



**Opinion of the Bioethics Unit,
Directorate General of Human Rights and Rule of Law
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ON

Compliance of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” with the standards laid down in the Convention on Human Rights and Biomedicine and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin

1. General Human Rights Principles

General principles of Transplant Law are in conformity with general human rights principles of Convention and Additional Protocol:

- (1) equitable access to transplantation services for patients;
- (2) respect for autonomy;
- (3) protection of persons unable to consent;
- (4) minimisation of risks and maximisation of benefits;
- (5) dignified treatment of the deceased;
- (6) confidentiality of personal data;
- (7) prohibition of financial gain.

2. Incompatibilities with Convention/Protocol

No clear incompatibilities

Nevertheless advisable to revise several provisions of Transplant Law so as to ensure compliance with Convention and Protocol

2. Incompatibilities with Convention/Protocol

1. **Living donation of bone marrow and haematopoietic stem cells by minors**
 - **Transplant Law:** Article 8: contains 2 conditions
 - removal of bone marrow and haematopoietic stem cells from a minor
 - 1) may only be carried out upon the notarised written consent of the lawful guardians or custody and guardianship authority
 - 2) shall not be permitted in case of explicit written or oral objection of the minor
 - **Convention/Protocol:** contain 3 additional conditions
 - 1) there is no compatible donor available who has the capacity to consent;
 - 2) the recipient is a brother or sister of the donor;
 - 3) the donation has the potential to be life-saving for the recipient
 - **Recommendation:** amend Article 8 to include 3 additional conditions

2. Incompatibilities with Convention/Protocol

2. Acceptability of living donation

- **Transplant Law:** Article 8: contains 2 conditions
 - organ or tissue removal from a living person
 - 1) may only exceptionally be carried out
 - 2) is subject to prior medical examination and approval by an expert committee
- **Convention/Protocol:** contain 3 additional conditions
 - 1) there is a clear therapeutic benefit for the recipient;
 - 2) there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness;
 - 3) there is no serious risk to the life or health of the donor
- **Recommendation:** amend Article 8 to include 3 additional conditions

2. Incompatibilities with Convention/Protocol

3. Free and informed consent for living donation [1]

- **Transplant Law:** Articles 8 and 9: contains 3 conditions
 - 1) living organ donor should be informed about the potential deterioration of his or her health due to the organ removal;
 - 2) living organ donor has a right to obtain full and objective information on his or her state of health and on the consequences that may occur due to organ removal;
 - 3) coercion of an individual to give his or her consent is prohibited
- **Convention/Protocol:** contain 4 additional conditions
 - 1) living organ donor should beforehand also be given appropriate information about the purpose and nature of the removal;
 - 2) living organ donor should be informed of the right to access to independent advice about the risks involved;
 - 3) living organ donor may freely withdraw consent at any time and without formal requirements;
 - 4) living organ donor is not under any undue pressure to consent

2. Incompatibilities with Convention/Protocol

3. Free and informed consent for living donation [1]
 - **Recommendation:** amend Articles 8 and 9 to include 4 additional conditions

2. Incompatibilities with Convention/Protocol

3. Free and informed consent for living donation [2]

- **Transplant Law:**
 - contains no provisions on use of surgical residues (e.g. amniotic membrane, femoral heads and heart valves) for transplant purposes
- **Convention/Protocol:**
 - surgical residues may only be used for transplant purposes if before their removal the patient had been informed about the storage and the intended use of these body parts
- **Recommendation: amend Transplant Law to make this explicit**

2. Incompatibilities with Convention/Protocol

4. Procedure of certification of death

- **Transplant Law:** Article 11 + Resolution No. 228
 - organ removal from a deceased person is only permitted after the pronouncement of death
 - certification of death is issued by a multidisciplinary council of physicians
 - 1) who should not be involved in the removal of organs or tissue from the deceased person
 - 2) who should not be involved in the transplantation of these organs or tissues
- **Convention/Protocol:** contains additional condition
 - physicians who certify death should not have any responsibilities for the care of potential organ or tissue recipients
- **Recommendation:** amend Article 11 and/or Resolution No. 228 to include this additional condition

2. Incompatibilities with Convention/Protocol

5. Informed consent of the recipient

- **Transplant Law:** Article 12
 - 1) transplantation shall be carried out upon the written consent of the prospective recipient;
 - 2) the prospective recipient should before have been informed in writing about the potential deterioration of his or her health that may result from the forthcoming medical intervention
- **Convention/Protocol:** contains 3 additional conditions
 - prospective recipient should also have been given appropriate information
 - 1) about the purpose and nature of the implantation;
 - 2) the consequences and risks of the implantation (which will include information on the potential deterioration of health);
 - 3) the alternatives to the intervention
- **Recommendation:** amend Article 12 to include 3 additional conditions

2. Incompatibilities with Convention/Protocol

6. Living donation of tissues

- **Transplant Law:** Articles 8 and 10
 - impression may arise that almost all provisions on living donation are restricted to living organ donors (cf. Articles 8 and 10 apply to “organ retrieval”)
 - misunderstanding results from the definition of “organ retrieval” in Article 1: “Organ retrieval shall mean a medical intervention to recover organs and (or) tissues from a living or deceased donor.”
- **Recommendation:**
 - replace in Article 1 “Organ retrieval” by “Organ and (or) tissue retrieval”
 - replace in Articles 8 and 10 reference to “Organ retrieval” by “Organ and (or) tissue retrieval”

