TALLINN UNIVERSITY OF TECHNOLOGY
School of Business and Governance
Department of Law

Polina Blokhina

THE LEGAL IMPLICATIONS OF THE MEANINGS OF STORAGE AND INFORMED CONSENT FOR UMBILICAL CORD BLOOD DONATION

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Supervisor: Jenna Uusitalo

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… Polina Blokhina, 03.01.2021……
(signature, date)
Student code: 177690 HAJB
Student email address: polinablokhina774@gmail.com

Supervisor: Jenna Uusitalo
The paper conforms to requirements in force

……
(signature, date)

Co-supervisor:
The paper conforms to requirements in force
……
(signature, date)

Chairman of the Defence Committee: / to be added only in graduation thesis /
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ABSTRACT

Human health is the highest good, many other benefits and values lose their significance without. Proclaiming the right to protection of health and medical care as one of the basic constitutional rights, the state is obliged to implement a set of measures to preserve and strengthen the health of the population, including through the development of state, municipal and private health systems, establishing legal guarantees for everyone to receive the necessary medical and social assistance. This paper examines legal implications, specifically outlining the necessity of informed consent, in the biomedicine field related to stem cell donation and banking, as well as all the necessary steps of such procedure as umbilical cord blood collection and its storage. The aim of this paper is to analyze the appliance and cruciality of informed consent, meaning legal issues of organizing medical activities that regulate the collection and use of stem cells, as well as, its banking factors. In this case, the umbilical cord (placental) blood cells. In addition, the proposals for solving the issues mentioned below will be suggested. This paper covers biomedicine procedure from legal perspective, highlights all the important contractual obligations (informed consent in particular), points out property rights and all the aspects of the storage of umbilical cord blood collection, as well as rises the question of whether pregnant women are aware of such procedure and know that the blood elements are their property.

INTRODUCTION

The development of modern medicine opens up new opportunities and perspectives for people. The progress of biomedicine has discovered new methods of treatment of different diseases that contributed to the rise of advanced medical services that involve the use of human biological materials: stem cells, blood, and other human body tissues. One of the most performed biomedical procedures is umbilical cord blood extraction[1]. The umbilical cord is a tube that connects a child to the mother's placenta, providing oxygen and nutrient-rich blood, at the same time, removing all the waste. The procedure of extraction of the umbilical cord blood includes the collection of the umbilical cord and blood components from the placenta after giving birth. The umbilical cord blood contains stem cells that are widely used for therapeutic purposes: it helps to treat more than 80 hematopoietic and genetic diseases, including leukaemia, Alzheimer's disease, blood disorders, multiple myeloma, and other diseases[2]. Umbilical cord blood stem cells have been used for more than 25 years and more than 30,000 cord blood stem cell transplantations have been performed worldwide[3]. In order to proceed with this research, a qualitative method will be carried out through literature review and comparative analysis of different Member States' legislations on a given research topic.

The umbilical cord blood is stored in public and private biobanks. In the public biobanks (a person voluntarily donates the umbilical cord blood for public use and research, i.e. it will be used to help other people) the donor will not be able to use it for private purposes in the future. Additionally, in public biobanks, there are no storage fees[4]. In private biobanks, a straightforward system stores the umbilical cord blood for the personal use of the donor and his/her family. The storage can be extended to a long term and concomitantly storage 'increasing' fees will apply[5].

[1] Sullivan M. J. (2008). Banking on cord blood stem cells. Nature Reviews Cancer, 8, 554–563
[2] Gluckman E, Broxmeyer HE, Auerbach AD, et al. Hematopoietic reconstitution in a patient with Fanconi's anaemia by means of umbilical cord blood from an HLA-identical sibling. New Engl J Med. 1989;321:1174–8.
[3] Karen K. Ballen, Eliane Gluckman, Hal E. Broxmeyer Blood. 2013 Jul 25
[4] Gunning J. Umbilical cord blood: banking and clinical application. Law Hum Genome Rev 2004;20:217–25
[5] Rubinstein P. Why cord blood? Hum Immunol 2006;67:398–404

As stated above, the stem cells that are contained in the umbilical cord blood are of high value and use, as this medical procedure itself. As for any medical procedure or any other services in our day to day - to - day life, there has to be a contract between two or more parties. Contracts are an integral tool that allows you to regulate the relations of subjects of any field at different stages of relations. Modern living conditions oblige a person to conduct his activities in a contractual relationship in order to protect his own interests and the interests of the second party. Besides that, we can face legal issues related to contractual obligations, when concluding a contract or nonperformance of it. When a person is entering into a medical contract, he must fully acknowledge all his rights and all the steps of the medical procedure[6]. It is expected that healthcare professionals are aware of both legal and medical aspects when they provide a health service.

Before the beginning of any procedure, the doctor has to ask for a valid informed consent from the patient. The patient is actively involved in planning the treatment process and evaluating its effectiveness. However, his trusting relationship with his physician is replaced by formalized contractual obligations built on a legal basis. The patient should be informed about his state of health, his diagnosis, the prognosis of the course of the disease and the expected treatment methods[7]. However, in nowadays life, there are plenty of cases that show that either patient or health service provider is at fault for not following contractual steps: it is either patient's negligence (i.e. not reading terms and conditions of the agreement thoroughly) or the lack of the explanation from the doctors side on all the steps of medical procedure and a special emphasis has to be made of the possibility of risks and their frequency. Statistics show that doctors do not always take consent as a necessary action. It has been considered to be medical providers' mismanagement and was reported in Canada, Australia, New Zealand, Germany, the United

[6] Council of Europe- The European convention on human rights. Strasbourg, 1953
[7] Gunning J. Umbilical cord blood: banking and clinical application. Law Hum Genome Rev 2004;20:217–25

Kingdom, and the United States[8]. Referring to the umbilical cord blood collection, it has to be said that pregnant women are not always aware of the existence of such procedure, the value of the stem cells it consists of and the fact that they are entitled to it.

