A statement to express gratitude and appreciation to the European colleagues for the support in developing the public health system in Ukraine.

“The COVID-19 pandemic revealed that people’s health and lives must be a priority for the national governments, and the health care system must work effectively and efficiently. We appreciate that the experts of the project ‘Support to Ukraine in developing a modern public health system’ put a lot of effort in strengthening the capacity of Public Health Center of Ukraine (UPHC) and regional Public Health Centres. This helps achieve common goals: reforming the public health system of Ukraine and creating conditions for high health care quality for all Ukrainians, which was stated under the Association Agreement between Ukraine and the EU.

Such cooperation allows adapting the best European practices in disease control and prevention to Ukrainian conditions, as well as forms the basis for building a sustainable modern blood system in accordance with EU Directives. The analysis, revision of regulations and updating of legislation are the important components for accomplishing this task. Hence, the task force consisting of health experts was created, including representatives from the project, the Ministry of Health, the Verkhovna Rada Committee on public health, medical assistance and medical insurance, UPHC and blood donation promoting NGOs. The task force developed a number of recommendations that formed the basis of draft law #3648 “On the safety and quality of blood donation and blood components”, which was voted by Ukrainian parliament at first reading in June 2020. There is still a lot of work ahead, and we expect the law on blood donation to be adopted soon.

Establishing an effective public health system in Ukraine is a long-time process. Therefore, thanks to the professional technical support of international colleagues, we are going to enhance the capacity and expertise among Ukrainian health workers. This will lead to developing an efficient plan on epidemiological surveillance and control of infectious and non-infectious diseases, as well as to improving the quality of management processes, creating the donor registers and common blood transfusion standards, promoting voluntary non-remunerated blood donation and establishing the independent competent authority in the blood safety area.”
On June 9, the experts of the project “Support to Ukraine for Developing a Modern Public Health System” along with the representatives of the Delegation of the European Union to Ukraine Virginija Dambrauskaite (Policy Officer Health and Social Policies Support Group to Ukraine), and Frederik Coene, (First Counsellor), met the Minister of Health, Mr Maxim Stepanov to discuss further cooperation on the currently ongoing health care reform.

Team Leader Dr Predrag Duric highlighted that the project team is working in cooperation with Ukrainian partners in order to strengthen and modernise the public health system in Ukraine. He stressed out that the access to safe blood, timely and high-quality disease prevention and surveillance are important elements for the operation of such a system.

According to the Minister of Health, Mr Stepanov, the professional support of international experts will help to implement the second step of the reform considering international standards. Additionally, due to the project technical assistance, the Ukrainian medical professionals will be better prepared for the new potential challenges.
Responding to the request of Ukrainian healthcare professionals, a series of videoconferences “Response to COVID-19 Pandemic: what we have learned so far” was conducted in May and June with a particular emphasis on COVID-19 risk and prevention and on COVID-19 ARDS treatment.

The experts from Germany – Ralf Reintjes, who is a professor for Epidemiology and Surveillance at Hamburg University and Tampere University, shared his knowledge on the epidemiological background and new findings. Further, Dr Gunther Mertens, the Chief Medical doctor and the director of the Interdisciplinary Vascular and Diabetes Centre at the Heinsberg Municipal Hospital, who has been working with one of the most affected regions in Germany, shared his experience on COVID-19 treatment and answered previously collected questions of Ukrainian healthcare professionals.

The experts covered the following topics related to SARS-CoV-2:
- prevention, treatment and risks caused by the disease;
- epidemiological situation around COVID-19 and estimated expectations on disease spread in Ukraine and worldwide;
- effectiveness of personal hygiene measures and protective equipment for health professionals;
- medical sorting and interaction with patients;
- groups at higher risk and mortality;
- the effect of the infection on immunity and the likelihood of reinfection;
- predictions about the invention of the vaccine.