2. Incompatibilities with Convention/Protocol

7. Prohibition of financial gain [1]

- **Transplant Law:** Article 5
 - organs and tissues “shall not be objects of civil transactions except for unrequited ones”
 - prohibition of “compensated transacting and advertising of an offer and/or a demand for human organs and/or tissues”
- **Convention/Protocol:**
 - more emphasis on unpaid and voluntary donation as a fundamental underlying principle
 - includes prohibition of compensation in other kind than money
- **Recommendation: amend Article 5 to make more explicit**
 - **the principle that donation of organs and tissues is voluntary**
 - **the prohibition of transactions for financial gain and comparable advantage**

2. Incompatibilities with Convention/Protocol

7. Prohibition of financial gain [2]

- **Transplant Law:** Article 9: compensation of costs of living donor
 - right to reimbursement of costs incurred by the necessity to restore his or her health due to organ retrieval
 - temporary incapacity ; disability of living donor
- **Convention/Protocol:** additional aspects eligible for compensation
 - 1) compensation of costs incurred by (potential) donors before donation;
 - 2) compensation of all of the costs incurred by donors post-donation;
 - 3) loss of income by (potential) donors linked to the donation
 - 4) compensation in the event of complications resulting from the donation
- **Recommendation:** amend Article 9, to the extent that these 4 aspects currently are not covered

2. Incompatibilities with Convention/Protocol

7. Prohibition of financial gain [3]

- **Transplant Law:**
 - Transplant Law contains no sanctions in the event of infringement of the provision prohibiting financial gain
- **Convention/Protocol:**
 - appropriate sanctions should be applied in the event of infringement of the provision prohibiting financial gain
- **Recommendation:** attach appropriate sanctions to the infringements of the prohibitions of financial gain and advertisement, to the extent that other legislation (e.g. Articles 164 and 348 Criminal Code) does not already do so *

* Where appropriate, inspiration could be found in the Council of Europe Convention against Trafficking in Human Organs.

3. Gaps as compared to Convention/Protocol

1. Removal and transplantation of cells

- **Transplant Law:** Article 2
 - field of application of Law does not include human cells intended for transplantation, with the exception of haematopoietic stem cells
- **Convention/Protocol:**
 - provisions (of Protocol) that are applicable to tissues also apply to cells
- **Recommendation:** consider including cells in the scope of the Transplant Law, or adopting another legal instrument that specifies, where relevant, similar conditions for the removal and transplantation of cells than the ones that apply to organs and tissues

3. Gaps as compared to Convention/Protocol

2. Medical follow-up of the living donor and the recipient

- **Transplant Law:**
 - does not contain any provisions on the medical follow-up of the living donor and the recipient, with a view to monitoring and guaranteeing their long-term health
- **Convention/Protocol:**
 - requires that appropriate medical follow-up shall be offered to living donors and recipients after transplantation
- **Recommendation:** include in the Transplant Law a provision stipulating that appropriate medical follow-up shall be offered to living donors and recipients after transplantation

3. Gaps as compared to Convention/Protocol

3. Traceability of organs and tissues

- **Transplant Law:**
 - does not contain any provisions on the traceability of organs and tissues
- **Convention/Protocol:**
 - indicates that it is necessary to “ensure the collection and recording of the information required to ensure traceability of organs and tissues”
- **Recommendation: explicitly address in the Transplant Law the importance of the traceability of all organs and tissues removed, allocated, and transplanted in the Republic of Belarus**

3. Gaps as compared to Convention/Protocol

4. Confidentiality and anonymity

- **Transplant Law:**
 - does not pay specific attention to the issues of confidentiality and anonymity
- **Convention/Protocol:**
 - requires that all personal data relating to the donor and the recipient have to be considered to be confidential and that these may only be collected, processed and communicated according to the rules of professional confidentiality and data protection
- **Recommendation:**
 - **directly address in the Transplant Law the principle of confidentiality**
 - **include a provision so as to guarantee the anonymity of donors and recipients who are not related**

4. Suggestions for implementation

1. To the extent that this would not yet be the case, it is advisable to **establish a dedicated authority** (National Transplant Organisation) entrusted with the coordination and supervision of all aspects of the Belarusian transplant system.
2. It is advisable to **establish an integrated system of vigilance**, which could consist of: (1) a centralised system for traceability of organs and tissues; (2) a national living organ donor registry; and (3) a central reporting and management system for serious adverse events and reactions.
3. It is advisable to explicitly address the organisation and maintenance of **transplant waiting lists** (e.g. through special registries) and the **rules of allocation** either directly in the Transplant Law or in supplementing decrees.
4. To the extent that this would not yet be the case, it is advisable to adopt regulations on international cooperation, including provisions ensuring that **imported organs comply with the same quality and safety standards** that apply to organs removed and transplanted in the Republic of Belarus.
5. To the extent that this would not yet be the case, it is advisable to implement an **easily accessible system of binding declarations of willingness** regarding post-mortem organ removal for transplantation.

4. Suggestions for implementation

5. It is advisable to amend Article 11 of the Transplant Law to the effect that a **possible declaration of objection** on the part of the spouse, the close relatives or lawful guardians should be **primarily based on the deceased person's expressed or presumed wishes**.
6. It is advisable to explicitly address the importance of **informing** health professionals and the public **about the need for organs and tissues, as well as about the conditions relating to removal and transplantation**, including the regime of consent or authorisation for donation after death.
7. It is advisable to amend Article 8 so as to ensure that **also organ removal from a living donor who is a close relative of the recipient is made dependent upon a decision on the feasibility of organ removal**, which would also necessitate for this type of living donation ascertaining that there is no financial gain.
8. To the extent that **comprehensive information and awareness-raising campaigns** are not yet being conducted, it is advisable to initiate them.