



ANNEX C1: Twinning Fiche

Project title: Strengthening Blood Safety System in Georgia

Beneficiary administration: National Center for Disease Control and Public Health, Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

Twinning Reference: GE 18 ENI HE 01 19

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**EU funded project
*TWINNING TOOL***

List of Abbreviations

AA	Association Agreement
BA	Beneficiary Administration
BB	Blood Bank
BE	Blood Establishment
BC	Beneficiary Country
BI	Beneficiary Institution
BSL	Biosafety Level
BTS	Blood Transfusion Service
CDC	Centers for Disease Control and Prevention
DCFTA	Deep and Comprehensive Free Trade Area
ELISA	Enzyme-linked immunosorbent assay
ENI	European Neighborhood Instrument
EQA	External Quality Assessment
EQC	External Quality Control
EQM	External Quality Management
EU	European Union
EUD	EU Delegation to Georgia
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GoG	Government of Georgia
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
ICRC	International Committee of the Red Cross
ISBT	International Society of Blood Transfusion
JAS	Jobs Action Sheet
LA	Legal Approximation
LEPL	Legal Entity of Public Law
MESCS	Ministry of Education, Science, Culture and Sport
MoIDPLHSA	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
MoJ	Ministry of Justice
MS	Member State
NAT	Nucleic Acid Testing
NCA	National Competent Authority
NCDC	National Center for Disease Control and Public Health
NGO	Non-governmental organization
PAO	Programme Administration Office
PL	Project Leader
PSC	Project Steering Committee
PT	Professional Testing
RAMA	State Regulation Agency for Medical Activities
RTA	Resident Twinning Advisor
SOP	Standard Operating Procedure
STE	Short Term Expert
TA	Technical Assistance
TAG	Technical Advisory Group
TAIEX	Technical Assistance and Information Exchange Instrument
ToR	Terms of Reference
TTI	Transfusion Transmissible Infection
VUD	Voluntary Unpaid Donation
WB	World Bank
WHO	World Health Organization

1. Basic Information

1.1 Programme:

EU support for the Implementation of the EU-Georgia Association Agreement, ENI/2018/041-415, Direct Management

“For applicants from the United Kingdom: Please be aware that eligibility criteria must be complied with for the entire duration of the grant. If the United Kingdom withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that applicants from the United Kingdom continue to be eligible, the beneficiaries from the United Kingdom will cease to receive EU funding (while continuing, where possible, to participate) or be required to leave the project on the basis of Article 12.2 of the General Conditions^[1] to the grant agreement.”

1.2 Twinning Sector: Health and Consumer Protection

1.3 EU funded budget: 1 300 000 EUR

2. Objectives

2.1 Overall Objective:

The overall objective of the project is to support public health policies and programmes to prevent the spread of communicable diseases, through promoting the safety of substances of human origin and ensuring the highest possible quality level of blood transfusion service in Georgia.

2.2 Specific objective:

The specific objective of the project is to upgrade national blood safety legislation and to strengthen national institutional capacities in accordance with European regulations and the Association Agreement with the aim to provide equal safety standards of blood components across the nation, assure safety of blood related services and prevent the spread of blood borne infections by blood transfusion.

2.3 National strategies and international agreements

The Twinning project is fully in line with the requirements of the EU - Georgia Association Agreement (AA) including Deep and Comprehensive Free Trade Area (DCFTA) and aims to support further effective implementation and fulfillment of the objectives set out in the AA. Under AA Georgia has undertaken the responsibility to carry out approximation of national blood safety legislation to the EU acts in accordance with the provisions of EU acquis on blood safety (chapter 15 (Public Health), article 356, clause (d), article 356, Annex XXXI).

General needs and targets for improvement in blood safety system in Georgia are reflected in the strategic documents of the country and international agreements as follows:

The Georgian Socioeconomic Development Strategy "Georgia 2020" which emphasizes the quality of care as one of the long-standing concern in Georgia's healthcare system since mass privatization and marketization of medical establishments was not counterbalanced by appropriate regulatory mechanisms designed to protect the patients' right to receive high-quality medical services or efficient systemic measures to monitor the quality of healthcare in medical settings. The strategy "Georgia 2020" places greater emphasis on preventive measures and improvement of mechanisms for the protection of patient safety through the further improvement of regulatory system, medical training and licensing mechanisms in accordance with international standards.

The Government Program for 2018-2020 "Freedom, Rapid Development and Welfare" pursues innovative reforms in healthcare policy and emphasizes the need of comprehensive initiatives toward

^[1] Twinning manual Annex A2

strengthening of disease prevention from responding to disease to both preventive measures and early diagnostics and preempting complications. The program recognizes the need for adopting good manufacturing and laboratory practices (GMP/GLP) standards in pharmaceutical manufacturing.

The 2016-2020 Strategic Plan for the Elimination of Hepatitis C Virus in Georgia was launched by the government of Georgia in response to a national Hepatitis C epidemic and sets an ambitious goal to eliminate hepatitis C virus by 2020. The program combines screening and treatment targeting 90% of HCV-infected individuals, treatment of 95% of those with chronic HCV infection, and attainment of cure in 95% of those treated for HCV infection. Blood transfusion has been identified as a significant mode of transmission for HCV in Georgia and a special chapter was dedicated to the issues of blood safety in the elimination strategy, which identifies main gaps and sets key targets and milestones for the comprehensive reformation of blood transfusion system.

The Georgia HIV/AIDS National Strategic Plan for 2019-2022 targets 90% of all people living with HIV to know their HIV status, 90% of all people with diagnosed HIV infection to receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy to have viral suppression by 2020. Number of prevention interventions for retention of HIV transmission by blood transfusion is planned within the HIV Strategic Plan.

