

Final Report:

Technical Assistance Support for the Strengthening of Blood Transfusion Services in Selected Countries Under the President's Emergency Plan for AIDS Relief (PEPFAR)

December 2012 to March 2018



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ACRONYMS AND ABBREVIATIONS

AABB	American Association of Blood Banks
AIHA	American International Health Alliance
AuRC	Australian Red Cross
CDC	Centers for Disease Control and Prevention
CIMS	
EDQM	European Directorate for the Quality of Medicines & HealthCare
ELISA	enzyme-linked immunosorbent assay
EU	European Union
EQA	external quality assessment
HCMC	Hennepin County Medical Center
IDTM	ID Consulting for International Development of Transfusion Medicine
MAC	Medical Accreditation Center
MBC	Memorial Blood Centers
мон	Ministry of Health
NBTS	National Blood Transfusion Service
NBTC	National Blood Transfusion Center
NMAPE	National Medical Academy of Postgraduate Education
	Oblast Blood Center
PEPFAR	President's Emergency Plan for AIDS Relief
QM(S)	quality management (system)
	Republican Blood Center
	Scientific and Production Center of Transfusiology

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SOP	Standard Operating Procedures
TWG	Technical Working Group
тот	training of trainers
TTI	transfusion transmitted infection
URS	User Requirement Specifications
VNRBD	Voluntary Non-Remunerated Blood Donation
WHO	World Health Organization

Executive Summary

American International Health Alliance (AIHA) has been the primary partner for the Centers for Disease Control and Prevention (CDC) Cooperative Agreement GH000861. This agreement which covered the period of 2012-2018, was to provide technical assistance support for the strengthening of blood transfusion services in select countries in the Asia Region including Central Asia, Ukraine, and Cambodia. The project was supported by funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

The purpose of the project was to strengthen the implementation of safe blood programs and precautions against the medical transmission of HIV, thereby ensuring a safe and adequate blood supply, a priority area for PEPFAR. AIHA provided expert guidance and technical assistance to the Ministries of Health (MoH) and the National Blood Transfusion Services (NBTS) in Kyrgyzstan, Kazakhstan, Tajikistan, Ukraine, and Cambodia, countries affected by HIV/AIDS and other transfusion-transmissible infections (TTIs), for the development and implementation of a national safe blood program with demonstrable and sustainable results. Another goal of the project was the development of sustained local capacity to continue these programs after the project ends - an additional intent under PEPFAR.

Success for the project relied on close partnerships with the CDC located both in Atlanta and in each country, as well as with the MoH, NBTS, and as applicable, other implementing organizations in each country. Technical expertise was provided by transfusion medicine and blood bank professionals and in collaboration with ID Consulting for International Development of Transfusion Medicine (IDTM), Global Healing, and the Australian Red Cross (AuRC).

Assessments were conducted in each country with the results providing the basis for developing work plans focusing on key areas requiring improvement. A common deficiency in all countries was the lack of knowledge and the absence of a quality management system (QMS). According to World Health Organization (WHO), "Quality systems are the key to ensuring the availability of safe blood for all patients needing transfusions." A QMS is a foundational requirement for any organization as it provides a framework within which activities are established and performed in a quality-focused way and are continuously monitored to improve outcomes. As such, this was a primary area of focus in the countries and included trainings that were both didactic and practical in nature. Local participants developed templates for quality plans and other quality processes that could then be customized by each institution. In addition, a vein-to-vein approach was used in providing technical assistance in the operational areas. Training included the recruitment of volunteer non-remunerated blood donors (VNRBD), blood collection and donor care, laboratory processing and manufacturing, storage and distribution of blood components, and the clinical use of blood for transfusion.

During the project, AIHA conducted over 80 trainings and presentations for over 2,561 participants and contributed to the development of over 8 national guidelines on various topics pertaining to organizational infrastructure, recruitment of VNRBD, quality and technical standards, and guidelines for the clinical use of blood – all which contribute to blood safety and accessibility.

As a result, AIHA has significantly contributed to the national capacity of the blood service in the selected countries by improving human resources for health and implementing evidence-based guidelines to promote health systems strengthening.

Other achievements include establishing a set of local blood safety experts in Ukraine that have been recognized by the MoH to promote the sustainability of the project's efforts. Kyrgyzstan also trained a group of local experts from the Republican Blood Center(RBC) on the clinical use of blood who, in turn, trained clinical physicians in rural parts of Kyrgyzstan. Additionally, several project deliverables have

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been recognized as best practice in the region and have been replicated in other countries under the project. In 2016, for example, AIHA developed the National Guideline on the Clinical Use of Blood in Kyrgyzstan with technical assistance from international experts. This guideline was later adopted, contextualized, and implemented under the project in Cambodia, Tajikistan, and Ukraine, further contributing to better standards for blood safety in the region.

Another exciting outcome from the project is the early development of a regional network for the national blood systems in Central Asia with the sharing of best practices. As an example, the quality manager from the NBTS in Kazakhstan visited the NBTS in Kyrgyzstan and provided advice on accreditation; and the head physician, also from Kazakhstan, provided physician training on the clinical use of blood in Tajikistan.

This report is a summary of the approach, activities and accomplishments achieved through this cooperative agreement as it pertains to Central Asia and Ukraine. In addition, challenges faced during the project are addressed. Most notable is the decreased funding for the project from the original award and the constant changes with the government and MoH in Ukraine. Despite the multiple challenges, the outcomes of the project have been successful and have improved the quality and safety of the blood supply in the selected countries.

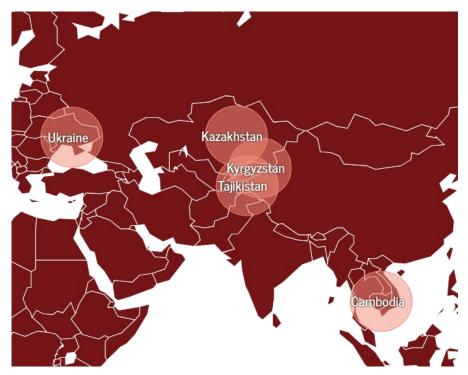
The final report for Cambodia provided by the AuRC, the implementing partner for the activities in Cambodia, has been included as an attachment.

Introduction

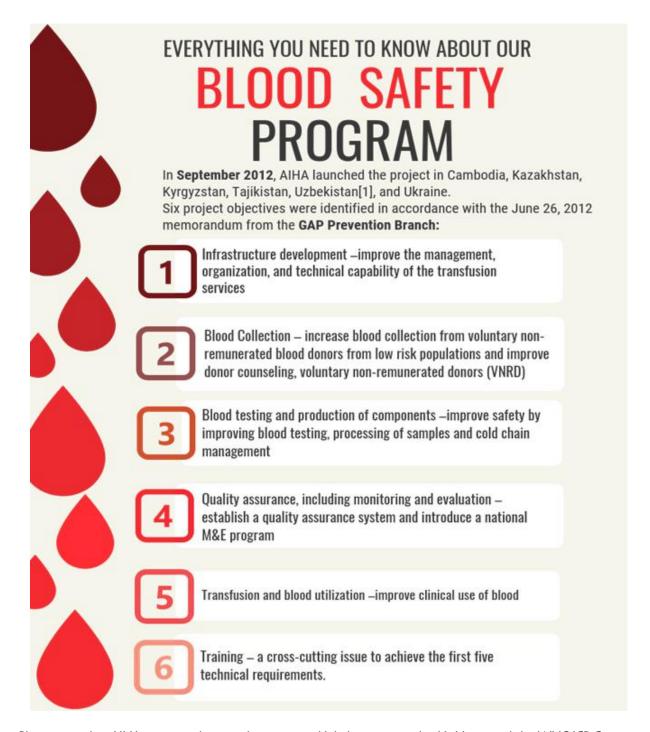
Access to a safe and sufficient supply of blood and related products and services, including blood transfusion, is a critical element of any health system. Unfortunately, many people who need transfusions — especially those who live in low- and middle-income countries around the world — do not have timely access to safe blood. According to the WHO, activities related to blood collection, testing, processing, storage, and distribution should be coordinated at the national level through effective organization and integrated blood supply networks. Furthermore, national blood systems should be governed by national blood policies and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. WHO reports that in 2013, 68 percent of all countries had a national blood policy. Additionally, 58 percent of countries have specific legislation on safety and quality standards for blood transfusion, ranging from 79 percent of highincome countries down to just 41 percent of low-income countries. There is also a marked difference in the level of access to blood between low- and high-income countries, as evidenced by the whole blood donation rate, which ranges from a median of 32.1 donations per 1,000 population in high-income countries to 14.9 in middle-income countries and 7.8 in low-income countries. As a result, there is a need in many low- and middle-income countries for expert technical assistance to strengthen the rapid implementation of safe blood programs and precautions against the transmission of HIV and other transfusion transmitted infections.

Most of Central Asia and Ukraine are classified as lower-middle income countries and experience limited access to safe and adequate blood as indicated above. The structure of blood transfusion services

in Central Asia and Ukraine are similar to other former Union of **Soviet Socialist Republics** countries. In Central Asia, the countries are divided into administrative units called oblasts and each oblast has its own blood center. Each OBC only operates and provides services to the population within the oblast's geographical area. All Oblast Blood Centers (OBCs) report to the RBC, which sits in the capital city and serves as the NBTC that provides technical training and support to the OBCs. Similarly, in Ukraine, there is one OBC for each of its oblasts. However, Ukraine does not have a NBTC, which often challenges blood service delivery due to the absence of having a



nationally coordinated blood service and policy.