This paper will evaluate and review the legal application to umbilical cord blood collection procedure, aspects of its storage, as well as to what extent mothers and their children are legally protected. The aim and focus of this research are to identify the level of patients' awareness of their property rights relating to the use of their body tissues, the potential storage of it and understanding of how the whole process should go in accordance with the law. A major emphasis of this paper will be made on the consent meaning. The research questions therefore are: how and when it has to be obtained (informed consent), as well as, what legislative changes should be required to better reflect informed consent and whether or not these changes have to be regulated by national law or added to the EU or Council of Europe legislation. The author will bring up the European regulations on the provisions for the umbilical cord blood banking, such as Directive 2004/23/EC, explaining all the factors of the given procedure from a legal perspective and provide case examples for further clarification of the issue[9]. Throughout the paper, the author will suggest a possible resolve or at least minimization of the discussed question and its legal consequences.

1. THE DISCOURSE OF THE LAW.

Currently, medical law is a complex independent branch of law, a system of regulatory acts or norms governing organizational, property, personal relations arising in connection with the conduct of sanitary and epidemiological measures and the provision of medical and preventive

[8] William T. Shearer, Bertram H. Lubin, Mitchell S. Cairo, Luigi D. Notarangelo. Cord Blood Banking for Potential Future Transplantation. Pediatrics. 2018

[9] Skene L. Legal rights in human bodies, body parts and tissue. J Bioeth Inq 2007; 4: 129-133.

care to citizens. The correlation and interconnection of law and medicine, which are considered to be two branches of public relations - is currently causing increased attention. An integral component of the successful development of civil society is human rights. Each of us, acting as a patient, wants to be confident that our rights and legitimate interests are protected by law. Medical law is a legal industry, a system of legal regulation of relations in the field of medical insurance and healthcare, in other words, all relationships that arise regarding the provision, organization, and payment of medical care. This type of law represents a scope of legal rules governing the mutual relations of patients, their legal representatives and medical workers that arise between these categories of people in the process of providing medical care. As the World Health Organization (WHO) stated in 1948: "Health is a state of complete physical, spiritual and social well-being, not just the absence of diseases and physical defects." WHO has proclaimed the principle in full compliance with which "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every person."[10] The reforming of modern healthcare, the functioning of insurance medicine and the development of an appropriate legislative framework is on the path to increasing the responsibility of entities providing medical care and insurance medicine for the quality of medical care provided, for violating the rights of patients established by law. This determines the presence of a large circle of people interested in developing a universal mechanism for ensuring and protecting the rights of citizens in the provision of medical care, which allows to correctly resolve conflicts arising from the poor quality of medical services. There has to be an understanding of differences between the law in an objective and subjective sense. In the objective sense, the law is a system of legal norms, expressed in relevant regulatory acts and not depending on each individual. The patient's right in an objective sense, therefore, is determined by the totality of legal norms, legislatively enshrined in regulatory acts regulating relations in the healthcare sector. In a subjective sense, the law is a system of existing rights and freedoms, their specific powers arising from and dependent on the will and consciousness, especially in the process of their use. A patient is a person who has applied to a medical institution of any legal form for a private practitioner to receive diagnostic,

[10] World Health Organisation. Preamble to the Constitution of the World Health Organisation as adopted by the International Health Conference, New York, 19-22 June, 1946

therapeutic, and preventive care, regardless of whether he is sick or healthy. Patient's rights - specific rights derived from general civil, political, economic, social and cultural human rights, regulated when receiving medical care and related services or in connection with any therapeutic effect carried out to citizens[11].

1.1. The Oviedo Convention

The Council of Europe governs protection of human rights in the application of the achievements of biology and medicine since 1980. During this period, a sufficient number of documents were adopted, but the central one is the Convention for the Protection of Human Rights in the Field of Biomedicine. This convention was opened for signature in 1997 in the city of Oviedo in Spain and, therefore, still bears the name of the Oviedo Convention. Oviedo Convention is the first international legally binding document, which enshrined the already established rule that no medical intervention can be carried out without patient's consent[12]. General provisions of the principle of informed consent are given in Article 5 of the Convention: medical intervention can only be carried out after the person concerned will give his/her voluntary informed consent; in order to give the consent, this person (patient) in advance receives full information about the purpose and the nature of the intervention, as well as its consequences and risks; in addition, the patient may at any time freely withdraw this consent[13]. It must be said that consent is not considered as a fact of expression of will, but as a process, allowing a person to make voluntary and informed choices regarding planned intervention.

1.2. Legal protection

[11] Council of Europe – ETS n° 164 - Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997.
[12] Roberto Andorno, "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law", Journal of International Biotechnology Law, 2005
[13] Convention for the Protection of Human Rights in the Field of Biomedicine, 1997

The development of science expands our horizons in the field of health, opening up new opportunities in the field of medical treatment, diagnosis and preventive measures. At the same time, there are reasons to fear the wrong approach or misuse of these opportunities to the detriment of patients' rights to inviolability, independence and respect for their privacy. Issues that are faced in biomedicine are often considered to be problems of a very complex and delicate nature. For building trust and developing practical approaches, characterized by both efficiency and respect for the person, it is necessary to timely solve problems arising in the field of human rights, both on national and international level[14]. The great importance of this topic for Europe is clearly evidenced by today's enforcement practice of the European Court of Human Rights, from where it can be seen that the principle of informed consent, incorporating ethical, medical and legal aspects, needs a comprehensive analysis[15]. It is very important that all people whose work is somehow related to biomedicine, know the key principles for protecting human rights that are spelled out in the Council of Europe Conventions[16]. It shall be mentioned that special responsibility in this case (human rights in medical law) lies with the representatives of healthcare and law. Informed consent is a fundamental principle of bioethics. What information should be provided to patients before any medical interference? How to get patient consent in emergency situations? How to resolve the contradictions between medical indications and patient desires? Medical workers are obliged to answer such questions, as well as, lawyers who also need specialized knowledge to ensure effective legal protection against improper or malicious biomedical practice[17].