The National Center for Disease Control and Public Health Strategic Plan of 2018-2022 identifies main functions and objectives of NCDC, outlines its mission, vision and mandate, and promotes active collaboration with international partners. The plan gives a high priority to the building up reference laboratory capacities on the bases of NCDC including external quality control of testing transfusion transmissible infections at blood establishments within the frames of the State Safe Blood Program.

3. Description

3.1 Background and justification

3.1.1 Background

The National Center for Disease Control and Public Health (NCDC) is a legal entity under public law under the state control of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia (MoIDPLHSA), which independently carries out public health, scientific and educational activities and the scope of its mission is oriented on protection and improvement of health of the Georgian population through evidence based prevention, preparedness and timely response to public health threats. NCDC mandate includes a broad spectrum of roles and activities aimed at developing and implementing national health programmes and strategies, performing public health research and monitoring but also providing continuing education for health professionals. A precondition of implementation of NCDC mandate is its strong infrastructure, modern laboratories, highly trained human resources and an effective organizational structure (as presented in Annex 2).

The NCDC is a key implementer of the 10 preventive state programs with growing financing and a spectrum of priority directions, including State Safe Blood Program which aims at ensuring high quality and safety of blood, availability and equal accessibility to blood products, meeting the patients' needs in an adequate manner, administering transfusion if indicated only, and implementation of safe blood sustainable policy based on ethical norms, social values and economic factors.

The State Safe Blood Program was launched in Georgia in 1997 and provides antibody testing of donor blood for HCV, HBV, HIV, and syphilis performed by blood banks, routine external quality control of transfusion transmissible infection (TTI) testing at blood establishments, confirmation testing for HIV and Hepatitis C screening positive donations, popularization of repeat unpaid donations and administration of Unified Electronic Donor Database with the last four components carried out by NCDC per se.

Apart of the State Safe Blood Program covering the costs for blood testing, the Universal Healthcare Program (implemented by Social Service Agency), provides payment to hospitals for each blood transfusion episode thus ensuring free of charge service for patients.

Currently, Georgian blood transfusion system consists of 22 blood establishments holding state license in industrial transfusiology performing approximately 100000 donations per year. Of these, 18 blood banks (more than 80%) are private organizations, and 16 blood establishments (out of 22) participate in the State Safe Blood Program (location of blood banks provided in Annex 3).

Over the recent decade, state program budget has significantly increased and reached 1.8 million GEL from 1 million GEL and a number of successful efforts has been implemented toward the prevention of transfusion transmissible infections, resulting in steady reduction in the prevalence of TTIs among donor population and increase in the rate of the voluntary non-remunerated donors from 5% to 30%, in particular:

Since 2005, a Unified Electronic Blood Donor Database operates in the country, which incorporates donor demographic, blood testing, distribution and transfusion records. Since 2018, participation in the donor database became mandatory for all blood establishments and hospitals thus making it possible to establish hemovigilance from blood establishments to hospitals and from blood donor's vein to blood recipient's vein.

Since 2017, elements of results based financing have been introduced in the State Safe Blood Program paying additional sum to blood banks for attracting repeat, voluntary unpaid donors.

Since 2018, confirmation testing has been introduced for Hepatitis C antibody positive blood donors through state Hepatitis C Management programs, which eliminated financial barriers to in-depth diagnostics and increased accessibility to the treatment services for blood donors as well as for general population. In addition, all HIV screening positive samples are referred to the AIDS Center that performs confirmation testing and provides tracking of infected blood donors and their contacts. Both of them, HIV/AIDS and Hepatitis C Management Programs provide in-depth diagnostic and treatment services for persons with confirmed diagnosis.

Two parallel EQA mechanisms have been implemented for blood banks participating in the State Safe Blood Program through: (a) retrospective retesting of blood aliquots randomly selected from blood banks which is performed by NCDC's Lugar Center (a BSL 3 laboratory), and (b) proficiency testing (PT) provided by internationally accredited reference laboratories on the contractual bases between blood banks and international laboratories.

In Georgia, blood transfusion sector is regulated by the following legal documents and all of them will be affected by this Twinning project:

- Law of Georgia on Donation of Blood and Blood Components;
- Law of Georgia on Licenses and Permits;
- Decree of The Minister of Labour, Health and Social Affairs of Georgia №110/N on Transfusion Centers Further Development, dated on 14th March, 2001;
- Decree of the Minister of Labour, Health and Social Affairs of Georgia №14/N on Approval of Rules for the Preparation, Storage and Usage of blood and blood components, dated on 14th January, 2002;
- Decree of the Minister of Labour, Health and Social Affairs of Georgia №241/N on Determining of Blood and Blood Components Donation Contraindications, dated on 5th December, 2005;
- Resolution of the GoG №385 on Approving Provisions on the Rules and Terms of Issue of a Medical Practice License and an In-patient Facility Permit, dated on 17th December, 2010;
- Resolution of the GoG №74 approving Technical Regulations - Obligatory Norms for Functioning of Blood Transfusion Centers, dated on 15th January, 2014;
- Resolution of the GoG №539 on Approval of Technical Regulations for Blood Establishments, dated on 5th September, 2014;
- Decree of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia №01-2/N on Processing and Delivery of Medical Statistical Information, dated on 18th January, 2016;
- State Safe Blood Program endorsed by the Resolution of the GoG on Approval of the State Health Care Programs.

