“Free and informed consent as a core principle of the protection of human rights in the field of biomedicine”

13, Kirov str., Minsk (Crowne Plaza, Hall King)
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Programme & Proceedings of the Conference

Programme

09.00 – 09.30	**REGISTRATION OF THE PARTICIPANTS**
09.30 – 10.00	**OPENING** ***Moderator**: **Ms Larissa S. Lukina,** Head of the Council of Europe Information Point in Minsk* • **Mr Valeriy A. Malashko,** Minister of Health of the Republic of Belarus • **Ms Elena L. Bohdan,** Head of the Department of Medical Services, Department of Medical Care, Ministry of Health of Belarus; Head of the National Bioethics Committee • **Mr Oleg O. Rummo,** Member of the Permanent commission for international affairs and national security of the National Assembly's Council of the Republic of Belarus; Head of the Republican Scientific-Practical Centre of Organ and Tissue Transplantation • **Mr Christos Giakoumopoulos,** Director General of the Directorate General of Human Rights and Rule of Law, Council of Europe
10.00 – 12.15	**Session 1 – PRINCIPLE OF FREE AND INFORMED CONSENT. GENERAL APPROACH**
10.00 – 10.55	***Moderators**: **Ms Elena L. Bohdan,** Head of the Department of Medical Services, Department of Medical Care, Ministry of Health of Belarus; Head of the National* Bioethics *Committee; **Ms Tatiana N. Neshataeva,** Judge of the Court of the Eurasian Economic Union* • **Council of Europe perspective. Principle of free and informed consent in the Oviedo Convention** **Ms Anna Mikhedenko**, Manager of Project "Bioethics: protection of human rights in biomedicine" in the framework of the Council of Europe Action Plan for Belarus, Bioethics Unit of the Council of Europe • **Principle of free and informed consent in the case-law of the European Court of Human Rights** **Mr Dmytro M. Tretyakov,** Senior lawyer at the European Court of Human Rights **Discussion**
10.55 – 11.15	**COFFEE BREAK**
11.15 – 12.15	**Moderator: Mr Elmar Doppelfeld,** member of the Committee of Bioethics (DH-BIO) of the Council of Europe, chairman of the "European Network of Research Ethics Committees (EUREC)"; **Mr Vladimir P. Moroz**, doctor of science in law, Deputy Director of the Institute for retraining and qualification upgrading of judges, prosecutors and legal professionals at the Belarusian state university • **Constitutional framework of Human Rights protection in the field of biomedicine** **Mr Grigory A. Vasilevich**, doctor of science in law, chair of Constitutional law, Belarusian State University **Mr Dmitry G. Vasilevich,** phd in law, professor, Office of the Prosecutor general of the Republic of Belarus • **Implementation of the principle of free and informed consent in healthcare in Belarus** **Mr Andrey A. Bobtchenok,** Head of the Legal Department, Ministry of Health of Belarus **Mr Robert A. Chasnoit,** Head of the Republican Committee of Belarusian trade union of the health professionals **Discussion**

12.15 – 14.00	**LUNCH BREAK**
14.00 – 17.00	**Session 2 – SPECIFIC ASPECTS OF THE APPLICATION OF THE PRINCIPLE OF FREE AND INFORMED CONSENT. CHALLENGES AND BEST PRACTICES.**
14.00 – 15.20	***Moderator: Mr Dmytro M. Tretyakov,*** *Senior lawyer at the European Court of Human Rights;* ***Ms Valeriya N. Sokolchik****, doctor of science in philosophy, professor of public health and healthcare of the Belarusian Medical Academy of Postgraduate Education,* • **Free and informed consent for medical intervention** **Mr Ronalds Rožkalns**, expert in medical law, member of the drafting group of the course HELP on bioethics • **Informed consent in the sphere of paediatric surgery. Comparison of medical and legal practices in the Federal Republic of Germany and in the Republic of Belarus.** **Mr Yurii G. Dzehtsiarou,** doctor of science in medicine, professor of paediatric surgery at the Belarusian State Medical University • **Free and informed consent in the healthcare practices: sphere of oncology** **Ms Nataliya N. Antonenkova**, Deputy Medical Director of the N.N. Aleksanodov Republican Scientific-Practical Centre of Oncology and Medical Radiology **Discussion**
15.20 – 15.35	**COFFEE BREAK**
15.35 – 17.00	***Moderator: Mr Yurii G. Dzehtsiarou,*** *doctor of science in medicine, professor of paediatric surgery at the Belarusian State Medical University;* ***Ms Anna Mikhedenko****, Manager of Project "Bioethics: protection of human rights in biomedicine" in the framework of the Council of Europe Action Plan for Belarus* • **Free and informed consent in the sphere of biomedical research** **Mr Elmar Doppelfeld,** member of the Committee of Bioethics (DH-BIO) of the Council of Europe, chairman of the "European Network of Research Ethics Committees (EUREC)" • **Free and informed consent in the field of transplantation of organs and tissues of human origin** **Mr Kristof van Assche,** Research professor in health law and kinship studies, University of Antwerp, Belgium • **Transplantation of organ and tissues of human origin in the Republic of Belarus: medical and legal aspects of presumed consent** **Mr Siarhei P. Liashchuk,** Head of the National Transplant Registry of the Republican Scienfic-Practical Centre of Organ and Tissue Transplantation **Discussion**
17.00 – 17.15	**CLOSING REMARKS**
	• **Ms Anna Mikhedenko**, Manager of Project "Bioethics: protection of human rights in biomedicine" in the framework of the Council of Europe Action Plan for Belarus • **Ms Elena L. Bohdan,** Head of the Department of Medical Services, Department of Medical Care, Ministry of Health of Belarus; Head of the National Bioethics Committee

SESSION 1: PRINCIPLE OF FREE AND INFORMED CONSENT. GENERAL APPROACH

The Council of Europe's perspective: principle of free and informed consent in the Oviedo Convention

Ms Anna Mikhedenko, Manager of Project "Bioethics: protection of human rights in biomedicine" in the framework of the Council of Europe Action Plan for Belarus, Bioethics Unit of the Council of Europe

Today's event is dedicated to the principle of voluntary informed consent, which is a key principle in the protection of human rights in the biomedical field.

The Council of Europe has been involved in the protection of human rights with regard to the application of biology and medicine since the 1980s.

A sufficient number of documents has been adopted during this period, although the main document is, of course, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine," the text of which can be found in the handouts you have received today.[1] This convention was opened for signing in the Spanish city of Oviedo in 1997, which is why it is called the Oviedo Convention.

In the 20 years since it came into force, the Oviedo Convention has become one of the Council of Europe's key documents on the protection of human rights and is of great significance not only in Europe, but also in the world as a whole.

The Oviedo Convention was the first internationally legally binding document that formalised the long established rule that medical intervention cannot be carried out on a person without that person's prior consent.

We are talking here about recognising the autonomy of the individual in his or her relations with healthcare workers and moving away from the paternalistic approach. The European Court of Human Rights, which we will talk about later, sees the implantation of this principle through the prism of respect for private life and the right to personal integrity.[2]

In this presentation, I would like to talk about the provisions of the Oviedo Convention on informed consent, touching upon the following:

– general provisions,

– certain special aspects (complex situations), and

– possible exceptions.

1) The general provisions of the principle are set out in Article 5 of the Oviedo Convention:

– An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

– This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

– The person concerned may freely withdraw consent at any time.

[1] 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 dated 4 April 1997 (CETS No. 164) // https://rm.coe.int/168007d004

[2] See: Research Report "Bioethics and the case-law of the Court" // http://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf

It is important that consent is viewed not as an expression of will, but rather as a process that allows the person to make a voluntary and informed choice about the planned intervention.

A) Informing the individual forms an important part of this process

Informing the individual should be appropriate both **in form and in content**:

– The medical worker is obliged to provide the patient with objective information about the nature and possible consequences of the proposed medical intervention and explain the alternatives to such intervention before such procedure is carried out.

This information should, in particular, address the improvements that may result from the treatment and the risks associated with it, and not only those that are typical of the given type of intervention, but also those that may arise in connection with the individual characteristics of the patient such as age and other health issues.

– As for the **form** in which the information is delivered, it should be done so in a language that the person understands. In order to make it easier for the person to understand, it may be essential to present this information in written form as well.

If it is not an emergency situation, the patient should be given time to think. The exact amount of time given may vary depending on the nature and consequences of the proposed medical intervention.

An emphasis must not be placed on filling in a specific form. Because, I repeat, consent is not simply a signature on a form, but a process that should be adapted to the situation at hand (whether this is basis for the intervention, the individual characteristics of the patient or his/her medical condition). If the patient has not read the consent form, has not understood its contents, or had no other choice but to sign, his or signature is no guarantee that the necessary consent to medical intervention has been obtained.

B) Voluntary consent also assumes that the person shall not be subjected to unreasonable pressure or influence. To an individual who is in a vulnerable position, even the slightest pressure can be enough to make them feel they are being forced into giving consent against their will. Pressure may also be a factor in situations where there is a trusting relationship between the patient and the person asking for consent. This can happen, for example, when a patient is undergoing tests and the physician performing the tests in the same person requesting consent.

Pressure can also manifest itself in the form of promises of financial or other kinds of rewards or benefits (for example, promotion or high exam grades, which may be contingent on giving consent to take part in a study, etc.). Pressure involves influencing an individual to agree to something they would not agree to under normal (non-pressure) circumstances.

Voluntary consent also implies that it may be **withdrawn** at any time. Exceptions in this case may be situations in which physicians have already begun to intervene and it is impossible to stop (or reverse the effects), or doing so would put the life or health of the patient in danger. One example of this is emergency surgery.

C) The manner in which consent is expressed can be implicit or explicit. Explicit consent is, in turn, divided into oral consent and written consent.

Regardless of the manner in which consent is given, informing the individual in the appropriate manner is the key and decisive element in determining the validity of such consent.

What is more, the manner in which consent is given often depends on the nature of the proposed medical intervention. Thus, tacit consent is usually seen as the best option when it comes to interventions that involve everyday medicines (again, provided that the individual concerned has been adequately informed beforehand).

Invasive medical procedures may require explicit, documented prior consent. Explicit written consent is also required for participation in research involving medical intervention and for procedures involving the removal of an organ from a living donor (see articles 16 and 19 of the Convention).

2) A) There are cases when an individual is unable to give consent

… due to their age, mental disability or other reasons (they are in a coma, for example).

It is for domestic law in each country to **determine, in its own way, whether or not persons are capable** of consenting to an intervention and taking account of the need to deprive persons of their capacity for autonomy only where it is necessary in their best interests.[3]

Once a person is deemed incapable of giving his or her consent, it is necessary to determine the conditions for ensuring his or her protection if medical intervention is considered as a treatment option.

These conditions are set forth in Article 6 of the Convention, which states that intervention should only be carried out:

1) For the direct benefit of the person concerned. The only possible exceptions to this rule are biomedical research and organ and tissue removal, as provided for by articles 17 and 20 of the Convention.

2) When consent is given by a legal representative or an authority or a person or body provided for by law.

It should be emphasised here that we are not talking in this case about providing consent on behalf of the individual concerned, but rather about authorisation that should always be given in their best interests.

In such cases, the legal representative, authority or person must be informed about the purpose and nature of the intervention, as well as its consequences and risks before making an informed decision.

B) The patient's ability to make informed choices on their own behalf must be preserved as much as possible:

Therefore:

1) the **opinion of minors** must be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity (ability to formulate their own opinions).

That is, under certain circumstances the consent of a minor may be seen as a necessary and even sufficient condition for carrying out a medical intervention. As noted in the Explanatory Report to the Oviedo Convention, this condition is consistent with Article 12 of the United Nations Convention on the Rights of the Child, which stipulates that "States Parties shall assure the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child."[4]

2)

a) If an adult who does not have full legal capacity is temporarily able to make such decisions (for example, if his or her illness is progressing in a favourable manner),

[3] As defined in Article 42 of the Explanatory Report to the 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 // https://rm.coe.int/16800ccde5

[4] United Nations Convention on the Rights of the Child // http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx

then consent to intervention must be obtained from them in accordance with Article 5 of the Convention.

b) If such capacity is not established, then the individual concerned should, where possible, be involved in the process of obtaining consent. Their opinion must be ascertained and taken into account, having explained to them the importance of carrying out the medical intervention and the conditions for doing so.

C) The legal representative, authority or person should be allowed to withdraw permission at any time, unless the exceptional circumstances mentioned above apply. However, appeals to withdraw permission in this manner are considered exclusively in the interests of the person concerned.

That is, if a person who is capable of giving consent to medical intervention has the right to withdraw that consent, even if it is contrary to his or her own interests, then withdrawing permission is possible only in the interests of the patient.

D) In addition, compliance with professional obligations requires physicians to act in accordance with the interests of the patient. It is thus a duty of the physician to protect the patient against decisions taken by a person or body whose consent is required that are not in the interests of the patient; in this respect, national law should provide effective (working) appeals mechanisms.[5]

E) The provisions set forth in Article 9 of the Convention were innovative for their time. The article stipulates that a person may express their wishes relating to a medical intervention in advance of a situation that would require them to take such a decision but are not in a state to do so. In addition to emergency situations, this rule can be applied specifically to persons suffering from progressive diseases such as dementia. So, in the event that an expected situation arises, the previously expressed wishes of a patient with regard to a medical intervention should be taken into account.

Thus, as a general rule, any medical intervention requires consent.

However, the **Convention provides for exceptions** to this general rule subject to observance of clearly defined conditions.

1) Thus, if a person is formally considered capable of consenting but in reality his or her capacity for making a decision about the proposed treatment is seriously impaired by a mental disability,[6] medical intervention:

– may be carried out in strict accordance with national law (it is for domestic law in each country to ensure effective control and appeal procedures);

– should be aimed at treating the patient's mental disorder, provided that

– without such treatment, serious harm is likely to result to the patient's health.

Medical intervention without consent is an extreme measure that should be taken only if a less intrusive alternative is not available.

In cases where not treating a given illness does not cause serious harm to the health of the person concerned, then treatment without consent is excluded as an option.

2) The second exception provided for by the Convention is emergency situations, which prevents the physician from obtaining the appropriate consent or authorisation:

The Convention establishes that a physician may, without waiting for the consent of the individual concerned or authorisation from his or her legal representative, perform any medically necessary intervention for the benefit of the health of the individual concerned.[7]

[5] See: Article 48 of the Explanatory Report to the Oviedo Convention.
[6] Article 7 of the Oviedo Convention.
[7] See: Article 8 of the Oviedo Convention.

This exception applies to interventions that are necessary in order to save the life of the individual concerned, or which for medical reasons need to be carried out immediately.

However, even in such situations, physicians should take all reasonable measures to ascertain the possible wishes of the individual concerned.

3) Finally, the Convention allows restrictions to be placed on the rights of the patient in the event that such restrictions are prescribed by law and are necessary in a democratic society if order to protect public interests (whether it is to ensure public order, prevent crime or protect public health) or the rights and freedoms of others.

People who are familiar with the 1950 Convention for the Protection of Human Rights and Fundamental Freedoms will notice that these restrictions repeat certain elements of Article 8, Paragraph 2 of the European Convention on Human Rights.

These restrictions are applicable to the provisions regulating consent to medical intervention, except for cases involving biomedical research (see articles 16 and 17 of the Oviedo Convention) or the removal of organs and tissue from living donors for transplantation (see articles 19 and 20 of the Oviedo Convention).

One example could be the need to isolate persons suffering from infectious diseases in the interests of public health. Protecting the rights and freedoms of others can also serve as a basis for conducting tests ordered by the courts with the aim of establishing familial ties or identifying a person as part of a criminal investigation.

Concluding remarks

1) Voluntary and informed consent is a fundamental principle of the protection of human rights in the biomedical field aimed at ensuring respect for the right to personal integrity, which is guaranteed specifically in articles 3 and 8 of the European Convention on Human Rights.

2) This is primarily a process, the successful course of which depends on compliance with all the necessary conditions. Informing the individual concerned in a timely manner an integral part of this process.

Principle of free and informed consent in the case-law of the European Court of Human Rights[8]

Mr Dmytro M. Tretyakov, Senior Lawyer at the European Court of Human Rights

Unlike the Oviedo Convention, which guarantees human rights in the biomedical field, the European Convention on Human Rights guarantees human rights in all areas of life. However, the Oviedo Convention and the European Convention on Human Rights both deal with the same rights – the right to life, the right to freedom and the right to respect for private and family life – and the understanding of these rights should be the same for both documents. Accordingly, the practice of applying the European Convention on Human Rights in cases involving biomedicine is an organic part of general practice and can be applied by analogy to other circumstances. The European Convention on Human Rights has a unique monitoring mechanism which guarantees individuals and groups the opportunity to file complaints regarding the violation of their rights. The states that have ratified the Convention have undertaken to respect human rights in their territories and, accordingly, these states can be taken to the European Court of Human Rights for violating such rights. In turn, the European Court of Human Rights has the authority to examine the circumstances of an individual case and pass a verdict on whether the state in question did indeed violate the rights of the appellant. It is the European Court of Human Rights which, through the consideration of private cases, creates the practice of applying and interpreting the Convention. This is the subject of the present discussion.

The principles and concepts developed by the European Court of Human Rights should also be taken into account when interpreting the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. At the very least, this conclusion follows from the provisions of the Oviedo Convention itself, which refers to the European Convention on Human Rights in its Preamble. Moreover, Article 29 of the Oviedo Convention authorises the European Court of Human Rights to "give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention." And despite the fact that no such opinions have been given, it is easy to predict that the European Court of Human Rights will rely on its accumulated experience if the need to do so arises – experience which is largely based on the provisions of the Convention that directly concern the protection of the dignity of the person and respect for their rights and personal integrity. The practice that we are interested in has primarily been developed by the European Court of Human Rights in the context of considering complaints under articles 2 (protecting the right to life), 3 (prohibiting torture and inhuman or degrading treatment or punishment) and 8 (the right to respect for private and family life) of the Convention.