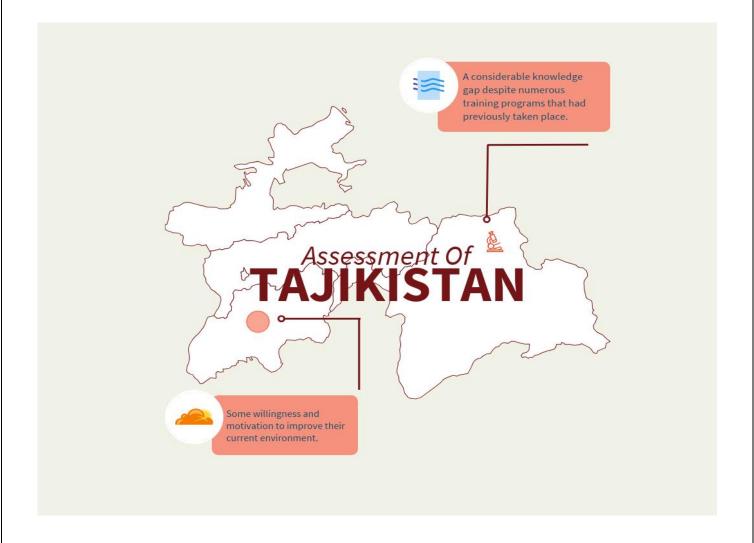


Please note that AIHA never implemented activities in Uzbekistan since the MoH rejected the WHO/CDC project proposal.

Further, AIHA engaged international experts to conduct baseline assessments of the blood services in Kyrgyzstan, Tajikistan, and Ukraine. Based on the findings and recommendations of these assessments, AIHA refined the focus of the project in each country.



- The senior leadership at the RBC was motivated and eager to implement improvements in the blood system and had strong support from the MoH.
- The blood system faced many challenges beginning with limitations in the infrastructure, including the existence of numerous restrictive decrees and regulations that required review and updating to international standards.
- The blood centers passed a resolution to address reformation of the blood system, an improvement from the previous system of independently-run OBCs and existence of several hospitals that also collected blood. Assistance in implementing such a plan was evident as not all stakeholders were apprised of the plan nor considered ensuring an adequate blood supply. The reform process impacted blood supply and the blood centers needed assistance to prepare.
- There was a lack of standardization with processes and procedures, with some OBCs more progressive than others in areas such as recruitment and retention of VNRBD and implementation of quality procedures. In general, QMS was absent with the focus primarily on quality control versus quality assurance.
- The collection and processing of blood into components were weak with a lack of understanding of how to meet hospital and patient needs, i.e. availability of platelets; and availability of storage units in hospital transfusion units was lacking. Although staff was required to attend periodic training for license renewal, an opportunity existed to improve training and education for all levels of staff.



- Initial impressions with the deputy director of the RBC and the directors at the two OBCs in Khatlon indicated some willingness and motivation to improve their current environment.
- The assessment team was not able to complete a full assessment. However, the initial assessment indicated a considerable knowledge gap despite numerous training programs that had previously taken place. Top priorities indicated by the deputy director of the RBC included cold chain storage in hospitals, availability of equipment and consumables at the blood centers, and development of a VNRBD program. Evidence of QMS was also lacking.



- A national blood system was lacking in Ukraine with each OBC operating independently, resulting
 in a lack of standardization in processes and procedures, overall absence of QMS, limited efforts
 to recruit and retain VNRBD, inconsistent availability of certain blood components due to lack of
 appropriate storage equipment, and variation in interpretation of existing national decrees.
- Some blood services were more advanced in specific areas than others depending on the director of the blood center and availability of funds, or integration and support from local governments.
- A lack of communication and coordination also existed between the MoH, State Services, and blood centers, for example in the follow-up of HIV positive donors.

FIRST ELEMENT Pre-accreditation assessment Second Element EQA Third Element Information Systems Fourth Element Remediation and Targeted Technical Assistance National Blood Service

National Blood Service Accreditation Requirements



However, beginning with fiscal year 2015, PEPFAR shifted its focus on quality and sustainability strategies requiring the realignment of blood safety technical assistance activities "to focus on core PEPFAR quality objectives, including accreditation, quality assurance, and use of data for evidencebased decisionmaking". Following this shift, blood safety technical assistance activities followed a new framework based on three primary output indicators, (I) development of accreditation roadmaps, (2) external quality assurance, and (3) blood service information systems, and one primary outcome indicator, accreditation. Working toward these indicators, technical assistance activities were targeted at achieving the technical standards required for accreditation as indicated in the figure.

SUCCESS STORY

UKRAINE

Recruitment of Volunteer Non-Remunerated Blood Donors



Remarks from Krov.ua representative, Ms. Ow

"It is encouraging to hear some of the centers are actively recruiting volunteer blood donors and have implemented processes to assist them in the transmition to a VNRBD blood supply."

Importance of Raising Awareness

The need for donation is a key element in recruiting VNRBD. Most donors either do not know enough about blood, the donation process, or have never been asked. Blood transfusion service personnel also need to be educated and taught the techniques for recruiting and retaining individuals to become VNRBDs.

"With PEPFAR programs we set out to make the world a better place. When what we share and teach is acted upon, it is inspiration. What is happening in Ukraine truly validates that when people focus on patients, are committed to improvement, and take advantage of low cost materials and social media, good things will happen."

- Ms. Botos





Under the Centers for Disease Control and Prevention-funded project, "Technical Assistance Support for the Strengthening of Blood Transfusion Services in Selected Countries under the President's Emergency Plan for AilDS Relief (PEPFAR), AIHA provided training and education on strategies and techniques for encouraging the public to donate blood and how to recruit and manage a donor recruitment program

Key Strategy for Ensuring Safety of Blood Transfusion

In many resource limited countries, reliance for blood donations is from family/replacement or paid donors rather than volunteer non-remunerated donors (VNRBD) from low risk populations. The danger of collecting blood from these populations is that they have a significantly higher prevalence of transfusion-transmitted infections. In Ukraine, there has been a reluctance to move toward a 100% VNRPBD base. Although current legislation allows for VNRBDs, donors can also donate for a small payment. Substantial benefits are also provided to special donors who are recognized for their multiple donations. Recruitment and acceptance of VNRBD is sporadic, alkthough Krov.ua, a local non-governmental organization, actively recruits volunteer donors.

The Emotional Side of Donating Blood

Leslie Botos, an international expert on public relations and marketing for a blood center, provided information on the importance of reaching out to the emotional side for donating blood, including sharing patient stories and the benefits of blood transfusion in saving lives. Simple, low cost marketing tools using digital media such as Facebook, Twitter, or taking a short video using an iPhone were shared with participants. A toolkit was also provided with templates that could be customized for creating posters, flyers, and banners to recruit blood donors. Jo Anna Ow, another expert, addressed the role of donor recruitment in the blood center, including the roles and responsibilities of a donor recruiter, how to set up blood drives, and how to schedule drives to meet inventor needs. Representatives from local blood centers who actively recruited donors shared their programs, as did the representative from Krov.ua.

The Success of The Workshops

Some participants immediately started taking ownership and posting ideas on their Facebook page. Another example of putting the information to use was finding that the templates from the toolkit were displayed on billboards throughout Kiev, advertising the need to donate blood. Most recently, Ukraine has ratified an associated agreement with the European Union (EU). For the blood transfusion services, this means that the government has agreed to harmonize their regulations with the EU blood directives, which includes collecting blood from a 100% VNRBD base.

PROJECT RESULTS Central Asia





Background

AlHA started providing technical assistance in Kazakhstan after a request was made by CDC/Almaty to redirect funds to assist in a short-term project requested by the MoH in Kazakhstan. The request was to provide two international consultants, one American and one European, to review and assist with finalization of the latest draft of the national guidelines on the "Clinical Use of Blood and Its Components." After the redirection of funds was approved, Dr. Gorlin, representing the United States, and Dr. Lozano, representing Europe, conducted the review of the revised Prikaz 666, National Guidelines on the Clinical Use of Blood and Its Components. The project culminated in Dr. Gorlin and Dr. Lozano participating in a two-day conference from September 23-24, 2013 on the Quality and Safety of Blood Transfusion in Health Care Facilities followed by visits to local hospitals. After this activity, AlHA and CDC met with Dr. Burkytbaev, Director of the Republican Research and Production Center of, and determined opportunities for AlHA to continue providing technical assistance to the blood service in Kazakhstan.

Clinical Use of Blood

- Dr. Chursin at the Almaty State Institute for Postgraduate Education developed a course on clinical indications for use of blood in collaboration with the Scientific and Production Center of Transfusiology (SPCT) in Astana. AIHA provided a copy of the German guidelines on blood
 - component therapy as a reference, which is considered to be one of the best in the EU. In March 2015, AIHA sponsored the 10-day training course for 39 physicians, which was conducted in Astana in collaboration with national trainers from the SPCT. AIHA also sponsored participants from Tajikistan and Kyrgyzstan to attend the course.
- From September 12-14, 2016, Dr. Jurkevich together with Dr. Lozano, European Regional Director for International Society for Blood Transfusion, traveled to Almaty, Kazakhstan in order to meet with the RBC staff and clinical transfusiologists and to present at the CDC Closeout Conference with the RBC. Per request from CDC, Dr. Lozano presented on best practices from the EU and the United States regarding hospital transfusion committees, clinical monitoring, and the latest updates on the shelf-life of blood components.

Donor Management

 AIHA engaged international consultants to provide technical assistance in Astana and at the September 2015 Regional Conference in Almaty on raising public awareness when recruiting VNRBD and crisis communication.

Infrastructure

- In January 2014, with the support of CDC and World Bank, AlHA conducted an assessment on Computer Information Management Systems (CIMS) at the SPCT in Astana and the RBC in Almaty. Based on this assessment report, AlHA provided continued assistance with the development of user requirement specifications (URS) for the SPCT in preparation for a request for bids from commercial vendors. AlHA engaged an international consultant to develop the URS after reviewing current processes with local stakeholders, and provided URS for the following modules in May 2014: donor; patient; stem cells, cord blood and bone marrow; HLA process, Bone Marrow Donor Registry database; data migration; and overall bidding requirements.
- AIHA provided finance-related technical assistance, sharing international experiences in the
 reimbursement of blood centers for the production of donor blood components. An
 international expert provided consultancy on financial cost accounting and cost recovery in July
 2014. The consultant met with Dr. Burkytbaev and the Vice Minister of Health of Kazakhstan,
 Dr. Baizhunusov, on July 3, 2014 to discuss the financial cost accounting system and primary
 recommendations, which was translated into a final written report.