3.1.2 Justification

Georgian healthcare system faces a number of challenges related to quality assurance of blood and blood components, absence of routine supervising system for blood transfusion services and preferably paid blood donation practice, which leads to high prevalence of transfusion transmitted infections. It is noteworthy that according to the results of the population survey on HCV seroprevalence conducted by NCDC and U.S. Centers for Disease Control and Prevention (CDC) in 2015, among Hepatitis C risk factors, history of blood transfusion was identified as a statistically reliable second risk factor following the injection drug users (21.4% of respondents with positive hepatitis C antibody had at least one blood transfusion episode in their lives). Ongoing weaknesses compound the main differences between national legislation and European regulations, including the following issues:

Current blood transfusion system in Georgia is fragmented, and the legal status of blood facilities has shifted towards profit-based model that makes it possible to have unhealthy competition compromising the quality of blood products. In addition, paid and replacement donations make up 70% of total donations raising serious safety and ethical concerns as majority of blood donations are collected from high risk paid donors.

At present, there is no stand-alone designated authority at central level bearing the exclusive responsibility for blood safety. However, many of the oversight functions are integrated into portfolios of different state regulatory and oversight agencies. Screening of blood is carried out with a single antibody (ELISA) testing which does not cut down the window period to as great extent as molecular testing. Besides, high rate of blood transfusion at clinical settings leads to unnecessarily explosion of patients to TTIs.

In conclusion, current legal provisions should be harmonized with EU regulations and the standard operating procedures within the State Safe Blood Program have yet to be aligned with European best practices and blood safety requirements that could be achieved by the implementation of the comprehensive reforms, including:

- Transition of blood establishments from for-profit organizational model to non-profit arrangements;
- Optimization of blood banks;
- Centralization of blood testing for transfusion transmissible infections;
- Strengthening regulatory capacities;
- Establishment of national reference laboratory for blood transfusion services;
- Introduction of high sensitive testing methodologies based on modern technologies and best practices,
- Introduction of effective quality control systems, and
- Transition from paid donation practice to voluntary, repeat, non-remunerated system.

For all these reasons, increased concerns about the impact of diseases caused by transfusion transmissible infections encouraged the Georgian health care authorities to give much higher priority to blood safety and led to the intention to apply to the European Commission for institutional cooperation to advance in the reformation of blood transfusion system.

3.2 Ongoing reforms:

In June 2017, a technical working group was established by the Decree of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia №01-127/O, dated June 7, 2017, entitled “Creation of a Working Group in order to Ensure Safety of Blood Production and Transfusion in Georgia”. The working group is tasked with (a) reviewing the acting regulations in the field of blood production and bringing them in line with the EU directives on blood safety, (b) upgrade licensing requirements for blood establishments, (c) develop unified standards for blood collection and TTI testing, (d) elaborate proposals for establishment of centralized TTI testing capacities and introduction of high sensitive testing methodologies (such as nucleic acid testing, HIV combo etc.).

Currently, **the Blood Safety Working Group** is actively working on revising/updating national blood regulations. The Twinning project will be an important support to the group in terms of developing legislative framework in-line with EU requirements and supporting institutional strengthening of NCDC and other state entities subordinated to the Ministry.

In July 2017, an amendment was made to the Decree of the Minister of Labour, Health and Social Affairs of Georgia №01-2/n (dated January 18, 2016) entitled “Processing and Delivery of Medical Statistical Information,” which made mandatory participation in the Donor Electronic Database for all blood banks and hospitals performing blood transfusions despite their legal-organizational status and involvement in the State Safe Blood Program.

In October 2017, an amendment was made to the Decree of the Minister of Labour, Health and Social Affairs of Georgia №241/N (dated December 5, 2000), entitled “Blood Donation Contraindications”, introducing mandatory unpaid donations and mandatory nucleic acid testing for the blood donors with high behavioral risk.

In June 2019, with the financial support of the Global Fund, two nucleic acid testing (NAT) systems/machines have been purchased by NCDC. NAT screening piloting is planned later this year with scaling up and full implementation prospects within the Twinning period.

General Policy and legislative process

The National Policy Planning System Reform Strategy, adopted by the Government of Georgia in August 2015 recognizes the current weak link between the policy planning process and legislation drafting, the absence of practice of legislative impact assessment and the weak institutional capacity of ministries in legal drafting. The OECD/SIGMA 2018 assessment in the policy development and coordination area highlights a number of weaknesses in the quality of policy planning (costing, monitoring, coordination and public consultation), which are currently being addressed through the PAR roadmap and action plan. The document specifically notes the reoccurring problem with implementation of laws, which can be attributed to the low quality of laws due to weaknesses in the law-making process. There is a pressure to complete numerous legal reforms in the shortest possible time: "This situation inevitably places enormous pressure on the combined law-making resources of the Government and the Parliament and leaves little time for essential elements of a well-ordered law-making process, such as regulatory impact assessments or proper consultation with civil society." Improvement of the legislative drafting process and quality of legislation is now a priority area of action for the Administration of Government under the Prime Minister (steering the policy-making process) and all line ministries. This primarily involves the Administration of Government, Ministry of Justice, and Ministry of Economy and Sustainable Development. In order to meet the targets and obligations in law making process the Government introduced changes in Law on Normative acts (amended on June 13, 2018) and Regulation of the Government (amended on August 24, 2018). These amendments put more emphasis on concordance with EU *acquis* and Regulatory Impact Assessment (RIA.)

To sustain the legal approximation process the Ministry of Justice (MoJ) with the support of the EU assistance (below mentioned projects Association Agreement Facility and Legal Drafting projects) elaborated Legal Approximation Guidelines and Manual. These documents provide key principles and techniques of approximation that will guide and orient legal drafters throughout the approximation process. The documents are under finalization and after official adoption by the Government should be used consistently, not only by MoJ, but also by all line ministries, and institutions tasked with the approximation exercise. Such proceedings will help to ensure the achievement of a steady and sustainable approximation path.