1.3. Property rights: do patients really understand ?

[14] Philip Alston, Ryan Goodman. International Human Rights. Oxford: OUP, 2013
[15] European Group on Ethics in Science and New Technologies. Opinion No. 19 on the ethical aspects of umbilical cord blood banking. 2004.
[16] World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects.
[17] Regulation EU No 536/2014

Generally, property rights are viewed as a "bundle of rights", which consists of the right to possess a good to use, to exclude, to enjoy the profits from it, as well as, to have the right to dispose of it, if the person who is the owner of the good wishes to do so[18]. When it comes to property rights in the human body, the discussion can take different terms: it depends on the way a person views and approaches the body. An example of such a case can be: A sees his body not as a part of property rights, meaning that he thinks that he is not an entitled owner of any material that is derived from it, on the contrary, B regards himself as an entitled owner of his body, therefore, any material that has been derived from him, is his soul property. This question of property in one's body specifically outlined by two main branches of law: Common Law and Tort Law. As it is known, Common Law accumulates property rights, in respect to one's own body, it has provided a number of protections. It can be mentioned that Common Law is a body of unwritten laws that are based on precedents established by the Courts. Such protections have the power to grant certain property rights in the body. However, it is worth mentioning that Common Law does not regard those rights as property, in addition to that, Common Law does not express a clear position on whether or not we have the right to profit from our bodies. Whereas, Tort Law is a type of branch of law that covers most civil lawsuits, where the main principle is to offset the offence to a person and grant relief from those offences of others, typically that is done by a monetary compensation. Tort Law grants protection from physical invasion and non consensual physical contact. For instance, a doctor who was not able to receive the informed consent from the patient before performing any kinds of treatment, commits a battery. The doctrine of Tort Law suggests that the law grants us the right to acquire our own bodies and to ban other people from using our bodies, it also grants us the right to handle our bodies as we desire to. According to the World Health Organization (WHO): "In any country and region of the world, the customs that are connected to childbirth, if they do not threaten the health, should be respected. Placenta, umbilical cord, umbilical cord blood - child's property". Biologically, umbilical cord blood belongs to the newborn, but the child is not able to either show his rights to it or express consent to its use. In order to collect and to place the blood for

[18] Skene L. Legal rights in human bodies, body parts and tissue, 2007.

storage, informed consent of the mother (parents) is required - both for donation and for autologous use[19]. Being transferred to a third party, umbilical cord blood ceases to be the property of the child. If the mother decides to store the blood privately, then it continues to be the property of the child, who, when he grows up, already decides whether to continue storage in the future or not[20].

2. UMBILICAL CORD BLOOD BANKING

For the collection of human tissues and their potential storage for subsequent use in research requires, voluntary informed consent or permission in accordance with the rules is, again, required[21]. Storage (banking) of cellular material can be private (personal) or public (donor). In public storage, cellular material is accepted on a voluntary basis free of charge[22]. The purpose of public storage is to provide cellular material for both scientific and therapeutic purposes. The principles of public storage of cellular material are developed, implemented and operate on the example of storage of donated blood and its components. Financing of such storage is carried out at the expense of state funds. Such storage systems are supported in Western Europe countries, for example, Spain, France, Germany, Switzerland etc. Individual banks are integrated into the international system of cord blood banks, which provides faster selection of cellular material required for transplantation. For instance, in Russia, the storage of stem cells is included in the list of licensed types of medical activity, which ensures the quality and safety of its service. However, nowadays, public custody does not have support at the federal level and, therefore, financial support. The creation of cryobanks in most cases is an initiative of the constituent entities of Russian Federation, at the moment, 5 cord blood banks have been

[19] Hardcastle R. Law and the human body: property rights, ownership and control. Oxford: Hart Publishing, 2007.
[20]European Group on Ethics in Science and New Technologies. Opinion No. 19 on the ethical aspects of umbilical cord blood banking. 2004.
[21] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001.
[22] Vmal Singh, Abishek Saini, Neeraj Kumar, Marisha Kalsan. Blood Generation from Stem Cells: An Overview. International Journal of Science and Research (IJSR) ISSN (Online): 2319-7064. 2016

created in the constituent entities of the Russian Federation and one bank has federal subordination. As of personal storage (banking), today it does not have a normative regulation; it is carried out exclusively on a reimbursable basis of a civil law contract. The purpose of personal storage is the ability to use biological material by its owner in the future in the event of a disease in the treatment of which cell technology can be applied. The storage of cord blood cells is not included in any government guarantee program, it is an initiative and is paid exclusively at the expense of the citizens, who wished to use this opportunity. Personal storage is carried out both in state and in cryobanks that are part of the private healthcare system[23]. When storing cellular material, the safety and quality of this service must also be ensured. European Member States' experience in this matter relies more on a public, rather than a state, accreditation system. Professional communities prescribe a standard that ensures the quality of products (services), and then, on a voluntary basis, an accreditation procedure is carried out with mandatory subsequent inspection. In the United States, for example, issues of accreditation of activities related to the storage of cord blood are both public organizations and state-authorized bodies.

3. THE NEED OF CONSENT

As it was already mentioned earlier, in all possible kinds of relationship between two or more parties, there has to be a contract, which regulates the parties' interests. In medical law, it plays an important role, as it is directly connected to the patient's well-being, which is considered to be one of human's biggest wealth. Although doctors generally have limited time to talk with patients, it is necessary to remember that informed consent is also as important as the treatment itself. It is not just bureaucratic requirement: informed consent strengthens patient confidence in the doctor, increases his personal responsibility and thereby improves the expected forecast

[23] O'Connor MA, Samuel G, Jordens CF, Kerridge IH. Umbilical cord blood banking: beyond the public-private divide. J Law Med 2012; 19: 512-516

treatment. Therefore, the basic requirements for the information that is needed to inform the patient before the intervention are: purpose (reasons) of the intervention; the nature of the proposed intervention; potential risks and benefits; projected outcome of the proposed manipulations, possible complications and side effects interventions (including individual characteristics, such as age or the presence of any pathologies); alternatives to proposed procedures; all procedures related to treatment, as well as potential damage, injury, pain or other discomfort resulting from the treatment; reference to the right to an independent opinion, in addition, all the main factors of storage of umbilical cord blood[24]. The European Union has identified a number of principles that need to be strictly followed when collecting and testing (scientific purposes) stem cells in the clinic: respect for human dignity; autonomy (informed consent, respect for privacy, confidentiality), justice and benefit (protection of health); freedom of research[25]; voluntary informed consent of the patient to use techniques; objective assessment of the risk / benefit ratio; protecting the health of the patient involved in the clinical study[26]. The development of the concept of informed consent marked a shift in the relationship between the patient and the doctor - from the paternalistic judgment of medical specialists to the patient's right to make a decision, backed up by an exhaustive medical information. Informed consent comes from the principle of autonomy or self-determination, which along with the principles of "do good" and "do no harm", as well as the principle Justice is the foundation of medical ethics[27] . In the context of medical law, autonomy means freedom of action of a person based on a self-accepted plan. Respect for autonomy means recognition of the law and ability of a person to make personal choices[28]. As it was already mentioned earlier, in accordance with Article 5 of the Oviedo Convention, medical intervention may be carried out only after the relevant person gives

[24] James J. McCartney. Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections. Albany Law Review, Vol. 65, Pp. 597-624, 2002

[25] International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences (CIOMS)

[26] Han MX, Craig ME. Research using autologous cord blood — time for a policy change? Med J Aust 2013; 199: 288-289

[27] Merlin G. Butler, Jay E. Menitove. Umbilical cord blood banking: an update. J Assist Reprod Genet. 2011

[28] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ 23 November 1995 No L. 281 pp. 0031-0050.

his voluntary written consent[29]. The most important criteria for informed consent include: patient's awareness and understanding of the information received; voluntary consent without coercion or inappropriate influence; clear understanding of the right to recall consent at any time.