Quality Management

• The AIHA team developed a set of presentations on a QM course for the SPTC in Astana. The QM curriculum was based on the WHO training programs, which was further customized by Dr. Tarasova in Astana to include local normative regulations, case studies, and a test to meet state postgraduate education requirements.



Background

In January 2013, AIHA traveled to Kyrgyzstan to meet with CDC/Central Asia and MoH to introduce the project and agree on the preliminary plan to conduct the baseline assessment. AIHA returned in February 2013 with technical consultants from HEAP to participate in stakeholder meetings with the MoH, RBC, and OBCs, and to conduct pre-assessment visits in Bishkek and Osh.

On June 19, 2013, the MoH issued a governmental order in support of the project's national-level baseline assessment. Subsequently, a team of international consultants conducted the assessment of the OBCs, hospitals, and AIDS Center laboratories. In November 2013, AIHA sponsored a national stakeholders meeting to present the findings and recommendations of the assessment. Attendees included representatives from the MoH, RBC, OBCs, hospitals in Bishkek, and CDC.

Based on the recommendations from the international experts, an implementation plan for 2014 was developed. Key focus areas included the reformation of the blood services and development of a VNRBD program. In addition, the development of quality standards and national regulations for the clinical use of blood became primary objectives, as outlined in the 2012-2014 Blood Service Development Program of the Kyrgyz Republic.

Accreditation

- In 2016, AIHA developed a roadmap for accreditation and a tool for self-assessment that was based on international standards. The roadmap and a tool were introduced to the RBC team and to all OBCs. AIHA conducted mentoring visits to provide guidance to the Naryn, Talas, Karakol, Batken, and Osh OBC on how to prepare for accreditation in accordance with the roadmap.
- From November 27 to December 2, 2016, AIHA invited Dr. Tarassova to meet with Dr. Maya Makhmudova, AIHA's former Country Director for Central Asia, and key stakeholders to assess the possibility of professionally accrediting the blood service and assess its competence and compliance in developing national accreditation standards.
- A two-day mentoring visit to Batken and to Jalalabad OBCs took place from June 20-24, 2016 with Dr. Makhmudova, the RBC quality manager, and the RBC deputy director. The purpose of the visit was to review the assessment findings and work plan for improvement.

On March 10, 2017, AIHA organized a round table meeting for 27 participants with representatives from the MoH Technical Working Group (TWG), RBC, and Medical Accreditation Commission (MAC), the authorizing body for accreditation, to discuss the development of accreditation standards, the revised roadmap for accreditation, and the approval procedure for accreditation. The objective of the round table meeting was to determine the next steps on how to meet the accreditation requirements established by MAC.



• From August 14-17, 2017, AIHA organized a three-day workshop in Issyk-kul on developing accreditation standards for the blood service. In total, the workshop included 20 participants, including representatives from the MoH, MAC, and RBC.

Clinical Use of Blood

- Beginning in January 2014, a TWG appointed by the MoH collaborated with international experts to develop guidelines on the clinical use of blood. The guidelines are based on internationals standards of practice (European Union (EU), American Association of Blood Banks (AABB), Germany, WHO, UNICEF) and evidence-based medicine. In October 2014, a final draft was submitted for review by the Evidence Based Medicine Department of the MoH, and subsequently the new national clinical guidelines were adopted by the Minister of Health in February 2015 as federal regulations. The adoption of the new national clinical guidelines as a national regulatory document is significant as it requires all clinicians in Kyrgyzstan to follow the guidelines. In addition, medical schools in Kyrgyzstan are required to revise their curricula in accordance with the new clinical guidelines.
- In September 2014, AIHA engaged an international expert to present a webinar on pediatric risks and guidelines for transfusion.
- In March 2015, AIHA provided a national training of trainers (TOT) program in collaboration with international consultants and 15 physicians from the OBC and Republican hospitals.
- AIHA printed and distributed 425 copies of the new clinical guidelines starting in May 2015.
- Based on new clinical guideline, a new course on Clinical Transfusiology for postgraduate education was developed and approved by the MoH in September 2015.



- Between May and September 2015, AIHA supported national trainers from the RBC in conducting national-level trainings on the new clinical guidelines for 321 clinicians. Specific topics included the use of blood components, pre-transfusion testing, the transfusion process, and adverse events.
- After the refocusing of PEPFAR priorities on accreditation in 2015, clinical use of blood stopped being a priority for technical assistance. However, AIHA continued to provide technical assistance when conducting mentoring visits at the OBCs and the associated hospitals and supported the training of clinicians on the new guidelines through the National Academy of Post-graduate Education in 2016.

- In 2017, AIHA finalized the monitoring forms to assess the clinical transfusion process at hospitals with the goal of improving the clinical interface between blood centers and hospitals.
- From August 10-12, 2017, AIHA provided technical assistance to the RBC in conducting monitoring and mentoring visits at four hospitals in Bishkek to improve their operations on the clinical use of blood. To assess their clinical transfusion processes, AIHA used monitoring forms that were developed by the project. The monitoring forms align with the clinical guidelines and allow for standard guidance to be provided.

Donor Recruitment

- The proposal titled, State Program of Voluntary Unpaid Blood Donation of the Kyrgyz Republic for 2013-2017, was developed by representatives from the RBC, the Red Crescent Society of Kyrgyzstan, and CDC. AIHA reviewed the proposal, suggesting metrics for monitoring the implementation of the program, and provided a letter of support for the proposed program. The proposal was presented and approved by the MoH, which executed a government decree to form the Inter-Agency Coordination Board to plan and coordinate the program.
- In 2014, AIHA signed a contract with the Red Crescent Society of the Kyrgyz Republic to provide training and conduct activities to raise public awareness on the need for volunteer blood donations. Red Crescent, together with Club 25 and the RBC, conducted activities for World Blood Donor Day. Other Red Crescent activities included developing promotional material, including a video on blood donation in both Kyrgyz and Russian that was played continuously on television the week prior to World Blood Donor Day. AIHA also provided support to the RBC in developing promotional materials commemorating World Blood Donor Day.
- In August 2014, AIHA sponsored a three-day workshop on VNRBD. The workshop brought together representatives from the RBC, Red Crescent Society of Kyrgyzstan, Club 25, and the cabinet ministries to collaborate on developing a recruitment strategy for the coming year. The 25 participants learned how to use patient stories, how to develop key messages to begin the branding process, and how to collaborate with the media to raise public awareness. Participants developed a plan for working together using National Blood Donor day in September 2014 as the kick-off to their year-long plan.

Infrastructure

- In May 2013, AIHA and technical experts from IDTM participated in an interactive roundtable event to develop an action plan on restructuring the blood supply system in Kyrgyzstan and developing the 2013-2015 program to recruit VNRBD.
- Finance-related technical assistance was provided in June 2014 to support the new blood service structure. An international consultant worked with RBC's chief accountant and deputy director and provided a presentation to MoH representatives.
- In 2016 and 2017, AIHA supported the technical maintenance of CIMS used at the RBC and OBCs via contract with Innovasystems. The CIMS solved issues associated with the automation of blood centers and laboratory process operations by (1) receiving and archiving donor data, prepared blood component data, and laboratory device data, (2) executing reports, and (3) maintaining a register of exempt donors. As a result, the CIMS ensures the accuracy and reliability of data used in determining the safety and acceptability of donors and blood distributed for transfusion.

Laboratory

• With approval from CDC, AIHA assisted the RBC in acquiring new equipment for infectious disease testing by enzyme-linked immunosorbent assay (ELISA) methodology. Prior to the

- purchase of a semi-automated microplate washer and microplate reader, the RBC did not have any backup equipment available in the event of equipment failure.
- In preparation for the receipt of new equipment provided through the KfW/EPOS project, AIHA provided training in January 2015 with webinars and Skype conference calls. An on-site training on equipment validation was provided March 31-April 2, 2015, for approximately 25 participants at the RBC in Bishkek. Participants included the directors and quality managers from each OBC and all department heads from the RBC.

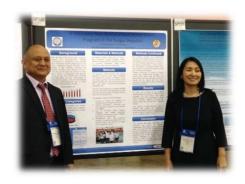
Quality Management

- A five-day interactive QM Workshop was conducted in November 2013. A quality specialist
 from AlHA and two international experts provided the training, which was based on the WHO
 QM Course. The workshop had 29 participants, including RBC representatives, OBC directors
 and quality managers, and clinicians from the Republican hospitals in Bishkek.
- Onsite mentoring of quality systems at RBC and six OBCs (Osh, Jalal-Abad, Talas, Issyk- Kul, Batken, and Naryn) was initiated at the end of March 2014 and continued into April 2014. The purpose of the mentoring was to support the QM training conducted in November 2013 by assisting in the transfer of theory to practice. Mentoring activities were conducted by AIHA staff, an international specialist, the RBC Quality Manager, and RBC deputy directors. Topics included a review of quality systems, change management, the importance of procedures and document control, developing quality monitors, proper blood sample identification, maintaining the cold chain process, and mechanisms for developing a clinical interface with hospitals and clinicians. In addition, training on the introduction of quality and quality systems was provided for blood center staff.
- AIHA assisted the RBC in the development of Quality and Technical Standards for the Blood Services of the Kyrgyz Republic, which were based on international guidelines, recommendations, and standards of the EU, European Directorate for the Quality of Medicines & HealthCare (EDQM), WHO, AABB, and the U.S. Food and Drug Administration. A work group appointed by the MoH reviewed and customized the standards in accordance with normative documents. The Quality and Technical Standards were approved as a prikaz by the MoH in September 2014.
- A mentoring trip to Kyrgyzstan took place from June 1-5, 2015 to revise a draft order on the
 quality and safety of donated blood and blood components. Other recommendations included
 suggestions to streamline processes and reconsider discontinuing practices that are not aligned
 to international standards of practice or that are unsupported by current data from the RBC.
- A national TOT workshop took place October 12 16, 2015 in Bishkek. The training included a two-day program with an in-depth review of the self-assessment tool for quality systems and donor collection requirements. Participants representing the RBC and 6 OBCs completed a self-assessment for their facilities and a report on the findings was provided to the RBC. The results were used to develop a roadmap/action plan to address the identified gaps.
- Dr. Semenov provided on-site consultation from March 2 5, 2016 on Prikaz Order 544, which
 provides detailed technical instructions for the blood services in Kyrgyzstan. The prikaz was
 approved by CDC and the MoH in June 2016. AIHA printed and distributed 500 copies of the
 prikaz at the national level.
- To finalize the development of standard operating procedures (SOPs) for the blood service, AIHA organized a 5-day practical workshop from May 23-27, 2016 for the quality managers and directors from the RBC and all OBCs. Faculty consisted of three international consultants, Dr. Semenov, Dr. Zinkin and Dr. Makhmudova, who provided technical assistance with the revision of the entire set of SOPs for the blood services.