Along the legislative process the Government is proceeding with the rational organization of state administration and clear accountability lines between institutions, including supervision and reporting between line ministries and agencies. The Civil Service Bureau (CSB) is tasked with the development of uniform civil service state policy. Functional reviews of the line Ministries has been already done and currently the CSB is performing an analysis of state agencies with the intention of identifying and putting forward reforms to improve the organization of PA, to streamline their mandates, enforcement mechanism as well as policy making process.

In this regard, the project will ensure consistency between the review of the organizational set-up of the beneficiary institution with the national legislation regulating the organization of the state administrations and above mentioned analysis of the state agencies.

3.3 Linked activities:

In the recent years, a number of projects and missions, financed by different donors have been contributing to upgrading of blood safety in Georgia.

The Strategic TAIEX Expert Mission on the Approximation of National Blood Safety Legislation to EU Regulations took place in 18 - 20 June 2018, Tbilisi, Georgia. The aim of the assistance was to provide the beneficiary technical consultation on the upgrading of blood safety in Georgia through approximation of the national blood safety legislation with the respective provisions of the Union acquis; to share the information on statutory models and best practice of the organization of blood transfusion service in EU countries; to instruct the beneficiary on the quality management and licensing/accreditation mechanisms of blood establishments. The expert report is available on the official website of the European Commission¹ (as provided in Annex 4).

Further, Technical Assessment of the communicable diseases surveillance and control system in Georgia in accordance with the Health Chapter of the EU - Georgia Association Agreement is tentatively planned in autumn 2019 by the European Commission's Directorate General for Health and Food Safety (DG SANTE).

Other activities implemented over the last five years were supported by US CDC, the Global Fund, WHO and the Global Healing as listed below:

- **The Global Fund** - 2012-2015 Plan of Development of Quality Management System of the Blood Transfusion Service of Georgia was developed in 2015;
- **U.S. Centers for Disease Control and Prevention** - Annual recommendations for the successful implementation of the Georgia's HCV Elimination Program (including Blood Safety section) have been developed by the international Technical Advisory Group (TAG).
- **WHO** - Georgia volunteered to participate in the World Health Organization's Joint External Evaluation (JEE). And currently is in the process of self-evaluation.
- **The Global Healing** (U.S. non-governmental organization) - Series of webinars on blood quality management systems were conducted and English translation of the national blood legislation was carried out in 2016-2017;

Related Programmes and Projects

The reform of Public Administration (PAR) is of utmost importance for the country and the process is supported through donor community. The EU total contribution to the "Support to the Public Administration Reform in Georgia" 2016-2019, is EUR 30 000 000 Euro. Out of which EUR 20 000 000 is budget support share and EUR 10 000 000 for complementary support. The objective of the programme is to improve the efficiency, accountability and transparency of the public administration of Georgia, in line with the key Principles of Public Administration that have been developed by OECD/SIGMA in close cooperation with the European Commission. It will have a particular focus on the improvement of the policy planning and coordination capacities and processes in the central public administration. The MoIDPLHSA is one of the selected beneficiary ministries of this programme.

Project Title: "Support to the Public Administration in Georgia"- EU funded; Duration: 2019-2021; Description: The objective of the project is to improve the efficiency, accessibility, accountability and transparency of the Georgian Public Administration in accordance with European principles of Public administration and best practices. More specifically, the project is mainly focused on improving the results-based approach in policy planning, development, coordination, monitoring and evaluation, increasing the awareness of the Civil servants and streamlining the implementation of the civil service reform in public institutions, improving the intra and inter-ministerial business processes related to policy making and service delivery enhancing thus the efficiency of the administration and the quality of service delivery, strengthening policy development and implementation of the anti-corruption and transparency national policies. The MoIDPLHSA will benefit from the senior non-key expert (SNKE) on Public Health, who will provide technical expertise in strategic conceptualization, planning and monitoring of the National Health System

¹ Expert report of the TAIEX Expert Mission on the approximation of the National blood safety legislation to the EU Regulations:

<https://webgate.ec.europa.eu/TMSWebRestrict/sendReports?eventID=66143&view=list&key=2fe05636a938e536394acf52aa1551ac>

Strategy. The SNKE on Public Health will also provide advice and support aimed at analyzing the Provider payment mechanisms, as well as Strategic purchasing and also provide advice and support aimed at building organizational cohesion and flexibility.

Project Title: “Capacity Building of the Civil Service Bureau of Georgia to Implement the Civil Service Reform” - EU funded; Duration: 2019-2020. Description: The objective of the project is to enhance the professionalism of the civil service in Georgia. More specifically, the project aims to strengthen the institutional and Human Resource (HR) capacities of the Civil Service Bureau (CSB) to manage the implementation of the Civil Service Reform, through the reinforcement of the legal framework, introduction of modern Human Resource Management (HRM) information system, tools and techniques, development of training scheme for HR managers and improvement of Assets Declaration Monitoring system.

Project Title: Facility for the implementation of the Association Agreement in Georgia - EU funded; Duration: 2015-2018; Description: The project provided policy advice and capacity building support to the Georgian Government in coordinating the implementation of the Association, strengthening the institutional capacities of the line ministries and other public institutions to carry out the required reforms, including on policy development and legal approximation processes. Since February 2019, phase II of the aforementioned project has been launched. Duration: 2019-2021.