3.1 Cases with failure in performing informed consent

If medical care is carried out within the framework of a law that complies with the requirements of the Oviedo Convention, and medical intervention is carried out to protect health, European Court verifies whether intervention was necessary and whether patient rights are respected[30]. In such matters, it is being turned to international standards, including the Oviedo Convention, and, inter alia, the requirement to obtain voluntary and informed consent of the patient or his legal representative for medical intervention. Such consent must meet certain criteria: it should be voluntary, should be given after receiving all necessary information about the upcoming procedure, as well as to be clearly expressed.

3.1.1. Petrova v. Latvia, no. 4605/05, 24 June 2014

In several cases against Latvia, concerning the transplantation of organs of the deceased, the European Court saw the problem precisely in the quality of legislation. Latvia's legislation operates presumption of consent to organ transplantation and, on this basis, in case of deceased persons, organs are removed for further transplantation. Legislation, however, did not provide an effective appeal system for such a presumption. In the case of Petrova v. Latvia, the applicant found out about the organ harvesting from her deceased son only some time after his death. The Court stated that the legislation of Latvia did not meet the requirements of clarity in regards to the consent that had to be taken from the deceased person's representative[31].

[29] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention)
[30] Convention on Human Rights and Biomedicine, 1997
[31] Petrova v. Latvia, no. 4605/05, 24 June 2014

3.1.2. Elberte v. Latvia, no. 61243/08, ECHR 2015

In the Elberte v. Latvia case, the Court reiterated its findings regarding the quality of Latvian legislation. In this case, it was about organ harvesting from the applicant's dead husband. It should be noted that the European Court did not speak against the system presumptive consent, leaving the question of choice between presumptive and express consent to the posthumous organ donation, at the discretion of states, but still brought up the questions of consent that have to be obtained before any medical intervention[32].

3.1.3. N.B. v. Slovakia, no. 29518/10, 12 June 2012 and I.G. and Others v. Slovakia, no. 15966/04, 13 November 2012

Consent that does not meet the specified criteria is tantamount to the absence of the consent. For example, in cases of N.B. against Slovakia[33] and I.G. and others against Slovakia, the Court finds a violation of the Convention in connection with the sterilization of the applicants without obtaining their consent before the procedure[34].

3.2. Informed consent

Following the implementation of the Human Tissue Act (2004) of the United Kingdom, the obtaining of consent is a formal requirement for the collection or 'procurement' of human tissues. Informed consent is considered to be one of the most important ethical and legal requirements of modern biomedicine field[35]. It is a prerequisite for medical intervention. Briefly, its content is that before the medical intervention, the doctor must inform the patient all the necessary information that would allow the patient to independently and rationally make the

[32] Elberte v. Latvia, no. 61243/08, ECHR 2015
[33] N.B. v. Slovakia, no. 29518/10, 12 June 2012
[34] I.G. and Others v. Slovakia, no. 15966/04, 13 November 2012
[35] Lokesh P. Nijhawan, Journal of Advanced Pharmaceutical Technology and Research.Informed consent: Issues and Challenges, 2013.

appropriate decision (express consent or refusal); subsequent intervention is carried out only with the consent of the patient. The main goal of informed consent is to provide the patient with all the necessary information for his self-determination (autonomous decision) regarding a particular medical effect[36]. It also should be mentioned that the legal standards that help obtaining informed consent are different in every jurisdiction, respectively, the interpretation of those standards rapidly expands[37]. The informed consent rule also serves as a mechanism for protecting the patient from violations of his rights, abuse of his situation, and actions of medical workers against his interests. After receiving informed consent from the patient, the doctor is obliged to inform the patient with a full amount of information, which includes the aims of the procedure, the expected benefits, the necessary conditions for it, the possible risks, and other harmful effects (pain, discomfort, long-term consequences, etc.), as well as all possible alternatives (if there are any) to this intervention. In the case of umbilical cord blood collection, the medical service provider has to give detailed information regarding all the possible ways of storage of umbilical cord blood and how it will be used in future. In order to achieve all legal requirements regarding informed consent, it is necessary to start involving patients when making the decisions, even though such involvement sometimes might be limited (the doctors shall set certain boundaries when allowing patients to make decisions regarding their health). In cases where the informed consent failed to be obtained, that can cause legal action.

3.3. Ethical issues in informed consent

Medical ethics is a branch of applied professional ethics, which is an integral part of biomedical ethics and which regulates human relations in medicine "vertically" (doctor - patient) and "horizontally" (doctor - doctor). The predominant attention is paid to the rights and obligations of the doctor in relation to patients, as well as to the normative regulation of relationships

[36] Vawter, et al., “A phased consent policy for cord blood donation”. Transfusion, 42, 1268-1274.
[37] Daniel E.Hall, Allan V. Prochazka, Aaron S. Fink, “Informed consent for clinical treatment”, 2012

"within" the medical profession[38]. The formation and development of bioethics is associated with the process of transformation of traditional ethics in general, medical and biological ethics in particular[39]. It is caused, first of all, by sharply increasing attention to human rights (in medicine, these are the rights of the patient, physician, etc.) and the creation of new medical technologies that generate many problems that need to be solved, both from the point of view of law and morality[40]. There are four main principles of medical ethics: justice, autonomy, beneficence and non - malificience[41]. It is universally recognised that autonomy is the most vital ethical consideration that underscores informed consent[42]. The autonomy includes the patients' rights to regulate what kind of treatments to undergo, those treatments must be accepted by the doctors. It should be mentioned what it is that makes the consent informed, the patient should fully intrust to the information that was provided by their doctor. The doctor must be completely honest with his patient in order for the consent to be valid. Speaking of the principle of justice, it has to be said that it shall be applied when the doctor decides what kind of treatments shall be offered to the patient, as well as, which ones shall be withheld. Autonomy of the patient is protected mainly by the consent to treatment, which he gives after he receives information about his state of health [43]. The principle of informed consent has been established in modern healthcare along with the recognition of the priority importance of human rights in all spheres of life.