This series of educational materials was aimed at supporting the response to SARS-CoV-2 in Ukraine and sharing the knowledge on treatment measures. More than 450 Ukrainian healthcare professionals participated in the four videoconferences and had the chance to learn more from the experts’ experience in the German health care system.
On July 3, the Ukrainian Crisis Media Center hosted a briefing on the development of Ukraine’s blood system that is expected to be witnessed if the Ukrainian Parliament will adopt the new law #3648. The representatives of the Ukrainian Parliament, Center for Public Health of Ukraine, Donor UA, Blood Agents, and the blood safety key expert of the EU-funded project “Support to Ukraine for developing a modern public health system” took part in this event. All experts stressed that Ukraine urgently needs to build a new modern and safe blood system that both meets the patients’ needs and international standards, in particular EU requirements. This goal cannot be achieved without an extreme makeover of the current blood safety legal base, the experts emphasized.

The project’s Key Expert on Blood Safety, Dr. Mohammed Abouelfarag, provided an analysis of the current legal framework for blood transfusion in Ukraine, highlighting its main weaknesses and areas for improvement. One of the main drawbacks of the existing legal base, according to the expert, is that it does not cover all links of the blood transfusion chain which are very different from other types of health services. As the blood transfusion chain extends beyond the clinical and laboratory medicine to cover not only those conventional disciplines, but also social science and manufacturing activities, it requires more attention. Dr. Abouelfarag also emphasized other inherited flaws of the current blood safety legislations in Ukraine such as its complexity, abundant technical details beyond required, and inconsistency with some European and international standards.

The participants of this briefing stressed that the adoption of the new law “On safety and quality of donor blood and blood components” #3648 will help to fill the gaps, resolve the issues and provide basis to establish a modern blood transfusion system in Ukraine capable of delivering enough of safe, high-quality blood and blood components to all patients on time.
The project experts conducted the survey on public health reform perception among health care professionals

The KAP survey was conducted in July and August. This survey had been designed to identify knowledge, attitudes and practices of public health professionals related to public health reform. To do the research, the project experts shared the preliminarily designed questionnaire with the health care professionals from Kyiv and regional laboratory centres of Ivano-Frankivsk, Chernivtsi, Vinnytsya, Luhansk, Kherson, Lviv, Rivne, and Kirovohrad oblasts, as well as the rPHCs of Cherkasy, Lviv, Sumy, Kherson, Volyn, Zhytomyr, Kirovohrad, Rivne oblasts and UPHC. In total, 36 responses were received and evaluated.

The information from the survey will help formulate recommendations for the development of public health in Ukraine and to adapt and focus its activities on supporting the expert role of specialists in the public health sector.

Key Expert in blood safety took part in the webinar on the legislative changes in the blood safety system

On June 26, the Public Health Centre (UPHC) organized a webinar on the legislative changes in Ukraine’s blood safety system with reference to the European Union blood safety legal framework. The Blood Safety Key Expert of the EU project “Support to Ukraine for developing a modern public health system”, Dr Mohammed Abouelfarag, provided a presentation on the current status of the Ukrainian legislation on blood transfusion and explained the main changes that will take place after the new law is adopted.

Dr Abouelfarag highlighted that the legal framework for the blood system in Ukraine is one of the most complex frameworks worldwide as it includes over a hundred of different legal pieces on blood transfusion. The existing legislations are outdated, restrictive, incomplete, and reflect neither actual practices nor international standards, he added. The key expert also pointed out that in addition to such complicated legal base, Ukraine has a very complex and highly fragmented blood services provision system, which results in the inconsistency of services provided and many quality issues.

Speaking about the development of a modern blood system in Ukraine, the Dr Abouelfarag said: “Our goal is to build an effective blood safety system that is founded on a legal (statutory) basis aligned with EU requirements. This system will be composed of two independent arms to avoid any conflict of interest: the first is to create an independent blood regulatory authority taking care of oversight, and the second arm is a good quality blood services provision.” He also revealed the essential principles covered in the new draft law. These principles include, but not limited to, voluntary unpaid blood donation, blood establishments’ licensing, quality management in blood establishments, traceability, donor consent and confidentiality, blood testing, processing and distribution requirements.