3.4 List of applicable *Union acquis*/standards/norms:

Georgia has the obligation to approximate its legislation with the Union *acquis* referred to in Annex XXXI of the Association Agreement, according to the provisions of the 4 blood directives. It is expected that this Twinning project will cover all priorities stipulated in the directives, in particular:

Union <i>acquis</i>	Corresponding national regulations
Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components	<ul style="list-style-type: none"> - Law of Georgia on Donation of Blood and Blood Components - Law of Georgia on Licenses and Permits - Resolution of the Government of Georgia №385 on Approving Provisions on the Rules and Terms of Issue of a Medical Practice License and an In-patient Facility Permit, dated on 17th December, 2010 - Decree of the Minister of Labour, Health and Social Affairs of Georgia №14/N on Approval of Rules for the Preparation, Storage and Usage of blood and blood components, dated on 14th January, 2002 - State Safe Blood Program
Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	<ul style="list-style-type: none"> - Resolution of the Government of Georgia №74 approving Technical Regulations - Obligatory Norms for Functioning of Blood Transfusion Centers, dated on 15th January, 2014 - Decree of the Minister of Labour, Health and Social Affairs of Georgia №241/N on Determining of Blood and Blood Components Donation Contraindications, dated on 5th December, 2005
Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and	<ul style="list-style-type: none"> - Resolution of the Government of Georgia №539 on Approval of Technical Regulations for Blood Establishments, dated on 5th September, 2014

specifications relating to a quality system for blood establishments	- Decree of The Minister of Labour, Health and Social Affairs of Georgia №110/N on Transfusion Centers Further Development, dated on 14th March, 2001
Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	Decree of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia №01-26/N on Processing and Delivery of Medical Statistical Information, dated on 25 th March, 2019

In addition, new regulations, normative acts, rules and standards should be developed and implemented in order to cover existing gaps between national and EU legislation.

3.5 Components and results per component

At the completion of the project the following results are expected to be achieved under this Twinning project:

Component 1/Mandatory Result 1: Approximation of Georgian primary and secondary legislation with the Union acquis on blood safety (Annex XXXI) performed

Under the Association Agreement, the approximation of the blood directives shall be completed within 5 years after the entry into force of the Agreement. Taking into consideration the time pressure, the Ministry's working group intensively works on the upgrading of the Law and standards. Therefore, the Twinning project will play a crucial role in the transposition of the EU Directives' requirements. The Twinning project will take into account and use all these previous preparations made by the Ministry's working group as a basis for its activities. More specifically, this component aims at legal approximation through identifying gaps in national regulations, developing legal papers and accompanying documents in accordance with Union acquis and promoting their approval in the Georgian Government.

Sub-Result 1.1: National regulatory framework in blood safety revised and upgraded in accordance with Union acquis on blood safety

Specifically, the process of delivering sub-results will focus on developing the legal framework and respective supporting documents for establishment of the National Competent Authority (NCA)/Inspectorate for blood transfusion services, a centralized TTI testing laboratory, a Reference Laboratory, as well as for transition from for-profit to non-profit organizational models of blood establishments and introduction of obligatory non-remunerated blood donations and of high sensitive methodologies at centralized testing laboratories.

Component 2/Mandatory Result 2: A well-organized, nationally coordinated blood transfusion system established and functioning in accordance with the provisions of the Association Agreement

This component envisages a wide range of systemic and structural changes ranging from the strengthening of regulatory and controlling functions at central level and reorganizing the blood transfusion services, to improving laboratory capacities of blood production, establishing efficient quality control mechanisms, upgrading information systems and improving clinical use of blood and blood products.

Sub-Result 2.1: National Competent Authority established and fully functional to take the role, tasks and responsibilities required by EU Blood Directives

The project activities under this sub-result will focus on strengthening administrative structures and institutional capacities at central level to provide national coordination of the blood transfusion service, to promote uniform standards, to address availability of blood products and ensure consistency in the quality and safety of blood products and best transfusion practices. NCA can be constituted as new public/state body or specialized unit within the existing larger body, empowered to perform its duties with sufficient number of qualified and competent personnel and implemented quality system appropriate for the tasks it performs.

Sub-Result 2.2: Assessment of blood banks performed

The project activities under this sub-result will focus on conducting a comprehensive assessment of all licensed blood establishments (including all blood production aspects such as: organization, personnel, premises, equipment, documentation, quality systems et.) as well as on analyzing of gaps and prioritizing areas and needs for future interventions.

Sub-Result 2.3: reorganization of blood transfusion service (BTS) carried out

The project activities under this sub-result will mainly focus on developing the BTS reorganization strategy (optimization plan for blood preparation centers, establishment of blood collection centers) and implementation plan based on the assessment results as well as elaborating of contingency plan for covering possible needs of blood components during BTS reorganization phase including budget, logistical plan and international collaboration platforms with EU member states so that back up blood supplies are provided, blood sufficiency ensured and country's basic needs are met.

Sub-Result 2.4: Transition to the mandatory non-profit organizational form for blood establishments initiated

The project activities under this sub-result will aim at transforming profit-oriented organizational form of blood establishments to non-profit arrangements for which legal provisions and implementation plans will be developed within the frames of this Twinning project.

Sub-Result 2.5: Centralized TTI testing laboratory(s) established

The project activities under this sub-result will focus on developing the implementation plan for the establishment of the centralized TTI testing laboratory on the bases of state owned settings.

Sub-Result 2.6: National reference laboratory established

The project activities will aim at the establishment of the National Reference Laboratory (NRL) which will play reference role for performing EQA, investigation of infection transmission cases, providing confirmatory testing, assessment and selection of equipment and test-kits, supply of laboratories with quality control reagents etc. Specifically, under this sub-result an implementation plan for establishment of NRL will be developed and submitted to the decision makers.