It should be noted that the rights listed above, like the other rights guaranteed by the Convention, can be divided into several categories. The first of these involves absolute rights, particularly the right to life and the right to freedom from torture, which we have already mentioned. Violation of these rights cannot be justified under any circumstances. A perfectly reasonable question might arise here: What relation does the issue of voluntary and informed consent have to the prohibition of torture and inhuman or degrading treatment or punishment? After all, one cannot ask a person for permission to treat them badly, especially since the ban on such treatment is universal and absolute. Of course, in the context of Article 3 of the Convention, we are not talking about asking a person's permission to treat them badly. However, the lack of properly obtained consent can become a decisive element in determining whether or not a particular case demonstrates evidence of a violation of the Convention. Even so, if a case in which proper consent is obtained does not raise questions a violation of the Convention in principle, this does not mean that the same action

[8] The opinions expressed in this presentation are the author's own and do not necessarily reflect those of the Court

may not be deemed inhuman or degrading treatment under Article 3 of the Convention if such consent is not given. One example of this is the case of *Bataliny v. Russia*, where a patient at a psychiatric hospital was used as a test subject for a new drug in the interests of medical research.[9] The European Court of Human Rights referred to international standards (including the United Nations Convention on the Rights of Persons with Disabilities and the Oviedo Convention) considered it unacceptable to conduct scientific research into new drugs without the consent of the person concerned. Accordingly, the Court decided that the treatment to which the applicant had been subjected was inhuman and degrading as defined by Article 3 of the Convention.

Other rights guaranteed by the Convention allow the state to interfere and impose restrictions. Article 5 of the Convention guarantees the right to liberty and security. It does, however, list six exhaustive situations in which the liberty of a person may be deprived, and only one of these is related directly to the field of medicine. Article 5, Paragraph 1, Sub-Paragraph "e" allows "the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts or vagrants." This point is of lesser interest to us, however, in the context of voluntary informed consent.

However, the article that we will refer to most often concerns the category of rights where interference by the state is allowed in an unlimited number of situations, provided that certain conditions are met. We are talking here about Article 8 of the Convention, which guarantees the right to respect for private and family life. It is this article in particular that guarantees the individual autonomy and respect for his or her personality and physical integrity. Interference with the exercise of this right is allowed, "except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others." It is easy to see this condition as the purpose of intervention, as the protection of health is explicitly stated in the text of Article 8. Another issue is the principle of legality. If interference is not provided for by law, then it is by definition a violation of Article 8 of the Convention. An example of this is the rather unusual case of *Yuriy Volkov v. Ukraine*, in which the investigating officer personally took blood from the vein of the detainee for analysis, without recourse to medical personnel.[10] It was easy in this case for the European Court of Human Rights to establish that such treatment was in violation of Article 8 of the Convention, as it was illegal even under Ukrainian law, which clearly stipulates that only a qualified medical professional can take blood from a person.

In addition to the fact that interference in a person's private life should be carried out in accordance with the law, the law itself must be clear and accessible. In a number of cases initiated against the Republic of Latvia concerning the transplantation of organs of deceased people, the European Court of Human Rights saw the problem precisely as a matter of legislation. In Latvia, there is the presumption of consent for organ transplantation, and it is on these grounds that organs are removed from the deceased for further transplantation. However, the national legislation does not provide for an effective system of appeal against this presumption. In particular, in the case of *Petrova v. Latvia*, the applicant learned that the organs of her deceased son had been removed a considerable amount of time after the fact and was thus not afforded the opportunity to present an objection at a time when it would have made sense – i.e., before the transplant took place.[11] The court found that the legislation of Latvia did not meet the requirements of clarity with regard to the possibility of exercising the right to object to the removal of organs from a deceased relative's body. In the case of *Elberte v. Latvia*, the Court reiterated its findings with regard to Latvian legislation.[12] The case involved the removal of organs from the applicant's deceased husband. It should

[9] *Bataliny v. Russia*, Application no. 10060/07, 23 July 2015
[10] *Yuriy Volkov v. Ukraine*, no. 45872/06, 19 December 2013
[11] *Petrova v. Latvia*, no. 4605/05, 24 June 2014
[12] *Elberte v. Latvia*, no. 61243/08, ECHR 2015

be noted that the European Court of Human Rights in no shape or form spoke out against the system of presumed consent, leaving the issue of the choice between presumed and expressed consent to posthumous organ donation to the discretion of individual states.

If medical assistance is provided within the framework of a law that is in line with the requirements of the Convention and medical intervention is carried out for the purposes of protecting health, then the European Court of Human Rights ascertains whether such intervention was necessary and whether the rights of the patient were respected. The Court refers to international standards, including the Oviedo Convention, on such matters – among other things, the requirement to obtain voluntary and informed consent from the patient or his or her legal representative to medical intervention.

Such consent must meet certain criteria. As follows from the description, consent must be voluntary, it should be given after all the necessary information has been provided and expressed in a clear and deliberate manner.

Consent that does not meet the above criteria is, in fact, not consent at all. For example, in the cases of *N.B. v. Slovakia*[13] and *I.G. and Others v. Slovakia*,[14] the Court found a violation of the Convention in connection with the sterilization of patients without their prior consent. In another case against Slovakia concerning the same issue, *V.C. v. Slovakia*, the applicant gave her consent to sterilization before surgery.[15] The European Court of Human Rights was tasked with assessing the validity of such consent. According to the case file, the applicant was taken to hospital with contractions. Several hours into labour, the medical staff asked the applicant whether she would like to have more children in the future. When the applicant replied in the affirmative, she was told that if she were to give birth again, either she or her future child could die in the process. Frightened, the applicant told the medical staff to do whatever they wanted, after which she was presented with a sterilization consent form to sign. The applicant, who only completed six grades of school, and whose native language is Romani, said she did not understand the word “sterilization,” was frightened and her ability to understand was limited as she was in the process of giving birth. The sterilization procedure was carried out immediately after labour, following which the applicant suffered both physically and mentally. She filed a complaint with the European Court of Human Rights stating, among other things, that she did not give free, full and informed consent to sterilization. Upon consideration of the case, the European Court of Human Rights noted that there was no urgent need to perform the sterilization procedure, and that the applicant had signed the consent form during labour, lying on her back. The consent form itself was merely a document containing a single sentence to the effect that the patient has requested sterilization, with no explanation whatsoever. In the Court’s opinion, there was no evidence in the case to suggest that the applicant has been fully informed about the state of her health, that the consequences of the procedure had been explained to her, and that alternative options had been presented. Accordingly, informed consent was not obtained from the applicant. The state was in violation of Article 3 of the Convention.

Informed consent implies communicating information to the individual concerned in a manner and form that they can understand. What is more, additional explanation should be provided if the person concerned is confused or does not fully understand what is being said. This principle is not restricted in the practice of the Court to medical cases. An example that can be taken from another field is the confession of guilt in a criminal case. In the case of *Shabelnik v. Ukraine*, the applicant was informed that the Constitution guarantees him the right to not testify against himself, but was nevertheless warned that doing so could entail criminal liability.[16] In this situation, the applicant was confused and could not understand whether he should testify against himself or if he had the right to remain silent. As a result, the applicant provided a confession that was then used against him in a court of law. The

[13] *N.B. v. Slovakia*, no. 29518/10, 12 June 2012
[14] *I.G. and Others v. Slovakia*, no. 15966/04, 13 November 2012
[15] *V.C. v. Slovakia*, no. 18968/07, ECHR 2011 (extracts)
[16] *Shabelnik v. Ukraine*, no. 16404/03, 19 February 2009

European Court of Human Rights found that the applicant's rights had been violated, primarily because he had not been properly informed about his rights during interrogation.

Another key element of consent is its voluntary nature. Voluntary consent, just like the voluntary nature of any decision, depends on a number of factors, including whether or not the person is under the control of an organ that intends to obtain such consent from them. In the case of *Juhnke v. Turkey*, the applicant was under the control of the police. She was detained and interrogated on suspicion of involvement with the Kurdistan Workers' Party. After being interrogated, the applicant was subjected to a gynaecological examination, the aim of which was to protect the police officers from possible accusations of sexual misconduct. According to the applicant, the examination was carried out against her will. Witnesses testified that the applicant had initially refused the procedure, but had been persuaded to go through with it by the doctor. According to the doctor himself, he told the applicant that the examination was necessary in accordance with the law; what is more, it was to protect her own interests. In examining the case, the European Court of Human Rights pointed to the vulnerable position of the detainee. Being under the complete control of the police, she could not have been expected to oppose the gynaecological examination forever. Furthermore, the description of the facts in the case suggests that the doctor had presented the examination as a compulsory measure, which could have caused confusion on the part of the applicant. The European Court of Human Rights found the applicant's allegation that she had been forced to have a gynaecological examination to be unsubstantiated. However, the Court did find that the applicant's consent to the examination could not be considered voluntary and informed.

In the abovementioned case of *V.C. v. Slovakia* regarding sterilization, the European Court of Human Rights also noted that not only was the consent given by the applicant not informed, it was also not voluntary given her vulnerable state and the circumstances in which the consent was obtained.

In addition to these two primary characteristics, consent must be expressed clearly and with respect to the proposed intervention. The fact that the applicant consented to something in the past cannot serve as the basis for presuming consent to a similar kind of interference in the future. One example in this instance is the case of *Glass v. the United Kingdom* in which a mother, as the legal representative of a disabled child, expressed opposition to the use of diamorphine on her son during one of his frequent hospitalizations. The physicians nevertheless decided to administer the drug, with the state subsequently referring to the fact that the applicant had agreed to a course of treatment with the use of morphine during a previous hospitalization. The European Court of Human Rights noted that, first of all, the applicant consented to the use of a different drug. Secondly, that was in the past. Consent given in the past cannot constitute grounds for medical intervention against the person's will. Thus, intervention in this case was not based on clear and voluntary consent. What is more, as a general comment, it should be noted that human beings are changeable by nature: they can change their minds, moods and opinions; they can both form and ruin relationships with others. This is why Article 5 of the Oviedo Convention states that "the person concerned may freely withdraw consent at any time" with regard to medical intervention.

Moreover, the consent of the individual concerned must be informed. Here we can turn once again to the previously mentioned case concerning sterilization, where the state of the applicant and the urgency with which the medical staff wanted to obtain consent to the procedure eliminated the possibility of her making an informed choice; she was not afforded the opportunity to discuss the possible consequences, options and risks with her husband and family before making a decision.

Conscious consent also depends on whether or not the person concerned is able to make an informed choice in general, or in a specific situation. This is why in such cases, medical staff should make sure that the person has this capacity. In the case of *Arskaya v. Ukraine*, which did not concern consent to treatment, but rather the refusal of the applicant's son to

receive treatment, the main problem was that, despite the fact that the applicant's son demonstrated obvious signs of mental disability, the medical staff accepted his refusals to undergo certain types of treatment and examination. This eventually led to his death 11 days after hospitalization, as the physicians were unable to make the correct diagnosis and determine the best treatment. The European Court of Human Rights concluded that the physicians should have checked whether or not the refusal of the applicant's son to receive treatment was linked to his inability to make fully informed decisions. The Court found that the main problem was the absence of rules regulating the procedure for determining the capacity of patients to make informed decisions, including obtaining informed consent to treatment from them. This case demonstrates that the role of the state is not limited to abstaining from the interfering in the private lives of individuals, as it may also involve measures being taken to protect the right to intervene. Such obligations are called positive. Depending on the circumstances, both medical intervention and the lack of medical intervention may be considered violations of the Convention. In other words, sometimes the state fails to fulfil its negative obligations, and sometimes it fails to fulfil its positive obligations. And both may apply to a single instance of intervention. Take such an invasive intervention as abortion, for example. In the case of *Vo v. France*, an abortion carried out as the result of a medical error was deemed to be in violation of Article 3 of the Convention.[17] Similarly, in the case of *R.R. v. Poland*, the applicant's inability to make an informed decision about whether or not to have an abortion, which was caused by a delay on the part of the medical services to confirm a pathology in the foetal development of the applicant's unborn child, was also deemed to be a violation of Article 3.[18]

To conclude this report, I would like to mention that obtaining voluntary and informed consent, in addition to being correlated with the obligation to respect the rights and dignity of the individual, is extremely important for the state and representatives of the medical professions for another reason – the more transparent and understandable the procedure for obtaining voluntary and informed consent, the easier it will be for the state to avoid accusations of violating the right to respect for private life. In this context, I feel it is appropriate to mention the heart-breaking tragedy of the case of *Evans v. the United Kingdom*, which concerned conscious choice and responsibility for that choice.[19] The details of the case are thus: the applicant had been unable to conceive, so she and her partner turned to a clinic for treatment. Medical tests revealed that the applicant had started to develop malignant tumours in both ovaries. She was told that both ovaries would have to be removed, but before that, some eggs could be taken for in vitro fertilization. The applicant and her partner attended a special consultation where the details of the operation were explained to them. They were also told that they would have to sign a consent form for in vitro fertilization, and that they would both have the right to withdraw consent before the embryo implantation. The applicant asked whether it would be possible to freeze the unfertilised eggs, to which the medical professional replied that such procedures were not carried out at that clinic and that an operation of that kind would have a lower chance of success. At this point, the applicant's partner started to assure her that they would be together, that he wanted to be a father and that there was no need to freeze the unfertilised eggs. As a result, the applicant and her partner signed the consent form for in vitro fertilization, with both consenting to fertilization. Six months after the operation to freeze the embryo was carried out the couple broke up. Soon after, the applicant's partner went to the clinic to withdraw his consent for in vitro fertilization and demand that the embryos be destroyed. The applicant appealed through the courts for the right to preserve the embryos, but the courts denied the appeal on the grounds that she understood the terms to which she had agreed and should have been aware that the consent of both parties was required in order for the embryos to be used. Moreover, he former partner had the legal right to withdraw his consent to in vitro fertilization. The European Court of Human Rights expressed

[17] *Vo v. France* [GC], no. 53924/00, § …, ECHR 2004-VIII
[18] *R.R. v. Poland*, no. 27617/04, § …, ECHR 2011 (extracts)
[19] *Evans v. the United Kingdom* [GC], no. 6339/05, § …, ECHR 2007-I

sympathy for the applicant, but determined that the relevant provisions of the legislation on consent for in vitro fertilization were clearly spelled out and that, more importantly for the present discussion, the applicant was made aware of these rules. As a result, the Court did not establish the fact of a violation of the Convention. This is an example of how a state, by giving the applicant the opportunity to make a conscious, voluntary and informed decision, and thus assume responsibility for that decision, both fulfilled its obligations and at the same time relieved itself of the responsibility for the decision made by the person concerned.

This example, despite its tragic nature, demonstrates the importance in every case of obtaining voluntary informed consent to medical intervention from the individual concerned or their legal representative, except in the most urgent of cases.

Thank you for listening.

Constitutional framework of Human Rights protection in the field of biomedicine

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IMPLEMENTATION OF THE PRINCIPLE OF VOLUNTARY AND INFORMED CONSENT TO MEDICAL AID ACCORDING TO THE LEGISLATION OF THE REPUBLIC OF BELARUS

The Social and Economic Development Program of the Republic of Belarus for 2016 to 2020, approved by Decree of the President of the Republic of Belarus No. 466[20] dated December 15, 2016, underlines that the national medicine is up to the world standards on any and all fields. This particularly includes cardiology, oncology, traumatology, neurosurgery, obstetrics and gynaecology, pediatrics, and transplantology. There have been introduced such new up-to-date forms of medical aid as general practitioner out-patient departments, institute of family physicians. Measures are taken to develop high-end medicine. According to the Program, 1,784 transplantations, including 305 liver transplantations (among them 2 'liver-kidney' complexes), 160 heart transplantations, 1,305 kidney transplantations, 12 'kidney - pancreas gland' complex transplantations, 2 lung transplantations were performed during 2011-2015 years in the Republic of Belarus. Moreover, as for the level of heart transplantation accessibility, the Republic of Belarus is in the top ten countries of the world: in 2014, 45 surgeries were performed, which makes up 4.8 surgeries per 1 million of population (ranking the 9th place in the world). It is emphasized that according to the report of the United Nations Fund for Population Activities (UNPFA) for 2014, Belarus took the 1st place in the world in reducing the maternal mortality level and is among 42 states, where 100 percent of babies are delivered with the help of qualified health professionals.

Medical achievements assume humane treatment, respect for the individual, represented by the patient in this context, who enjoys relevant rights and bears certain duties.

The principle of voluntary and informed consent to medical aid is one of the fundamental ones in the area of rule-making and law enforcement in healthcare. It is not directly reflected in the Belarusian legislation. However, the analysis of the constitutional principles and norms, provisions of the current legislative acts shows its meaningful implementation. First of all, in the context of the matter under investigation, let us address such aspects as the general idea of medical aid, scope of necessary information to solve the medical aid issues, voluntary basis for decision-making on getting medical aid, range of actors making decision on consent to medical aid, legal fundamentals for ensuring the principle of informed and voluntary receipt of medical aid etc.

The basis for the national legislation in the said domain of relations is the Constitution of the Republic of Belarus as well as the Law "On Healthcare", orders and decrees of the President of the Republic of Belarus, and other legislative acts, including of the Ministry of Healthcare of the Republic of Belarus.

According to the Constitution of the Republic of Belarus, the State, all of its bodies and officials jointly and to the utmost safeguard and protect the rights and freedoms of the

[20] The Social and Economic Development Program of the Republic of Belarus for 2016-2020: Decree of the President of the Republic of Belarus On Approval of the Social and Economic Development Program of the Republic of Belarus for 2016-2020 No.466 dated December 15, 2016 (as amended on November 30, 2017) [Electronic resource]. / YurSpectr LLC, National Center for Legal Information, Republic of Belarus, Minsk, 2017.

individual and the citizen. The right to health protection is among such constitutional rights. It is the key right defining the content of the right to life to a significant extent. With poor health protection and low medical aid level, the value of many other rights and human freedoms diminishes. Human health is not only an asset but an integral part of social wealth.

The Belarusian Constitution contains a number of norms securing the human right to freedom of choice and warranting protection of life and health, getting of qualified medical aid. To begin with, let us note that the effective Constitution of the Republic of Belarus envisages a new type of relations between the State and the individual: it stipulates the refusal from paternalistic type of relationship and transfer to the type where the individual acts as an equal partner in relations with the State. It also displays itself in medical and legal relations to be discussed below.

According to Article 2 of the Constitution of the Republic of Belarus, the individual, his/her rights, freedoms, and guarantees of their implementation are the supreme value and purpose of the society and the State. The State is responsible to the citizen for creation of conditions for free and dignified personality development. The citizen is responsible to the State for strict performance of duties imposed on him by the Constitution. The provisions contained in this Article are fundamental for upbuilding the entire paradigm of social interaction. It relates not only to certain spheres of personal rights or implementation of political rights, but to concern for the individual as supreme value demonstrated in efficiency of the system of medical aid delivery to the patient.

Article 24 of the Constitution recognizes the right to life. This right does not come down only to the matter of presence or absence of death penalty in the legislation. It is wider in its content and includes the right to high (up-to-date) level of medical aid, healthcare, developed healthcare system, secure life, healthy environment, labor protection, suicide prevention etc. The success of the State efforts in this regard is evidenced by the fact that over the past decade the lifespan has increased, though we are behind the Nordic countries in this regard. As things go for a while, women are leading in this aspect: life expectancy is 79 years for women, and 69 years for men.