The expert stressed that the new proposed law mainly covers more static principles of blood safety and availability. At the same time, it leaves the more dynamic detailed technical requirements, that are subject to scientific and technological advances, to the other levels of legal hierarchy such as implementing regulation, Cabinet of Ministers orders, and Ministry of Health orders.
CAN YOU TELL US ABOUT THE REFORM PROCESS OF THE REGIONAL PUBLIC HEALTH CENTRES? WHAT INTERIM RESULTS HAVE ALREADY BEEN REACHED?

Many important steps have been taken to implement the public health policy. First of all, I must mention the establishment of a network of 21 regional public health centres in 2019-2020, including five regional centres that have established this year.

The second essential component of the reform is the financial support of regional public health centres. Within the public health program framework, proposals to the state budget for UAH 3.7 billion were made. From April 1, 2020, the regional centres received funding from the budget of almost UAH 173 million. With the Global Fund to Fight AIDS, Tuberculosis, and Malaria financial support, sub-grants were provided to 18 regional centres for over UAH 20 million.

The third significant result is the creation of regional public health programmes. For the first time, public health programmes have been developed for selected regions, which have already been approved in three regions, such as Sumy, Luhansk, and Cherkasy oblasts. Also, of note is the fact that some public health services, such as social support services for severely ill patients, which were previously funded by the GF grant, are now funded from the local budget.

One more important thing is the introduction of HIV and TB monitoring and evaluation services and medical statistics to public health centres. As of July 1, 2020, 15 public health centres have established departments for monitoring and evaluation of HIV, TB, and medical statistics that engaged specialists with experience in working with leading medical information systems.
PLEASE TELL US ABOUT THE MEASURES OF PUBLIC HEALTH CENTRES TO COUNTERACT AND OVERCOME THE CONSEQUENCES OF THE CORONAVIRUS PANDEMIC.

Each of the regional centres has taken many necessary steps in this regard. For example, the Lviv Public Health Center has developed an Infection Control Action Plan and provided relevant recommendations to Lviv Oblast health facilities. The Zhytomyr Center has developed a plan of operational anti-epidemic measures in health care facilities of Zhytomyr oblast in case of registration of patients with COVID-19 and set several algorithms related to the requirements for equipment for disinfection or medical waste management.

The Rivne Public Health Center has implemented a communication response plan to COVID-19; developed a program to prevent the spread, diagnosis, and treatment of COVID-19 in the Rivne region; and initiated the centre-based PCR testing for COVID-19.

WHAT ARE THE CHALLENGES OF IMPLEMENTING REGIONAL PUBLIC HEALTH CENTRES REFORM?

Some issues have been highlighted by regional public health centres, in the first half of 2020. The first problem is the lack of face-to-face meetings of local governments due to the quarantine, which slowed down the strategic decision process to prevent the spread of COVID-19.

The second problem is the redistribution of funds at the regional level in favour of the procurement of tests, drugs, and personal protective equipment for COVID-19, neglecting the needs in other public health areas.

The third point is that for regions with a low spread of the HIV and TB epidemic, the beginning of medical reform on April 1, 2020, provoked budget deficits and staff reductions (this is relevant for such cities as Lviv and Rivne).

The main challenge at the national level is the delay of registering the draft law on the public health system in the Parliament.

WHAT SUPPORT WOULD YOU LIKE TO OBTAIN FROM THE EU PROJECT “SUPPORT TO UKRAINE FOR DEVELOPING A MODERN PUBLIC HEALTH SYSTEM” FOR THE MORE EFFICIENT DEVELOPMENT OF THE REGIONAL CENTRES?

The first thing that might help regional centres to develop faster and more efficiently is the division of roles between different public health institutions, as well as the introduction of the coordination mechanism between the Public Health Department of the Ministry of Health of Ukraine, the Public Health Center, regional public health centres and laboratory centres.

We also look forward to getting some help with trainings, precisely in assessing the need for public health education, developing a national plan for public health professionals training, and identifying the essential professional competencies of public health staff.

