



SUPPORT TO UKRAINE FOR DEVELOPING A MODERN PUBLIC HEALTH SYSTEM

A project funded by the European Union and implemented by a consortium consisting of GFA Consulting Group GmbH, Hamburg, and the Finnish Institute for Health and Welfare, Helsinki.

The project continues its activities to assist Ukraine with a focus on advancing its progress towards EU accession under Component 1 and supporting the establishment of a modern Blood Safety System under Component 2.

Project Newsletter
September 2023

The EU continues to support Ukrainian public health and blood safety system for additional two years

Starting July 2023, the Delegation of European Union in Ukraine granted the project "Support to Ukraine for Developing a Modern Public Health System" extension until May 2025. Accordingly, the project continues its activities to assist Ukraine with a focus on:

- Advancing its progress towards EU accession in the public health area;
- Supporting the establishment of a modern Blood Safety System that is aligned with the EU requirements and can operate under war conditions.

Hence, providing technical assistance to the Ministry of Health of Ukraine (MoH) in areas of public health and blood safety will be ongoing along with the potential further cooperation with Government Office for Coordination of European and Euro-Atlantic Integration.

Supporting the development of strategies, laws, bylaws, resolutions of the Cabinet of Ministers, and MoH orders required to ensure alignment with the EU requirements and implementing relevant EU legislations will remain the project's top priority along with the organisation of relevant study visits and international public health events for Ukrainian public health and blood safety professionals.

Along with strengthening the cooperation between Ukraine and European Centre for Disease Prevention and Control (ECDC), Directorate General for Health and Food Safety (DG Sante) and other relevant EU public health entities, the project will continue building a strong partnership with Ukrainian transplant coordination center (UTCC) in the area of blood transfusion

and blood system capacity building processes by:

- Supporting the advancement, implementation and adaptation of the voluntary non-remunerated blood donation (VNRBD) campaign and increasing its reach-out throughout Ukraine;
- Developing and integrating the Blood Safety information space;
- Supporting the operationalisation of the three pillars of the blood system such as National Blood Transfusion Council, Competent authority and blood committee, including human capacities building, development of operational guidelines and references, policies and plans;
- Supporting the development of a national hemovigilance system;
- Providing technical support to establish blood reference laboratories;

- Supporting health facilities that practice transfusing blood and blood components to patients (e.g. hospitals, emergency services) to create standardised blood transfusion services including Appropriate Clinical Use of Blood and Patient Blood Management (ACUB and PBM);
- Supporting the preparedness of blood establishments to fulfil licensing requirements and the requirements of blood establishments good practice/ manufacturing GP/GMP (to produce plasma for fractionation);
- Supporting the implementation and adaptation of the blood costing and pricing methodology.

The project team looks forward to continuing the fruitful cooperation with Ukrainian public health institutions to make advantage of all the available technical support.



EuBIS Academy trainings for Ukrainian blood safety professionals

Spring months of 2023 were marked with numerous educational activities for the blood safety professionals in Ukraine and abroad, and we are delighted that the project supported the blood transfusion institutions in their capacities' improvement during these challenging times.

As part of developing capacities of the Competent Authority of the blood transfusion system, that is officially established under the State Service of Ukraine on Medicines and Drugs Control, two levels of the EuBIS training for the competent authority employees were conducted in collaboration with the EuBIS academy.

The online training seminar "From good practices to best practices in blood and blood components referring to GPG and GMP" by EuBIS Academy took place on 7 – 8 of March 2023, involving seventeen participants from State Service of Ukraine on Medicines and Drugs Control, Ministry of Health of Ukraine, State expert centre of the Ministry of Health of Ukraine, and UTCC.

The program was based on the EuBIS manual and guide and covered topics of: common regulatory requirements and quality standards, updated cross references to GMP/GP guidelines, general principles of quality management systems and inspections, regulations and regulatory framework, risk assessment, qualification, staff training and evaluation, inspection/internal audit. Participants were certified at the end of the seminar.