In the context of the matter under consideration, let us address Articles 25 and 28 of the Constitution. Thus in compliance with Article 25, the State provides for human freedom, personal immunity and dignity. The restraint or deprivation of the personal liberty is possible in cases and under the procedure established by law. It is important to note that this Article establishes prohibition on torture, cruel, inhuman or degrading treatment or punishment as well as on medical or other experiments without consent of the person. Article 28 formalizes the universal right to protection against unlawful interference with the personal (i.e. private) life, the honor and dignity of the person. It is known that legal liability, including administrative and criminal liability, is envisaged for violation of such right. As noted in the literature, the ‘private life’ category directly covers the personal life of the individual; his/her life in the family; health status; communication of the individual with other people, including via state-of-the-art technical aids for such communication[21] .

Article 45 of the Constitution of the Republic of Belarus is dedicated expressly to the right to medical aid, right to healthcare in general; it is also connected in a varying degree with implementation of the somatic rights bordering with the right to medical aid. Thus, according to its contents, the citizens of the Republic of Belarus are guaranteed the right to health protection, including free medical service in the state-owned healthcare institutions. The State creates conditions for medical service available to all citizens. The right of citizens of the Republic of Belarus to health protection is also ensured by development of physical culture and sports, environmental enhancement efforts, opportunity to use recreation centers and work safety improvement.

[21] S.A. Avakyan. The Constitutional Law of Russia. Academic Course: Teaching Aid: in 2 vol. V.1/ S.A. Avakyan. – 5th edition, revised and expanded. – M.: Norma: INFRA-M. 2014. – P.670.

Thus, the right to health protection has comprehensive contents, which includes the right to medical service, right to work safety and rest, right to sanitary epidemiological welfare, favorable environment, safe working conditions, according to the Constitution of the Republic of Belarus. However, medical aid is one of the main ways to realize the right to health protection, which is exercisable in the Republic of Belarus through various areas and branches, first of all, through the healthcare system. The foregoing constitutional provision has gained momentum in the Law of the Republic of Belarus “On Healthcare”, according to which the citizens of the Republic of Belarus have the right to free medical service ensured through:

- free medical aid based on the state minimal social standards in the field of healthcare in the state-owned healthcare institutions;

- medical aid in the state-owned healthcare institutions, non-governmental healthcare institutions and with the individual entrepreneurs performing medical activities under the procedure established by the legislation of the Republic of Belarus at the expense of own funds, funds of the legal entities and other resources not prohibited by the legislation of the Republic of Belarus;

- availability of pharmaceuticals;

- implementation of measures on sanitary epidemiological welfare of the population.

Both the European legal practice and our constitutional law envisage the possibility to restrict the rights, if necessary, for the purposes admissible in the democratic society. Therefore, according to Article 23 of the Constitution, restriction of human rights and freedoms is allowed only in cases envisaged by the legislation, in the interests of the national security, public order, morality protection, health of the population, rights and freedoms of other persons. Nobody may enjoy advantages and privileges that contradict the law.

In the Law of the Republic of Belarus “On Healthcare” the idea of medical aid is disclosed wider: it is a complex of medical services aimed at maintaining, strengthening and recovery of health of the patient, which includes preventive medical treatment, diagnostics, treatment, medical rehabilitation and dental prosthetics performed by health professionals. It enables to define the scope of ‘aspirations’ among the citizens, namely among the patients, for getting relevant medical services. The law understands a medical service as medical intervention or medical intervention complex as well as other actions performed at medical aid delivery (Article 1).

The purpose of the right of citizens to medical aid is to facilitate the recovery, maintenance and strengthening of health by means of the healthcare system created by the State. At that, due to its responsibility to the society and citizens, the State is entitled to and requires from the medical institutions, their officials and healthcare professionals the accessible, high-quality and qualified medical aid. And it may establish legal liability for improper delivery of the latter. In order to achieve the said social purpose, in case of a trauma or other disease of the individual, all available means of economic, social and medical nature are used. That means that medical aid has comprehensive contents and includes the right to preventive care, right to diagnostics and treatment, right to rehabilitation treatment, right to information on health status, right to give consent or refusal to medical intervention, right to prosthetic and orthopaedic and dental prosthetic treatment, as well as the right to measures of various social nature on nursing care for patients, incapacitated and disabled persons.

The right to health protection is ensured through creation of medical service available to the citizens, sophisticated healthcare system, possibility to use recreation centers, development of physical culture and sports.

Getting medical aid according to the legislation of the Republic of Belarus includes a range of citizens' rights at various stages, supported by the State's duty to provide the necessary scope of medical aid.

The legally capable citizen possesses the entire scope of rights and freedoms envisaged by the national legislative acts, including the Constitution, international treaties binding for the Republic of Belarus. Thus one should note the right-conferring role of universally recognized principles of the international law, which priority over the national legislation is stipulated in Article 8 of the Constitution. This fundamental norm bears evidence of the legislator's aspiration to build the independent state on legal democratic principles. The recognition of priority of the universally recognized principles of international law mean selection of the legal system development vector.

We believe that we basically have the relations pattern, according to which the patient's will acquires the decisive role in determining the nature and degree of medical aid to be provided to the person, i.e. a cooperation pattern is created between the indicated actors; the doctor and the patient are two equal partners, the patient being an independent, autonomous person.

The most important international legal source, which has fixed the principle of informed voluntary consent to medical aid is the CE 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)[22] (hereinafter referred to as the Convention). It was concluded on April 4, 1997 in Oviedo (Spain). Unfortunately, the foregoing Convention is not binding for Belarus, since we did not sign it and it was not subject to ratification. Due to huge importance of provisions contained therein, similarities of the national legislative norms on health protection as for purposes and contents, the international experience is valuable to us. Reference to this convention enables us to reveal the degree of compliance of our legislation and practices with the European standards as well as assess the necessity for further enhancement of legal regulation of relations in the said area.

The common legal framework on the European continent in an unbiased manner is formed also due to the fact that at preparation of draft constitutions of the new states, including Belarus as well, many provisions (ideas and norms) were copied from the constitutions of developed countries of Western Europe and the USA. The texts of the constitutions of Germany, France, Italy, Sweden, Switzerland and other countries, which accumulated necessary experience in transformations, that are also governed by the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) served as a guide. And naturally, common legal principles and norms suggest the single standard of actions.

Formally, ECHR is not legally binding for the Republic of Belarus due to the fact that our country is not a member-state of the Council of Europe. And the relevant attitude may exist to judgments of the European Court of Human Rights. However, in practice all the ECHR norms are basically accepted and taken to the next step in the legislation and practice in the Belarusian State. This is largely due to the fact that wording of the Constitution adopted in 1994 was prepared with regard to ECHR and the established practice of the European Court of Human Rights and the then-functioning European Commission of Human Rights. This conclusion is confirmed by comparison of the contents of the Constitution of the Republic of Belarus with that of ECHR. In connection therewith, judgments of the European Court of Human Rights are of importance for our national legal system as it resolves disputes in compliance with the European Convention for the Protection of Human Rights and Fundamental Freedoms, which norms substantially are

[22] On Protection of Human Rights and Fundamental Freedoms with regard to the Application of Biology and Medicine: The Council of Europe Convention dated April 4, 1997 [Electronic resource]. – available at: http://hrlibrary.umn.edu/russian/euro/Rz37.html – access date: 04.02.2018.

similar to the provisions of the Belarusian Constitution, which stipulates the rights and freedoms of the individual and the citizen. Thus, it is useful to utilize the practices accumulated by the European Court[23] .

The foregoing Convention dated April 4, 1997 contains all rules, which by their purpose are in full accord with the aims stipulated in Article 2 of our Constitution: the individual, its rights, freedoms, and guarantees for implementation thereof are the supreme value and purpose of the society and the State.

Besides, our Republic has ratified two International Covenants: on Civil and Political Rights and on Economic, Social and Cultural Rights. The International Covenant on Economic, Social and Cultural Rights, being legally binding for our Republic, specifies measures aimed at ensuring the highest attainable standard of physical and mental health. They must include:

- ensuring reduction in mortinatality and infant mortality, and providing for healthy evolution of child;

- improving all aspects of environmental physiology, industrial worker health;

- prevention and treatment of epidemiological, endemic, professional and other diseases and control thereof;

- creating conditions, which would provide for medical aid and medical care in case of a disease.

The Convention dated April 4, 1997 takes into account the provisions of the Universal Declaration of Human Rights by the United Nations General Assembly dated December 10, 1948, the European Convention for the Protection of Human Rights and Fundamental Freedoms dated November 4, 1950, the European Social Charter dated October 18, 1961, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights dated December 16 1966, the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data dated January 28, 1981, the Convention on the Rights of the Child dated November 20, 1989. In other words, one may state that in respect to medical aid the Convention dated April 4, 1997 integrated the total of relevant legal norms of high international level.

According to the literature, the Convention dated April 4, 1997 is a binding document in the area of human rights protection at introduction of scientific achievements in the field of genetics, biology and medicine, in connection with medical aid delivery. The Convention ‘defines general framework of human rights protection in connection with application of achievements in biology and medicine, within which framework the states may develop their own legislation’[24] .

According to Article 5 of the Convention, when applying for medical aid, the citizen is fully entitled to be informed of the potential exposure of the medical intervention and the possible consequences of not performing such intervention. Such person should receive relevant information on the purpose and nature of the intervention as well as on its consequences and risks. Such person may at any moment withdraw his/her consent without hindrance. The right to informed and voluntary consent to medical aid is directly connected with the right to privacy.

When touching upon the matter of informed consent, it should be noted that in practice it is usually based on the doctor-patient trust, particularly where the doctor gives full and comprehensive information on positive and negative effects of the medical intervention. The

[23] See, for example, A. Mikhedenko. Bioethics Matters Currently Important to Russia Through the Lens of Judgements of the European Court of Human Rights. pp.58-69. Precedents of the European Court of Human Rights. Special edition. M.: Razvitye pravovykh system, 2017.- 88 p.

[24] L. Lvoff. The Principle of Voluntary and Informed Consent in the Oviedo Convention. - Precedents of the European Court of Human Rights. Special edition. M.: Razvitye pravovykh system, 2017.- 88 p.

medical intervention means any impact and (or) other manipulation performed by the health professional as part of medical aid delivery. However, many factors are not legally formalized here: how such information should be given to the potential patient, the degree of its completeness, in what form it should be presented (verbally or in writing), how much time may be allocated for the patient's decision-making process etc. Such issues are important not only for the patient but for the doctor as well, for protection of his/her rights if any claims arise against him/her. In this connection, let us take note of the principle of private autonomy discussed in the literature being considered the doctor-patient unity and dialogue, resulting in the right of choice and the responsibility being shared between the patient and the doctor, on their mutual and active participation in the decision-making process, but upon condition of informed and voluntary decision-making by the patient, even if a willful refusal from treatment will cost the patient's life[25] .

The informed consent is the principle of biomedical ethics assuming the patient's right to receive full information on his/her health status, on possible ways of treatment, the risks related to such treatment and, vice versa, failure to deliver medical aid. It is the doctor's duty to give full information to the potential patient. The ethical norms, peculiarities of emotional (psychic) status of the patient and other factors must be complied with the doctor-patient communication preconditioning the necessity for considerate behavior of the doctor, including when he/she has to inform the unpleasant truth to the patient.

In this connection, we believe that at the level of the Ministry of Healthcare of the Republic of Belarus it is necessary to approve detailed templates of documents on informing the patients during their preparation to the medical intervention. The currently existing practice, which is limited to signing the relevant documents, does not allow to see the scope of information received by the patient. In our opinion, it is necessary to investigate this issue on the national level more carefully to consider the scope of the information to be presented and putting it in writing with participation of the patient and the authorized doctor and, in certain cases, of the council of physicians. It would be useful to envisage among other rights of the patients the right to be informed on qualification of the medical specialists, other health professionals, who will deliver medical aid to such patient, prior to getting at least the complicated medical aid.

As defined in Article 10 of the Convention, each individual has the right to privacy, including when it refers to his/her health information. Each individual is entitled to get acquainted with any collected information on his/her health status. At the same time, it is necessary to respect the wish of the individual not to be informed in this regard. In exceptional cases, only by law and only in the interests of the patient, the implementation of the right to get acquainted with any collected information on his/her health status may be restricted. Such approach is stipulated in the Law of the Republic of Belarus "On Healthcare" as well.

When presenting the relevant scope of information to the patient, one may state that his/her will is based on objective evidence, he/she takes the voluntary (conscious) decision.

According to Article 5 of the Convention, the medical intervention may be performed only after the relevant person has given his/her voluntary informed consent. Article 44 of the Law of the Republic of Belarus "On Healthcare" recognizes the right of consent to medical intervention. The distinction is made between simple and complicated medical interventions. Everything that according to the legislation is not included into the notion of the complicated medical intervention may be considered the simple medical intervention.

The matter on who should give voluntary consent to the medical intervention is solved depending on the citizen's legal capacity. As a rule, adult patients take the decision on

[25] Fundamentals of Bioethics: Teaching Aid / Ya.S. Yadevich [and others.]; under the editorship of Ya.S. Yadevich, S.D. Denisov. – Minsk: Vysheyshaya shkola, 2009. – p.45

getting medical aid on their own. Exceptions from this rule have been established in relation to certain categories of citizens:

minors: upon written consent of one of the parents, adopters, guardians, custodians;

persons recognized as legally incompetent under the procedure established by law: upon written consent of their guardian;

persons unable to make conscious decision for health reasons: upon written consent of husband (wife) or one of the close relatives (parents, children of majority age, brothers (sisters), grandchildren, grandfather (grandmother)).

The consent to the simple medical intervention is given verbally by patients or their legal representatives. The data on consent to the simple medical intervention is entered to the medical documents by the health professional. The minors at the age of fourteen to eighteen years old are entitled to give their own consent to the simple medical intervention. The withdrawal of consent to the simple medical intervention is made by the persons, who gave such consent. The data on withdrawal of consent to the simple medical intervention is entered to the medical documents by the health professional.

The mandatory condition for performance of the complicated medical intervention is the availability of prior written consent of an adult patient or his/her legal representative. The consent of the patient to the complicated medical intervention is covered in the medical documents and signed by the patient or his/her legal representative.

The list of complicated medical interventions is approved by Decree of the President of the Republic of Belarus No.619 “On Improvement of Material Incentives for Certain Categories of Health Professionals” dated December 26, 2005 (as amended on January 01, 2014). As it follows from the name and the recitals of this Decree, it was published for the purposes of improvement of material incentives for health professionals of the state-owned healthcare institutions, state-owned medical scientific organizations. The Decree refers to delivery of high-tech medical aid and performance of complicated medical interventions. It is assumed that in compliance with the requirements of the Law of the Republic of Belarus “On Healthcare” regarding the receipt of prior written consent to perform complicated medical intervention, such consent will also be required in case of delivery of high-tech medical aid. In such case, though high technologies being used, one should assess the extent of exposure on the organism. For example, the decree has included such surgical medical interventions to heart and aorta as coronary artery (mammary) bypass surgery on functioning heart and under cardiopulmonary bypass; artificial circulatory support devices, life support measures under cardiopulmonary bypass etc., into the list of high-tech medical aid On February 27, 2006, the Ministry of Healthcare of the Republic of Belarus adopted Enactment No.8 (as amended on December 20, 2008) “On Approval of the List of High-Tech Medical Aid”.

There may occur such situations, when the necessity for medical intervention is urgent. According to the Belarusian law, in cases when the complicated medical intervention is to be performed urgently (emergency case) and legal representatives are absent or it is impossible to find them, the decision is taken by the council of physicians and, if it is impossible to hold a council, the decision is made by the attending physician with putting an entry to the medical documents. The attending physician (the council of physicians), who made the decision and performed the emergency-caused complicated medical intervention must notify the head of the healthcare organization as well as the legal representatives at the earliest possible opportunity. It meets the requirements of Article 8 of the Convention dated April 4, 1997.

The consent to complicated medical intervention may be withdrawn by the patient or legal representatives, unless the medical intervention has already started and its termination or return to the initial condition is either impossible or may cause risk to the patient’s life or health. The withdrawal of consent to the complicated medical intervention and the information on impossibility to satisfy such withdrawal with indication of the relevant

reasons should be entered in the medical documents and signed by the patient or his/her legal representatives.

In cases when during the medical intervention the patient is unable to express his/her will, the wishes expressed by him/her earlier are be taken into account accordingly. In this connection, it was useful to find out on the national level, in what entries such (earlier expressed) withdrawal is recorded. Because emergency access to the patient's medical records may be provided not in every case, especially when the patient is not chronically ill. Information technologies are more and more widely used in the system of the Ministry of Healthcare. Such issue may be resolved with their help as well. There are facts, though rare, when people make tattoos on their bodies read as 'do not resuscitate". In some cases, such choice could be conscious, in others, such tattoo could be caused by bravado. The individual must realize seriousness of such wording as under certain circumstances the doctor may refuse to deliver medical aid. There are such examples in foreign practice.

The patient's consent to the complicated medical intervention is entered in the medical documents and signed by the patient or his/her legal representatives and the attending physician.

The list of simple medical interventions is defined by the Ministry of Healthcare of the Republic of Belarus with the Simple Medical Services Classifier available.

Let us take note of the provisions of Article 6 of the Convention where it refers to protection of the persons unable to give their consent. It contains serious guarantees for such persons. Medical intervention in relation to the minor, who is unable to give his/her consent as required by law, may be performed only with permission of his/her legal representative, an authority or a person or an institution defined by law. The own opinion of the minor is considered as a factor, which significance increases depending on the age and degree of maturity. Thus, the consent to the medical intervention may be given not only by the close relatives, e.g. parents, but other entities (authorities, institutions defined by law) as well. In our opinion, it is important inter alia because of potential situations when contrary to the interests of the minor the parents would not give consent to medical intervention, which necessity is quite evident. We assume that the foregoing provisions of the Convention dated April 4, 1997 should be stipulated in the Law of the Republic of Belarus "On Healthcare".

According to the Law of the Republic of Belarus "On Healthcare", the consent to the medical intervention in relation to the minor is given upon written consent of one of the parents, adopters, guardians, custodians. Such version of the Law excludes the stalemate situation when the other parent (adopter, guardian, custodian) is against the medical intervention, and it will not be performed due to such circumstances. The consent of one of the foregoing persons will be sufficient. The situation may be different when the person or the legal representative insists on medical intervention, but the doctor (the council of physicians) is of the opinion that there is no such need, e.g., recovery may be achieved not by surgical but therapeutic means. It would be a good practice to stipulate in the national legislation the doctor's right to deny such medical intervention, which entails risk to human life and health. However, it is not completely clear, for example, when it refers to exercising some somatic rights, including shaping of face, other parts of the body etc.