- In 2017, AIHA provided technical assistance in reviewing the updated Prikaz 544 and Prikaz 272.
 Both documents provide clear guidance on the processes that should be followed by the blood service to ensure an effectively coordinated system.
 - Prikaz 544 provides detailed technical instructions for the blood services in Kyrgyzstan. The prikaz was approved by CDC and MoH in June 2016 and distributed. However, there was a request to add a chapter that stipulates the regulations related to the transportation of blood products. The updated order was approved by MoH in March 2017.
 - Prikaz 272 focuses on centralizing and reforming the blood supply system in Kyrgyzstan.
- In 2017, AIHA also finalized the monitoring forms to assess the QMS of the blood service. AIHA uses these forms when conducting monitoring and mentoring visits in order to provide standard guidance to the blood service on how to improve operations.
- In 2017, AIHA finalized, printed, and delivered 50 copies of the SOPs to the RBC in order to improve QMS processes of the blood service. The SOPs are instructions on how a particular task should be undertaken within a particular work area. The specific areas of work include donor selection, performing venipuncture, TTI testing, blood grouping, storage and transportation, and all the supporting activities, such as the maintenance of equipment, calibration, training, error management, and cleaning.
- The first deputy director from the RBC and quality manager participated in the National Annual Conference in Astana, Kazakhstan on April 8, 2017, that is organized by the SPCT, followed by the training on QMS at the SPCT from April 11-15, 2017.

Other Activities

In support of the RBC, AIHA sponsored a regional conference October 8-10, 2013 commemorating the 80th anniversary of the Blood Service in Kyrgyzstan. A primary focus of the conference was the presentation of the draft Guidelines for the Clinical Use of Blood and the newly approved Quality and Technical Standards. AIHA also sponsored international participants from Kazakhstan, Tajikistan, Uzbekistan, Armenia, Russia, Spain, and the United States to attend the conference. The international participants presented on the blood services in their own countries, hemovigilance, patient



- blood management, transfusion committees, the latest updates on red blood cell and platelet transfusions, and t-cell therapy for hematologic malignancies. The conference was attended by 85 participants. Opening remarks were provided by the Deputy Minister of Health, Dr. Kaliev, who praised collaboration within this project as very efficient and beneficial for the country. AIHA sponsored RBC Director Dr. Karabaev and one of his deputies, Dr. Kanat Bektemirov, to attend the AIHA-supported regional conference in Kazakhstan in September 2014.
- The following month, AIHA sponsored Dr. Karabaev and his first deputy, Aiganysh Satybaldieva, to attend the AABB Annual Meeting, which took place October 24-29, 2014, in Philadelphia, PA, and to continue on a study tour to the Memorial Blood Centers (MBC) in Minneapolis, MN. The

team presented two posters at AABB on the volunteer nonremunerated blood donor program and the quality program in Kyrgyzstan. Following the AABB meeting, the attendees visited the American Red Cross Biomedical Services Penn-Jersey Region in Philadelphia where they observed whole blood and apheresis collections, component manufacturing and hospital services where blood is stored and distributed to local hospitals. The group also visited the University of Pennsylvania Hospital Transfusion Service and observed both manual and automated pretransfusion testing,



component storage, and their apheresis unit. In Minneapolis, the attendees were hosted by Dr. Jed Gorlin, AlHA consultant and medical director of MBC and the transfusion service at Hennepin County Medical Center (HCMC). The attendees observed the operations and integration of quality throughout the operational systems at the blood center and visited a high school blood drive. At HCMC, the participants attended the Emergency Room grand rounds and received a tour of the HCMC simulation site used for training and preparing staff for medical trauma situations and visited the transfusion service.

- From December 1-2, 2016, CDC/Central Asia organized a closeout conference for the CDC Cooperative Agreement with the RBC in Bishkek. Dr. Makhmudova, AlHA Country Director for Central Asia, represented AlHA at the conference and made several presentations on project accomplishments and inventory management. AlHA also supported Dr. Tarassova attending the conference.
- On October 24, 2016, Jean Stanley, AIHA's Principal Investigator for the Blood Safety Program, made an oral presentation at the AABB conference on "Strengthening the transfusion service in the Kyrgyz Republic".

Training Chart

<u>2013</u>

Title of Training	Training Location	Date of Training	Total Number Trained
QMS in Blood Service	Karakol	November 11-15, 2013	30

<u>2014</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Follow-up workshop on QM	Jalal-Abad	April 1-2, 2014	10
Follow-up workshop on QM	Osh	April 3-4, 2014	13
Follow-up workshop on QM	Naryn	April 8-9, 2014	13
Follow-up workshop on QM	Karakol	April 10-11, 2014	39
Follow-up workshop on QM	Talas	April 14-15, 2014	27
Follow-up workshop on QM	Batken	April 17-19, 2014	20
Webinars on QM	Bishkek	May 2014	20
Webinars on QM	Issyk-kul	June 9, 2014	20
Financial Management in Blood service	Bishkek	June 6, 2014	20
Voluntary Blood Donor Program for Mass Media	lssyk-kul	August 11-15, 2014	30

<u>2015</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Clinical Use of Blood - Miguel Lozano	Bishkek	March 28-29, 2015	27
Equipment validation - Jean Stanley	Bishkek	March 30-April 1,2015	27
Clinical Use of Blood	Batken	May 4-7, 2015	27
Clinical Use of Blood	Djalalabad	May 18-20, 2015	28
Clinical Use of Blood	Bishkek	May 25-30, 2015	21
Clinical Use of Blood	Osh	June 1-4, 2015	36
Clinical Use of Blood	Talas	June 8-10, 2015	29
Clinical Use of Blood	Naryn	June 15-17, 2015	27
Clinical Use of Blood	Kara-kol	June 18-20, 2015	18
Clinical Use of Blood	Uzgen	August 17-19, 2015	22
Clinical Use of Blood	Cholpon-Ata	August 27-29, 2015	20
Clinical Use of Blood	Kyzyl-Kiya	September 2-5, 2015	32
Clinical Use of Blood	Bozor-Kurgan	September 9-12, 2015	34
Safe Blood Donation	Bishkek	October 13-14, 2015	36
Self-assessment and Accreditation	Bishkek	October 13-14, 2015	36

<u>2016</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Development SOPs for Blood centers	lssyk-kul	May 23-27, 2016	20
On-site training on Quality Assessment and preparation to accreditation	Batken	June 18-21, 2016	6
On-site training on Quality Assessment and preparation to accreditation	Jalalabad	June 22-25, 2016	15
On-site training on Quality Assessment and preparation to accreditation	Naryn	October 18-19, 2016	13
On-site training on Quality Assessment and preparation to accreditation	Kara-kol	October 20-21, 2016	6
On-site training on Quality Assessment and preparation to accreditation	Talas	October 25-26, 2016	12
On-site training on Quality Assessment and preparation to accreditation	Batken	November 8-9, 2016	6
On-site training on Quality Assessment and preparation to accreditation	Osh	November 10-11, 2016	15

<u>2017</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Round Table Meeting: Accreditation Standards for Kyrgyz Republic	Bishkek	March 10, 2017	27
Workshop on Development Accreditation Standards	lssyk-kul	August 14-17, 2017	20

Webinars

Date	Торіс
January 16, 2015	Equipment Validation Plan
November 24, 2016	Equipment Validation Plan
December 7, 2016	Infection Control and Blood Safety
December 21, 2016	Documentation System
January 11, 2017	Cold chain and Inventory Management
April 5, 2017	Status and Prospects of the Blood Service in Kyrgyzstan
April 11-12, 2017	(I) Experience of Implementing Transfusion Committee in Kazakhstan Republic (2) Implementation of external audit as effective hemovigilance tool for quality improvement of Transfusion Committee in Kazakhstan Republic
July 11, 2017	Clinical Transfusiology: Acquired Coagulopathy, IVDC
July 12, 2017	Acute Hemorrhagic Shock

Final Report: Project to Strengthen Blood Transfusion Services

July 18, 2017	Alternative Therapy with Colloids
July 19, 2017	Obstetrician Bleedings
July 25, 2017	Hemostasis in Surgery

List of Publications

- National Guideline on the Clinical Use of Blood
- Prikaz 272
- Prikaz 544
- Prikaz 666
- SOPs
- Quality and Technical Standards for the Blood Services of the Kyrgyz Republic
- VNRBD Plan



Background

In January 2013, AIHA traveled to Tajikistan to meet with CDC/Asia and MoH to introduce the project and agree on the preliminary plans to conduct the initial assessment. AIHA returned in February 2013 with representatives from CDC and technical consultants from HEAP in order to conduct preassessment visits in Dushanbe and Khatlon Oblast. Unfortunately, the trip was cut short following a meeting with Dr. Aziz Odineav, the Director of the RBC, who refused technical assistance from the project. As a result, the project was forced to come to a halt.