National reference laboratory can be established either as a single standing structure or its functions might be integrated within the centralized testing laboratory or one of the state owned blood banks.

Sub-Result 2.7: Nucleic Acid Testing for screening of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and HCV introduced at centralized testing laboratory(s)

The project activities under this sub-result will mainly focus on developing the implementation plan for the introduction of high sensitive methodologies at centralized testing laboratories (such as nucleic acid amplification test (NAT) and other risk-reduction technologies such as pathogen inactivation) to ensure a quality assured testing of all donated blood for TTIs, including HIV, hepatitis C, hepatitis B, syphilis and other infections, where relevant, in conformity with the latest scientific and technical procedures that reflect current best practices.

Sub-Result 2.8: Requirements for a quality systems to maintain the highest possible standards in all aspects of blood transfusion developed and implemented

The project activities under this sub-result will emphasize efforts on developing a quality system for blood establishments that will embrace the principles of quality management, quality assurance, and continuous quality improvement, including personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, contract management, non-conformance and self-inspection, quality control, blood component recall, and external and internal auditing, specifically the following targets will be addressed within this section:

Sub-Result 2.9: Unified Electronic Donor Database upgraded

The project activities under this sub-result will focus on upgrading of national information systems in terms of safety, quality, traceability, accountability, and hemovigilance issues in relation to the Georgian blood sector.

Sub-Result 2.10: National Haemovigilance Network established

The project activities under this sub-result will be directed to establish the haemovigilance/look-back

surveillance system to monitor adverse events and reactions in blood donors and blood recipients and investigate suspected window-phase and/or occult infections and/or suspected infection transmission cases.

Sub-Result 2.11: Unnecessary blood transfusion at clinical settings reduced

Blood transfusion can be a life-saving procedure, however, liberal transfusion strategies are associated with increased length of stay, morbidity, and mortality compared to restrictive transfusion practices. These unnecessary transfusions cause direct patient harm, generate excessive costs for health systems, and waste important, limited resources. Therefore, activities under this sub-result will focus on developing and implementing national guidelines on criteria, indications and proper use of blood and blood components at clinical settings.

Component 3/Mandatory Result 3: Blood transfusion services based on voluntary blood donation are able to ensure safe, adequate and sustainable blood supplies

In Georgia, blood transfusion system is dependent to predominantly paid and varying degrees of family/replacement donors. Building a sustainable base of safe blood donors requires a long-term approach that requires not only the establishment of an effective voluntary blood donor programme but also improved public awareness and acceptance of the importance of blood donation as a social norm. The ultimate goal of this project is to collect blood only from voluntary, non-remunerated blood donors at low risk of acquiring infections that can be transmitted through unsafe blood and blood products.

Sub-result 3.1: Awareness of the general population and specific target groups on blood transfusion increased

The project activities under this sub-result will focus on developing an effective communication strategy and conducting intensive informational and educational campaigns to raise awareness in the field of blood transfusion among decision makers, key stakeholders, general public, and target groups, private sector and civil society.

Sub-result 3.2: Donor recruitment services strengthened at blood centers

Effective donor recruitment and retention relies on fundamental principle to keep the active donor pool healthy and to expand the pool size as well as on dedicated and committed staff with special skills and experience in donor communication, education and motivation. Therefore, activities under this sub-result will aim to support donor recruitment and retention at individual blood centers and to enhance coordination modes with national blood safety program.

Component 4/Mandatory Result 4: Capacity of relevant state authorities and other key stakeholders strengthened to ensure safety and quality of blood transfusion service

The efficiency of the blood safety policy, the feasibility of the institutional changes envisaged by this project and implementation prospects of EU standards and best practices will largely dependent on developing a critical pool of competent human resources with clear understanding and solid knowledge of a new legislation, guides and regulations in the field concerned. Therefore, strengthening capabilities of the beneficiary organizations, line ministries/agencies and medical and administrative personnel of the blood establishments and clinical facilities is crucial.

Sub-result 4.1: Capacities of the National Competent Authority and Beneficiary Administration strengthened

The project activities under this sub-result will focus on assessing, proposing and implementing plans for developing/strengthening institutional capacities of NCA, NCDC, MoIDPLHSA and other stakeholders to perform inspections of blood establishments and provide overall coordination and oversight of the blood transfusion system. Further, assessing administrative structures and institutional capacities of beneficiary organization and other stakeholders, and identifying areas of intervention/training needs necessary for effective implementation of the upgraded regulations.

Sub-result 4.2: Capacities of the centralized laboratory and healthcare institutions (blood establishments, hospitals) strengthened

Project activities under this sub-result will include assessment of laboratory capacities, identifying training

needs and developing competent human resources for effective functioning of centralized testing and reference laboratories as well as provide trainings to blood bank and hospital personnel in the implementation of the upgraded regulations.

3.6 Means/input from the EU Member State Partner Administration(s):

Member State(s) is/are kindly requested to develop activities in the submitted proposal which are needed in order to achieve the results stipulated in the fiche.

The MS PL will be expected to devote a minimum of 3 days per month to the project in his/her home administration. In addition, as co-chairperson, he/she will coordinate from the Member State side the work of the Project Steering Committee (PSC), which shall meet in Georgia on a quarterly basis at least. MS Project Leader may participate in the project also as short-term expert (STE). In this case the MS Project Leader should satisfy requirements stipulated in the fiche for both the Project Leader and the relevant STE profile.

The RTA will be located in the premises of the NCDC in the beneficiary country on a full time basis and will be responsible for the direct implementation of the project under the overall supervision of the MS Project Leader. The RTA will maintain day-to-day cooperation with the beneficiary administration and coordinate the work performed by the STEs. The RTA will have a key role in the coordination of the inputs required for the successful implementation of all the project activities.