In our opinion, the consent of the minor at the age over 14 years old must be decisive in case of performance of the complicated medical intervention. It should be stipulated in the law. So far, in our opinion due to primacy of norms of the Civil Code, the minors, who have acquired legal capacity in full according to the established procedure, may decide on their own whether to give their consent to the medical intervention.

When informing the minor on the necessity for such intervention, presence of the legal representatives, whose opinion must be heard by the minor, is desirable. Let us remind here that the minors over 14 years of age bear criminal and administrative liability for

certain crimes and administrative violations. It would be useful, if necessary, to ensure participation of the psychologist during conversation held by the doctor with the minor patient. As for the minors younger than 14 years old, there may arise various real-life situations: e.g., parents give consent to (simple and complicated) medical intervention. Such consent is decisive. Another case: parents do not give consent to medical intervention though it is of vital importance according to the council of physicians. The reasons for refusal may be of various nature, including the religious grounds. We believe that in such situation the opinion of the council of physicians of the relevant medical institution should be decisive. Such decision may be challenged in court by the parents or other legal representatives. Such norm should be stipulated in the Law “On Healthcare”.

The approach similar to receipt of consent to the medical intervention in relation to the minor is stipulated in the Convention dated April 4, 1997 for the case of medical intervention to the minor recognized as legally incompetent under the procedure established by law or unable to give his/her consent due to health conditions: it may also be performed only with permission of his/her representative, an authority or a person in the process of obtaining the permission if possible. It would be also useful to stipulate this in the Law “On Healthcare”.

It is important according to Article 6 of the Convention it is requirement to provide the information, envisaged in Article 5 of the Convention, to the foregoing representatives, authorities, persons or institutions, in full scope and of true nature.

The voluntary basis of consent to medical aid also assumes an option to withdraw the consent at any moment in the immediate interest of the relevant person.

The national legislation stipulates special requirements with regard to psychiatric help delivery. The consent to its delivery is given and executed in compliance with the legislation of the Republic of Belarus on psychiatric help delivery. In particular, there exists the Law of the Republic of Belarus No.349-Z “On Psychiatric Help Delivery” dated January 07, 2012 (as amended on December 24, 2015). The Law stipulates the procedure supporting the implementation of the principle of informed voluntary consent to receive psychiatric help. It is also allowed to force psychiatric help, i.e. without consent of the patient or his/her legal representative as well as for compulsory psychiatric examination to be held for reasons and under the procedure established by the Law.

The Law proceeds from the presumed absence of mental disorder (disease).

The psychiatric help is delivered in case of availability of a prior consent of the patient, except for certain cases. In case of voluntary application for psychiatric help, the patient or his/her legal representative gives consent to psychiatric help delivery, which is recorded in medical documents and is signed by the patient or his/her legal representative and the medical specialist. The psychiatric help to the minor patient at the age below fourteen years old as well as to the person recognized as legally incompetent under the procedure established by law is delivered upon written consent of the legal representative. If one of the parents, adopters of the minor at the age below 14 years old objects to it or in case of their absence or absence of any other of his/her legal representative as well as in case of absence of the legal representative of the person recognized as legally incompetent under the procedure established by law, psychiatric help is delivered upon decision of the guardianship and custodianship agency. The decision of guardianship and custodianship agency may be challenged under the procedure established by the legislative acts.

The basis for compulsory hospitalization and treatment is the court judgement on compulsory hospitalization and treatment. The court judgement on compulsory hospitalization and treatment is made in case the person with mental disorder (disease) and resisting treatment is in condition, which shows his/her immediate danger to himself/herself and (or) other persons; his/her helplessness; potential substantial harm to his/her health due to deterioration of mental health if such person is left without psychiatric help. Resisting treatment by the person includes refusal of hospitalization to the psychiatric hospital; failure

to comply with the doctor's prescriptions, internal conduct rules, unauthorized suspension of treatment procedures in cases when psychiatric help in the psychiatric hospital is delivered with his/her consent or consent of his/her legal representative. In emergency cases, the decision on necessity of hospitalization is made by the medical specialist. The patient taken to the psychiatric hospital upon decision of the medical specialist is subjected to psychiatric examination to be held by Medical Consultative Board (MCB) within 24 hours from hospitalization. In case MCB comes to a conclusion on necessity of compulsory hospitalization and treatment, the psychiatric hospital applies to court at the place of residence (place of stay) of the patient or the psychiatric hospital location for his/her compulsory hospitalization and treatment, with enclosed medical statement on the necessity for compulsory hospitalization and treatment made by Medical Consultative Board, within 48 hours from hospitalization of the patient, exclusive of weekends and holidays. As we see it, the national law in this regard corresponds to spirit and letter of the Convention dated April 4, 1997, including Article 7 thereof.

The scientific and technological progress (achievements in medicine, genetics, biology and other sciences) created new conditions for improving the quality of human life. If earlier the individual was considerably focused on changing the outer world, which still continues, at present, there is also an opportunity to change human body itself, modify it, suspend own life (cryonics), select sexual identity and swap gender, resolve issues related to donation and transplantation of organs for organism regeneration. The principle of informed voluntary consent is basic here as well. New opportunities and tendencies of the present-day society development precondition the necessity to solve a range of issues of legal, social, religious, and economic values. However, those issues will be the subject matter of further research and analysis. At the same time, we are sure that accession of the Republic of Belarus to the EC 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) would play a positive role in enhancement of the national legal system.

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Session 2 – SPECIFIC ASPECTS OF THE APPLICATION OF THE PRINCIPLE OF FREE AND INFORMED CONSENT. CHALLENGES AND BEST PRACTICES.

Free and informed consent for medical intervention

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What is Informed Consent?

Informed consent is the corner stone of the protection of person's integrity as well as one of the patients' rights. Informed consent is not merely a formal signature at the end of consent form, but the process itself enabling the person making an individual choice.

Informed consent is voluntary agreement given by a competent person (or the authorisation given by the legally designated representative if the person concerned is not able to consent) for any intervention in the medical and biomedical field (medical treatment, organ and tissue donation, transplantation, participation in a biomedical research etc.) after receiving, considering and understanding comprehensive information about provided intervention.

The essential criteria of informed consent are that the person has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the person.

Autonomy

The development of informed consent concept marked a shift in patient-doctor relationship: from paternalistic judgment of clinical expert to decision-making power of the patient supported by comprehensive medical information.

Informed consent derives from the principle of autonomy or self-determination, which beside principles of beneficence, non-maleficence and justice forms the core of medical ethics.

In the context of medical law, autonomy implies freedom of action by a person of a self-decided plan. Respect for autonomy means the recognition of the legitimate right and the capacity of a person to make personal choices.

According to Article 5 of the Oviedo Convention an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

However, patient's autonomy does not imply the right for the patient to receive every treatment he or she may request, in particular when the treatment concerned is considered inappropriate (for instance, request for computed tomography (CT) when the same diagnostic information can be reached by conventional x-ray examination). In such cases a doctor is entitled to make use of so called professional autonomy which is subject to his or her professional judgment following the principles of beneficence and non-maleficence as well as justice.

Elements of Informed Consent

Information, freedom to decide and capacity are the core elements of informed consent.

What Information to be Told to a Patient Before the Intervention?

Although doctors are usually faced with limited time for patients' care, it must be remembered the informed consent is as important as the medical treatment itself. It is not just a bureaucratic requirement, but it facilitates the patient's trust in doctor, patient's own responsibility, thus improving the expected outcome of health care.

So, the main requirements of information to be told to a patient before the intervention:

- the purpose (the reasons) of intervention;
- the type and nature of the intervention proposed;
- the potential risks and benefits, the prognosis of proposed manipulation. the possible complications and side effects of the intervention (including individual characteristics of each patient, such as age or the existence of other pathologies);
- alternatives to the proposed procedures, including the effect of non-treatment;
- all procedures related to treatment, as well as the possible damage or injury, pain or other discomfort resulting from treatment;
- proposal to provide additional information regarding particular treatment;
- note for the right to a second opinion.

The provided information should be:

- honest, objective and intelligible;
    - it is not acceptable that the information is hidden from a patient just because a doctor believes it would prevent the refusal from intervention causing excessive troubles;
    - purpose consistency - taking blood samples for tests doesn't entitle a doctor to use them for medical research.
- given in a manner that ensures that a patient can understand it (for instance, ensuring written information for deaf-mute patients, ensuring translation services for foreign patients if necessary (however, it does not mean a doctor is forced to know tens and hundreds of languages, but the health care facility must at least attempt to make communication possible);
- as simple and approximate as possible avoiding specific medical terminology which might confuse a patient;
- adjusted according to the patient's ability to understand taking in account patient's age, maturity, education, previous experience and other individual factors (for instance, more detailed and simpler explanations needed for a 80 years old lady comparing to 25 years old youngster).

As for the necessity for written form of information - it may vary from one country to other. Written form of information, illustrations and similar materials may accompany verbally expressed information for better understanding, although these materials don't liberate a health care professional from duty to provide clear and comprehensive verbal information.

Besides the provided information should be:

- timely. The time necessary to consider the proposed treatment depends on its nature and consequences. The rule: the more serious is intervention and its possible consequences, the more timely it must be discussed with patient.

    - For instance, the ECtHR case VC v. Slovakia (2011)[26] concerned the sterilisation of a Roma woman in a Slovakian hospital. The ECtHR held: “it does not appear from the documents submitted that the applicant was fully informed about her health status, the proposed procedure and the alternatives to it. Furthermore, asking the applicant to consent to such an intervention while she was in labour and shortly before performing a Caesarean section clearly did not permit her to take a decision of her own free will, after consideration of all the relevant issues and, as she may have wished, after having reflected on the implications and discussed the matter with her partner." (para. 112);

- sufficiently (adequately) amounted.

The issue that is quite frequently misunderstood is that only very exceptionally the doctor may decide not to inform the competent patient if there is a strong and objective evidence the information could have a significant adverse impact on and could cause serious harm to the patient (possible suicide by the patient after communication of the medical prognosis).

Patient's Freedom to Decide

Patient's consent is considered to be free if:

- there is lack of pressure or undue influence (for instance scientifically unfounded warnings of unwanted outcome in case of refusal of provided medical intervention);

    - In the case Konovalova v. Russia (2014)[27] the ECtHR found that the unauthorised presence of medical students during the birth of the applicant’s child violated her right to respect for private and family life (Article 8 of the ECHR) on account of the lack of sufficient procedural safeguards against arbitrary interference with the applicant’s rights in the domestic law at the time. The involvement of medical students in the “study process” had been vague, without specifying the scope and degree of that involvement, and was presented in such a way as to suggest that participation was mandatory and the applicant had no other choice;

- it is given on the basis of adequate and timely provided information which corresponds to the nature and possible consequences of particular medical treatment;

- the person concerned may freely withdraw consent at any time once he or she has been fully informed of the consequences of such decision, although professional standards and obligations as well as rules of conduct which apply in such cases may oblige the doctor to continue with the particular treatment so as to avoid seriously endangering the health of the patient.

[26] Application no. 18968/07; 08/02/2012; http://hudoc.echr.coe.int/eng?i=001-107364
[27] Application no. 37873/04; 16/02/2015; http://hudoc.echr.coe.int/eng?i=001-146773

Patient's refusal to an intervention as part of right to free and informed consent is often expressed in written form, but definitely requires health professional's full and detailed explanation of possible consequences in case of such refusal;

- the same problem as in case of acquiring consent - just requesting signature under the refusal form is not sufficient and valid.
- "The Court recognises that the refusal of potentially life - saving medical treatment on religious grounds is a problem of considerable legal complexity, involving as it does a conflict between the State's interest in protecting the lives and health of its citizens and the individual's right to personal autonomy in the sphere of physical integrity and religious beliefs" (ECtHR case Jehovah's Witnesses of Moscow and Others v. Russia (2010), para 134).

Capacity to Consent

As for the capacity to consent, it is for domestic law in each country to determine whether or not persons are capable of consenting to an intervention and taking account of the need to deprive persons of their capacity for autonomy only where it is necessary in their best interests.

In order to assess patient's ability to provide informed consent, it may be necessary to evaluate ability:

- to understand: patients should be able to understand essential information;
- to appraise: patients should be able to appraise the situation in which they find themselves, recognise the problem and evaluate the consequences of treatment in their own situation in relation to their own scale of values or view of things;
- to reason: patients should be able to reason, compare options proposed and weigh up their risks and benefits;
- to state a choice: patients should be able to make a choice, and express and substantiate it.

Limitations of Scope of Informed Consent

Although the principle of free and informed consent constitutes a general rule it might be subject to limitations expressed in Article 8(2) of the ECHR. The limitations must be:

- in accordance with the law;
- serves a legitimate purpose;
- is necessary in a democratic society (there is fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights).

Several expressions of such limitations:

- compulsory vaccination;
    - "The interference with the applicant's physical integrity could be said to be justified by the public health considerations and necessity to control the spreading of infectious diseases in the region. Furthermore, according to the domestic court's findings, the medical staff had checked his suitability for

vaccination prior to carrying out the vaccination, which suggest that necessary precautions had been taken to ensure that the medical intervention would not be to the applicant's detriment to the extent that would upset the balance of interests between the applicant's personal integrity and the public interest of protection health of the population" (ECtHr case Solomakhin v. Ukraine (2012)[28], para 36);

- mandatory X-ray to prevent tuberculosis
    - In case Acmanne v Belgium (1984)[29], ECtHR held that a Belgian law requiring children to undergo an x-ray examination to prevent tuberculosis was not in breach of article 8 ECHR. Thus, while a large range of choices as to how and to what extent one's physical integrity is maintained fall within the scope of the right to private life, article 8 does not embrace an unlimited right to do with one's body as one pleases;
- on the opposite in the case of gynecological examination against person's will the ECHR stated: "(..) the Court finds that the gynecological examination which was imposed on the applicant without her free and informed consent has not been shown to have been "in accordance with the law" or to have been "necessary in a democratic society". There has accordingly been a violation of the applicant's rights under Article 8 of the Convention." (ECtHR case Juhnke v. Turkey (2008)[30], para. 82).

Protection of Persons Not Able to Consent

Article 6 of Oviedo Convention covers the provisions designed to protect persons who are not able to consent due to either their age (minors or elderly persons) or their mental incapacity or similar situations (illnesses, accidents or coma).

Protection of Persons Not Able to Consent - Minors

- Following established case law, where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person provided for by law.
    - "The Court considers that the decision to impose treatment on the first applicant [a severely handicapped child] in defiance of the second applicant's [child's mother] objections gave rise to an interference with the first applicant's right to respect for his private life, and in particular his right to physical integrity" (ECtHR case Glass v. the United Kingdom (2004)[31] para 70).
- However, the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity (Article 6.2 of the Oviedo Convention and Article 12 of the Convention on the Rights of the Child.
- The legislation of several States provides entitlement of persons formally not yet reaching the age of majority to consent substantively to provided medical intervention.
- The age at which a minor patient is entitled to make substantive decisions vary from state to state (for instance, 14 years in Latvia, 15 years in Slovenia and Denmark, 16

[28] Application no. 24429/03; 24/09/2012; http://hudoc.echr.coe.int/eng?i=001-109565
[29] Application no. 10435/83; 10/12/1984; http://hudoc.echr.coe.int/webservices/content/pdf/001-74749?TID=ihgdqbxnfi
[30] Application no. 52515/99; 13/08/2008; http://hudoc.echr.coe.int/eng?i=001-86255
[31] Application no. 61827/00; 09/03/2004; http://hudoc.echr.coe.int/eng?i=001-61663

years in Spain and United Kingdom). It is legal assumption that being so old a patient is matured enough to give consent without consulting parents or guardians on every occasion.

- For example, in the United Kingdom Gillick competence refers to a term used in medical law to decide whether a child (16 or younger) is able to consent to his or her own medical treatment without the need for parental permission or knowledge (the case Gillick v West Norfolk and Wisbech Area Health Authority[32])

Protection of Persons Not Able to Consent - Adults

According to Articles 17 and 20 Oviedo Convention:

- where an adult is not in fact capable of giving free and informed consent to a given intervention, the intervention may, nonetheless, be carried out provided that:
  - it is for his or her direct benefit, and
  - authorisation has been given by his or her representative or by an authority or a person or body provided for by law.

Besides where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons (for instance, accidents or states of coma):

- the incapacity to consent must be understood with regard to the intervention in question, not any medical procedure;
- the patient shall as far as possible take part in the authorisation procedure.
- the decisions taken must be as close as possible to what he or she would have decided and wished if he or she had been able to consent, or to ensure that the decision taken would be in the patient's best interests.
- adults, who have been declared incapable but at a certain time do not suffer from a reduced mental capacity (for example because their illness improves favourably), they must, according to Article 5 of the Oviedo Convention, consent themselves.
- The person or body whose authorisation is required for the intervention to take place on a person not able to consent must be given adequate information about the consequences and risks involved.
- The person or body concerned may withdraw their authorisation at any time, provided that this is done in the best interest of the patient not able to consent.
- Following a duty to protect the person not able to consent against decisions which are not in the best interest of this patient, the doctor may challenge the withdrawal of authorisation taking in account the professional standards (Article 4 of the Oviedo Convention).

[32] [1985] 3 All ER 402, [1986] AC 112, [1985] 3 WLR 830, [1985] UKHL 7, [1986] 1 FLR 229

Emergency Situation

Article 8 of the Oviedo convention states: when because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

In such circumstances a doctor is entitled to act immediately without waiting until the consent of the patient or the authorisation of the legal representative where appropriate can be given.

Prerequisites:

- this possibility is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent;
- the possibility is limited solely to medically necessary interventions which cannot be delayed (not only for life-saving interventions);
- the intervention must be carried out for the immediate benefit of the individual concerned;
- however, a doctor must make every reasonable effort to determine what the patient would want getting to know it from either a patient himself or herself or from the representative of patient.

Informed consent in the sphere of paediatric surgery. Comparison of medical and legal practices in the Federal Republic of Germany and the Federal Republic of Belarus

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As society becomes more modernised, informed and better off, people's perceptions of the conditions of existence are considered desirable are changing. To a large extent, this concerns healthcare. In an increasingly information-driven world, access to data on health risks is expanding. Knowledge is now beyond the limits of the community of health professionals. People are increasingly demanding security systems in the field of healthcare. Lawsuits regarding medical treatment have become so common that most doctors are prosecuted at some point during their careers. And the amount of money demanded in compensation continues to grow steadily. According to lawyers, the best protection in these cases is flawless documentation, the written consent of patients to perform any kind of medical intervention, and the early detection and rapid elimination of complications.