3.4. Legal issues in informed consent

Informed consent that a patient signs himself to, from a legal point of view, is not regarded as consent itself, but as a proof that the patient is signing himself to a specific procedure or

[38] Vawter, et al., "A phased consent policy for cord blood donation". Transfusion, 42, 1268-1274.
[39] Neil C. Manson, Onora O'Neill. Rethinking Informed Consent in Bioethics. Cambridge: Cambridge University press, 2007.
[40] Ruth R. Faden, Tom L. Beauchamp. A History and Theory of Informed Consent. New York : Oxford University Press, 1986.
[41] Gunning J. Umbilical cord blood: banking and clinical application. Law Hum Genome Rev 2004;20:217–25
[42] Ethical considerations for Clinical Trials on Medical Products conducted with the Paediatric Population. Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use. 2008.
[43] Rubinstein P. Why cord blood? Hum Immunol 2006;67:398–404

treatment at that specific time of the signing of the paper. As it is known, legally, no person, in this case a doctor, has no right to touch the patient, not even treat him without his permission. The legal term for such intervention is “battery”, which is considered to be a physical assault and if done is punished by law[44]. Therefore, we come to the conclusion that a consent shall be obtained for any types of procedures except a physical examination that is a part of a patient's routine. However, it shall be mentioned that there are cases when consent can not be obtained or is just simply not possible to. For instance, the doctor realizes that the patient is in the state of emergency, meaning on the operation table, and is in need of extreme measures, in such circumstance the doctor may perform all the procedures without the patient’s consent. In case of umbilical cord blood collection, the procedure shall be talked out to the mother (parents) of the unborn (yet) child before the delivery, respectively, the consent shall be obtained in a written form before the upcoming delivery, as in this procedure everything has to be done in a fast matter, because the umbilical cord blood can be collected only within 10 minutes from the moment the child has been delivered. Also, it shall be noted that the doctor must make sure that the consent is valid under the national law of the country of the expected delivery of the child.

4. LEVEL OF AWARENESS ON UMBILICAL CORD BLOOD COLLECTION PROCEDURE

There was research carried out in five EU states: France, Germany, Italy, Spain and the United Kingdom. The aim of this research was to find out the level of awareness, knowledge and the general attitude of cord blood procedure (collection, donation, banking)[45]. This research specifically points out the knowledge and awareness of the mothers (parents). It is stated that it increases with age the level of education that is provided to them and the overall duration of pregnancy. However, a vast majority of women are not informed of such procedure at all or its

[44] Skene L. Legal rights in human bodies, body parts and tissue. J Bioeth Inq 2007; 4: 129-133.
[45] Katz, G., Mills, A., Garcia, J., Hooper, K., McGuckm, C., Platz, A. et al. Banking cord blood stem cells: attitude and knowledge of pregnant women in five European countries. *Transfusion*. 2011; 51: 578–586

general aspects. In addition to that, the survey provides the specific number of women that gain information form their doctors which is 6%, this shows that European Union states do not popularize the education aspect on umbilical cord blood, respectively, its use and its value nor, the doctors provide the necessary and most of the times much needed information regarding the procedure[46]. That results in the issues that are discussed in this paper, such as ethical, meaning the doctor is not being truthful to his patients and with-holding the information from the patient. Legal issues such as not obtaining the consent and collecting the umbilical cord blood in a hidden manner, which is, of course, illegal in itself, and later, keeping the blood for further medical expertises. This research specifically identifies the level of parents' knowledge on the given procedure on a low standing point. That survey shows that over 50% of people were not able to properly define the use of cord blood procedure. The absence of knowledge highlights the incompetence of the source and, therefore, the quality of the information that the source provides. In addition to that, parents do not have a clear understanding of the actual value of such biomaterial (cord blood) and the applicability of it (use), some of the interviewed couples or mothers stated that they simply were not informed by their doctors , which again shows that healthcare providers do not bring up the matter of this procedure and the topic of the umbilical cord blood collection in general. As it was already mentioned, parents have a great lack of knowledge on umbilical cord blood collection, donation and banking. Therefore, European Government shall carry out a research to identify the knowledge of healthcare professionals' and how they introduce the expecting parents, because the option of cord blood banking and donation has been known to parents over 25 years and, perhaps, now is the time to point out the gaps in the knowledge of the doctors, so there is a lack of clarity and transparency from medical professionals' side, because as this research shows, that women age 25 or less, specifically ethnic minority, less aware of banking and donation, in addition to that, it shows that most participants have been self-reported, meaning finding out the information by themselves, what's more, ten studies identified that parents were finding out the information on the internet, however, this

[46] Katz, G., Mills, A., Garcia, J., Hooper, K., McGuckm, C., Platz, A. et al. Banking cord blood stem cells: attitude and knowledge of pregnant women in five European countries. *Transfusion*. 2011; 51: 578–586

information can not be qualified as reliable as information provided by the healthcare provider[47]. Regarding the cord blood use, out of five papers that discussed cord blood use awareness, only one of those papers outlined the high level of knowledge and these persons who were knowledgeable were already parents. Remaining three papers stated a considerably low awareness amongst people regarding the respective issue, which again brings us back to the realization that, first of all, healthcare providers not always fully inform their patents on all possible procedures and outcomes and, second of all, lack of education, provided by the states.