However, on October 23, 2014, the MoH approved the request by CDC / Central Asia on behalf of AIHA to provide technical assistance in Tajikistan. A work plan was agreed on by Dr. Odinaev for technical assistance consisting of a course on clinical use of blood and training on the pathology of hemostasis.

Transfusion Medicine

AIHA conducted the first of three bedside training on the clinical use of blood at three Republican hospitals in Dushanbe. A two-day training session was presented on February 3-4, 2015, at the Republican Medical Center, the largest medical facility in Tajikistan. AIHA also facilitated two on day training sessions at the Republican Oncologic Hospital and at the Republican Perinatal Center prescribing clinicians and senior nursing staff were trained. Additional trainings were conducted in Hudjan and Kurgan-Tyube in May 2015 and, respectively 72 and 65 clinicians were trained.

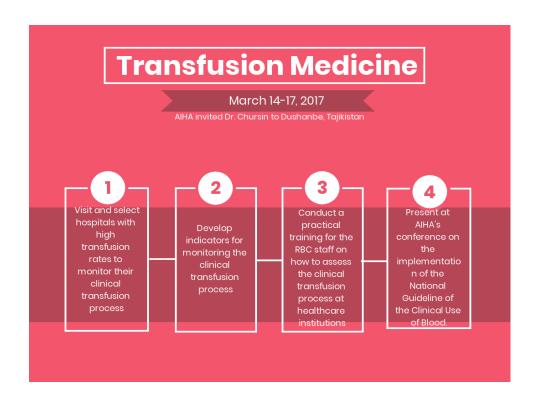


A bedside training for clinicians on the clinical use of blood took place October 28 - 30, 2015, in the Kulyab oblast. The trainings included presentations on blood components, including the indications, dosage, pre-transfusion testing, and contraindications; hemostasis; assessment on the efficiency of transfusion in emergency care; and post-transfusion adverse events – diagnosis, classification and emergency care. Clinical cases on adverse events and reactions following transfusion were presented for discussion.

• AIHA provided technical assistance to the RBC and facilitated a round table discussion on December 13, 2016 with representatives from RBC and OBC, and other key clinicians to review the National Guideline on the Clinical Use of Blood. From January to March 2017, AIHA provided technical assistance on finalizing the guideline. In June 2017, AIHA printed and distributed one thousand copies of the guideline to the blood service. The guideline is a formative document for Tajikistan on the storage, transportation, and clinical use of blood and its components. The guideline is in both Russian and Tajik.



- From March 14-17, 2017, AIHA invited Dr. Chursin to Dushanbe, Tajikistan to (1) visit the RBC and select hospitals with high transfusion rates to monitor their clinical transfusion process, (2) develop indicators for monitoring the clinical transfusion process (3) conduct a practical training for the RBC staff on how to assess the clinical transfusion process at healthcare institutions, and (4) present at AIHA's conference on the implementation of the National Guideline of the Clinical Use of Blood.
- On March 16, 2017, AIHA conducted a conference for 57 participants, including RBC staff, OBC staff, and hospital clinicians, to discuss the implementation of the National Guideline on the Clinical Use of Blood.
- AIHA developed monitoring forms to assess the clinical transfusion process at hospitals. AIHA
 used the monitoring forms developed for AIHA's Blood Safety Project in Kyrgyzstan and
 adapted them for the blood service in Tajikistan.



Quality Management

- A QM assessment was conducted from February 7 13, 2016 at the RBC in Dushanbe using the
 assessment checklist created for Kyrgyzstan. International consultant, Dr. Zinkin, and Dr.
 Makhmudova conducted the assessment and provided on-site training and guidance in quality
 system documentation, shared a template for SOPs, assisted in the development of an
 organogram, and an inventory list of equipment.
- National training on QMS and development of clinical guidelines was conducted in Dushanbe by Dr. Zinkin and Dr. Makhmudova on May 30-June 3, 2016 for 30 participants from the RBC and at the national level. The aim of the training was to strengthen the QMS on a national level and to develop national guidelines on the clinical use of blood.

Other Activities

- AIHA sponsored two participants from Tajikistan to present at the October 2014 regional
 conference in Kyrgyzstan. AIHA also sponsored one participant from Uzbekistan and two
 participants from Tajikistan appointed by their respective ministries of health to attend the
 September conference in Almaty.
- In March 2015, an international expert conducted an assessment of the CIMS at the RBC and an
 affiliated center. The assessment was in response to a number of complaints by the RBC
 regarding the CIMS. AIHA's technical expert provided a written report with observations and
 recommendations for improvement in the use of the CIMS in April 2015.

Training Chart

2015

Title of Training	Training Location	Date of Training	Total Number Trained
Clinical Use of Blood & Hemostasis	Dushanbe	February 4-8, 2015	60
Clinical Use of Blood & Hemostasis	Khudjand- Oblast Maternity Hospital	May 5, 2015	32
Clinical Use of Blood & Hemostasis	Khudjand- Oblast Maternity Hospital	May 6, 2015	40
Clinical Use of Blood & Hemostasis	Kurgan-Tube - Oblast Hospital	May 6, 2015	40
Clinical Use of Blood & Hemostasis	Kurgan-Tube – Maternity Hospital	May 7, 2015	25
Clinical Use of Blood & Hemostasis	Kulyab-Tube - Oblast &Maternity Hospital	October 29-30, 2015	58

2016

Title of Training	Training Location	Date of Training	Total Number Trained
QM and Development of Clinical Guidelines	Dushanbe, SRBC	May 30-June 4, 2016	30
Round Table for discussion Clinical Guidelines	Dushanbe, SRBC	December 13, 2016	14

2017

Title of Training	Training Location	Date of Training	Total Number Trained
Conference: Implementation of the National Guideline on Clinical Use of Blood	Dushanbe	March 16, 2017	57
Practical Training: Conducting Audits in Transfusion Care	Dushanbe	March 17, 2017	8

List of Publications

National Guideline on the Clinical Use of Blood

PROJECT RESULTS <u>UKRAINE</u>



Background

In December 2012, AIHA traveled to Ukraine and met with representatives from CDC/Headquarters and CDC/Ukraine to kick off the project and discuss the approach, the current status of blood safety in Ukraine, etc. AIHA returned to Ukraine in February 2013 to meet with the MoH and conduct a national stakeholder meeting in order to introduce the project and the baseline assessment. The baseline assessment was conducted from April to September 2013 in six pilot sites with technical assistance from CDC/Ukraine and experts from Global Healing:

- April 13 20, 2013: Zhytomyr and Kyiv Oblast (Bila Tserkva)
- May 25 June 1, 2013: Lviv and Rivne
- July 15 19, 2013: Kyiv City and Lugansk
- September 16-20, 2013: Odessa

After completing the baseline assessment, AIHA sponsored a three-day stakeholder meeting in October 2013, gathering representatives from the pilot sites, the MoH, State Service of Ukraine to Counter-act HIV/AIDS and other Socially Dangerous Illnesses (SSH), National Medical Academy of Postgraduate Education (NMAPE), non-governmental organizations, and the public relations group MCG. The purpose of the meeting was to present the findings and recommendations of the assessments conducted earlier in the year and to begin developing work plans based on these recommendations.

Following a meeting with the MoH, seven blood centers and their hospitals with the highest blood use were selected as pilot sites for the project. The blood centers are Kyiv City Blood Center, Kyiv OBC, Zhytomyr OBC, Rivne OBC, Lviv OBC, Lugansk OBC, Odessa OBC, and OHMATDIT – a national specialized children's hospital in Kyiv. Unfortunately, Lugansk OBC was removed as a pilot site due to the ongoing turmoil and fighting in Eastern Ukraine.

Clinical Use of Blood

- On April 26, 2017, AIHA participated in the VI-th International Medical Forum Congress in Kiev and co-organized sessions on transfusion medicine with the NMAPE. The project-trained, local experts presented on topics, including the clinical use of blood, hemovigilance, and QMS. In total, 135 participants attended.
- In September 2017, AIHA conducted one Training-of-Trainers (TOT) in Kiev for ten local specialist in transfusion and clinical medicine.
- From September to December 2017, six on-site trainings on the appropriate clinical use of blood components were conducted in all pilot oblasts of the project, with a total of 492 participants trained.
- From January to February 2018, AIHA conducted a series of webinars on the appropriate clinical use of blood for hospital staff from the project sites.

Computer Information Management System

• In In collaboration with SSH, AIHA provided assistance in the process of selecting a CIMS for a national donor registry. An international consultant assessed two computer systems at Kyiv OBC and provided a report on observations and recommendations. This information was also



- shared with the OBCs in March 2014. AIHA worked with CDC to provide input to a draft concept document and offered work group recommendations for the national CIMS.
- In July 2014, AIHA's international consultant provided assistance in the development of URS with a small TWG. No further assistance was provided due to the dissolution of SSH, which was reorganized under the MoH.
- AIHA also provided information on the implementation of a barcoding system as an interim step
 to the CIMS and ISBT 128 requirements. Technical assistance was offered for a hardware
 assessment, however the MoH decided to use local experts.
- MoH identified two CIMS existing in Ukraine to be assessed by AIHA expert: Kharkiv system and Crystal Finance.
- From March 20-24, 2017, AIHA invited Eileen Selogie to Kyiv and Kharkiv, Ukraine to evaluate two existing CIMS previously identified by the MoH. The objective of the assessment is to determine if either system meets the safety and reliability requirements for use in a national blood system. The vendors of both CIMS, Crystal Finance Millennium and IC-Smart, provided a demo of their product, additional information, and answers to questions during the assessment. Dr. Voloc and Dr. Serhiienko traveled to Kharkiv from August 14-16, 2017 and Zaporizhzhia from August 28-30, 2017 to collect additional information on the CIMS in order to strengthen the CIMS assessment report.