A separate issue is the application of these approaches in paediatrics.

When it comes to minors, informed consent is usually given by parents or legal representatives. This is fixed in Article 6 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine adopted by the Council of Europe. As a general rule, parents cannot refuse treatment for a child whose life is in danger.

In the Republic of Belarus, a fairly broad range of legislative acts ensuring the rights of children has been adopted. These are legal documents of a general and special nature that contain specific norms guaranteeing the rights and interests of the family and child.

The new Belarusian legislation on children is based on the most important international legal documents developed by the United Nations containing the basic requirements of state policy on the family and children.

The first question that arises is: At what age does a child acquire legal capacity and become a full-fledged citizen?

Definition of the concept "child." According to Part 1, Article 1 of the Convention on the Rights of the Child adopted by the UN General Assembly on 20 November 1989 and ratified by Decision of the Supreme Court of the Republic of Belarus on 28 July 1990, "For the purposes of the present Convention, a child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier." When translated into Russian, the term "human being" was conveyed as a literal combination of the words "human" and "being."

The Law of the Republic of Belarus "On the Rights of the Child" (No. 2570-XI) dated 19 November 1993 took note of the fact that the term sounded unnatural in Russian and introduced the following definition: "For the purposes of this Law, a child means an individual below the age of eighteen years (the age of majority) unless under the law applicable to the child, majority is attained earlier." Thus, a child is recognised as any person under the age of 18, unless the age of majority has been reached earlier.

In legal language: a natural person is the subject of civil law (the bearer of rights and duties). This is clearly defined for delictual dispositive capacity and dispositive legal capacity. These issues are established in the national legislation.

The moment at which legal capacity begins is a subject worthy of discussion. The question arises: "At what age and under what conditions does a natural person acquire legal capacity?"

The first country to answer this question on a legislative level was Germany. According to the Bürgerliches Gesetzbuch (the civil code of Germany), legal capacity is acquired at birth and relinquished at death or declaration of that person's death.

At the same time, the level of legal capacity changes with age, and full legal capacity is recognised as beginning when the person turns 18.

*Article 16 of the Civil Code of the Republic of Belarus defines "*Legal Capacity of Citizens" as follows*:*

1. The capacity to have civil rights and to bear duties (civil legal capacity) shall be recognised in equal measure for all citizens.
2. The legal capacity of a citizen shall arise at the time of his birth and be terminated by death.

Resolution No. 254/75 of the Ministry of Health of the Republic of Belarus and the Ministry of Statistics and Analysis of the Republic of Belarus "On the transition to the criteria recommended by the World Health Organization for live and still birth" dated 9 November 1993 defines the concept of live birth.

"Live birth is the complete expulsion or extraction of the product of conception from the mother's body regardless of the duration of pregnancy, with the foetus breathing or exhibiting other signs of life such as a heartbeat, pulsation of the umbilical cord or voluntary muscle contractions, regardless of whether the umbilical cord is cut and separated from the placenta.

Thus, the legal beginning of a person's life predetermines the beginning of his or her legal protection, as well as their civil legal capacity.

In layman's terms: the state protects its citizens from the moment of birth.

With the improvement of the national healthcare system, infant mortality (as an integral indicator of paediatric healthcare performance) was 3.2 cases per 1000 new-borns in 2016. The main causes of infant mortality today are: congenital defects and conditions that occur in the perinatal period and require intensive medical care – care that is impossible to provide without first obtaining informed consent.

By way of example, we can cite a case involving the death of a child during a home birth.

In 2017, a lawsuit was filed against a woman whose child had died following a home birth. The woman was charged with causing death by negligence (under Article 144 of Part 1 of the Criminal Code of the Republic of Belarus, which carries a penalty of up to three years' imprisonment). Initially, the child protection services worker was determined to be the victim in the case. However, the defendant's lawyers filed a petition for the husband to be recognised as the victim. The court granted the petition and the husband was named as the sole victim. According to the verdict of the court, the defendant was found guilty of causing death by negligence (under Article 144 of Part 1 of the Criminal Code of the Republic of Belarus) and sentenced to six months in prison, to be served in a penal colony settlement.

Three months later, the provincial court reviewed the case and reversed the original verdict.

The existing national legislation in the Republic of Belarus does not regulate the issue of childbirth. A woman has the right to give birth at home if she so wishes (it is not prohibited) and cannot be forced to have her child at a hospital. Doing so would constitute a violation of her constitutional rights.

At the same time, if a woman chooses to have her child at home, she cannot expect to receive the help of medical professionals. The only legal means of delivering a child (professionally assisting childbirth) in the Republic of Belarus is at a state maternity hospital.

More than 100 home births took place in the Republic of Belarus last year. According to Ministry of Health data, 90% of women who give birth at home are later hospitalised at healthcare facilities due to various complications.

"The decision made by parents to give birth at home, without the assistance of a medical professional, and without informing the healthcare authorities… is a criminal act perpetrated against the child."

Minister of Health of the Republic of Belarus Valery Malashko

Paediatric surgeons face the following challenges in their practical activities:

- difficulties obtaining consent;
- parents not agreeing to medical (surgical) intervention.

There are numerous examples of parents, for various reasons, refusing to give their consent to emergency surgical intervention (avascular necrosis, lower- and middle-third forearm fractures resulting from meningococcaemia, refusing blood transfusions on the grounds of the patient belonging to the Jehovah's Witnesses).

Jehovah's Witnesses refuse blood transfusions and any other kind of blood intake, whether it be whole blood or any of its four major components – red blood cells, white blood cells, platelets or plasma. There are no exceptions to this, even if it is a question of saving a person's life (this differs from other prohibitions: for example, deception is allowed in order to save a life; and drugs can be taken for medicinal purposes).

Every member of the organisation is strongly encouraged to fill in, and carry with them at all times, a form stating that they do not consent to a blood transfusion.

At a September 2017 meeting, the Expert Council under the Commissioner for Religious and Ethnic Affairs examined the issue of whether or not to order a state religious expert evaluation of the teachings of the republican association of Jehovah's Witnesses.

The experience of the Russian Federation can be cited here as an example of a possible approach to the issue. By decision of the Supreme Court of the Russian Federation, the Administrative Centre of Jehovah's Witnesses in Russia and all its 395 regional branches was recognised as an extremist organization and is banned throughout the country.

To resolve issues in such cases, the following approach has been used and is recommended.

In accordance with Paragraph 3 of Decree No. 18 of the President of the Republic of Belarus "On additional measures for the state protection of children in dysfunctional families" dated 24 November 2006, in exceptional circumstances involving a direct threat to the life or health of a child, the guardianship and custodianship agency has the right to take the decision to remove the child in compliance with Article 85*, Part 2 of the Code of Republic of Belarus on Marriage and the Family.*

In accordance with Article 85 of the Code of Republic of Belarus on Marriage and the Family dated 9 July 1999 (adopted under No. 278-3 by the House of Representatives and approved by the Council of the Republic on 24 June 1999), "Removal of a child without the deprivation of parental rights by decision of the court or guardianship and custodianship agency," the court may decide to remove a child and transfer him or her to the guardianship and custodianship agency without depriving the parents of their parental rights if leaving the child with the parents presents a danger to his or her life or health.

In exceptional circumstances involving a direct threat to the life or health of a child, the guardianship and custodianship agency has the right to take the decision to immediately

remove the child from the parents or persons to whom the care of said child has been legally entrusted. In such cases, the guardianship and custodianship agency must notify the public prosecutor immediately and, within seven days of such decision, file a motion with the court to have the parental rights of one or both parents taken away or for the child to be removed on a permanent basis.

As if the existing difficulties in obtaining consent weren't enough, any medical intervention is accompanied by risks of complications and other consequences. And it is not known whether or not these complications will arise. While the consequences of each kind of effect on a person's health are not always preventable, they are predictable. Since they can be predicted, measures are being taken to prevent them when providing medical care.

The legal formulation is as follows: infringement on the health of the patient extends to medical aid carried out with informed voluntary consent that deviates from accepted medical technologies and any kind of medical aid delivered without informed voluntary consent.

The legislation also states that the patient has the right to: receive, in a manner that is clear and understandable to them, information about the status of their health, the methods used to provide medical assistance, the qualifications of the attending physician and other medical professionals directly involved in the provision of medical assistance; participate in the process of selecting the methods of medical assistance to be provided; refuse medical assistance, including medical intervention, with the exception of cases provided for the this Law (Article 41).

The ideal model of medical activity is one in which conditions are created for an equal partnership to exist between patients and healthcare professionals. With regard to obtaining informed consent from the patient to medical intervention, there are two approaches to informing the patient:

- the doctor-centred approach;
- the patient-centred approach.

The main distinguishing feature (question) here is who has the dominant role in the doctor–patient relationship.

All the information that is necessary for the patient to make a decision about medical intervention can be combined into four blocks:

1. Information about the patient's current (initial) health status, and the prognosis for his or her future life and health:

– information about the illness that prompted the patient to visit the doctor in the first place;

– information about concomitant illnesses, the patient's general health, age, drug tolerance and reaction.

2. Information about the options for possible (or necessary) medical intervention (examinations, treatments, rehabilitation):

– information about treatment options;

– information about the most suitable method of treatment proposed by the physician in the given situation;

– information about the effectiveness of the proposed method of treatment and the probability of complications and failures;

– information about the probability of unforeseen circumstances and actions of the physician arising;

– information about the necessity and urgency of medical intervention.

3. Information on the rights and responsibilities of the patient:

– information about the need to attend all appointments and duties of the medical staff;

– information about the rights and duties of the patient during and after treatment.

4. Information about the medical institution:

– information about the medical institution and the attending physician (licenses, certification, years in the profession, medical category, academic credentials);

– information about the duties and responsibilities of the medical institution and health professionals with regard to the patient.

Types of consent

As a rule, the most basic and simple routine procedures that have a very low potential for complications can be carried out with the oral consent of the patient. In practice, difficulties may arise when it comes to deciding whether a particular type of medical intervention can be classified as simple or complicated, although in terms of legislation this issue has been formally resolved.

The list of simple medical interventions was approved by Decree No. 49 of the Ministry of Healthcare of the Republic of Belarus “On the establishment of a list of simple medical interventions” dated 31 May 2011.

Given the current trend towards increased responsibility due to the insistence of patients that they be fully informed about everything and receive the highest standards of service, we need to move to a system whereby written consent is obtained for simple as well as complicated interventions.

This is conditioned by the fact that oral consent makes it almost impossible to control the amount, level and quality of information given to the patient by the medical staff. And this makes it more difficult in court proceedings to prove that information was in fact given.

Even such a seemingly simple procedure as a routine examination can result in the administrative or criminal prosecution of the attending physician if the basic rules of patient examination are not followed (examination of the genitals and rectum should be carried out in the presence of two or more other people, with the consent and knowledge of the parents). The most serious possible consequences of noncompliance with the norms are accusations of paedophilia.

Forms of expressing content and the procedure for obtaining it from patients

The oral and written forms of giving informed consent are different. As a kind of marker or guide, medical interventions are divided into two categories, simple and complicated, for the purposes of obtaining written consent.

The advantages of obtaining informed consent to medical intervention in written form are:

– from a legal perspective, it is a more appropriate option both for the medical facility in question and for the patient in terms of proving the correctness of their respective actions if legal proceedings are initiated;

– the patient has the opportunity to carefully study the consent form at their own pace before making an informed choice about possible intervention;

– medical professionals have greater incentive to draw up consent forms and thus provide treatment in the proper manner;

– the physician demonstrates greater discipline when carrying out medical intervention;

– it saves time for the physician.

The list of complicated medical interventions was approved by Presidential Decree No. 619 dated 26 December 2015, with the latest amendments being adopted in 2013. The Decree also approved a list of hi-tech medical interventions, which should necessarily be classified as complicated as well.

According to the recommendations put forward by international acts, in instances where medical intervention is known to cause physical suffering and/or various levels of harm to the patient's health, informed consent must be obtained in writing. Such consent can be in the form of an entry in the patient's medical history certified by the patient's signature, or a separate release form or affidavit signed by the patient.

In accordance with Article 44 of the Law "On Healthcare," prior written consent is a necessary condition of carrying out a complicated medical intervention. Consent to a complicated medical intervention is documented by an entry in the medical records and signed by the patient or by his or her legal representative (in the case of minors and patients with disabilities who are not able to consent themselves), spouse or close relative (with regard to patients who are unable to make an informed decision due to health reasons) and the attending physician.

The patient and attending physician are required to sign and spell out their signatures. This is because examinations of handwriting are not always reliable when it comes to identifying the person who signed due to the lack of a sufficient number of markings needed to perform a complete investigation. It is thus necessary for all significant documents to include both the signatures and written surnames in order to facilitate the work of the handwriting analyst if so required.

It should be noted that, from a legal standpoint, a standard consent form to an operation, in which the patient consents to "standard" treatment and a "standard" operation, does not satisfy the requirements of "informed consent" and does not constitute an "unrestricted license" for the physician to prescribe any kind of treatment or operation at his or her discretion. Consent is required in a form that demonstrates the patient has a knowledge and understanding of the issue. In order for such consent to be obtained, the patient should be informed about all the risks to which a person of sound mind would attach significance when deciding whether or not to consent to a medical intervention.

Specifics of obtaining consent

According to Article 44 of the Healthcare Law, if a complex medical intervention needs to be performed urgently (an emergency), and the persons indicated in Part 2, Article 18 of the Law are absent or cannot be located, the decision shall be made by the medical council, and, in the event no such council can be held, by the attending physician with appropriate records in medical documentation. The attending physician (or medical council) that has made the decision and performed urgent complex medical intervention shall notify the head of the healthcare organisation and the persons indicated in Part 2, Article 18 of the Healthcare Law as soon as possible.

Informed consent to medical intervention for minors is obtained from their parents or legal representatives. This approach is formalised in Article 6 of the Convention on Human Rights and Biomedicine adopted by the Council of Europe. As a general rule, parents cannot refuse treatment of a child whose life is in danger.

In European countries (the Netherlands, Norway, Finland, France) the law requires doctors to find out the will of minors who are able to comprehend information of medical nature.

In some countries, the law recognises the right of minors over a certain age (12–14 years old) to seek medical assistance without parental consent when it undoubtedly meets their interests. There is no such provision in national legislation.

A patient or his/her representative has the right to refuse hospitalisation or medical intervention or demand termination of either of the two. Should this happen, the possible consequences of such refusal shall be explained to these persons in an accessible form. Refusal of medical intervention and hospitalisation shall be recorded in medical documentation with an indication of possible consequences and signed by the patient or his/her representative and the medical officer. The recognition of patients' autonomy and right to refuse treatment also implies recognition of their right to control their lives, i.e. to refuse life-sustaining measures.

Detailed documentation is a reliable means of protection against unjustified claims.

In this context, it is worth paying attention to the rule outlined in the Legal Medicine Guidelines: "The degree of effort invested into the documentary record of a patient's consent should always be weighed against the risk of possible claims".

Informed voluntary consent is more than just a legal doctrine or a pitfall for specialists. It is one of the basic notions underpinning the ideology of personal rights and the appropriate doctor–patient relationship.

Let us take an example of informed consent for anaesthetic treatment at the Charite Clinic of Paediatric Surgery, Berlin.

Given the large amount of foreign patients, the text of the consent is offered in German, English, Turkish and Russian.

> Explanatory information and past medical history questionnaire for child anaesthesia
>
> Please read the questionnaire and fill it out as soon as possible!
>
> *(Parents don't just sign or simply read the document – they actively work with it; they have to answer questions about past medical history and indicate any allergy, which means they become liable for what they sign.)*
>
> Anaesthesia is envisaged for the operation scheduled for _____ (date/time)
>
> Dear parents, dear young patient,
>
> The explanatory information sheet in your hands aims to inform you (and your child) about different anaesthesia methods. It will help you prepare for the conversation with the anaesthetist (hereinafter simply referred to as the doctor). The doctor will discuss with you the anaesthesia method that best suits your child and will thoroughly explain to you the advantages and disadvantages as well as the risks and side effects of the anaesthesia method in question. During this conversation, the doctor shall explain the anaesthesia procedure to your child (provided he/she has already reached an appropriate age) in a simple and comprehensible way.
>
> - Infections in the area of needle or catheter entry, which in most cases are easily cured with medicines. In extremely rare cases bacteria may get into the blood stream (bacteraemia) and lead to general infection with blood poisoning (sepsis) or inflammation of heart valves (endocarditis), which require intensive medical care. Due to the possible required use of somebody else's blood or organic tissue adhesive (fibrin), infection is possible in rare cases, for instance, by hepatitis viruses (consequence: liver inflammation), or, in extremely rare cases, by HIV (later consequence: AIDS);
>
> - Damage to skin and soft tissue (abscesses in the site of injections, death of tissue, irritation of nerves and veins) as a result of injections performed before, during or after the operation. For the most part these are easily curable, however may lead to long-term damage (scars, pains) in unfortunate circumstances;
>
> - In very rare cases, pressing or stretching when getting into the position required for the operation may result in the damage to nerves, accompanied by

impairment of sensitivity and paralysis, which usually just go away on their own over some time;

- In very rare cases, nausea and vomiting are possible as a result of the use of painkillers (opioids). The danger of gastric content getting into a lung leading to a pneumonia and potential prolonged damage of pulmonary tissue is especially probable if the recommendations to refrain from eating, drinking, etc. in advance/refrain from smoking before the anaesthesia are not observed;

- In rare cases, slight allergic reactions (hypersensitivity) to medication, for instance, nausea, itches or skin rash, are possible, but most of them go away on their own or are easily curable;

- In very rare cases, severe allergic reactions are possible, accompanied by swelling of the mucous membrane of the larynx, failure of the heart or the circulation system, respiratory distress and cramps, which require intensive medical treatment or resuscitation and may result in permanent damage due to the insufficient blood supply to organs (e.g. brain damage, kidney failure);

- In extremely rare cases, blood clots (thrombi) may emerge in veins, or occlusion of vessels may occur due to their movement (leading to e.g. pulmonary embolism, stroke), which may result in insufficient blood supply to certain parts of the body with subsequent damage to organs. Taking medication that reduces blood clotting (thrombosis prevention) may lead to increased bleeding later (e.g. formation of haematomas).

The Ministry of Healthcare of the Republic of Belarus is currently drafting a form of differentiated informed consent for various types of medical intervention.

Conclusion

1. Interaction between the medical and legal communities is required to solve problems that arise during patient treatment in order to prevent a potential conflict of interest.

2. It is necessary to explore the existing best international practice in the area of organising and obtaining informed consent for treatment as well as the use of this approach to protect the rights of both patients and doctors.