We would be glad if the EU Project could help us improve the quality of communication programmes and the process of distributing messages on the topic of health (including the ones about health risks) through modern media and social marketing channels, so that we can reach both professional audiences and other target groups.
WHAT INCONSISTENCIES WITH EU LEGISLATION HAVE YOU NOTICED IN THE UKRAINIAN LEGAL FRAMEWORK REGARDING BLOOD TRANSFUSION?

The Ukrainian draft contains not only Directive 2002/98/EC but also covers contents form Commission’s Directives on scientifically and technical implementation. In the draft of the law, there is a mix of principles and technical implementations of those directives. A law is a text which is meant to be a framework, a reflection of the government will. It should be complemented by normative texts setting technical standards based on the latest scientific data. The latter, being much more technical and prone to change depending on the state of scientific and medical knowledge, should be the subject of ministerial decrees or any other documents compatible with Ukrainian legislative texts.

While the latest draft is in line with the directives, the decisions to improve the organization in terms of supervision and control at the national level are yet to be made.

CONSIDERING THE DRAFT LAW STRUCTURE, WHAT KEY ELEMENTS SHOULD THE DOCUMENT CONTAIN?

The basic law should contain the following elements:

- Objectives and scope;
- Implementation framework;
- General responsibilities and duties of the different level involved in the national transfusion organization. This includes the rules and the responsibilities of blood establishments, such as the condition of licensing, inspection by the health authorities, responsible person, staffing and training, quality assurance and documentation.
- Another important element is hospital blood bank, which forms the blood component to a patient and can be split into the following parts: cold chain and blood component conservation and immuno-haematological lab, patient ABO grouping, compatibility testing.
- Provisions for the quality assurance and safety of blood and blood components processing.

Daniele Sondag

Senior consultant on blood safety in developed and developing countries

Interview
donor identification, examination, eligibility and status; donation’s testing; and, obviously, blood components production, storage and distribution.

WHAT ARE THE MAIN PRINCIPLES OF VOLUNTARY NON-REMUNERATED BLOOD DONATION ACCORDING TO THE EU STANDARDS?

The principles governing voluntary and unpaid donation of blood and blood components highlights that Member States shall take the necessary measures to encourage voluntary and unpaid blood donation with a view to ensure that blood and blood components are provided from such donations to the possible extent.

In the majority of the countries in Europe, the donors are not paid, but compensation for expenses is permitted. However, plasma for fractionation is in some countries collected form paid donor. Compensation means reparation strictly limited to making good the expenses and inconveniences related to the donation. While incentive means inducement/stimulus for donation intending to seek financial gain or comparable advantages”.

In conclusion, in Europe, all countries agree on the fact that the donation for voluntary non-remunerated donor for blood and blood components is beneficial in terms of safety. However, the situation with fractionation plasma, is different. Most countries accept medical products derived from plasma from paid donors even if an effort is made at European level to tend towards self-sufficiency in plasma from unpaid donors.

HOW CAN WE USE THE INTERNATIONAL EXPERIENCE TO REFORM THE BLOOD SYSTEM IN UKRAINE?

There are several possibilities for transfusion organisation, either very centralised, completely decentralised or even mixed ones. The aim is to provide high quality of blood and blood components in sufficient quantity to all citizens of the country. Consequently, the organisation of transfusion should be modelled on the health services organisation. The European Directives indicate the way forward for an optimal transfusion organisation.

WHAT ARE THE MAIN CHALLENGES OF THE NATIONAL BLOOD SYSTEM REORGANISATION?

For Ukraine, the most urgent is to vote and implement legislation on blood establishments and hospital blood banks. Some guidelines are also necessary for transfusion establishments and blood banks in order to standardise practices throughout the country. The protection of donors and patients should be taken into consideration and be the guideline of the legislative arsenal.

The overall project’s objective is to support the modernization 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 supports the consolidation and empowerment of the newly created Public Health Centre of Ukraine (UPHC) and supports the creation of a modern Blood Safety System in Ukraine.