Donor Management

- An introduction to raising public awareness of the need to donate blood was first addressed at the stakeholder meeting in October 2013.
- In 2014, AIHA collaborated with NMAPE to develop a manual on donor marketing and donor recruitment. Two international experts contributed to the manual and NMAPE's Oleksandr Sergienko added information on current Ukrainian blood donation laws. Together, the material was published as a practical handbook that could be referred to as a reference for blood services. NMAPE also had the authority to give the handbook the stamp of the Ministry of Education, so that it can be used as a textbook at the university level.
- AIHA engaged two international experts to conduct a workshop on donor recruitment at Feofania Clinical Hospital in Kyiv in October 2014. A total of 19 individuals representing the pilot sites, Feofania Clinical Hospital, students from the NMAPE specialization course on transfusiology, Krov.ua, and NMAPE participated. The first day provided an introduction to donor recruitment, including defining the elements that make up the Donor Recruitment Department and the role of a donor recruiter, how to plan projections, working with other departments in the blood center, and establishing relationships with the community. Local best practices from Zhytomyr



OBC, Rivne Oblast Hospital, and Krov.ua were also shared with the participants. The second day focused on building a brand for a cause, creating key messages, communicating during crisis and challenging times and presentation of a toolkit of materials including flyers, banners, postcards, etc., that each facility could take home and use. As with the other workshops and trainings, NMAPE also provided attestations for continuing education for the participants through the Kyiv City Health Administration. In December, it was noted that the templates

- from the toolkit were being displayed on billboards in Kyiv Oblast. In addition, several of the participants had incorporated some of the banners on their Facebook page. The same two international experts also participated in the transfusiology section of the annual NMAPE conference. The two experts spoke briefly on the same topics as the workshop.
- A two-day training-of-trainers workshop on donor collection and donor care was conducted September 2014 for 16 heads of collections departments and quality managers. The workshop was taught by an international consultant in Bila Tserkva at the Kyiv OBC. In addition to theoretical information, participants practiced the proper technique for an arm scrub when preparing the venipuncture site and role-played communication skills with the donor during the donation process. A training manual developed by the international expert and in collaboration with NMAPE was provided to the participants. Attestations for continuing education for the participants were provided by NMAPE through the Kyiv City Health Administration.
- In January 2015, a webinar on recognition and treatment of donor adverse events was presented to 20 blood center directors, donor collection staff, and quality managers.
- As a follow-up to the September donor management and donor care workshop, a Skype
 conference took place in December with the consultant who taught the course and the
 participants from the workshop. Participants shared the improvements made at their facilities
 since the workshop, including training of staff, adhering to the procedure, and incorporating
 more interaction with the donor. A couple of sites were changing the procurement of blood
 bags to those with diversion pouches to reduce the risk of bacterial contamination.
- A June 13, 2016 meeting took place with Iryna Slavinska, President of the Ukrainian Association
 of Young Blood Donors, (krov.ua / donor.ua) to discuss project plans, priorities and their
 suggestions for collaboration to strengthen project sustainability such as promotion of voluntary
 unpaid donations at the Kyiv OBC, better use of donor.ua database for ensuring provision of
 better information for donors, and identifying HIV-positive persons to enter HIV care and
 treatment programs.

Education and Capacity Building

- In terms of local capacity building, representatives from some of the pilot sites have become more involved in national activities. Dr. Tetyana Tereshchuk, deputy head of Quality from Zhytomyr OBC, presented during the March 15-16, 2016 laboratory conference on practical aspects of quality audits, processes and procedures, both in the plenary session and in the breakout session for blood service staff. Dr. Oksana Mulyarchuk, Deputy Head Physician on Quality in Kyiv City Blood Center, was the head specialist in the medical department of the MoH of Ukraine from March to September 2017, and has been taking a leading role in developing processes to address the linkage between the blood center and HIV/AIDS center in Kyiv City. Dr. Oleksandr Serhiienko, from Kyiv City Blood Center and representative of NMAPE, had been appointed the head of the blood safety sector of the MoH from April to June 2016, and is now the blood safety technical expert for AIHA. Dr. Oksana Maryniuk, Deputy Head Physician on Organization at Kyiv City Blood Center, is a member of the TWG of the Public Health Center of the MoH of Ukraine on hepatitis prevention strategy. Several experts from the project pilot sites have participated as members of the MoH of Ukraine TWG on Blood Safety.
- From October 22-25, 2016, Dr. Alexandru Voloc, AlHA/Ukraine's Country Director and Dr. Oleksandr Serhiienko, AlHA/Ukraine's Blood Safety Technical Expert, participated and presented a poster titled "Strengthening the blood service in Ukraine" at the AABB Conference in Orlando, Florida.
- From December 7-8, 2016, AIHA conducted its annual stakeholders meeting in Kyiv.

- On October 4, 2017, AIHA presented on "National Blood System: European commission requirements" at the Scientific and Practical Conference with International Participation "Plasma for fractionation. Reality and perspectives" organized by the All-Ukrainian Association of Blood Service of Ukraine.
- On October 10, 2017, AIHA Blood Safety Technical Expert, Dr. Oleksandr Serhiienko, participated in MoH roundtable on "Government regulation of donor blood components and medicinal products collection and production".
- On December 5, 2017, AIHA conducted a stakeholders meeting to discuss project results and achievements over the past five years and the next steps for project continuity and sustainability.
- On January 30, 2018, AIHA participated in the U.S. PEPFAR Ukraine 2018 Country Operational Plan Stakeholder Meeting.
- On March 13, 2018, AIHA presented on project achievements at the Annual Conference for the Ukrainian Association of Laboratory Diagnostics.
- The Association of Blood Transfusion Services of Ukraine invited AIHA to present at their April 2014 conference on blood safety. The meeting was geared toward scientific attendees. AIHA presented on the topic of "Compatibility Testing in the United States," which was well received. Approximately 45 people were in attendance.
- In October 2014, CDC / Ukraine Blood Safety Advisor Dr. Nataliya Podolchak participated as a speaker in the AABB Annual Meeting program, "Global Blood Safety Programs," describing the blood services in Ukraine, along with current challenges and steps being taken to strengthen blood safety. In addition, Dr. Podolchak participated in a study tour that included the American Red Cross Biomedical Services Penn-Jersey Region in Philadelphia, the University of Pennsylvania Hospital Transfusion Service, MBCs and HCMC in Minneapolis.



Infrastructure

• In February 2014, AIHA conducted a two-day training on cost accounting to a select number of blood center directors and their financial accountants, along with representatives of the MoH. The aim of the training was to introduce participants to a cost accounting method that includes all aspects of operations related to the collection and processing of blood and blood components. The intended outcome was to develop a standardized methodology for all blood centers to use as a way to determine the real cost of a unit of blood. As a result of the interactive training session, it was determined that a costing model would be developed by the participating centers.



• On July 15, 2015, a stakeholders meeting took place in Kyiv with representatives from the MoH and all project pilot sites. The purpose of the meeting was to provide an update on project activities, sharing of information from the Sweden study tour that took place in May, and future plans. During this meeting, the MoH announced that it supported the formation of a blood advisory group that would communicate directly with the MoH on blood safety issues per AlHA's recommendation. The first official meeting of this group, called a Coordinating Council, took place on

September 28, 2015.

With assistance from AIHA, the Central California Blood Center (i.e. the project's former partner) and the Charity Fund "Ukrainian Resource Center" donated a bloodmobile to the MoH for the blood service in Ukraine. A bloodmobile is a mobile blood donation center. which is equipped with everything necessary for a blood donation procedure. The donated bloodmobile is the first bloomobile ever to be in use in Ukraine. Using this bloodmobile, the Kyiv City Blood Center



collected 30 units of whole blood. On July 18, 2017, AlHA, MoH, and the Charity Fund "Ukrainian Resource Center" co-organized a blood drive at the MoH to officially present the bloodmobile.

- On March 19, 2018, AIHA, as members of the MoH TWG on Blood Safety, provided technical assistance to the Public Health Center in calculating the cost of equipping a blood center according to the WHO and EU requirements.
- On March 22, 2018, AIHA participated in a meeting for the MoH TWG on Blood Safety on the updated Strategy of Blood System Development in Ukraine.

Inventory and Cold Chain Management

From October 3-6, 2016, AIHA conducted a training in Zhytomyr on inventory and cold chain management based on EU requirements. AIHA supported two international consultants from the blood center in Barcelona, Dr. Joan Grifols and Dr. Jaime Tabera, to lead the training for 29 participants. The training presented the principles of equipment qualification and



- validation in blood storage, issuing, and transportation, explained how to align the national regulation on blood storage and transportation with the EU requirements, and reviewed the best practices for inventory management.
- On December 6, 2017, AIHA conducted a TOT on inventory and cold chain management in Kyiv, Ukraine.
- In February and March 2018, AIHA conducted a set of trainings for hospital staff in Kyiv City pertaining to (1) the organization of blood banks in healthcare establishments and (2) inventory management and transportation of donor blood and blood components.

Linkage to HIV Care and Treatment

 From December 2017 to March 2018, AIHA granted a subaward with the All-Ukrainian Network of People Living with HIV/AIDS to implement activities that link blood donors with a confirmed HIV test result into the cascade of HIV/AIDS prevention, care and treatment services in Kyiv City.



Transfusion Transmitted Infections

A five-day workshop on testing of TTI was
conducted on April 4 – 8, 2016. Dr. Margarida Amil and Francisco Dias, EU consultants with
expertise in donor testing delivered the workshop for 35 participants from the project
demonstration sites and Feofania Hospital. The consultants addressed international standards of
practice for TTI testing as well as moderated discussions with the participants on current
practices and regulatory requirements for TTI testing in Ukraine.