The RTA should be supported by component leaders who will be responsible for the coordination, guidance and monitoring of their components, analyze the component areas and draft relevant thematic / technical contributions. They will liaise with MS Project Leader and his/her counterpart and have daily contacts with RTA and BA counterpart.

Furthermore, the RTA should be supported by a permanent RTA assistant. The RTA assistant should be in close collaboration with the beneficiary administration. RTA assistant will perform general project duties and providing translation and interpretation services as necessary, practical arrangements for the project, such as organizational issues of expert missions, conferences, trainings, seminars, maintaining project records, etc. The RTA assistant is responsible to the RTA and hired by the RTA through an appropriate selection procedure. Until the RTA can select and hire an assistant, the BA makes a member of its staff available to support the RTA in his/her daily tasks. When the nature of the project suggests that the volume of translation and/or interpretation requested would be considerable, a language assistant can be hired in addition.

To achieve coherence in the implementation of all activities pertaining to the specific components and accomplish mandatory results/outputs, Component Leaders (short-term experts) will be designated to each specific component who will coordinate the intervention of all other Member State(s) experts mobilized for the same component. Beneficiary institution will assign a Component Leader counterpart for each component who will be the permanent interlocutor of the MS Component Leader coordinating the specific component. The Component Leaders will work in close collaboration with the RTA and the Beneficiary counterparts in order to achieve mandatory results/outputs pertaining to the specific component and to contribute to overall success of the project.

The profile, exact number and specific Terms of Reference for each Component Leader along with the names and functions of the Component Leader counterparts will be defined at the Work Plan preparation stage by the MS Project leaders and/or the RTA and its counterpart. The ToRs will specify the detailed inputs of the Component Leaders and the duration of their missions.

Specialist civil servants/staff of approved mandated bodies will be made available by the Twinning Partner (MS) to support the implementation of the activities and agreed with the beneficiary administration. This fiche will define general indicative qualifications and tasks for short term experts (STEs). The detailed ToRs for each STE will be developed at the work plan preparation stage by the PL and/or the RTA and their counterparts. The ToR will define specific expert input of the STEs and will specify the duration of their missions. The STEs will work in close collaboration with the RTA and his/her counterpart as well as with Component Leaders to support the project in achievement of the mandatory results as set out above.

The required MS experts must either be civil/public servants of the relevant MS administration or be permanent staff of authorized mandated bodies. All experts must comply with the requirements set in the Twinning Manual 2017 (update 2018).

Minimum two visibility events will be organized in the course of the implementation of the project; Launching event at the start of the implementation and the Closing event at the end of the implementation of the project activities.

Proposals shall include only the CVs of the proposed PL, of the RTA and of the Component Leaders (STEs CV should not be included in the MS proposal).

3.6.1 Profile and tasks of the PL:

Profile:

- A high ranking current official of a Member State administration with a sufficient managerial position in health policy development/implementation/coordination;
- University level education in a relevant discipline (e.g. Medicine or Public Health), or equivalent professional experience in a related field of minimum 5 years;
- Should have at least 3 years' experience in the field of public health administration;
- Previous experience in the field of project management, with a demonstrable record of organizational leadership and reform implementation;
- Good understanding of regulatory/supervisory system of BTS and its organizational models in a Member State;
- Comprehensive knowledge of EU public health legislation with special focus on blood safety;
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to various components of this project;
- Experience in international collaboration in public health;
- Excellent command of spoken and written English;
- Good communication, presentation and interpersonal skills;
- Good leadership and managerial skills;
- Excellent Computer literacy.

Tasks:

- Overall direction, supervision, guidance and monitoring of the project;
- Mobilization of the necessary expertise in support of the efficient implementation of the project;
- Lead an operational dialogues, advocate, thrust and back up the project at political level;
- In cooperation with the PL counterpart signing and submission the interim quarterly and final project reports prepared with the support of the RTA to the concerned authorities;
- Produce project impact assessment with the support of the RTA;
- Formal signing of project work plan(s) and/or their updates;
- Ensuring timely achievement of the project results;
- Provision of legal and technical advice whenever needed;
- Co-chairing of project steering committees.

3.6.2 Profile and tasks of the RTA:

Profile:

- University level education in a relevant discipline (e.g. Medicine or Public Health) or equivalent professional experience in a related field of minimum 5 years;
- Proven contractual relation to a Member State administration or mandated body;
- At least 3 years of professional experience in the field of quality and safety of substances of human origin (with focus on blood safety);
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of BTS organization, management, quality control and supervision;
- Working experience on EU blood safety legislation in a Member State would be an asset;

- Collaboration experience with WHO, ICRC, ISBT and other relevant international organizations would be an asset;
- Good team-working, communications, presentation and interpersonal skills;
- Good organizational and project management skills;
- Strong analytical and report writing skills;
- Excellent command of spoken and written English;
- Excellent Computer literacy;
- Previous experience in project management would be an asset.

Tasks:

- Overall coordination of project implementation and of all activities;
- Develop the initial and subsequent work plans, and project progress reports together with PL to be submitted to the Steering Committees;
- Provide technical input to the project whenever needed and provision of advice in his/her field of expertise;
- Coordinate activities of the team members in line with the agreed work plan to monitor quality of their outputs and enable timely completion of project outputs;
- Liaise with PL counterparts and daily contacts with RTA counterpart;
- Liaise with EUD Project Manager and Programme Administration Office (PAO);
- Liaise with key stakeholders, other relevant projects and relevant Georgian institutions;
- Contribute to the work of the sector development process set up in the Beneficiary Country.