Free and informed consent in the sphere of biomedical research

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Introduction

Usually improvement of healthcare is regarded as the main motivation for biomedical research. However different from this opinion two sources for the interest on biomedical research can be identified. The one is linked to human nature if we follow Aristotle: "All men by their nature seek knowledge" (Aristotle, metaphysics). Healthcare and its improvement is the other incentive and has been the leading justification for physical interventions since antiquity, combining treatment and gaining knowledge. Hippocrates himself postulated research for the benefit of patients: "The physician must take care that curable diseases do not become incurable. He must know how to prevent incurability of diseases. He must be experienced in incurable diseases to avoid any useless treatment". (Hippocrates, de articulis reponendis 58).

In conclusion biomedical research is stimulated by the wish to enhance knowledge of the human being as such, a movement which was addressed as "curiosité" namely in Western Europe e.g. in the 17th century.

The other stimulus is the aim to improve healthcare, often known as "salus aegroti" and characterized by the expression "today's research is tomorrow's healthcare".

Gaining knowledge as such and knowledge to be applied require the fulfilment of two fundamental conditions: Freedom of research as the scientific principle and protection of research participants as the principle of the same quality.

Instruments adopted by the Council of Europe

There are various approaches to bring freedom of research and protection of research participants to an acceptable, fruitful synergy. A number of the relevant documents have been issued by non-governmental organisations including professional associations. As a prominent example the Declaration of Helsinki of the World Medical Association is mentioned. Proposals of these groups are subsumed under the term "soft local" indicating that they do not have any legal binding force by their origin. Legally binding instruments with different scopes – clinical drug trials, clinical trials on medical devices, academic research and more – have been adopted by many States. These national regulations follow mostly existing international provisions. Regarding the international level regulations of the European Union are binding for its Member States. However these instruments address with legally binding force only clinical drug trials and clinical trials on medical devices. In contrast the instruments adopted by the Council of Europe cover the whole field of biomedical research. The instruments are imbedded in a specific system.

The Oviedo Convention[33] as the basic provision entails the principles for the protection of human rights and fundamental freedoms in relation to the application of biology and medicine. Conditions for free informed consent in general and in particular for the research field are defined, freedom of research is underlined in the same way as the duty to protect research participants. The protective provisions of the Convention itself or other protective provisions of the same quality apply. The relation between risk and benefit of research is addressed. The Convention covers the field of research on persons not able to consent –

[33] 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 (ETS No 164)

avoiding the term “incapacitated” - , minors or adults suffering e.g. from specific diseases or being victims of traffic injuries. For research involving persons not able to consent the Convention accepts the substitution of free informed consent by authorization, given by a representative according to national law. Research with a potential direct benefit for the represented person may be authorized. In addition research without such a potential direct benefit may be allowed under condition of a national legal regulation and only if the limitations “minimal risk” and “minimal burden” for the involved person are followed. The terms “minimal risk” and “minimal burden” are legally defined by the “Research Protocol” (see footnote 3).

The Convention gives the frame for the more specific regulation by its Protocol on Biomedical research[34]. Convention and Protocol are legally binding instruments which enter into force by signature and ratification of States as laid down in the Convention.

Biomedical research on tissues or cells of human origin stored in collections or biobanks becomes more and more important for the enhancement of scientific knowledge and by that way for treatment as a whole. The legal positions concerning the use of such materials, if removed and stored with the free informed consent of a donor or with the authorization of the representative, vary from State to State in such a manner, that the adoption of a common legal instrument was not yet possible. To harmonize also this research field the Committee of Ministers adopted on 11 May 2016 the second version of a specific Recommendation[35] which is not legally binding.

The instruments of the Council of Europe are the only provisions covering all kind of biomedical research involving human beings. They are compulsory for all researchers including physicians. The “Guide for Research Ethics Committee Members” has been adopted by the “Steering Committee on Bioethics (CDBI)” CDBI of the Council in 2010 with the aim to promote the harmonized implementation of these provisions in the Member States.

Kinds of Biomedical Research

There are different classifications of biomedical research. For clarification the following short description of kinds of biomedical research contains fields for which, in conformity with the instruments of the Council of Europe, free informed consent, even in different variations according to national law, is compulsory.

Experimentation involving human beings, starting in the 18th century and becoming a central field of biomedical research since the 19th century, is performed as basic research, e.g. in anatomy, biochemistry, or physiology, with our without physical interventions. The aim is the improvement of the understanding of the human being, of its structure, of its diverse functions, of its physical or psychological reactions to e.g. artificial stress. The expected benefit can enhance knowledge and contribute to science. In addition clinical research and healthcare may gain profit.

Clinical research is mostly performed with physical interventions e.g.in surgery, internal medicine, or other clinical fields. An important field of clinical research is dedicated to drug trials and to clinical trials on medical devices. The latter kinds are often misunderstood as biomedical research as such – they are important, but not the whole. Clinical research mainly aims to improve treatment and specific knowledge of clinical situations. The first expected benefit is development of healthcare which might be associated also with deeper knowledge of the course of diseases. Science surely can profit.

[34] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical research, Strasbourg, 25.I.2005 (CETS No 195)

[35] Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origin, *Adopted by the Committee of Ministers on 11 May 2016*

Observational research e.g. as medical epidemiology assesses the behaviour of populations to gain data for preventive trials to change „life style“ of a population and by this way to improve the health situation. The research may be performed e.g. by the use of questionnaires.

Research on biological materials of human origin and related data is one of the most expanding fields of biomedical research aiming to gain knowledge for different purposes like drug development or prevention of infectious diseases.

Qualification and Quality

Persons should only be asked to participate in research projects of proven quality with an acceptable proportion of risk and benefit, carried out by qualified researchers. The researcher shall be “duly” qualified as written in several provisions. This term of course must be specified in relation to a specific research project. For a physician as principal investigator normally the full specialisation in the field of research is required. Collaborating investors should have at least a sufficient experience in the research field. The research team must be able to react to contingencies or adverse events. It must be safeguarded by the principal investigator that the duty of care prevails all scientific interests. Similar conditions are applicable if the principal researcher is member of a different discipline like psychology, biochemistry or biophysics as examples. The qualification of the research team is assessed independently by the competent bodies (see below).

The research project must fulfil the international accepted conditions: scientific quality in accordance with international scientific principles, conformity with national and international law and ethical acceptability.

Proportion of Risk and Benefit

For treatment, e.g. in surgery, internal medicine including the use of licensed drugs or medical devices, risks and benefits are known on basis of statics containing results of the application of the various methods. This does not mean that there is no risk, but it can be calculated. The situation in research is different. The researcher enters new fields, the project may result in favourable and beneficial outcomes, results may not fulfil the expectations and may even bring harm for the participants. The provisions of the Council require a calculation in relation to the research field. As a general rule risk and burden for research participants shall be minimised as much as possible in view of the envisaged project. Minimising does however not mean “minimal”.

For research without an expected potential direct benefit for the participants – often healthy volunteers - only acceptable risk and acceptable burden are admitted. This type of research is performed mainly for basic scientific purposes. For research with a potential direct benefit, performed on persons able or not able to consent risk and burden must not be disproportionate to the potential direct benefit for the person concerned. Research without a potential direct benefit on persons not able to consent may only performed under conditions of “minimal risk” and “minimal burden” for the involved participant. Both terms, rather new in the elaborating period of the Oviedo Convention, are legally defined by the “Additional Protocol concerning biomedical research”[36].

[36] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical research, Strasbourg, 25.I.2005 (CETS No 195)

Examination and Approval

Before beginning a research project including the recruitment of participants its structured assessment is obligatory as laid down, like in other documents, in the provisions of the Council of Europe.

Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee. Research may only be undertaken if the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of research, and multidisciplinary review of its ethical acceptability. Some remarkable points may be underlined: required are scientific merit of the project and ethical acceptability as assessed by a multidisciplinary review. This ethical review is a condition for the approval by a competent body.

Examination and approval as such are required by these provisions of the Council of Europe. However the specific procedure is left to the States. The competent body for an approval may be a specific authority, entitled to give it for all kinds of biomedical research or only for separate fields like drug research or research on medical devices. The competent body may be a research ethics committee. The assessment may be also performed by a research ethics committee and by an authority deciding independently from each other. Moreover the outlined conditions for the quality assessment can be proven all together by one body or by different bodies, e.g. ethical acceptability by a research ethics committee, scientific quality by a scientific committee and conformity with law by a juridical institution.

Assessment of Biomedical Research by Research Ethics Committees

Research ethics committees should in addition to their main responsibility themselves assess the justification and scientific quality of a submitted research project and its conformity with law. If the committee is not entitled by national law to screen these two aspects it must be convinced that they are covered by documented decisions of the legally competent bodies. The main task for research ethics committees is the assessment of the ethical acceptability of a research project. As guiding principles for this assessment "Autonomy, Beneficence and Justice" are accepted as laid down in the Belmont Report.[37] These principles may be interpreted in relation to e.g. national legislation, tradition, history, religion. However the basic principle that no human being may be used as a tool in the interest of others must not be overruled. The "Additional Protocol concerning biomedical research" (see footnote 3 on page 2) contains detailed regulations on the position and responsibilities of research ethics committees. An appendix to this Protocol lists the items to be presented to the committee for assessment of a project. The ethics committee is not bound by this list but is entitled to require additional information on the submitted project. Establishment, structure and composition, legal competence, bylaws and rules for procedure, requirements for the qualification of members, appointment of members and other points differ from State to State. To harmonize this field the CDBI of the Council of Europe adopted in 2010 the "Guide for Research Ethics Committees Members". The title "Guide" clearly indicates that the document is a proposal to cover all relevant fields of research ethics committees.

Consent to Research – Questions in Discussion

The term "free informed consent" is worldwide used by different institutions. However its understanding and interpretation show a variety of positions. It is discussed whether a person entering an officially appointed research institution e.g. for healthcare gives an implicit consent to participate in research. In contrast the necessity of an explicit consent is

[37] Belmont Report, US Federal Register, 18th of April 1979

discussed and preferred even in this case – healthcare and research are different approaches.

A similar discussion is known concerning the scope of consent: can a consent be given only for a specific research project or for projects in a defined research field like e.g. oncology or more restricted haematological oncology?

Cultural factors like tradition, history, jurisdiction or religion have an important influence on the realisation of free informed consent. In most States with European or similar tradition only the individual consent is accepted in accordance with the Oviedo Convention (Article 5):

"General Rule for Consent

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time."

However in regions of Asia and Africa with different cultural tradition consent may be given as a mixture between individual consent and consent of the community. It may also be possible that only the authorities of the community decide on participation or non participation of its members in a research project.

A general question is raised by the proposed term waiver of consent for specific research projects as e.g. foreseen by the Declaration of Helsinki. Since fundamental rights and freedoms are in question, such a waiver should only be declared by an authority or by a research ethics committee legally entitled for, provisions in documents of professional organisations are not sufficient.

A specific problem is linked with consent for scientific use of stored human biological material. It is agreed that removal of such material and storage for research use in the future need free informed consent of the donor or authorization by the legal representative. In some States the stored material may be used without a specific consent of the donor under condition that the project has been assessed by a research ethics committee. In other States the principle of individual consent even for these situations is maintained. The Recommendation on scientific use of stored material[38] tries to respect both situations in respect of the legislation of the Member States of the Council of Europe.

Scope of Consent or Authorization

The scope of consent and of authorization addresses similar situations: the specific conditions for the agreement of a person to participate in research or for the substitution of such an agreement by the legal representative. Both problems are therefore considered together.

Specific consent or authorization apply to research with physical interventions like research in surgery, drug trials, trials on medical devices, removal of tissue for a defined, single research project. For research without physical interventions specific consent or authorization is also appropriate, e.g. for observational studies using questionnaires. If those research projects are widened or changed, the given specific consent or authorization is no more valid, they have to be asked for in view of the new scientific approach.

There are fields for which a non-specific consent (often addressed as "broad consent") or a non specific authorization is more appropriate to safeguard the purposes of research and the scientific use of achieved results and stored materials. This non-specific consent or authorization may be given only on the basis of an appropriate information as precise as

[38] Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origin, *Adopted by the Committee of Ministers on 11 May 2016*

possible on further use of stored biological material. The non-specific consent or authorization may be linked or not to a specific scope concerning the further use. The donor shall decide on any further contact in relation to the use of the stored material, contact may be accepted, required or refused. In case of a nonspecific authorization it must be safeguarded that the represented person, having gained or regained the ability to consent, is informed on that authorization. The person may agree with the authorization or withdraw it.

The research project for which a non-specific consent or authorization has been given shall be subjected to an independent examination by a research ethics committee and submitted for approval by a competent body if required by national law. This specific provision may appear difficult but intends to safe the fundamental rights and freedoms of donors of material.

Any anonymization of tissue and related data require an appropriate information on the consequences, given to the donor or to the legal representative. The anonymization needs consent or authorization. Consent or authorization may include restrictions for the scientific use of the anonymised material.

Legal Conditions for Consent or Authorization

If a research project including the information for participants has been assessed by the ethic committee with a positive outcome and has been approved by an authority in conformity with national law the recruitment phase may start. Envisaged participants, able to consent, shall be duly informed (see below) and thereafter asked for consent. This consent will be informed, free, express, specific or not specific and will be documented. Refusal or withdrawal of consent must not lead to discrimination or disadvantages, specifically not to exclusion from medical care.

If there is any doubt on the ability of the person to consent an assessment of that ability should be performed in conformity with national law and relevant regulations. If the ability to consent is not confirmed the person concerned may not be involved in any research projects which can be performed with the same expected results on persons able to consent. Specific research projects however can only performed involving persons not able to consent like minors or persons who lost this ability temporarily or for ever due to e.g. traffic injuries or diseases. In these situations free informed consent may be substituted by an authorization in conformity with national law. According to national law a representative, an authority, a person or a body designated for by law may authorise the participation on basis of full information. The authorization may be refused or withdrawn without any discrimination or disadvantages for the represented person.

Among others some requirements for authorization are underlined. The person has not objected or does not object to involvement in research and is as much as possible included in the decision on authorization. It is proven that research of comparable effectiveness on persons able to consent is not possible. Results of research on persons not able to consent are needed for medical care or basic understanding of health problems of this specific group. Authorization may be given for research with a potential direct benefit for the person involved. Under the conditions of “minimal risk” and “minimal burden” research for the benefit for others may be authorized in a legal framework. Research on biological material needs an authorization by the legal representative.

The legal representative shall act for the best interest of the person concerned.

Collections - Biobanks

The removal of human tissue and storage for future research use require a non-specific free informed consent or a non-specific authorization as defined above. The scientific use and

storage of human tissue removed for other purposes, e.g. for diagnostic analyses, require also a non-specific consent or a non-specific authorization. It is not acceptable that residual tissues after treatment procedures, sometimes called “left overs”, are used for scientific purposes without consent or authorization. A represented person having gained or regained the ability to consent shall be informed on a previous authorization. The person may confirm or withdraw the decision of the legal representative. It is up to a donor to decide on future contacts with the collection or biobank. Research projects using material form collections or biobanks need an assessment by a research ethics committee and, if required by national law, an approval by a competent body.

Condition for a valid Consent to Research

Freedom of decision on basis of an appropriate information on the research project is the condition for consent or authorization to a research project. The freedom of decision of an envisaged participant may be touched by the hope for better medical care. In addition financial incentives or non-financial awards such as goods of different type may influence the wish to participate. The social situation of a person may accelerate the willingness to participate in a research project. Special attention should be paid to avoid any coercion for members of groups, e.g. military units or clinical staff. A similar attention is required if vulnerable persons are envisaged as participants. Research on persons deprived of liberty needs in view of their involvement a specific consideration. In some States their participation is forbidden by law, some States allow it in the frame of legal regulations. The influence of cultural factors on the freedom of decision as described above may not be forgotten.

Finally it is emphasised again that the legal representative shall only decide freely in the best interest of the represented person and must not receive advantages or awards by the authorization.

An adequate information as condition for valid consent will be given in a comprehensible form and will be documented. It contains the purpose, overall plan, possible risks and benefits of the project. The envisaged participant is informed on the opinion of the research ethics committee and on the approval by a competent authority, if required by national law. Part of the information is the explication of rights and protective safeguards prescribed by law. The right to refuse or to withdraw the consent or the authorization at any time is underlined. If applicable in view of the research project, during the information procedure specific attention is given to the use of removed and stored tissue, identifiable data, anonymization of tissue and data. The nature, extent, duration, and burden of the research project for the participant are duly explained. The presentation of available preventive, diagnostic, therapeutic procedures is added, specifically if these methods are a real alternative to those in the project. Important for safety reasons is the information on response to adverse events or to concerns and how qualified medical care will be in place. The candidate should know all provisions for compensation in the case of damage. The respect for private life and assuring confidentiality of personal data are other important points of the information scale. The question of access to information on the research outcomes has been an object of a long standing discussion in relation to Article 10 of the Oviedo Convention containing the right to know or not to know. The participant should be informed on this right. Any information with relevance for his health or for the health of his family should offered. He should know how this information will be given. Handling incidental findings is included. On request of the participant overall results of the project are presented in a understandable manner. Any question on potential further use of the results such as in a commercial way, concerning specifically biological material or data should be answered as precise as possible. Information on the source of funding the project complete the information. May be that persons hesitate or refuse to contribute to a project financed by a sponsoring institution which they do not accept.

This list of items is not exhaustive and may be changed or widened according to specific situations.

Asking Free Informed Consent or Authorization

Free informed consent should be sought in the way of a personal interaction between researcher and envisaged participant or with the legal representative. The researcher should explain the research project and answer to questions of the envisaged participant or of the legal representative in a manner that understanding is achieved. In case of conflict of interest or dependency between the researcher and the envisaged participant a neutral person of appropriate quality should be charged to ask free informed consent or authorization. The way to seek consent or authorization and the information material should be assessed by an ethics committee. The use of electronic media for this important step of involving persons in research projects is still in discussion.

Refusal or withdrawal of free Informed consent or authorization merit specific attention in view of protection of participants and should be appropriately addressed during the personal interaction as mentioned above. It is again underlined that refusal or withdrawal of consent or authorization must not be followed by discrimination, exclusion from medical care or other disadvantages for the person concerned.

If a person or a legal representative intends to withdraw the consent respective the authorization the researcher should explain the consequences of this step. Consequences may be expected for the quality of the research project as such but also for the person concerned. However the researcher should offer as a protective provision further medical care which might be necessary as follow up in relation to the methods and interventions used in course of the project. Withdrawal of consent or authorization for research using biological materials and associated data needs a specific consideration. National law may provide that data and biological material may be destroyed and no more used if identifiable. National law may contain different solutions such as keeping data from specific research for a certain time period or storing material in an anonymised form in a biobank.

