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## ORGAN DONATION IN THE REPUBLIC OF BELARUS: 10 YEARS OF EXPERIENCE, ETHICAL PROBLEMS AND THE PROSPECTS FOR DEVELOPMENT

The first liver transplantation in the Republic of Belarus was performed on April 3, 2008 at the 9<sup>th</sup> Clinical Hospital healthcare institution in the City of Minsk under the supervision of O. O. Rummo. The procedure necessitated the further development of organ transplantation practices, which was an entirely new field for the country at the time. For this purpose, the Ministry of Health of the Republic of Belarus intensified its efforts in 2008–2013 in the area of organ donation, implementing a transplantation technology programme, which included:

- drafting and improving a legislative and regulatory framework for organ donation and transplantation coordination;
  - training highly skilled professionals;
- establishing national transplantation and transplantation coordination services;
- establishing the Organ and Tissue Transplantation NCAR attached to the 9th Clinical Hospital healthcare institution in the City of Minsk;
- reviewing matters related to transplantological care at board meetings and treatment and control council sessions of the Ministry of Health of the Republic of Belarus once or twice a year; and
- introducing a transplantology training course and chair at Belarusian Medical Academy of Postgraduate Education (BelMAPO) public education institution.

Large-scale efforts were thus initiated in this area. Pursuant to the Law of the Republic of Belarus "On Human Organ and Tissue Transplantation" dated 04.03.1997 (as amended by Law No. 207-Z of the Republic of Belarus dated 09.01.2007, Law No. 407-Z of the Republic of Belarus dated 13.07.2012 and of Law of the Republic of Belarus No. 232-Z dated01.01.2015), the Ministry of Health has drafted and approved the following regulations in the area of human organ and tissue transplantation:

- Resolution No. 228 of the Ministry of Health of the Republic of Belarus "On Approving the Instruction on the Procedure for the Declaration of Death and Repealing Resolution No. 47 of the Ministry of Health of the Republic of Belarus dated 02.07.2002" dated 20.12.2008 (as amended by the Resolution No. 210 of the Ministry of Health of the Republic of Belarus dated 28.12.2012);
- Resolution No. 2 of the Ministry of Health of the Republic of Belarus "On Approving the Instruction on the Procedure for the Removal of Organs and (or) Tissues from Deceased Donors Upon Declaration of Their Death"

dated 04.01.2010 (as amended by Resolution No. 209 of the Ministry of Health of the Republic of Belarus dated 28.12.2012 and Resolution No. 37 of the Ministry of Health of the Republic of Belarus dated 10.04.2015);

- Order No. 6 of the Ministry of Health of the Republic of Belarus "On Approving Certain Clinical Protocols on Human Organ and Tissue Transplantation" dated 05.01.2010, which approved clinical protocols on the transplantation of: hearts; kidneys; hematopoietic stem cells for adult patients; corneas and amniotic membrane sclera; autologous and allogeneic skin; and livers.
- Decree No. 619 of the President of the Republic of Belarus "On Improving the Material Incentives of Certain Categories of Medical Workers" dated 26.12.2005 (as amended by Decree No. 328 of the President of the Republic of Belarus dated 13.06.2008; Decree No. 467 the President of the Republic of Belarus dated 24.09.2009; Decree No. 29 the President of the Republic of Belarus dated 16.01.2012; Decree No. 8 the President of the Republic of Belarus dated 08.01.2013; Decree No. 94 the President of the Republic of Belarus dated 28.02.2013; and Decree No. 552 the President of the Republic of Belarus dated 01.12.2014). This regulation expanded the list of hi-tech medical interventions by adding the conditioning of deceased donors before removal of human organs and (or) tissues for transplantation and the removal of human organs (in whole or in part) and (or) tissues for transplantation, resulting in wage increases for specialist doctors performing these hi-tech medical procedures: by 250% for doctors of the highest qualification category and by 200% for doctors of the first qualification category.
- Resolution No. 134 of the Ministry of Health of the Republic of Belarus "On Certain Matters of Human Organ and Tissue Transplantation" dated 29.08.2012 (as amended by Resolution No. 124 of the Ministry of Health of the Republic of Belarus dated 16.12.2015 and Resolution No. 111 of the Ministry of Health of the Republic of Belarus dated 18.10.2016).

Posthumous organ donation has been legislated, paving the way for the establishment of a transplantation coordination service. The administrative and organizational steps taken by the Ministry of Health of the Republic of Belarus in the form of resolutions adopted by its treatment and control council sessions played a decisive role in this, since Order No. 311 of the Ministry of Health of the Republic of Belarus "On Certain Matters of Organization of Organ Removal for Transplantation" dated 07.06.2005 had not been performed in full. Decision No. 3 dated 30.03.2011 provided for the establishment of coordination divisions in all regions of the country (4.5 doctor positions + 4.5 medical registrar positions), including staffing and providing the necessary facilities, medical equipment and disposable materials. For reference: contract positions for doctors in charge of organ