Quality Management

- AIHA was invited by Zhytomyr OBC and NMAPE to participate in a course on QM in December 2013. The course was a repeat of one given the previous May, which included a week of practical training at the blood center QC laboratory followed by a five-day QM course conducted by AIHA consultants. AIHA sponsored representatives from the pilot sites and Jean Stanley, AIHA Principal Investigator, and Mary Lieb, U.S. blood bank expert on QMS conducted this training.
- The AIHA team helped develop quality indicators for collecting baseline data from the pilot sites. Metrics included indicators that were not monitored or evaluated on the mandatory Form 39 report. The indicators were submitted to the pilot sites for input and evaluation on ability to collect the requested data in March 2014. However, the MoH must give official approval before data can be collected. An introductory training on monitoring and evaluation for 13 blood center directors, deputy directors, and quality managers was provided via webinar in July 2014.

- AIHA sponsored a five-day TOT workshop on equipment validation at OHMATDIT in September 2014 in collaboration with NMAPE. An international consultant taught 12
 - participants how to write a validation plan including installation qualification, operational qualification, performance qualification, and discrepancy resolution. The practical example for validation was performed on a new centrifuge for component preparation at OHMATDIT. The AIHA trainer also provided equipment validation manuals to participants.
- Following a PEPFAR Site Improvement through Monitoring System (SIMS) assessment of Kyiv City Blood Center in December 2014, it was determined that all pilot sites needed to strengthen their QM programs, including a focus on quality improvement.
- AIHA provided training that included a
 webinar in January 2015 on reviewing quality
 systems and developing a quality policy. Some 25 blood center directors, quality managers, and
 representatives from the MoH participated.
- In February 2015, AIHA conducted a workshop on quality plan development for 21 quality managers and department heads from the pilot sites. At the end of this workshop, a generic quality plan was developed that could be customized to meet the needs of each pilot site.
- A webinar training was provided on quality indicators and critical control points in March 2014, for 23 participants from the pilot sites.
- In April 2015, a two-day workshop was conducted on the recognition, prevention and treatment of donor adverse reactions and an introduction to quality management, improvement and auditing. The workshop took place at the Zhytomyr OBC with participation from heads of departments of Zhytomyr blood centers and the local transfusion service, collection staff and quality managers from other pilot sites, the head of the local blood center's AIDS laboratory, and a representative from NMAPE.
- In July 2015, AIHA conducted a QM workshop on continuous quality improvement for quality managers and head physicians from the blood service to reinforce an understanding in identifying critical control points in quality system processes and selecting quality indicators as a method for measuring performance. During this workshop, AIHA also introduced the European Blood Inspection System (EuBIS) inspection guide to the pilot sites in order to conduct selfassessments.
- In August 2015, AIHA spent time in Bila Tserkva with the staff at the Kyiv OBC, who agreed to pilot the Quality System sections of the EuBIS guide. The intent of the pilot was to determine if the guide would be usable and what preparations would be required in terms of technical assistance, before asking our pilot sites to perform a self-assessment. It was determined that a general review should be conducted with all pilot sites prior to the self-assessment.
- A five-day workshop was conducted by AIHA on the quality and technical requirements according to the EU directives. The workshop took place from February 22 26, 2016 at Feofania with 30 participants from the demonstration sites, Kyiv City Blood Center, and Feofania. The aim of the workshop was to review the EuBIS Inspection checklist which was used by the pilot sites for conducting a self-assessment. The workshop included practice activities, such as developing a training plan, training checklist and competency evaluation, developing a process validation plan, and reviewing corrective action-preventive action case studies that

- included presentations by the participants. The final report was developed and provided to CDC on September 2, 2016.
- Judy Sullivan, an international consultant in quality, participated in a scientific and practical conference on "Building a Quality System for Clinical Laboratory Testing in Ukraine," organized by the Association of Quality Assurance in Laboratory Medicine in Ukraine. Ms. Sullivan gave a presentation during the plenary session, conducted a breakout session for Blood Service and Microbiology representatives on QMS, and a master class for all participants on QMS. On March 17, Ms. Sullivan spent the day at OHMATDIT and provided a workshop for the staff at the National Reference Laboratory on the topic of ISO15189 accreditation, including steps for preparation towards accreditation and her perspective as an inspector. Ms. Sullivan also met with the Department of Transfusiology staff and provided guidance on implementation of their quality system.
- In May 2016, AIHA has signed trilateral agreements with Ukrmedlab and six pilot sites to cover
 the cost of control panels for participation in proficiency testing/external quality assessment for
 HIV, HBV, HCV and syphilis testing. All project blood centers have participated in this external
 quality assessment (EQA) program for HIV testing and passed.
- From November to December 2016, AIHA supported the development of a QMS TOT manual written by 12 national experts and reviewed by Dr. Serhiienko and Jean Stanley. The draft version of the manual was presented at AIHA's annual stakeholder's meeting in December 2016. AIHA printed 800 copies of the manual for distribution to the blood service. The manual included a data storage device with electronic files of document templates and video lectures, including all of the QMS webinars that AIHA has conducted.
- From December 5-6, 2016, AIHA organized a QMS TOT for 12 national experts in Kiev. The TOT was led by Dr. Serhiienko and Jean Stanley. The training discussed how to effectively give a presentation and conduct a training. Based on this primer, the participants provided feedback on the QMS presentations that the national experts had already prepared for the All-Ukrainian Blood Service Association conference.
- From December 8-9, 2016, AIHA supported the All-Ukrainian Blood Service Association in conducting a national conference with participation from head physicians and other representatives from all the blood establishments in Ukraine. The conference focused on the
 - basic principles of a QMS for nonproject blood service sites. The training was conducted by the national trainers that participated in the TOT from December 5-6, 2016.
- In December 2016, all six of AIHA's blood service sites participated in stage II of the EQA scheme on viral hepatitis and HIV lab testing accuracy to ensure continuous quality assurance of the project's testing premises. In September 2017, the AIHA's project sites also participated in stage III of the EQA scheme. AIHA purchased the control panels for the



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В САУЖБІ КРОВІ

- National Reference Laboratory for Clinical Diagnostics and Metrology to conduct the assessments. The project sites showed 100% performance on all testing assessed.
- From March to April 2017, AIHA conducted on-site trainings on QMS in all six project sites to build the capacity of local experts and project sites. They were led by local trainers with guidance from Dr. Serhiienko.



SIMS

	CINAC		" CCE	Score, %				
#	SIMS Date	Blood Establishment	# CCEs assessed	Dark	Light	Yellow		
			assessea	green	green	T CIIO W		
I	05-29- 15	Zhytomyr OBC	2	100				
2	06-18- 15	Rivne OBC	2	50	50			
3	11-11- 15	Kyiv City Blood Center	2	50	50			
4	11-20- 15	Kyiv Oblast OBC	2	100				
5	08-09- 16	Odesa OBC	2	100				
6	08-09- 16	Transfusion Department- Odesa Oblast Pediatric Clinical Hospital	2	50	50			
7	07-28- 16	Lviv OBC	2	50	50			
8	07-28- 16	Transfusion Department - Lviv City Emergency Hospital	2		50	50		
9	07-11- 17	Zhytomyr OBC	2	100				
10	08-10-	Lviv OBC	6	50	50			
11	17	Transfusion Department - Lviv City Emergency Hospital	7	43	43	14		
12	08-11-	Rivne OBC	6	83	17			
13	17	Transfusion Department – Rivne Oblast Hospital	6	33	50	17		
14	09-19- 17	Kyiv OBC	5	60	40			
15	09-21-	Odesa OBC	5	80	20			
16	17	Transfusion Department – Odesa Oblast Pediatric Hospital	5	80	20			
17	03-17- 17	AIHA office (A_03_02 – In-service training)	I	100				
18	03-25- 17	Kyiv City Blood Center	2	100				

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	06-19-	Transfusion Department/Blood Center -				
19	17	National Specialized Pediatric Hospital	2		100	
	17	OHMATDITmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmm				

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Training Charts

<u>2013</u>

Title of Training	Training Location	Date of Training	Total Number Trained
QM in Blood System	Zhytomyr OBC	December 9-12, 2013	П

<u>2014</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Cost Accounting. Calculation of the cost of one unit of blood	Kyiv OBC	January 21-22, 2014	П
M&E Training	Skype	July 29, 2014	13
Hemovigilance	Skype	September 3, 2014	10
Donor Care	Kyiv OBC	September 11-12, 2014	16
Validation of Equipment for Blood Component Production	National Pediatric Hospital	September 15-19, 2014	12
ToT: Donor Recruitment	Feofania Clinical Hospital	October 14-15, 2014	19
Follow-up to September ToT: Donor management and care	Skype call	December 18, 2014	5

<u>2015</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Donor Reactions	Webinar	January 28, 2015	20
Follow-up to September ToT: Equipment validation	Skype call	January 21, 2015	5
Quality Systems	Webinar	February 4, 2015	25
Quality Indicators	Webinar	March 3, 2015	23
Quality Plan	Kyiv City Blood Center	February 16-17, 2015	21
Follow-up to Quality Plan and Quality Indicators	Skype/ Webinar	March 19, 2015	10
Donor Reactions	Zhytomyr OBC	April 15, 2015	20
Internal Audits	Zhytomyr OBC	April 15, 2015	20
Quality Management	Zhytomyr OBC	April 16, 2015	25
Continuous Quality Improvement	Kyiv City Blood Center	July 16, 2015	19
EuBIS guide for self-assessment	Kyiv OBC	August 31 – September 2, 2015	9
QMS/ Quality Improvement	Lviv OBC	December 7-8, 2015	35

<u>2016</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Self-assessment of the Blood Service using the EuBIS Inspection tool, CoE/EDQM GPG and guidelines and the EC Directive 2005/62/EC	Feofania Clinical Hospital	February 22- 26, 2016	30
TTI testing in blood service based on EU requirements and standards	Feofania Clinical Hospital	April 4-8, 2016	35
Inventory and Cold Chain Management	Zhytomyr OBC	October 3-6, 2016	29
QM in Blood Service TOT Workshop	Kyiv	December 5- 6, 2016	12

<u>2017</u>

Title of Training	Training Location	Date of Training	Total Number Trained	
QMS Onsite Training	Kiev City Blood Center	March 10, 2017	37	