Blood transfusion sector advanced study visit to the Centro Nazionale Sangue in Rome

The next stage of the training in blood safety area was sending a team of four inspectors from the Competent Authority in the blood sector (State Service of Ukraine on Medicines and Drugs Control) and from the Specialised state institution "Ukrainian transplant coordination center" (UTCC) to attend the face-to face EuBIS advanced inspection training in Rome, Italy during April 2023.

The training was aimed at promoting knowledge in the area of quality and safety of blood and blood components and teach "from good to best practice in transfusion medicine". The seminar was built on previous EuBIS training courses with the scope to inform about the impact of the new regulation of good practice for blood and blood components in the European Union.



This event, organised by the EuBIS Academy in cooperation with the Centro Nazionale Sangue (CNS), gathered professionals in the area of blood transfusion from all over the world with the trainers from Germany, Italy, Spain, France and Portugal,

and covered advanced topics of the blood quality management and inspections. Among them, general guidelines, inspection/audit, validation, change control, corrective actions, risk assessment, haemovigilance, as well as human resources management and communication within blood units.

European Immunogenetics and Histocompatibility Conference in France: lessons learned for Ukrainian national blood reference laboratories

Establishing national blood reference laboratories is one of the priorities the project has set in cooperation with Ukrainian transplant coordination centre (UTCC). Hence, the 36th European Immunogenetics and Histocompatibility Conference, EFI, that took place on April 26 - 29, 2023 in Nantes, France, was crucial for Ukrainian specialists in terms of being introduced to the latest advances in this field.

This was pivotal to build the human capacities of the UTCC in the area of advanced red blood cells serology and related phenotyping and genotyping as these capacities are crucial to establish and run the red cells reference laboratory, especially during the wartime. With the project support, two UTCC specialists took part in the event aimed at sharing the research results and its laboratory applications in the field of immunogenetics and histocompatibility.



EFI is a European organisation that focuses on immunogenetics and runs an accreditation programme that provides an internationally recognised accreditation scheme for laboratories providing Histocompatibility & Immunogenetics (H&I) testing in support of blood transfusion, disease diagnosis and haematopoietic stem cells transplantation. This huge event stimulates scientists, clinicians, students, and industry from around the world to present innovative and significant research and clinical innovations in the field of immunogenetics and histocompatibility.

The Ukrainian participants of EFI2023 were able to grow their knowledge and establish effective new academic and industrial research collaborations leading to more successful further EU integration of Ukraine, as well as they were able to share research experiences and results, discuss challenges encountered and applied solutions in the area of blood safety and with regards to the national blood reference laboratory in particular.

Study visits to the Swiss and Portuguese blood competent authorities and transfusion services

During the period from 13 to 17 March 2023, the project organised a study visit to Switzerland and Portugal for a delegation from the Ukrainian Ministry of Health and UTCC, with the objective to get a first-hand experience and practical insights about the blood transfusion systems in these two

countries including structural, strategic, and operational elements of each system. The visit aimed at informing participants about the pros and cons of different models and consequently enable the Ukrainian decision makers to reach the most effective and efficient design for the blood transfusion system in Ukraine.



The delegates had guided visits to relevant institutions in both countries covering all organisational and operational aspects of blood services provision and blood regulatory systems. These visits were including formal presentations and case studies delivered by blood safety and transfusion field professionals from Portugal and Switzerland, who shared their experience related to the following topics:

- blood regulatory system framework;
- blood competent authorities' nucleus set up and management;
- national organisation of blood services;
- voluntary blood donor recruitment and retention, including national information and promotion campaigns;
- emergency response, blood stock management and technical audits;
- blood donation and transfusion activities;
- screening tests organisation;
- processing blood into components;
- cold chain and plasma storage;
- haemovigilance system organisation (legal framework, reporting and analysis).