removal and coordinating transplant procedures have been introduced in all regions. A coordination division operated in Minsk at the 4th Clinical Hospital healthcare institution between 2008 and 2010, and at the 9<sup>th</sup> Clinical Hospital healthcare institution since. Decision No. 5/2 dated 12.06.2012 provided for the opening (establishment) of staffed and equipped coordination divisions in the Vitebsk, Minsk and Mogilev regions, with coordination divisions already operating by that time in the Brest (15.04.2011) and Grodno (15.04.2012) regions, in addition to a coordination office in Gomel Region (07.06.2012). In accordance with that Decision, departments for the coordination of activities for the collection of donor organs for transplantation were opened in the Mogilev (02.07.2012) and Minsk (01.10.2012) regions, and a coordination office was opened in the Vitebsk Region (01.10.2012). The ratio of transplantation coordinator doctors per million people was 0.31 in 2008. By 2012, the figure had reached 3.3 per million and has remained at that level, which is sufficient for full-fledged operation of the service assuming its complete staffing.

By 2013, the development of organ transplantology and organ donation had created a basis for the establishment of a Uniform Transplantation Registry: a new version of Law No. 407-Z of the Republic of Belarus "On Human Organ and Tissue Transplantation" dated 13.07.2012 went into effect. The number of effective donors (removals) and, accordingly, of organ transplantations increased. The need to recording and supervise organ and tissue transplantations performed in Belarus arose. All regions received transplantation coordination divisions/offices. Three regions (Brest, Gomel and Grodno) received transplantation divisions that perform kidney and liver transplantations. In January 2013, a transplantology chair was opened at BelMAPO public education institution under the auspices of the 9<sup>th</sup> Clinical Hospital. Best international practices were studied ("Poltransplant," KST, NTB).

Article 10-2 "Uniform Transplantation Registry" (introduced by Law No. 407-Z of the Republic of Belarus "On Human Organ and Tissue Transplantation" dated 13.07.2012) provided for the creation of a Uniform Transplantation Registry in order to exercise supervision over the utilization of human organs and (or) tissues and to promptly offer medical care to people in need of transplants. The procedures for the establishment and operation of the registry were determined by the Council of Ministers of the Republic of Belarus. The Uniform Transplantation Registry launched operations in May 2013 as a stand-alone structural unit of the Organ and Tissue Transplantation NCAR. By that time, the number of effective cadaver donors had increased from 37 in 2008 to 170 in 2013 (an increase of 4.6 times) and 224 in 2017 (an increase of 6.05 times). At present (2017), the

Republic of Belarus has 23.6 effective donors per million of population, which is 13<sup>th</sup> in the world.

It is worth noting that cerebral circulation disorder was the leading diagnosis for cadaver donors during these years (79.7%), followed by traumatic brain injury (18.0%), which was the leading cause in early years of organ donation, and a small number of cases of post-resuscitation disease (2.3%). The average donor in the Republic of Belarus in 2017 was male (67%), aged 51–60 (44.2%), suffering from acute cerebral circulation disorder (77.2%), and subjected to multi-organ and (or) human tissue removal (73.6%).

The bioethical questions of doctor-patient and doctor-next of kin communication have always been and remain crucial for the transplantology and transplantation coordination services. Conversations of medical workers with the next of kin of potential donors (resulting in 53% of organ removal refusals over the period of 2015–2017) remain one of the factors under our control, offering a path for improving organ donation – something that we should keep working on in the future.

Substantial work has been accomplished in recent years in terms of expanding international cooperation with foreign organizations and national transplantation registries. Interaction has intensified with the European Committee on Organ Transplantation (CD-P-TO) and the Council of Europe Committee on Bioethics (DH-BIO).

## **CONCLUSIONS:**

- 1. It must be acknowledged that the Republic of Belarus has established a sustainable and well-structured transplantation coordination service staffed with highly skilled personnel.
- 2. Belarusian legislation offers a full legal framework for posthumous organ donation, a key pre-requisite for performing organ transplantations.
- 3. The transplantation coordination service in the Republic of Belarus carries out its mission to develop organ donation and ensure the provision of hi-tech transplantology care to the citizens of the Republic of Belarus.

## Development Outlook for Organ Donation in the Republic of Belarus:

- 1. Continued improvement and unification of the legal framework in the Republic of Belarus for organ donation and organ and tissue transplantation, including as part of the Eurasian Economic Space and the European Union (international exchanges of organs for transplantation, live organ donation).
- 2. Continued improvement of information technology: improvement of the operation of the Uniform Transplantation Registry software, building its

interfaces with transplantation patient waiting lists (for kidneys and livers), development of an organ donation computer program, and setting up an organ donor database.

- 3. Taking steps to improve the selection criteria and the quality of conditioning potential donors and increasing the incidence of multi-organ removals of human organs and (or) tissues at medical institutions.
- 4. Organizational and methodological preparatory work for performing a domestic and international audit of healthcare organizations participating in the organ donation programme and performing transplantations of human organs and (or) tissues.
- 5. Continued cooperation and interaction with international organizations in the areas of organ donation and transplantation of human organs and tissues, and participation in international projects.