QMS Onsite Training	Rivne OBC	March 16-17, 2017	42
QMS Onsite Training	Odesa OBC	March 23-24, 2017	35
QMS Onsite Training	Kyiv OBC	March 31, 2017	34
QMS Onsite Training	Zhytomyr OBC	April 6-7, 2017	45
QMS Onsite Training	Lviv OBC	April 19-21, 2017	75
Clinical Use of Blood TOT Workshop	Kyiv City Blood Center	September 25, 2017	17
Clinical Use of Blood Onsite Training	Odessa OBC	September 28-29, 2017	187
Clinical Use of Blood Onsite Training	Zhytomyr OBC	October 24, 2017	40
Clinical Use of Blood Onsite Training	Rivne OBC	October 26, 2017	92
Clinical Use of Blood Onsite Training	Lviv OBC	November 9-10, 2017	135
Clinical Use of Blood Onsite Training	Kyiv OBC	November 16, 2017	41

<u>2018</u>

Title of Training	Training Location	Date of Training	Total Number Trained
Organization of hospital blood banks in healthcare facilities	Kyiv Center of Emergency Medical Assistance and Medical Catastrophes	February 9, 2018	116
Organization of hospital blood banks in healthcare facilities	Kyiv City Blood Center	February 26, 2018	12
Strengthening activities to engage donors of blood and its components with a proven HIV test result in the HIV / AIDS prevention, care and treatment cascade in Kyiv	Ratsiotel Hotel, 52 Yamska St., Kyiv	March 1-2, 2018	22
Strengthening activities to engage donors of blood and its components with a proven HIV test result in the HIV / AIDS prevention, care and treatment cascade in Kyiv	The training center of the Charity Foundation "Network of People Living with HIV/AIDS"	March 12- 13, 2018	22
Inventory management	Kyiv City Blood Center	March 29, 2018	8

Webinars

Date	Торіс
May 4, 2017	QMS: Introduction
May 4, 2017	QMS: Regulatory framework of blood system in Ukraine
May 12, 2017	QMS: Personnel
May 12, 2017	QMS: Premises
May 16, 2017	QMS: Organization and Management
May 18, 2017	QMS: Documentation
May 23, 2017	QMS: Equipment and materials
May 29, 2017	QMS: Quality assurance. Qualification and validation
May 31, 2017	QMS: Evaluation. Audit
June 1, 2017	QMS: Evaluation. External quality assessment
June 7, 2017	QMS: Non-conformances Management
June 7, 2017	QMS: Process Improvement
June 9, 2017	Process Control: collection of donor blood and components
June 9, 2017	QMS: Process Control: Testing
June 12, 2017	QMS: Control process: Storage and Distribution
June 13, 2017	QMS: Process Control: Processing
June 13, 2017	QMS: Customer service
July 24, 2017	QMS: Supply Management
July 24, 2017	QMS: Change Control
July 25, 2017	QMS: CIMS
January 25, 2018	Appropriate Use of Blood Components: Introduction
January 26, 2018	Appropriate Use of Blood Components: Transfusion reactions
January 26, 2018	Appropriate Use of Blood Components: Blood Components: nomenclature, preparation, properties
January 29, 2018	Appropriate Use of Blood Components: Platelets
January 29, 2018	Appropriate Use of Blood Components: Plasma and Cryoprecipitate
January 30, 2018	Appropriate Use of Blood Components: Red Blood Cells
January 30, 2018	Appropriate Use of Blood Components: Pre-transfusion tests

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January 31, 2018	Appropriate Use of Blood Components: Organization of hospital blood banks in healthcare facilities
January 31, 2018	Appropriate Use of Blood Components: Hemovigilance

List of Publications

- Donor Management and Recruitment
- Quality Management in Blood Service Manual

Project Challenges

During the first meeting with CDC/Headquarters and WHO, AIHA was informed that funding for the project would be significantly reduced. Funding remained to be a key challenge in implementing the project in accordance with the original plan and with recommendations from the needs assessments. However, AIHA used the available resources to build the national capacity and actively engaged local specialist in project implementation.

Central Asia

• Kyrgyzstan:

- The MoH provided very limited financial support for the blood service.
- The management team at the RBC was weak and there was a lack of local experts at the beginning of the project.
- The regulatory framework for the blood service and transfusion medicine was outdated.
 Some regulations were not updated since the 1990s.

Tajikistan:

- There were conflicting priorities between project stakeholders for collaboration under this project. Specifically, Dr. Odinaev, the Director of the RBC, requested to procure supplies, such as blood bags. Therefore, Dr. Odinaev did not see a value of building technical capacity of his staff through trainings. However, due to continuous support from CDC, AIHA was able to implement a lot of activities in Tajikistan.
- Closeout in Central Asia: AIHA did not receive the expected funding for the final year of the
 project. In turn, AIHA had to abruptly stop project implementation in Central Asia in September
 2017. As a result, AIHA was not able to organize a closeout conference and limited closeout
 activities to preparing the Project Closeout Report.

Ukraine

- The MoH in Ukraine has been undergoing structural changes, which slowed the process of document discussion and approval.
- Not having a NBTC made it difficult to coordinate national efforts pertaining to blood safety.
- The political and military unrest in Ukraine resulted in delayed project implementation at the beginning of the project and the decision to not work with Lugansk OBC as a project site.

Project Sustainability

Through this project and with the continuous support of CDC and other stakeholders, AIHA was able to successfully strengthen the local capacity of the blood service.

- At the beginning of the project, the concept of QMS was very new to the blood service in all of
 the project's countries. However, starting from the third year of the project, the local experts
 led the development of national regulations, manuals, and SOPs, the facilitation of trainings, and
 the revision of postgraduate courses on this concept. These local experts are now considered
 leaders in the field of blood safety in their respective countries.
- In collaboration with local and international experts, AIHA helped to revise and update national guidelines in all of the countries. AIHA also supported the printing and distribution of the updated guidelines in order for them to be easily accessible and utilized by the blood service.
- Further, AIHA implemented innovative approaches in order to ensure the sustainability of the project. For example, AIHA started to provide trainings via webinars as of the third year of the project. Specifically, AIHA developed a set of webinars on QMS, clinical use of blood, VNRBD, etc. The webinars are now actively used at the national level, especially in Ukraine, for continuous professional development. These webinars have also been archived online so that the blood service will be able to access them in the future.
- AIHA also ensured that project activities were implemented in accordance with national priorities. For example, Ukraine is working towards becoming apart of the EU. As a result, AIHA actively participated in developing the national strategy for the blood service in Ukraine to align EU regulations. Also, AIHA actively engaged blood safety experts from the EU to provide technical assistance for the project in Ukraine.

Overall, AIHA used a multifaceted approach to ensure the sustainability of the project's achievements.

Concluding Remarks

Central Asia: Kyrgyzstan

Given the opportunity, AIHA recommends focusing technical assistance on the following:

- Accreditation:
 - Provide technical assistance to RBC in organizing monitoring visits to pilot accreditation standards.
 - Engage MAC to finalize the accreditation standards.
- **CIMS:** Support the technical maintenance of the CIMS used at the RBC to ensure the safety and traceability of its blood products.
- Clinical Use of Blood: Conduct monitoring visits for the clinical use of blood at hospitals at the national level.
- **Costing of Blood Products:** Provide technical assistance to the RBC on developing a sustainable financial cost accounting system based on best practice from Kazakhstan.

The majority of these activities were planned for the final year of the project, but not implemented due to the funding constraints explained above.

Ukraine

Due to support from CDC/Ukraine, AIHA was awarded funding to continue providing technical assistance to the blood service in Ukraine through AIHA's HRSA Twinning Center Program. The HRSA project will focus on the following areas:

- Accreditation: Assure that the blood service is working towards achieving compliance by meeting
 the requirements needed for international or national certification via a stepwise approach toward
 accreditation by a national or international accrediting agency for blood banks. Specific activities
 include participating in MoH TWG meetings and implementing the EuBIS self-assessment at a
 national level.
- Linkage between blood establishments and AIDS centers: Assure that blood establishments
 and AIDS centers implement and maintain regular information exchange about the identified people
 living with HIV, confirmatory testing results, and linkage of confirmed HIV-positive individuals to
 AIDS centers. Specific activities include issuing a subaward with the Ukrainian Network of People
 Living with HIV to implement the linkage mechanism in other regions of Ukraine.
- CIMS: Assist the MoH in Ukraine in selecting a CIMS to ensure the accuracy and reliability of data collected and used in determining the safety and acceptability of donors and associated blood distributed for transfusions. Specific activities include finalizing the CIMS assessment report and providing technical assistance for the MoH in implementing National CIMS.
- Education & Capacity Building: Participate in developing the training plan for post-graduate curricula/training that corresponds to international standards of practice. Specific activities include monitoring, conducting webinars, and printing guidelines on clinical use of blood.
- **Testing and Processing:** Enroll the pilot blood establishment that tests donors in an EQA scheme minimally for HIV, HCV, HBV and syphilis.

Acknowledgement

AIHA wishes to express its sincerest gratitude to the countless professionals across the globe who gave so generously of themselves to the project. AIHA's work has been so successful because these individuals demonstrated the courage and commitment to change; the patience, dedication, and hard work to gain new knowledge and skills; and a generous spirit of trust and collaboration. Together they made significant contributions to improving blood transfusion services for the people of Cambodia, Kazakhstan, Kyrgyzstan, Tajikistan, and Ukraine. AIHA also thanks CDC and the Ministries of Health in the selected countries for the opportunity and privilege of working so closely with them and for their steadfast support. Finally, AIHA gratefully acknowledges the contributions of our dedicated staff in Washington, DC, as well as our field office in Ukraine, whose work assured the successful management and implementation of the project and preparation of this report. The contents of this report are the responsibility of AIHA and do not necessarily reflect the views of CDC, the United States Government, or the MOH and governments in the selected countries.

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