5. LEGISLATION ON DONATION OF STEM CELLS IN EU

In March 2004, the European Directive (2004/23 / EC) entered into force to establish standards for the quality and safety of donation, receipt, testing, processing, storage and distribution of human tissues and cells[48]. This directive applies to all biobanks, cord blood banks (although blood banks or blood products are not included in this list) in the public sector. Some countries, such as Australia, Germany and France, have adopted standards for processing cord blood collection under GMP (good manufacturing practice) conditions. The same standard applies to the network of European banks EUROCORD. Generally, there aren't many policies that are in relation to cord blood collection specifically, however, there are ones that regulate the collection and storage process. In the United Kingdom, the situation takes the following term: all the processes mentioned are regulated by the Human Tissue Authority (HTA). HTA was founded under Human Tissue Act (2004) and is considered the UK's knowledgeable body under the EU Tissues and Cells Directive (EUTCD 2004/23/EC). The main function of the Human Tissue Authority is to counsel on the HT Act and make sure that all the activities performed under this

[47] Screnci M, Murgi E, Pirre G, Valente E, Gesuiti P, Corona F, Girelli G. Donating umbilical cord blood to a public bank or storing it in a private bank: knowledge and preference of blood donors and of pregnant women, 2012;10:331–337.
[48] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004

act are regulated. In order to succeed, the HTA provides guidance, codes of practice for the medical sectors, as well as, checking their work to make sure that license conditions are followed. The HTA governs the following activities: the removal, use, storage and disposal of human bodies, in addition to that, organs and tissues that have been derived from living or deceased bodies. The Human Application sector of the HTA governs the selection and evaluation of donors, procurement, testing and storage, as well as, the distribution of umbilical cord blood. In order to have the right to collect umbilical cord blood, the medical personnel has to apply for a specific license, that is regulated by the Human Tissue Authority, which states: "Staff have training in collecting cord blood, raising standards and making sure best possible quality of sample is taken; procedures which will help prevent any medical attention being drawn away from

mother or child during collection; a system is in place to make sure that the cord blood cells are traceable from collection to their use in treatments"[49].

6. LEGISLATION ON UMBILICAL CORD BLOOD PROCEDURE IN THE UNITED STATES OF AMERICA

As European Union has gaps in its legislations, specifically lacking necessary directives and regulations that will govern umbilical cord blood procedure and its main aspects, perhaps, it will be useful to mention that in the USA it has been broadly developed and is regulated by all sorts of documents[50]. Moreover, almost every state in America has its own educational program and laws that regulate the given topic[51]. Umbilical cord blood banking in the United States is regulated by law. The Institute of Medicine (IOM) in the United States issued a so-called expanded cord blood banking report in 2005. This document provides clear guidelines for medical staff to provide all expectant parents with objective information about the collection, use

[49] Human Tissue Authority, 2005

[50] Walker T, Steckler D, Spellman S, Haven D, Welte K, Boo M. Awareness and acceptance of public cord blood banking among practicing obstetricians in the United States,

[51] George J. Annas. American health law. Boston: Little, Brown, 1990.

and storage options for cord blood, so that families can make the right and timely decision for themselves: to save umbilical cord blood for possible use by members of their family or donate it to a public biobank or to dispose of it[52]. Today, 28 US states have legalized cord blood education programs, which cover 78% of all birth giving procedures[53]. Most US states follow IOM recommendations, and some states are at various stages in the development of such legislative procedures about the need to inform future parents about the possibility of cord blood collection, use and storage. Here are some of the states where cord blood procedure initiatives are regulated by law: in California, since 2008, medical staff has been encouraged to inform pregnant women of all the possibilities of preserving cord blood. Healthcare professionals are told to educate pregnant patients about the medical options regarding the umbilical cord blood collection, as well as, the Department of Health provides all the necessary information on the given matter in the California Prenatal Screening Program brochure. In Connecticut, since 2009, medical staff has been obliged to inform pregnant women in the 3rd trimester of pregnancy of all medically acceptable cord blood collection, use and banking options. In 2011, the Council for the collection of cord blood, consisting of 8 members, was created and the state program for the collection of cord blood was approved. In Illinois, since 2008, healthcare providers have been encouraged to provide pregnant women with full information on all options for donation and banking of umbilical cord blood before the third trimester of pregnancy. The Illinois Department of Public Health develops and distributes written materials for cord blood banking, which is enough for future parents to make an informed decision. Also, according to the legislation that was enforced in 2007, the Illinois Department of Public Health approved a network of public cord blood banks, and created a committee to advise the Department on managing a network of cord blood stem cell banks. In New Jersey, since 2008, healthcare workers have to inform pregnant patients as early as possible, preferably in the first trimester of pregnancy, on all issues regarding cord blood collection. The New Jersey Department of Health and Senior Services is also distributing

[52] Kharaboyan L, Knoppers BM, Avard D, Nisker J. Understanding umbilical cord blood banking: what women need to know before deciding. Women's Health Issues, 2007 Sep-Oct

[53] American Academy of Pediatrics, Work Group on Cord Blood Banking. Cord blood banking for future transplantation: subject review, 1999 Jul

educational brochures highlighting the value and potential of cord blood preservation. In 2005, New Jersey became the first US state to create the first publicly funded umbilical cord blood and stem cell bank.

7. EU MEMBER STATES' LEGISLATIONS ON PATIENT'S RIGHTS

Patients‟ rights throughout the EU vary from one country to another. The most prominent one is that the Member States hold the competence in the health domain. Furthermore different health care systems, procedures, cultures and priorities add to the variety of the legislation. An example of different legislation would be that some countries have a single law or act defining the rights of patients, whereas others use multiple pieces of legislation[54]. The approach differs also on the focus as some MS put more emphasis on the rights of patients and others more on the specific obligations of the healthcare providers. The EU Member States' legislations include: right to informed consent; right to information concerning own health; right to medical records; right to privacy; right to complain and compensation[55]. Most of the EU Member States' legislations mention informed consent as an integral part of every possible kind of medical intervention. Here are some of them:

7.1. The Netherlands

The rights of patients have a solid place in the Dutch legal system as several rights are placed in the Act on the medical treatment contract of 1 April 1995.31 The Act is a part of the Dutch civil code. The main purpose of the Act is to clarify and strengthen the legal position of the patient[56]. However, recently the Dutch government has provided the main patients‟ rights in one

[54] Law of Obligations Act, General Part of the Civil Code Act, passed 5 June, 2002.
[55] Smith-Tyler J. Informed Consent, Confidentiality and subject Rights in Clinical Trials. Proc Am Thorac Soc 2007
[56] Law No. 546. Health Act. 24 June 2005.

