BIOBANK CONCEPT in POLAND

Jarosław Czerwiński MD, PhD

Polish Transplant Coordinating Center Poltransplant

Department of Surgical and Transplant Nursing Medical University of Warsaw

Idea of BIOBANK

Long term storage of:

- **serum and tissue samples of deceased organ donors and of**
- **organ recipients' sera at a low temperature**

to their possible re-examination or complementary testing mainly in cases of adverse events in transplant recipients

Background

- Adverse events associated with organ procurement and transplantation from deceased donors require compliance with quality and safety standards
- Shortage of grafts makes it necessary to retrieve organs from donors with extended risk. This increases the risk of transmission with the graft from donor to recipient diseases difficult or impossible to identify before transplantation.
- Multi-annual access to biological material of deceased donors and the recipient and use them to test after transplantation improves the quality and safety of transplantation medicine, to which special emphasis is placed in Polish and European legislative acts

Essentials and strategic targets

Biobank is essential (imperative) tool in modern transplantation medicine to implement and evaluate quality and safety standards

Strategic targets

- Gathering and long-term storage of sera, lymph nodes and other tissues (eg, a fragment of the liver, where it will not be used for transplantation) from deceased organ donors in terms of their biological properties behave

- Collecting and long term storing of sera of organ recipients

- **Coding system of biological material of donors and recipients in a manner enabling identification of the organ donor and recipient (unique coding system compatible with transplant registries)**

- Electronic and classic records of accumulated material

Application of BIOBANK. Methodology - Examples

- **1. Extending or verification of previously performed virological tests in deceased donors and organ recipients as a control for the phenomenon of transmission of infection from donor to recipient (eg determination of anti-HBs, anti-HBcore)**
- **2. Genetic testing of biological material of the donor and recipient (these tests are not usually performed prior to transplantation), as the verification and control of serological tests (eg determination of HIV DNA/RNA in donors at risk of infection – NAT)**
- **3. Carrying out research in appropriate cases; finding a rare disease in the donor and recipient, whose detection before transplantation is difficult to perform because of time constraints associated storage organs or the lack of available methods at the present state of knowledge (eg Kreutzfeld-Jacob's disease)**
- **4. Biochemical or genetic evaluation and control of possible cancer transfer from donor to recipient (eg, testing for lymphoproliferative diseases)**
- **5. Re-examination of tissue typing to seek the causes of complications and adverse events in recipients (eg verification of HLA or cross match**

Biological material collected from deceased donors

- **Serum, lymph nodes, part of the liver which have potentially be used (often after many years) require proper collection, transportation, processing, storage at low temperature and labeling.**

- **This material will be taken immediately before and / or during the donation surgery.**

Biological material collected from transplant recipients. Recipient's safety

20 ml of blood is taken from a peripheral vein and after centrifugation (serum) will be sent to the Biobank

- **The risk for transplant recipients, whose blood will be processed accumulated in the BIOBANK will be associated only with a typical peripheral vein puncture (possibility of a hematoma in the place of the needle / cannula), it should be noted that the acquisition of blood will not be associated with additional puncture a vein and will be done with routine blood collection, which takes place at the transplant center to the final qualification of recipient.**

Recipient's informed consent

- Informed consent to the collection, processing, storage in a Biobank, and the possible use of this material for diagnostic purposes or research.
- For people whose health does not allow to become familiar with the information about the project and to give informed consent (eg, patients with hepatic encephalopathy), the patient's family member will express the consent and after restoring the patient's consciousness, as he himself . If in such situation, the recipient does not consent to participate in the study, samples of biological material will be disposed.
- Positive opinion of Bioethic Commitee of Medical University of Warsaw (is obtained)

BIOBANK tools and data-base

1. Low temperature freezer (ultralow freezer - freezing temperatures to minus 85 degrees) with display, an alarm system, device for providing emergency freezing.

2. Device for marking (labeling) containers with biological material, allowing its identification (unique labeling related to coding system implemented in national coding system for organs, tissues and cells.

3. The database kept in the electronic system and archive of paper documentation for the identification and characterization of organ donors and organ recipients.

4. Standard operating procedures for process and staff.

Relevance of BIOBANK

Implementation of the principles and standards of safety and quality of organ procurement and transplantation through monitoring and recording of adverse events in transplant recipients in accordance with:

- **Regulation Min of Health of 16 July 2007. on detailed conditions for the collection, storage and transplantation of cells, tissues and organs (Dz.U.07.138.973 dated. August 1, 2007, § 14).**

- **Directive 2010/53/UE of the European Parliament and the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation**

- **Communication from the Commission - Action Plan for the Organ Donation and Transplantation (2009-20015): strengthening cooperation between Member States."**