The hosting parties were: The Swiss Red Cross, blood transfusion center in Basel; The Swiss Agency for Therapeutic Products, Swissmedic; Porto and Lisbon blood and transplantation centres of the Portuguese Institute for Blood and Transplantation; and the Portuguese blood Competent Authority, Department of Quality in Health (DQH) in Lisbon. Ukrainian blood service professionals studied the existing best EU practices, got a better understanding of concepts and methods, and learnt about applied arrangements needed to implement new measures for reforming the national blood system.



Inha Skoropad

The head of the blood system development unit at the High-tech medical care and innovations Department of the Ministry of Health of Ukraine

➤ Please introduce yourself and your experience

Inha Skoropad, Head of the Blood System Development Unit at the Department of High-Tech Medical Care and Innovation, Ministry of Health of Ukraine, with practical experience in reforming the blood system in Ukraine, member of the operational headquarters of the Ministry of Health of Ukraine for coordination of activities in the field of donation of blood and its components, functioning of the blood system under martial law.

➤ What are the main goals of the national blood system development and how were they transformed over the martial law?

The main goal of the national blood system development is to ensure equal and timely access of patients to high-quality and safe blood components in sufficient quantities. The efforts of the Ministry of Health of Ukraine, as the central executive body that establishes the policy in the field of donation of blood and blood components and the functioning of the blood system, are aimed at building a productive and cost-effective national blood system in accordance with the requirements and standards of the EU Directives in this area.



Thus, the Law of Ukraine "On safety and quality of donor blood and blood components" provides for:

- creating three levels of a blood system structure with a clear division of functions and powers at the national (Ministry of Health of Ukraine, National Transfusion Centre and National Transfusion Committee, Competent Authority), regional (blood system entities) and hospital levels (healthcare facilities providing transfusion services);
- ensuring proper licensing of business activities of blood system entities, as well as state supervision and control over the activities of blood system entities.

The state policy in the field of donation of blood and blood components is human-centred, that means on the one hand we have the blood donors, and on the other hand, the blood recipients, and such a donation is based on the principles of voluntary non-remunerated donation of blood and blood components and promotion of such voluntary donor movements.

➤ How were the MoH activities in blood safety field coordinated during the martial law?

In view of the legal regime of martial law in Ukraine and in order to take measures to coordinate the activities of the blood system entities under such conditions, the Operational Headquarters of the Ministry of Health of Ukraine was established on the basis of the specialised state institution "Ukrainian transplant coordination center" (UTCC), which performs the functions of a National Transfusion Centre. The purpose of this headquarters is to ensure the uninterrupted provision with donated blood and blood components under martial law that meets both the needs of the healthcare system and of the security and defence forces.

On the initiative of the Ministry of Health of Ukraine and UTCC, the Government of Ukraine adopted a separate resolution of the Cabinet of Ministers of Ukraine that defines the mechanism for meeting the needs of the security and defence forces with donated blood and blood components. All entities of the blood system have switched to uninterrupted operation mode, and their activities are monitored on a daily basis.

I would also like to express my gratitude to the Delegation of the European Union and the team of the project "Support to Ukraine for developing a modern Public Health System", implemented by GFA Consulting group GmbH in consortium with the Finnish Institute of Health and Welfare (THL), for their active cooperation and technical support during the war.

➤ How did the dynamics of blood donation change after the start of the full-scale invasion and how is this process now adjusted?

Since the beginning of the large-scale aggression by the Russian Federation, a large number of citizens have responded to calls for donation of blood and blood components and are actively involved in donation. A significant percentage of people became blood donors for the first time, and today they are regular voluntary donors. The sincerity, concern and unity of our citizens and their systematic donations ensure regular replenishment of donor blood and blood components.