document. This document should go into force in 2010, therefore the document has not yet been included in this overview of patients‟ rights. Right to informed consent: Informed consent has two components: information and consent. This right to information stems from the patient's right of self-determination as laid down in articles 10 and 11 of the Dutch Constitution. This means that the medical treatment of patients is only allowed with their consent or that of people empowered to decide for them. Consent to treatment is a basic principle in healthcare and serves as the justification of the doctor(s) intervention. Right to information concerning own health: This right has been incorporated with the right to informed consent. Right regarding the medical records: The healthcare provider shall keep a record relating to the treatment of the patient. He/she shall use the file to record data concerning the health of the patient and the procedures performed on the latter. Right to privacy: The Dutch Constitution states that everyone shall have the right to respect for his/her privacy. Although the right to medical secrecy and the protection of the medical data are regulated, no specific regulations on the right to privacy for patients are stipulated in the Dutch Medical Law[57]. Right to complain and compensation: When a patient is not satisfied with the treatment provided, he/she has several options. He/she can file a direct complaint to the healthcare provider or to the complaint committee of the healthcare institute itself. The patient can try to file for compensation when a medical error has been made. However these procedures are very hard as it is the patient who needs to prove that a medical error has been made.

7.2. Italy

In Italy the rights of patients are regulated by the Code on Medical Ethics. However, this Code is not legally binding. Although there is no concrete and separate patients‟ rights legislation in Italy patients still enjoy certain rights. Right to informed consent: The Italian Constitution guarantees the inviolability of personal liberty. In particular, consent to medical treatment is covered by

[57] Legemaate, J. (2006). Staat van de Gezondheidszorg: Patientenrechten. Patiëntenrechten in Wetgeving en Rechtspraak.

Article 32 (2) of the Constitution. This article states that nobody may be forced to undergo any particular medical treatment, unless under the provision of the law[58]. Right to information concerning own health: The right of the patient to information about his/her health is not stipulated as a specific right. The Code of Medical Ethics deals with the obligation of granting information in the context of the right to informed consent. Right regarding the medical records: This right is not provided by the Code of Medical Ethics. This right may be deducted from section 92 of Article 96/2003 on data protection. But this mainly deals with the protection of the data and not with the above-mentioned rights. Right to privacy: The profession's secrecy is penalised by Art. 622 of the Italian Criminal Code. Additionally the Code of Medical Ethics also enforces professional confidentiality. The physician should maintain secrecy about everything that is entrusted to him/her and about what he/she can get to know due to his/her profession. Right to complain and compensation: In case of routine operation, medical professionals are subject to strict liability. In case of complex operations the courts call for a high level of professional care and attentiveness.

7.3. Germany

Germany does not have any specific legislation concerning patients‟ rights. It does have the Constitution (including some general Articles related to patients‟ rights), a Charter of the Rights of Patients (1999), Federal Law on Data Protection (1990), the Charter of Rights of Patients deprived of Medical Care (2005) and several court rulings on patient rights. Right to informed consent: The German Constitution, Art. 2 already states that everybody has the right to life and to physical integrity[59]. The freedom of the person is inviolable. In order to perform a medical treatment the consent of the patient is needed first. Right to information concerning own health: This right is combined with the right to informed consent as it also states that the patient should be fully informed prior to the medical treatment. Right regarding the medical records: The

[58] Spina, Alessandro and D'Auria, Massimo, Private Biobanks in Italy; An Overview of the Legal Framework , July 26, 2009
[59] Nys, H. & Stultiëns, L. (2005). Rechten van de Patient.

patient has the right to access his/her medical record. Right to privacy: Confidentiality between patient and doctor has been laid down in the German Criminal Code Art. 203. It states that it is a crime if a health professional reveals information without authorisation from the patient[60]. Right to complain and compensation: Complaints can be filed with the direct healthcare provider, furthermore patients‟ complaints committees are available for complaints, mostly already accommodated by the hospitals.

8. ANALYSIS

The issues that we face in the field of biomedicine are often very complex and sensitive matters. In order to build trusting relationships and develop practical approaches that are both effective and respectful towards the individual, it is necessary to address emerging human rights issues in a timely manner, both at the national and international levels. The first issue is a lack of coherent cooperation between the fields of medicine and law (i.e. doctors' lack of legal education). In particular, the clash between doctors and lawyers. Legal personnel/lawyers are accumulating the issues that they face specifically by the rule of law, meaning that all the problems have to be dealt in accordance with the national legislation of the country, where the issue initially was raised. The lawyers' legal education dictates their actions and they are not allowed to go off track, as once again, everything has to be dictated by the rule of law only. Whereas, Medical personnel/health service providers are dealing with the problems that they face a bit in a different way. Their actions are dictated by the circumstances that appear during the course of their day to day work. For example, when giving medical consultations, all kinds of circumstances may appear that will lead the doctor to act differently and, therefore, having a different outcome of the diagnosis[61]. Even though doctors have a protocol they have to follow when giving a diagnosis or obtaining consent, they do in fact sometimes or most of the time move from it. In that case, the

[60] Patienten und Pflegeanwaltschaft. (2009). Patientenrechte im Überblick.

[61] Jessica W. Berg, Paul S. Appelbaum, Charles W. Lidz, Lisa S. Parker. Informed Consent: Legal Theory and Clinical Practice. Oxford: Oxford University press, 2001.

lawyers have to step in and the clash raises more issues. The lack of legal knowledge hardens the doctors work and that can cause a bad diagnosis and overall a negative experience for the patient. Therefore, in order to have a working and positive environment both the lawyers and doctors have to co-work and consult with one another. Respectively, getting back to the obtaining of informed consent, it has to be said that health service providers have to be aware of the strict necessity of such legislation and the aftermath in case of absence of it. In obvious way of resolving such issue is to propose an educational course for medical personnel relating to issues of legal questions that may rise during the course of their practice, and to know how to approach them in order to give the full scope of information to the patient in a proper lawful way, therefore, the question of the level of patient's awareness on the informed consent and of given medical treatment rises respectively from the issues discussed above. As the research shows, some of the patients are completely unaware of such procedures as obtaining informed consent, in this case, when collecting umbilical cord blood, as well as the aspects of storage of it. The paper also outlines that patients are unconscious regarding their property right that they are entitled to when collecting human biomaterials. In order to raise the patients' awareness, their health service provider has to be the one to step in, the doctor has to provide full information regarding the existence of such a procedure, the process, the possible (benefits and shortcomings), as well as, the aftermath of the procedure. Coming up to the most important factors when informing the patient that are knowledge of the informed consent, when the consent should be obtained and all the steps to such legal procedure. Not all the patients know their rights (property rights specifically), which is an integral part of both medical and legal fields and as this paper showed, it has an enormous significance in European countries and is clearly demonstrated by the current law enforcement practice of the European Court of human rights. It is very important that all people whose work is related to the field of biomedicine in one way or another (health care and law), know the key principles of human rights protection set out in the European Council Conventions that form our common legal framework today. It is obvious that the principle of informed consent, which includes ethical, medical and legal aspects, needs to be fully analyzed from all the sides. Regarding the storage of the umbilical cord blood, the patients

