however, this academic view has not currently been tested in a British court[31] environment to our knowledge.

31 Finlay CJ in Dunne (an infant) v National Maternity Hospital [1989] IR 9

This is established where a doctor's practice has failed to meet an appropriate standard. The standard of the 'reasonable man' or the famous 'man on the Clap ham omnibus' who is said to be an ordinary person placed in the same circumstances is usually applied for most tort cases. However, where there has been a potential breach of professional duty, this is reinterpreted as that of the standard of comparable professional practice (Bolam v Friern)[32]

Civil considerations of negligence require doctors to act to an appropriate standard usually but not exclusively judged by the standard of their peers, whereas for criminal negligence the standard of practice has to result in serious harm from actions that could be considered to be incompetent or grossly negligent. Due to the greater availability of practice guidelines to guide the courts, doctors should always consider the implications and justification for deviations from accepted practices should the patient suffer harm, and doctors in training should be aware that they are expected to seek advice and assistance where they lack experience in order to preserve public safety. Adequacy of note keeping aiding defend any claims is vital.

Conflict of Interest

The legal doctrine in our country, at this time, supports the idea of a "unique nature law", but non-polisemic" where tort liability represents the common law and the contractual liability represents the derogatory, particular regime. Nevertheless, whenever a legal relationship is governed by a legally binding agreement, the contractual liability is applicable for the non-implementation of the provisions within this legal document. In the other cases, we will invoke the tort liability with respect to the damage caused by committing a wrongful act. We talk about the majority of points where the differences are only of "private medical moment" and not important.

The national and European legislator pays an attractive attention to the repair aim of the liability in relation to the preventive and tutorial function which describe innovations for drafting legal norms.

Legal need in Formulation conception of medical liability in Medical code/ Argumentations:

32 Finlay CJ in Dunne (an infant) v National Maternity Hospital [1989] IR 9

There is need to promote a proposition to create and establish in Ukrainian legislation Medical code. It's very important and need further discussions in Academic world and among practitioners in case practice

We need real concrete sanctions the normal professional action of the person responsible. Thus the professional's private liability (liability under private law), the health institutions, for doctors especially, through the special guarantee funds established for the repair of damages.

The legal doctrine in our country, at this time, supports the idea of a "monistic civil liability", but "dual" where tort liability represents the common law and the contractual liability represents the derogatory, special regime. In other words, whenever a legal relationship is governed by a legally binding agreement, the contractual liability is applicable for the non-implementation of the provisions within this legal document. In the other cases, we will invoke the tort liability with respect to the damage caused by committing a wrongful act. We talk about unanimous through majority where the differences are only of "fiduciary aspect" and not substantive.

There are many problems concerning legal and medical aspects of medical negligence in medical practice. The current legislation, respectively Law no. 95/ 2006[33] regarding the healthcare reform, governs in the medical malpractice domain that the medical personnel can be held liable in the following forms:

- Administrative - procedure that is conducted by analyzing a medical malpractice complaint by the Monitoring and Professional Committee for malpractice cases, established in the public health institutions of each county and in Ukraine;
- Civil - a procedure that involves advancing a civil action based on the principles (inevitable and respectful) of private liability to a court;
- Criminal - a procedure that involves lodging a criminal complaint against the standards governed by the Criminal Code, is more dangerous for protecting doctors in the court procedure for the reason that the civil action may be taken twice.

33 Moréteau O. France. In: Koziol H, Steininger BC, editors. European Tort law 2008. Wien/ New York: Springer; 2009. p. 282–3. Google Scholar

Regarding criminal liability, the conditions laid down by the Civil Code relating to one offense or more have to be regarded. Just as in the case of civil liability, when an element of the offense is missing, then the presumed guilty cannot be held legally accountable[34]. Although the proofs are in principle similar in civil and criminal proceedings (documents, witnesses, hearings, expertise) there is a difference regarding the steps that must be followed in dealing with the testimony?

The procedure for private medical responsibility of the medical staff requires filing a civil complaint that will be submitted to the agencies, usually investigating or prosecuting legal offense, and then its decision can be appealed to the superior court following the latter to give a decision that cannot be appealed finally.

After the investigation of the case, the Disciplinary Commission issues a decision that is communicated to the sanctioned doctor, the person who made the complaint, the Ministry of Health, the Executive and the person whom the sanctioned doctor has an employment contract with[35] hospital strictly and under private law.

CONCLUSIONS

Finally, it should be summarized on balance between the public and private interests in legal relations between doctors and their patients, since the main Keynote is that: we need real changes in European legislation with the aim to protect medical rights in medical practice. Since all changes to the possibilities and choices and leave the decisions to the patient are proposed in this article. Some doctors clearly want to be in that position, and for them, such behavior is fine; but most medical practitioners, when they are working without an informed consent of patient, protection human rights according to a liability under private law better. They need further defense with a professional lawyer in the branch of medical law, especially. Taking into consideration the underlined thesis of this paper research, it should be emphasized mainly on the importance of the doctor's rights protection. I'd like to note for medical practitioners that it's very important to help their patients in feeling careless and doctor's responsibility in the medical practice without negligence by

34 Galand-Caraval S. France. In: Faure M, Koziol H, editors. Cases on medical malpractice in a comparative perspective. Wien/New York: Springer; 2001. p. 102. Google Scholar

35 Martín-Casals M, Ribot Igualada J, Solé Feliu J. Medical malpractice liability in Spain: cases, trends and developments. Eur J Health Law. 2003;10:153. PubMedCrossRefGoogle Scholar

hoping for better for human health as the main growing for society always by protect them, no matter what happens. On this matter, we have seen doctors act simply as professionals, providing the medical services patients seek but not the counsel and support they also need.

While sombre in mood, in the conception of private liability, which implemented in legislation, of professional private responsibility reflects many currents cases in Europe. However, is need to examine the doctor–patient relationship, the context in which that relationship operates, and in particular, the influence of changes in the financing and better organization of health care system in Ukraine especially. The doctor–patient relationship deserves serious attention and protection during these dangerous risk times.

It should be underlined: that an important source of the malpractice problem is the changed the nature of private relationship between doctor and patient, which results from the rise of specialization, the branch of medical practice, and the mistakes of the doctor's, which don't conclude to negative result as usual, in case that there is no causal link between action (non) and damage. That's why; the doctors must know that legal aim (with advice of attorney in medical law) is very important on the all stages of their activity. Nowadays, a growing interest of the malpractice risk is changing the way doctors treat patients—in ways both carefully and deleterious but on balance between the public and private interests in modern society, especially in the practice of telemedicine. The negligence problem in medical practice is controversial, need deep analyses, and problematical in case practice. It is not likely to be resolved by anything less than a generally new approach to the renew enation of iatrogenic injuries and a determined effort by doctors to deal with their patients of balance between the private and public interests under the effective legislation in private law.

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