At the same time, the Ministry of Health of Ukraine, together with the project "Support to Ukraine for developing a modern Public Health System", UTCC and NGOs, launched two nationwide information campaigns "Your blood can fight. Become a donor" and "There are no holidays in war. Your blood will fight" to further attract voluntary unpaid blood donors. The campaigns helped to increase the level of self-sufficiency of the state in blood and blood components in adequate quantities.

➤ What are the latest MoH legislative developments in the field of blood transfusion?

In May 2023, the Ministry of Health of Ukraine adopted an order that defines the mechanism and organisational framework for the implementation, maintenance and regular improvement of the quality management system and good practices by the blood system entities.

Interview

This order enables the standardisation of the quality management system and implementation of the best European practices to ensure the quality and safety of the donated blood at all stages of the cycle - from collection to end use. Moreover, this order implements three EU directives on quality assurance and operational standards of the blood system entities into national legislation: 2002/98/EC, 2004/33/EC and 2005/62/EC.

Such regulatory acts of the Ministry of Health of Ukraine concerning the safety and quality of donated blood and blood components ensure the implementation of the requirements for traceability of donated blood and blood components, as well as the haemovigilance system to improve safety of the processes of donating blood and/or blood components, including during transfusion care services and direct transfusion of blood.

In order to prevent cases of shortage of donor blood and blood components for the transfusion care provided to the population during martial law or in the event of emergencies, a draft resolution of the Cabinet of Ministers of Ukraine on the import of donor blood and blood components into the territory of Ukraine was developed and submitted to the Cabinet of Ministers of Ukraine by the MoH team. It defines the specific condition of importing donor blood and blood components into the territory of Ukraine during martial law or in the event of man-made emergencies or natural disaster, that have an impact at the national level.

In the future, the blood system entities will need to have not only a licence to carry out economic activities of medical practice, but also a separate licence to carry out economic activities for the collection and testing of donor blood and blood components, regardless of their end use, processing, storage, distribution and sale of donor blood and blood components intended for transfusion.

➤ Please kindly reveal more details on the MoH information campaigns dedicated to blood donations and blood donors' recruitment.

The Ministry of Health of Ukraine regularly conducts information campaigns to encourage people to donate blood and blood components on a voluntary non-remunerated basis.

Every year, on June 14, Ukraine is celebrating the World Blood Donor Day with the involvement of state and local authorities through national campaigns aimed at highlighting the importance of donation, attracting new donors, and thanking professional donors and blood system employees.

Starting 24 February 2022, the Ministry of Health of Ukraine, together with the EU project, UTCC and NGOs, launched and kept track on the nationwide information campaigns to recruit voluntary unpaid blood donors, such as "Your blood can fight. Become a donor", "There is no holiday in war. Become a donor", "Your blood can fight. Become a donor".

➔ What support do you expect from the 'Support to Ukraine for developing a modern public health system' project in terms of the EU experience integration into blood safety reform?

I would like to express my gratitude to the colleagues of the EU project for their help and support in transposing European experience in the field of blood safety for the benefit of development of a sustainable, self-sufficient and powerful national blood system.

The immediate priorities in this sector are as follows:

- transformation of the financial and economic model of the blood system;
- training of specialists to inspect blood system entities for compliance with licensing requirements using European instruments;
- supporting development and implementation of the information and communication complex of the blood system;
- support creation of a reference laboratory for the blood system;
- strengthening informational and analytical activities, in particular by improving and unifying approaches of reporting;
- training of specialists of the blood system entities and healthcare facilities providing transfusion services of donated blood and blood components for the purpose of practical implementation of European integration changes.

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The overall project's objective is to support the modernisation and development of a sustainable Public Health System that is able to ensure disease prevention and control standards in line with EU legislation, requirements, and practices. The project shall contribute to strengthening national leadership and capacity in Public Health policy programming and implementation. The project continues its activities to assist Ukraine with a focus on advancing its progress towards EU accession under Component 1 and supporting the establishment of a modern Blood Safety System under Component 2.