have to know all the possible types of banking (private and public), as well as, for what purposes and other medical/legal formalities of this topic[62]. In order to improve informativity of the patients, the Member States shall opt for a relatively easy way of granting the information which can be in the form of a brochure or an online platform, as well as, an educational event which gives you an informative guide to the treatment. Patients want more help and guidance before they begin treatment for a disease or any other medical procedure. When comparing the US approach towards health in general and umbilical cord blood procedures specifically, we can see that the government of the country and every state in particular has its own legislation and detailed regulations on the given procedure. Therefore, we can see that the trend on umbilical cord blood is widely discussed and is regulated on national levels, whereas the European governments only have the EU Tissues and Cells Directive (EUTCD 2004/23/EC) and the Oviedo Convention which generally covers aspects of Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. The lack of legal source and the interpretation of them is the cause for the disputes that arise and the incompetence of both medical and legal branches to approach and solve the issue of the umbilical cord blood collection/banking.

Deriving from everything that is mentioned above, we come up to a self-rising question - whether it is sufficient that informed consent is regulated in national law or should it be added to the EU or Council of Europe legislation as well. On one hand, it could be suggested that it is enough that informed consent is regulated in the national law of each Member State. By doing so, the Member States independently regulate the implementation of the informed consent according to the will of their country and the specifics of their own national laws and regulations. This approach may be called a single-handed manner, as it is performed individually by each country. On the other hand, the regulation on informed consent can be admitted by the EU or Council of Europe legislation. In this case, a single rule will be spreaded over all Member States in case they ratify it. By doing so, the obtainment of informed consent regarding collection of cord blood will be regulated by a unified document. Potentially, this unified system will cause

[62] Brezis M, Israel S, et al. Quality of informed consent for invasive procedures. Inter J for Quality in Health Care2008

less agitation when applying this rule to the arised situation between patient and medical personnel.

9. CONCLUSION

As the paper's main topic of discussion is the legal implications of the meanings of storage and informed consent for umbilical cord blood donation, it has to be mentioned once again that the informed consent is a ground principle of biomedical ethics, which implies the right of the patient to get full information about their health status, about possible methods of treatment, the risks associated with treatment and, conversely, non-provision of medical care before the beginning of any kind of intervention. It is the doctor's responsibility to give full information to the intended patient. In accordance with Article 5 of the Oviedo Convention, medical intervention can only be carried out after the person concerned has given their voluntary written consent. The Oviedo Convention as a basic provision includes the principles of protection of human rights and fundamental freedoms in connection with the application of advances in biology and medicine. It defines the conditions for obtaining voluntary informed consent in general and in the field of research in particular, also emphasises the freedom of research to the same extent as the need to protect research participants, but again, no proper information has been carried out regarding umbilical cord blood procedure. The Directive 2004/23/EC of the European Parliament sets out standards of quality and safety for the donation, storage and the obtainment of consent from the patient. However, not all the patients are aware that such legal sources exist due to the fact that they are not informed by their doctors. This paper shows that a vast majority of women are not informed of umbilical cord blood collection and donation at all or its general aspects, as well as, that European Union countries do not popularize the education factor on umbilical cord blood, respectively, its use and its value nor, the doctors provide the necessary and most of the times much needed information regarding the procedure. The United States of America legislation can be taken as a sample for European Union to look up to in order to build an informative educational guideline for both patients and doctors to follow. As the

legislation in the EU still needs improvement, perhaps it will be reasonable and beneficial, in the first place, for the patients, to improve the laws and bring awareness by introducing such procedures like collecting umbilical cord blood and obtaining an informed consent for it from early stages of pregnancy or at least at the end of it. In order to improve the level of knowledge of the procedure and, respectively, the EU's legislation on it, educational events should be held where professionals in both medical and legal field are invited and informative brochures have to be provided by healthcare providers, so that people can learn things that are useful in applicable for their own lives (health), as well as, discuss and ask necessary questions in order to be fully acknowledged about the procedure that is being discussed. As the discussion has a medical implication in it, which is the key tool of an individual's life and well-being, the legal framework has to include more detailed information regarding such biomedical procedure as umbilical cord blood collection/donation, because of it being more popularized nowadays, due to the rise of biomedicine. As it was already mentioned above, there are a couple of legal sources that regulate biomedicine in general. However, as biomedicine, being a progressive and widely spread field of medicine, European Union Member States shall be aware of that and bring up new ways of implementing and enforcing the already existing legislations in order to be hand in hand with a progressive field of biomedicine to not create and to avoid any misunderstanding that may come up between lawyers, medical personnel and patients and to be able to handle them in accordance with the new applicable legislation that the Oviedo Convention and Directive 2004/23/EC result. As it was proposed in the "Analysis" chapter, there are two possibilities of going around the question of informed consent obtainment and what legislative changes should be required to better reflect informed consent. After summing up this research, the idea of a single document that regulates the law on informed consent is more prone to success than independant regulations for each Member State. The main reason for that is: when a single-handed document is applied to all the legislations, it makes the process of the implementation of its rules and norms more efficient in practise. Respectively, when a document is being handled methodically, the probability of minimizing the number of cases where informed consent was not obtained will decrease. In the proposed unified regulation, the following rules have to be outlined: the

definition of umbilical cord blood, the importance of it, the patient's full awareness of such existing procedure, the need for obtaining informed consent, list of probable risks for the patient and the child as well as the risks that the doctor may face in case of not fully informing the patient regarding all the rules and rights above. By introducing the unified document, it will be ensured that there is trust between patient and doctor, there are no possible legal breaches from both sides and there is full transparency and understanding between the two parties. In my opinion, this will create a less stressful experience for the woman, more favorable environment for medical personnel to perform their duty accordingly and not have any legal quarrel with legal personnel.

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