Free and informed consent in the field of transplantation of organs and tissues of human origin

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I. Introduction

I would like to start by gratefully thanking the organisers for inviting me to this important conference and for allowing me to visit the wonderful city of Minsk. In my presentation, I will focus on the topic of free and informed consent in the field of transplantation, with due attention to the different legal approaches across Europe.

After the first successful kidney transplantation in 1954, subsequent successes in the 1960s, and the discovery of cyclosporine as a powerful immunosuppressant in the 1970s, it became clear that a new ethical and legal framework would become necessary to deal with organ and tissue transplantation. Existing frameworks in the biomedical field were ill-suited since transplantation involved a medical procedure whereby, for the first time in history, human body material was reused. Moreover, the medical intervention also stood out because it was performed for the benefit of a third person. In the light of this characteristic it came as no surprise that the new ethical and legal framework would be developed on the basis of the framework governing biomedical research that had been codified sometime before.

The latter framework was guided by four principles. More specifically, these were: (1) beneficence (i.e. the duty to help the patient/participant); (2) nonmaleficence (i.e. the duty not to harm the patient/participant); (3) respect for autonomy; and (4) justice/solidarity. The newly developing transplant framework was governed by the same four principles, but specific emphasis was put on the principles of voluntariness and altruism. It was rightfully argued that the willingness of donors and the integrity of the transplant system would depend on the confidence of the general public that organs and tissues are ethically obtained and equitably allocated.

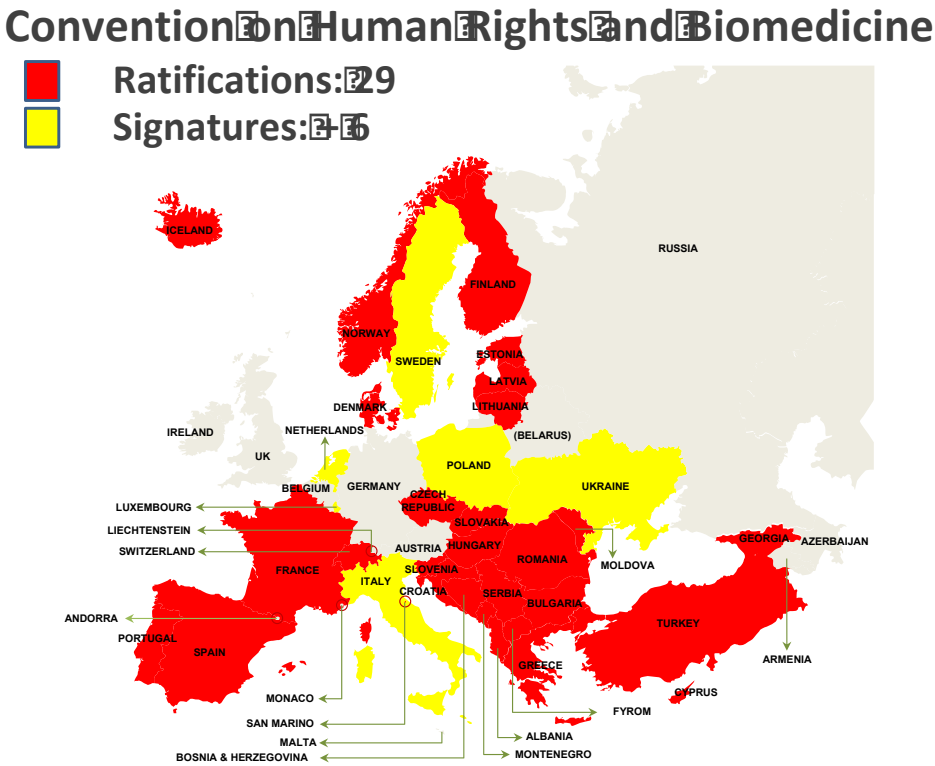
The requirement that free and informed consent needs to be obtained from organ and tissue donors and the prohibition of using financial inducements became the cornerstones of transplant regulations. They were incorporated in the first national transplant laws (e.g., Italy, Norway, and Spain) and, from the end of the 1970s onwards, in international guidelines on transplantation. In fact, the first international guideline was *Resolution (78)29 on Harmonisation of Legislation of Member States to Removal, Grafting and Transplantation of Human Substances*, issued by the Council of Europe in 1978 and calling upon Member States to include into their domestic transplant legislations the requirements that "substances of human origin" must not be removed from a living person without that person's free and informed consent, or from a deceased person when that person had objected, and that these substances must not be offered for profit.

Subsequently, these requirements were enshrined in a variety of guidelines issued by the World Health Organization (WHO), the World Medical Association (WMA) and The Transplantation Society (TTS).[39] The most important guidelines to date are the 2010 *WHO*

[39] World Health Organization. *Resolution WHA40.13 on Development of Guiding Principles for Human Organ Transplants*, 1987, available at http://www.who.int/transplantation/en/WHA40.13.pdf; World Health Organization. 1991. *WHO Guiding Principles on Human Organ Transplantation*, available at http://www.who.int/ethics/topics/transplantation_guiding_principles/en/index1.html; World Health Organization. *WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation*, 2010, available at http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf; World Medical Association. *Declaration on Human Organ Transplantation*, 1987, available at http://www1.umn.edu/humanrts/instree/organtransplantation.html; World Medical Association. *Statement on Human Organ Donation and Transplantation*, 2000/2006, available at https://www.wma.net/policies-post/wma-statement-on-human-organ-donation-and-transplantation; World Medical Association. *Statement on Human Tissue for Transplantation*, 2007, available at https://www.wma.net/policies-post/wma-statement-on-human-tissue-for-transplantation; World Medical Association. *Statement*

Guiding Principles on Human Cell, Tissue, and Organ Transplantation, the 2012/2017 *WMA Statement on Organ and Tissue Donation*, and two statements on living organ donation issued by the Ethics Committee of The Transplantation Society.

However, as has been indicated in earlier presentations, the first international legally binding instrument in the field of organ and tissue transplantation was the *Convention on Human Rights and Biomedicine* (the so-called *Oviedo Convention*), adopted in 1997 by the Council of Europe.[40] As can be seen on the map of Europe, it is currently ratified by 29 of the 47 member states of the Council of Europe.

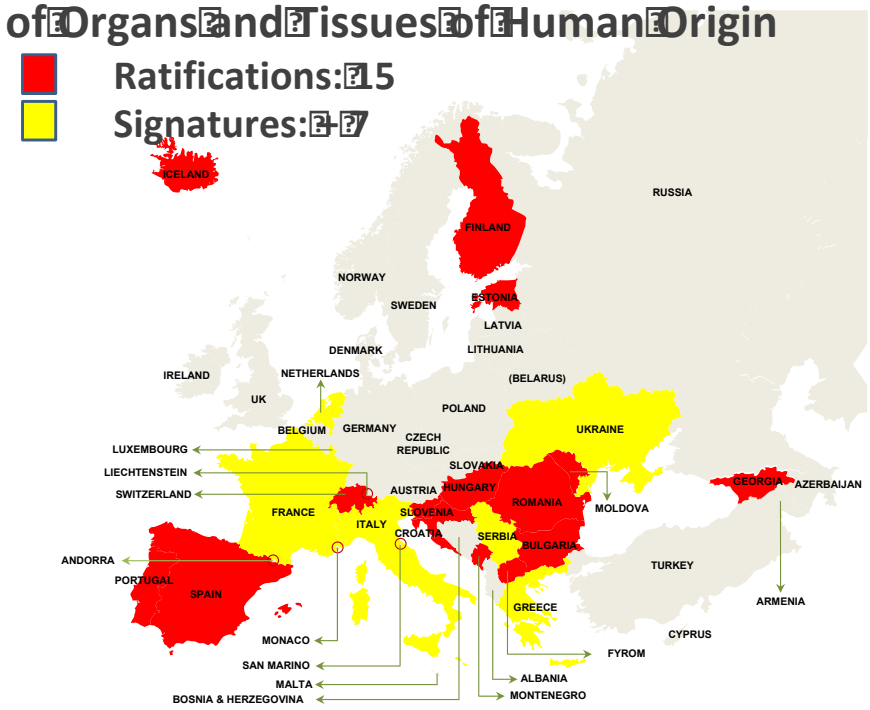


More detailed provisions on organ and tissue transplantation were introduced by its *Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin*, which was adopted by the Council of Europe in 2002, and, as shown on the map below, is currently ratified by 15 of the member states that have ratified the *Oviedo Convention*.[41]

on Organ and Tissue Donation, 2012/2017, available at https://www.wma.net/policies-post/wma-statement-on-organ-and-tissue-donation; The Ethics Committee of the Transplantation Society. The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor, *Transplantation*, 2004, 78(4): 491-2; The Ethics Committee of the Transplantation Society. The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor, *Transplantation*, 2006, 81(10): 1386-7.

[40] Council of Europe. *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 April 1997, CETS No. 164, available at https://rm.coe.int/168007cf98.

[41] Council of Europe. *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin*, Strasbourg, 24 January 2002, CETS No. 186, available at https://rm.coe.int/1680081562.



The ethical and legal importance of the *Oviedo Convention* and its *Additional Protocol* cannot be overestimated, since its provisions on donation and transplantation have, with very few exceptions, also been implemented by the member states that did not ratify these legal instruments.

II. Organ and tissue donation by a living donor

The *Oviedo Convention*, its *Additional Protocol concerning Transplantation*, and the aforementioned guidelines issued by the WHO, the WMA, and TTS have laid down three general principles regarding consent for organ and tissue donation by living donors. More specifically, these require that: (1) from a living person an organ or tissue can only be removed after that person has given express, free, informed, and specific consent; (2) consent should be given either in written form or before an official body; and (3) consent may be freely withdrawn at any time. I will now examine the requirement of free and informed consent in more detail.

a. Free consent

With regard to the voluntary nature of the consent, it is stipulated that the living donor's decision to donate should be free from coercion and undue pressure. More in particular, this means that the decision should not be the result of compulsion, coercive threats or offers, or defective beliefs induced by fraud or mistake. In addition, no financial inducements should have been used to obtain consent. Admittedly, decision-making in the context of living organ and tissue donation is often relatively instinctive, certainly where it involves a request from a close relative and the procedure could be life-saving. Certainly in the family context the social circumstances may result in a strong internal pressure to donate an organ or tissue. However, this is generally considered not to be violating the requirement of voluntariness and, hence, not to invalidate consent.

How can we guarantee that consent for living organ and tissue donation is voluntary? Across Europe, two types of measures have been introduced in transplant regulations. The first one

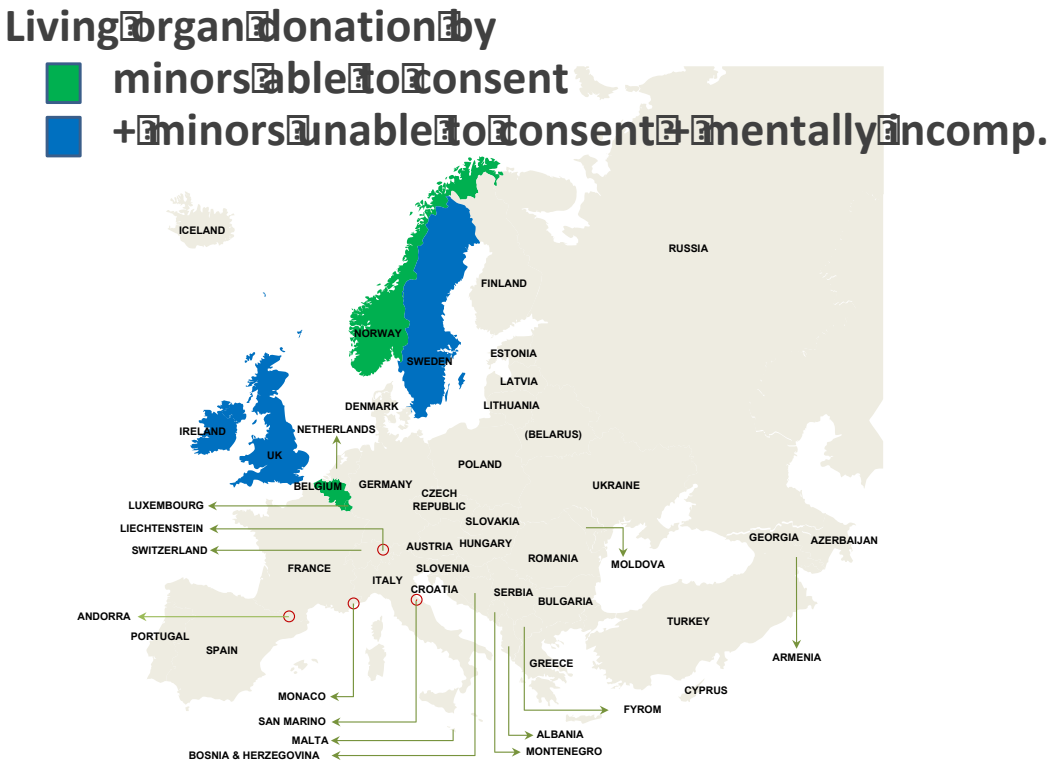
aims to guarantee the voluntary nature of living donation by restricting the categories of persons who are allowed to donate. These restrictions focus on: (1) the level of relatedness between the prospective donor and the intended recipient, and (2) the vulnerability of the prospective donor.

As to the required level of relatedness, it should be pointed out that all European countries allow donation by a close genetic relative and by a spouse, although some differences exist as to the required degree of consanguinity and as to the eligibility of a cohabiting partner to donate. In many European countries the level of relatedness that allows living donation has been extended beyond close genetic relatives and spouses/cohabiting partners, to also include close relatives by affinity (e.g., Bulgaria and France), persons with a close personal and emotional relationship with the intended recipient (e.g., Germany), and in some countries even persons who are genetically and emotionally unrelated (e.g., the Netherlands and the United Kingdom). It is sometimes argued that unrelated donors, who are also called Samaritan donors, are the ones that are most clearly altruistic. Others warn that there may be a real risk that unrelated donors donate for unacceptable reasons (e.g., remuneration) and that, in countries where they are allowed to donate, they should be properly screened.

Apart from focusing on a required level of relatedness, transplant regulations also prohibit some categories of persons to become a living donor out of concern for their inherent vulnerability and the resulting unlikelihood or even impossibility that they can give consent that is free and informed. These categories may include persons who serve or are otherwise dependent upon the recipient (e.g., Azerbaijan), prisoners (e.g., Albania and Slovakia), and pregnant women (e.g., Poland and Turkmenistan). It should be noted that, even in countries where the aforementioned categories are not explicitly mentioned in transplant regulations, it is likely that they are not allowed to donate, especially when it concerns living organ donation, because transplant teams may in practice refuse to consider them.

Special categories of persons who are generally not allowed to become living organ donors are minors and mentally incompetent adults. The reason is that these persons are as a rule not considered to have the capacity to understand the information provided and to be sufficiently independent, so that the requirement of free and informed consent is difficult or even impossible to fulfil. As to minors, a differentiation should be made between minors able to consent and minors unable to consent. Whether minors could be able to consent to an intrusive procedure of organ removal is determined by national law. In Europe, there are six countries where minors from a certain age are presumed to be able to consent to living organ donation (i.e., Belgium, Ireland, Luxemburg, Norway, Sweden, and the UK). In three of these countries (i.e., Ireland, Sweden, and the UK) minors who are unable to consent and mentally incompetent persons can exceptionally also be considered as living organ donors if this would be in their best interests (e.g., as a last resort to save the life of a sibling).

In all other European countries mentally incompetent adults and minors unable to consent are only allowed to donate regenerative tissue, in line with the provisions stipulated in the *Oviedo Convention* and its *Additional Protocol*. These conditions are, at a minimum, that: (1) there is no compatible donor with the capacity to consent; (2) the recipient is a sibling (although in some countries other close relatives may also receive); (3) the donation has the potential to be life-saving for the recipient; (4) there is specific and written authorisation of the legal representative or a body provided by law; (5) there is approval of a competent body; and (6) the potential donor is involved in the decision-making in accordance with his/her age or maturity, is informed, and does not object. Interestingly, in the aforementioned countries where living organ donation is allowed by minors who under national law are considered able to consent, or even by minors who are unable to consent and by mentally incompetent adults, the same six conditions will apply but this time also extend to organ donation. These countries are highlighted in green, and respectively in blue, on the following map.



The second main type of measure introduced in transplant regulations aimed at guaranteeing that consent for living organ and tissue donation is voluntary, is a mandated psychosocial assessment of the prospective donor. The purpose of such an assessment is to ascertain that the prospective donor has sufficiently developed cognitive and emotional capacities and is guided by altruistic motives. These motives have to be sincere and consistent with the person's past behaviour and not impaired by psychiatric disorder, guilt or impulsivity, and the person should be free from coercion, undue pressure, and financial inducements. Importantly, compatible donors who for one reason or another would be reluctant to donate, are in practice provided with the possibility to refuse donation without losing face, for instance by having the medical team announcing to the intended recipient that the prospective donor is not compatible (i.e., "white lies").

Several international guidelines contain recommendations on the psychological assessment of prospective donors and at international level some tools have been developed to that aim.[42] With regard to domestic transplant regulations and practices, significant differences exist as to the comprehensiveness of the evaluation, the involvement of (mental) health professionals or a body in the assessment, and the extent of its applicability (e.g., evaluation of every prospective donor or only of certain categories, such as unrelated donors, where domestic regulations allow them to donate).

b. Informed consent

As to the informed nature of the consent to living donation, the *Oviedo Convention*, its *Additional Protocol concerning Transplantation*, and the aforementioned guidelines issued by the WHO, the WMA, and TTS stipulate that: (1) information provided should be appropriate; (2) information should concern the purpose and nature of the removal itself; and (3) information should also be provided on the consequences and risks of removal and donation.

How can we guarantee that consent for living organ and tissue donation is informed? On the

[42] See in this respect, for instance, Kranenburg L. *et al*. The psychological evaluation of Samaritan kidney donors: A systematic review. *Psychological Medicine*, 2008, 38: 177-85.

basis of the aforementioned international instruments, domestic transplant regulations contain provisions as to the required style, content, and procedure regarding the provision of information. As to the style of the information, it is stipulated that the information should be provided in a language and in terms understandable by the prospective donor and that it has to be ascertained that the person concerned has indeed understood the information. It is recommended that the information is provided in writing. In practice this recommendation seems to be universally followed, at least where it concerns living organ donation.

