# Regulation of organ donation and transplantation in ESTONIA

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# Legislation

- Source document for legal issues:

**Procurement, Handling and Transplantation of Cells, Tissues and Organs Act**

passed in 29.01.2015, entered into force 01.03.2015

https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/502042015002/consolide

- Regulations of the Minister on the basis of it:
  - Selection criteria for donors;
  - Rules for procurement and handling;
  - Conditions and procedure for detection of brain death;
  - Accountability and statistics etc.

# Organisation

1. Transplantation council;
2. National transplantation agency;
3. Transplantation centre;
4. The procurers and handlers of cells, tissues and organs;
5. Estonian Health Insurance Fund;
6. State Agency of Medicines;
7. Health Board;
8. Ministry of Social Affairs.

# Transplantation council

… an independent advisory committee formed by the minister

- 15 members:

representatives of all levels of donor /transplant organisation + representatives of the organisations of patients and the relevant professional organisations.

- to submit proposals to the relevant organisations:

1) to determine and update the national need for the procurement, handling and transplantation of cells, tissues and organs;

2) to establish the strategic goals for the procurement, handling and transplantation of cells, tissues and organs;

3) to finance the procurement, handling and transplantation of cells, tissues and organs;

4) to promote the awareness on the donation of cells, tissues and organs.

# National transplantation agency

1) follow-up of the medical status of living organ donors;
2) traceability and biovigilance of organs 24/7;
3) organ transplant waiting lists 24/7;
4) distribution and international exchange of organs 24/7;
5) public education programs;
6) audits over the donation of cells, tissues and organs to establish the reasons for non-donation;
7) development of national quality and safety guidelines;
8) data interchange with the procurers, handlers, transplanters and the national agencies;
9) education and research related to the procurement, handling and transplantation of organs.

Responsible authorities: Ministry of Social Affairs / TUH

# Activity licence obligation

- Procurement and handling of human cells, tissues and organs:
  - State Agency of Medicines;
- Organ transplantation:
  - Health Care Board;
- Lab accreditation:
  - Estonian Accreditation Centre;
  - European Federation for Immunogenetics (EFI).

# Living organ donor

- Informed consent in writing;
- Medical examinations and tests ascertain fitness to donate and that the risk to the donor's own health is minimal;
- Only for transplantation into a person with whom the donor has a genetic or emotional connection;
- Psychological counselling;
- Life-long follow –up + health insurance (where appropriate).

# Deceased donor

- Conditions:
  - The death of the person has been established by a special procedure;
  - During lifetime, the deceased donor had express a wish to donate organs after his/her death or there is no information available that the person was against it;

    Pathway: national health information system → close relatives → emotionally close person or legal representative;

    NB! Other persons may not prohibit the removal of organs if the deceased person has consented in lifetime; and they may not allow it if the deceased person has refused in lifetime!
  - The removal of organs must not impede the conduct of forensic medical expertise.

# Brain death establishment

- 2 physicians: anaesthesiologist + neurologist / neurosurgeon;
- Prerequisites: the probable reason for the brain death is known and documented; hypothermia (>35’C) + effect of sedative, narcotic and/or muscle relaxation inducing substances + severe metabolic and endocrinal disorders + arterial hypotension are ruled out;
- 2 clinical assessments + apnoea test;
- The length of monitoring before the 1st assessment and between 2 assessments shall be decided by the same physicians;
- 1 additional examination of the following: EEG, TKD, angiography, SPET.

# Screening for infectious diseases

| Mandatory minimum by national legislation | TUH criteria for organ donors |
|---|---|
| HIV-1,2 Ab | HIV-1,2 Ag+Ab; HIV1,2 RNA |
| HBs Ag, HBc Ab | HBs Ag+Ab; HBc Ab;<br>HBc IgM; HBV DNA |
| HCV Ab | HCV Ab; HCV RNA |
| T pallidum Ab | T pallidum Ab |
| HTLV-1,2 Ab (where appropriate) | HTLV-1,2 Ab (where appropriate) |
| | CMV IgM + IgG |
| | EBV IgM + IgG |

# Organ transplant waiting list

- Multi-disciplinary expert committee:

  at least 5 physicians, incl. referring physician, competent transplant surgeon, internal medicine physician according to organ;

- All decisions (both registrations and removals) must be in writing with original signatures of all participants, as well as the patient’s (or his/her legal representative's) signature.
- Citizens of another EU MS or a third country may also be registered, if they:
  - guarantee the financing of the organ transplant ( prepayment or guarantee letter) and
  - confirm in writing that they have not registered on the waiting list of another state.

# Organ allocation

- The matching (medical) criteria must be developed by the competent surgeons and approved by national transplantation agency.
- In case of recipients with similar compatibility, the organ shall be transplanted:
  - 1st preference to an Estonian citizen;
  - 2nd preference to a citizen of another EU MS or a country of the EEA;
  - 3rd preference to a citizen of  a third country or to a person without citizenship.
- If there is no match with any of the patients on the waiting list, the organ can be offered to foreign countries in accordance with cooperation agreements.

# International collaboration

- Formal international contracts:
  - Ministries of Health of Latvia and Lithuania - exchange of surplus organs (since 1975 → revised 2013);
  - Scandiatransplant - exchange of surplus organs (2013);
  - Eurotransplant – exchange of surplus organs (2008);
  - Vienna University Hospital - collaboration in the field of lung transplantations (2009 - 2013) in the field of heart-lung transplantations (2015);
  - Helsinki University Central Hospital – collaboration in the field of heart transplantations (2013).

# Export to SCTP by centres 2013+

| State | Centre | Kidney | Liver | Lung | Heart | Pancreas |
|---|---|---|---|---|---|---|
| FI | Helsinki | | | 2 | 7 | |
| SE | Stockholm | 3 | 8 | | | 2 |
| | Uppsala | 1 | | | | 2 |
| | Gothenburg | 3 | 3 → 1 ET | 4 | 3 | 1 |
| | Skåne | | | | 7 | |
| DK | Copenhagen | 3 | 2 | 2 | 2 | |
| | Århus | | | | 1 | |
| NO | Oslo | | 10 → 1 Stock | 2 | 2+1* | 6 |
| | **77** | 10 | 23 → 1 ET | 10 | 22+1* | 11 |

# Traceability

- Unified coding system for all **donors** and harvested **tissues and organs**:

  EST 01 16 → EST KI L 1 01 TUH 010116

  → April 2017 – the Single European Code for tissues

- Common database with restricted access on a secure server of TUH, where it is possible to identify all the chain:

  donor ID ↔ donor code ↔ organ code ↔ recipient ID

- To ensure traceability, the necessary data must be preserved for at least **30 years**.

# Biovigilance

- Reporting of serious adverse events and reactions:
  - Initial report for suspected event without undue delay;
  - Final report within a reasonable time, not later than 3 months after;
  - Reports must be sent to the National transplantation agency (TUH) and State Agency of Medicines (SAM);
  - TUH organises an appropriate communication between all concerned procurement and transplant centres;
  - SAM notifies the competent authorities of concerned countries.

# State supervision

- Procurement and handling of human cells, tissues and organs, incl. quality and safety requirements:
  - **State Agency of Medicines;**
- Organ transplantation:
  - **Health Care Board;**
- State supervision shall be exercised at least once in every two years.

# Whom rain, whom the sun ....


*Photo : Priit Tammjärv 14.05.2015*