As to the content of the information, it is set out that this needs to be appropriate, meaning that it is as accurate, complete, and objective as possible. Moreover, information should be provided on the purpose and nature of the removal and on the consequences and risks of removal and donation. With regard to the latter provision, it should be pointed out that all domestic transplant regulations across Europe indicate that possible health risks should be mentioned. In most transplant regulations, this minimum requirement is extended to also include information on the psychological, economic, and social risks, and often also information on the alternative therapies for the intended recipient and the expected transplant outcomes for that person.

Finally, as to the procedure to be followed, it is required that the information should be provided by an experienced health professional who is not involved in the transplant procedure. In several countries, transplant regulations contain additional safeguards for living organ donation. For instance, an additional, independent physician may need to be present (and sign the consent form) (e.g., Germany and Poland) or the information may need to be provided by an independent expert committee (e.g., France). Invariably, it is stipulated that sufficient time should be foreseen between the moment of information and the moment of consent, and between the moment of consent and the actual removal.

c. Donor consent and independent approval

A crucial additional guarantee to ascertain that consent to living organ donation is free and informed relates to the procedure to register consent and obtain final approval. Obviously, the prospective donor consent needs to be given before, and to be registered by, the transplant team itself. In several countries the prospective living donor is assisted throughout by a dedicated professional whose only concern is the well-being of that person (i.e., the "living donor advocate") and often additional (mental) health professionals are also involved when a psychosocial assessment needs to be performed.

In addition to the provision of consent to the transplant professionals themselves, transplant regulations in all European countries require that an independent official body needs to give final authorisation. This body may take different forms, such as: (a) a medical council at the level of the healthcare facility (e.g., Russia and Ukraine); (b) a pluridisciplinary ethics committee at the level of the healthcare facility, either for all organ donors (e.g., Belgium and Montenegro) or for specific types of donors only (e.g., Albania and Croatia); (c) a pluridisciplinary ethics committee at regional level (e.g., Turkey); (d) a pluridisciplinary ethics committee or dedicated body at national level (e.g., Finland and the UK); (e) an official notary (e.g., Belarus, Hungary, and Romania); or (f) a judge, either for all organ donors (e.g., France, Italy, and Spain) or for specific types of donors only (e.g., Greece and Poland).

III. Organ and tissue donation by a deceased donor

The *Oviedo Convention*, its *Additional Protocol concerning Transplantation*, and the aforementioned guidelines issued by the WHO and the WMA state that organs and tissues may not be removed from the body of a deceased person unless consent or authorisation required by national law has been obtained and that, in any case, such removal must not be carried out if the person concerned is known to have objected to it when alive. Moreover, the general public has to be provided with appropriate information about the consent regime in place, including about how to register consent or refusal.

These general principles are implemented in the transplant regulations of all European countries. Across Europe applicable consent regimes may either involve explicit or presumed consent, with some having features of both regimes. In countries with an explicit consent system, significant differences may exist as to the modes of registration of consent to post-mortem donation, and as to the moment and frequency of requests to make a decision to register consent or refusal, when the person concerned did not yet do so.

Similarly, in countries with a presumed consent system, significant differences may exist as to the modes of registration and, more specifically, whether a national registry of refusal is established and, if so, whether there also exists a registry of explicit consent (aimed at precluding the possibility that the next of kin, to the extent that they would be consulted upon the death of their loved one, would still be able to go against the wishes of the deceased). In this regard, it should be noted that important differences may also exist as to the respect awarded to the wishes of the next of kin (e.g., whether they are always consulted; whether they are asked about the opinion that the deceased had towards post-mortem donation; and whether the medical team would refrain from organ removal when the next of kin vehemently opposes whereas the deceased was clearly in favour).

As is shown on this map, most countries in Europe use a presumed consent system, with several countries (e.g., Montenegro, Serbia, Ukraine, and Wales) having switched from an explicit to a presumed consent system in the last 5 years. Recently, Ireland and Scotland have also initiated changes to their transplant regulations with a view to changing to a presumed consent system. Moreover, in some other countries, such as the Netherlands and the UK (except for Scotland and Wales), a public debate on a possible move towards presumed consent is ongoing.

IV. Challenges to free and informed consent to organ donation

With regard to organ donation by a living donor some concerns exist about the compatibility of the requirement to provide the possibility to refuse or withdraw consent at any time, with the establishment of programmes of cross-over donation. Cross-over donation concerns two prospective donors who are medically incompatible to donate to their respective intended recipients but who donate instead to each other's intended recipient with whom they are medically compatible. Recently, proposals have been launched to extend existing programmes to also encompass possible donor/recipient couples from other, mainly developing countries (i.e., "global kidney exchange"). Apart from issues surrounding possible organ trafficking these programmes may make it much for difficult for reluctant persons to refuse or withdraw consent, without losing face to the original intended recipient.

In several countries a discussion is going on to relax acceptable donor categories so as to also include vulnerable and/or unrelated donors. Where vulnerable donor categories would be allowed to donate, it should be ensured that additional safeguards are provided so that these persons are not exploited. Where living organ donation from unrelated donors is, or would become, allowed, additional screening and approval mechanisms should be established to ensure that consent is free and informed, and that, more in particular, no financial inducements are involved. These additional measures would especially be necessary if donors and/or recipients are coming from abroad, posing a risk of so-called "transplant tourism". Screening and approval mechanisms would need to include clear protocols to verify identification documents and declarations, in the light of increasing incidences of donors and recipients with fake identity documents who pose as relatives to circumvent screening. Moreover, it would be commendable to incorporate additional experts, such a law enforcement officers or human trafficking experts, in the official body entrusted with the final authorisation of living organ donation.

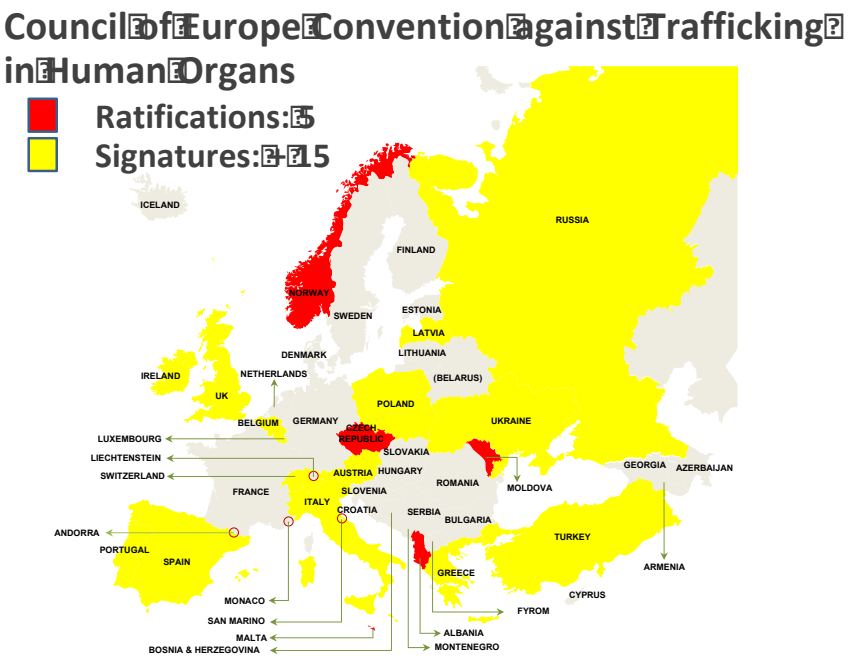
To remove disincentives to living organ donation, international guidelines advocate the reimbursement of reasonable and verifiable expenses that have been incurred by the donor.

Attention should, however, be paid that this reimbursement does not amount to financial gain or comparable advantage.

With regard to organ donation by a deceased donor, recent initiatives to increase the willingness to donate include giving priority on the waiting list to family members of persons who have registered consent to post-mortem donation, and payment of funeral costs. In this regard, caution should be taken that initiatives do not amount to financial gain or comparable advantage.

In addition, research indicates that awareness is frequently lacking about the consent regime in place and about how to register consent or refusal. To that aim, proper awareness-raising campaigns should be launched. Moreover, easily accessible means to register consent or refusal should be provided.

Finally, the most important challenge concerns organ trafficking. To combat organ trafficking, the *Council of Europe Convention against Trafficking in Human Organs* was adopted in 2015, defining organ trafficking as a variety of crimes involving the illicit removal of organs which state parties are required to criminalise under their domestic law. Illicit removal of organs is itself defined as: (a) the removal of organs from a living donor without the free, informed, and specific consent of that person; (b) the removal of organs from a living donor where, in exchange for the removal, the living donor or a third party has been offered or has received a financial gain or comparable advantage; (c) the removal of organs from a deceased donor without the free, informed, and specific consent of the deceased donor, or without the removal being authorised under domestic law; and (d) the removal of organs from a deceased donor where, in exchange for the removal, a third party has been offered or has received a financial gain or comparable advantage.[43] Building on the provisions of the *Oviedo Convention* and its *Additional Protocol concerning Transplantation* that call for the prohibition of organ removal without free, informed, and specific consent and for the prohibition of payment that constitutes a financial gain or comparable advantage, the *Convention against Trafficking in Human Organs* is the first international legally binding criminal law instrument aimed at combatting organ trafficking. It is expected to be widely implemented and, as is shown on the map below, it is currently already ratified by 5 member states of the Council of Europe. Consequently, it will enter into force on 1 March 2018.



[43] Council of Europe. *Council of Europe Convention against Trafficking in Human Organs*, Santiago de Compostela, 25 March 2015, CETS No. 216, available at https://rm.coe.int/16806dca3a.

Transplantation of organs and tissues of human origin the Republic of Belarus: medical and legal aspects of presumed consent

Mr Siarhei P. Liashchuk, Head of the National Transplant Registry of the Republican Scienfic-Practical Centre of Organ and Tissue Transplantation

In the Republic of Belarus, a legal model of implied consent for organs and/or tissue harvesting for transplantation after death is established by law.

The regulations on this matter are as follows:

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation endorsed by the 63rd World Health Assembly on May 21, 2010 (Resolution WHA63.22);

The Oviedo Convention (ETS No.164) and Additional Protocol on Human Organ and Tissue Transplantation (ETS No.164);

Law No. 28-3 of the Republic of Belarus dated March 4, 1997 'On human organ and tissue transplantation' (as amended in RoB Laws No. 207-3 dated January 9, 2007, No. 407-3 dated July 12, 2012, and No. 232-3 dated January 1, 2015), hereinafter referred to as the Law;

Law No. 55-3 of the Republic of Belarus dated November 12, 2001 'On burial and funeral business' (as amended and supplemented by Law No. 407-3 dated July 13, 2012);

Decision No. R-757/2012 of the Constitutional Court of the Republic of Belarus dated July 9, 2012 'On compliance of the Law of the Republic of Belarus 'On amendment of certain laws of the Republic of Belarus on the matters of human organ and tissue transplantation' with the Constitution of the Republic of Belarus';

Decree No. 1216 of the Council of Ministers of the Republic of Belarus dated December 27, 2012 'On the procedure for creating and maintaining the Unified Transplantation Register';

Decree No. 19 of the Ministry of Healthcare and Ministry of Justice of the Republic of Belarus dated March 18, 2013 'On approval of the Instructions for creating and maintaining the Unified Transplantation Register';

Order No. 578 of the Ministry of Healthcare of the Republic of Belarus dated May 6, 2013 'On creating the Unified Transplantation Register'.

Guiding Principle No. 1 of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation reads that cells, tissues and organs may be removed from dead bodies for transplantation only subject to the following:

(a) consent has been obtained as per the form required by law, and

(b) there is no reason to believe that the deceased person objected to the harvesting of organs.

It is specified in the comments to this Guiding Principle that, in particular, "depending on the social, medical and cultural traditions of each country as well as on the way in which families take part in decision-making regarding their health in general, the consent for organ and tissue harvesting from the deceased may be 'explicit' and 'implicit'. In both systems, any reliable evidence of such a person's objection to the post-mortem removal of cells, tissues or organs will impede such removal.

An analysis of global practice shows that at the moment there is no predominant trend on this matter. Obviously, every citizen should first determine their personal attitude towards this issue, while the state, for its part, should ensure a reliable legislative framework for the implementation of the decision made and the protection of the rights of its citizens.

In the system of explicit consent (the first system), which is sometimes called the ‘opting in’ or ‘informed consent’ system, cells, tissues and organs may be harvested from a cadaver provided that the deceased person had explicitly declared his/her consent for such removal while being alive. Depending on the law that is in effect in a specific country, such consent can be expressed verbally or recorded in a donor card, driver’s license or ID, or otherwise in the medical card or donor register. When the deceased leaves behind neither a positive nor a clearly negative decision on organ removal while alive, permission should be sought from a legally authorised person, usually a family member.

This can be exemplified by the case of Lithuania – a Western neighbour of Belarus – where there is a legal model of informed consent for human organ and tissue harvesting for transplantation after death and a system of donor cards. According to Lithuanian law, any legally competent citizen of Lithuania can fill out a form approved by the Ministry of Health at any medical institution and thus provide their consent for organ removal after death (all or some of them). Since 2015, this form has been available online on the website of the National Transplantology Bureau – NTB (https://ntb.lt).

The second system (currently in effect in Belarus) is the system of implied consent, otherwise called ‘opting out’ or the ‘presumed consent’ system, which allows harvesting material from a dead body for transplantation (in some countries – for anatomical study or for scientific purposes) unless the deceased person had expressed objection to organs removal while alive, which should be recorded in an official document as per an established procedure, or unless an informed party advises of the deceased’s objection to donation expressed while alive. Considering the ethical importance of obtaining consent, such a system should ensure people are fully aware of the existing policy and the unrestricted opportunity to object.

The advantages of the presumed consent system are as follows: it is the most convenient system for demonstrating altruism and becoming a donor, it allows for the maximum number of potential donors, and there is no need for donor cards. A disadvantage is that people who are unaware of this norm automatically fall into the ‘opting in’ category.

Despite the legal and regulatory framework available in the Republic of Belarus, it was necessary to implement a mechanism for the practical application of the presumed consent system.

In accordance with Article 10-2 “Unified Transplantation Register” (introduced by Law No. 407-3 of the Republic of Belarus dated 13 July 2012):

For the purpose of exercising control over the use of human organs and/or tissues and the prompt provision of medical aid to persons requiring transplantation, a Unified Transplantation Register is set up. The procedure for creating and maintaining the Unified Transplantation Register shall be determined by the Council of Ministers of the Republic of Belarus.

Thus, the Unified Transplantation Register Section was set up in May 2013 in the National Scientific Practical Centre of Organ and Tissue Transplantation at Minsk City Clinical Hospital No. 9 as a separate structural unit with a staffing table approved by the Ministry of Healthcare. The following structural divisions form part of the Unified Transplantation Register Section: the Office of the National Transplantation Register and the Office of the Central Register of Haematopoietic Stem Cells Donors.

According to the law, there are two ways in the country to express non-consent to human organ and/or tissue harvesting for transplantation after death – the basic and the additional way.

The basic way to express non-consent is a written statement from a citizen of the Republic of Belarus on his/her non-consent to organ and/or tissue harvesting for transplantation after death (registration in the national register).

In accordance with Article 10-1 'The right of citizens to express non-consent to organ harvesting for transplantation after death' (introduced by Law No. 407-3 of the Republic of Belarus of July 13, 2012), legally competent citizens have the right to provide their local state healthcare organisation (at their place of residence) or other state healthcare organisation where they receive medical treatment with a written statement of non-consent to organ harvesting for transplantation after death. As for minors, except those who have already become fully legally competent, and persons recognised as incompetent, such a statement may be provided by their legal representatives. As for persons who are unable to make informed decision for health reasons, such a statement may be produced by a spouse or close relative. The head of a state healthcare organisation, head of a structural division of a state healthcare organisation or those acting in their place should provide the respective information to the Ministry of Healthcare of the Republic of Belarus for its entry into the Unified Transplantation Register within six hours from the moment the state healthcare organisation receives a written statement about non-consent to organ harvesting for transplantation after death.

As of 5 December 2017, the Unified Transplantation Register contained 2,354 records on persons who had declared, as per the established procedure, their non-consent to organ and/or tissue harvesting for transplantation after death.

An additional method for declaring non-consent to organ and/or tissue removal from a deceased donor is a statement filed by relatives. In accordance with Article 11 "Conditions for organ removal from a deceased donor" (as revised by Law No. 407-3 of the Republic of Belarus dated 13 July 2012), no organs may be harvested from a deceased donor if the person, while alive, or the persons specified in Part 1 of Article 10-1 hereof, prior to his/her death, stated his/her non-consent to organ harvesting for transplantation after death in the manner prescribed by this Law. The removal of organs from a deceased donor is also prohibited if the heads of a state healthcare organisation, a division of the State Committee of Forensic Inquiry of the Republic of Belarus, or those acting in their place, prior to the removal of the organs, had received a statement of non-consent to organ harvesting for transplantation produced by a spouse or, in the absence of the latter, a close relative or legal representative of the deceased. Harvesting the organs of a deceased donor is also prohibited if a state healthcare organisation or a division of the State Committee of Forensic Inquiry of the Republic of Belarus had been informed of the person's non-consent to organ removal for transplantation prior to his/her death via a verbal or written statement in the presence of a medical specialist(s), other officials of the state healthcare organisation, a division of the State Committee of Forensic Inquiry of the Republic of Belarus or other persons who can testify to such denial.

Decision No. R-757/2012 of the Constitutional Court of the Republic of Belarus dated 9 July 2012 "On the compliance of the Law of the Republic of Belarus 'On amendments to certain laws of the Republic of Belarus on matters concerning human organ and tissue transplantation' with the Constitution of the Republic of Belarus" reads as follows: the Constitutional Court points out that the legislative establishment of a person's presumed consent to the removal of his/her organs and tissue for transplantation after death in the norms of the Law on Human Organ and Tissue Transplantation and Article 3 "Expression of will concerning the honourable treatment of a body after death" of the Law on Burial and Funeral Business is indicative of the right of state healthcare organisations to dispose of the organs of a deceased person with no consideration for his/her legal representatives unless the person had expressed a negative attitude towards organ harvesting in line with the established procedure. With such legal regulations that have positive implications on the development of transplantology in Belarus and pursuing humanitarian objectives of preserving a recipient's life and the rehabilitation of his/her health, it is important to balance the protected constitutional values, while guaranteeing the proper exercising of the rights of citizens, their relatives or legal representatives to express non-consent to organ harvesting for transplantation after death.

Conclusion

The legal model currently in effect in the Republic of Belarus in the form of presumed consent to organ removal for transplantation after death is (1) strictly regulated by Belarusian legislation on transplantology, (2) transparent and offers freedom for the expression of citizens' will, and (3) efficiently works to benefit the development of national transplantology (3).