The RTA will be introduced to the BC stakeholder of the project, counterparts and staff. He/she will attend trainings at the Commission Headquarters, including on the technical provisions of the Twinning Manual, the EU policy and cooperation framework and/or on the latest EU legislation in the relevant policy area/sector. The PL counterpart and the RTA counterpart can attend the trainings together with the RTA of the project.

3.6.3 Profile and tasks of Component Leaders:

Component 1: Approximation of Georgian primary and secondary legislation with the Union acquis on blood safety (Annex XXXI) performed

Profile:

- University level education in a relevant discipline (e.g. law/public health/medicine/transfusion medicine/economics) or equivalent professional experience in a related field of minimum 8 years;
- At least 3 years of professional experience in the field of public health/health legislation (with focus on blood safety);
- Good experience in standard setting and legal drafting processes relevant to the project scope;
- Good experience in capacity building activities;
- Specific knowledge in the field of standards, technical requirements and specifications related to safety and quality of blood and blood components would be considered as asset;
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of BTS organization, management, quality control and supervision;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Computer literacy.

Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;

- Preparing and conducting training programs, information and dissemination seminars with various stakeholders;
- Preparing timely proposals for any corrective measures;
- Provision of legal and technical advice and analysis whenever needed;
- Supporting RTA in report writing relevant to this component;
- Liaise with PL, RTA and their counterparts.

Component 2: A well-organized, nationally coordinated blood transfusion system established in accordance with the provisions of the Association Agreement

Profile:

- University level education in a relevant discipline or equivalent professional experience in a related field of minimum 5 years;
- At least 3 years of professional experience in the field of public health and or medicine (with focus on blood safety);
- Sound comparative knowledge of BTS organization and controlling/supervisory institutional structures (including accreditation, designation, authorization or licensing of blood establishments as well as Inspections and control measures);
- Relevant experience in capacity building activities and human resources development relevant to the scope of this component;
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to this component;
- Good understanding of legal and operational procedures for the enforcement of laws and sub laws relevant to this component;
- Demonstrated skills for effective negotiation, inter-personal, inter-institutional and political dialogue;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and advisory skills;
- Fluency in written and spoken English;
- Computer literacy.

Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing and conducting training programs, information and dissemination seminars with various stakeholders;
- Provision of legal and technical advice and analysis whenever needed;
- Preparing timely proposals for any corrective measures;
- Supporting RTA in report writing relevant to this component;
- Liaise with PL, RTA and their counterparts.

Component 3: Blood transfusion services based on voluntary blood donation are able to ensure safe, adequate and sustainable blood supplies

Profile:

- University level education in a relevant discipline or equivalent professional experience in a related field of minimum 5 years;
- At least 3 years of professional experience in the field of communication and visibility (with focus on popularization and encouragement of voluntary unpaid donations (VUD));
- Experience in drafting and implementation of VUD strategies for motivation, attraction, and retention of regular blood donors;
- Experience in building donor recruitment capacities at blood establishments;
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to this component;

- Good understanding of legal and operational procedures for the enforcement of laws and sub laws relevant to this component;
- Demonstrated skills for communication and social dialogue;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good team-working, presentation and advisory skills;
- Fluency in written and spoken English;
- Computer literacy.

Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing and conducting training programs, information and dissemination seminars with various stakeholders;
- Organizing VUD popularization campaigns, meetings and events;
- Preparing promotional materials;
- Provision of legal and technical advice and analysis whenever needed;
- Preparing timely proposals for any corrective measures;
- Supporting RTA in report writing relevant to this component;
- Liaise with PL, RTA and their counterparts.

Component 4: Capacity of relevant state authorities and other key stakeholders strengthened to ensure safety and quality of blood transfusion service

Profile:

- University level education in a relevant discipline or equivalent professional experience in a related field of minimum 5 years;
- At least 3 years of professional experience in the field of public health and or medicine (with focus on human resources management and professional development);
- Relevant experience in capacity building activities and human resources development relevant to the scope of this component;
- Good knowledge of legal approximation process, relevant EU legislation and institutional requirements related to this component;
- Good understanding of legal and operational procedures for the enforcement of laws and sub laws relevant to this component;
- Good communication, coaching and mentoring skills;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial and organizational skills;
- Good team-working, presentation and advisory skills;
- Fluency in written and spoken English;
- Computer literacy.

Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Preparing and conducting training programs, information and dissemination seminars with various stakeholders;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Provision of legal and technical advice and analysis whenever needed;
- Preparing timely proposals for any corrective measures;
- Supporting RTA in report writing relevant to this component;
- Liaise with PL, RTA and their counterparts.

The Project Leader and/or RTA are free to propose additional Component Leaders as they see fit, based upon the needs of the project and in agreement with the beneficiary counterparts.

3.6.4 Profile and tasks of other short-term experts

Profile:

- University level education in a relevant discipline or equivalent professional experience in a related field of minimum 5 years;
- At least 3 years of professional experience in the relevant field;
- Specific knowledge and working experience on legal approximation issues with focus on technical requirement for blood and blood components;
- Specific knowledge and working experience on quality systems for blood establishments;
- Specific knowledge and working experience on haemovigilance (SARE management);
- Specific knowledge and working experience on NCA organization (e.g. human and financial resources, procedures, infrastructure) and functions (authorization, accreditation, licensing, inspection, haemovigilance);
- Specific knowledge of organizational structure, statutory models and institutional capacities of blood transfusion service in her/his Member State;
- Specific knowledge and working experience on centralized TTI testing laboratory (including advanced testing methodologies such as NAT and other best practice technologies) and reference laboratory (e.g. human and financial resources, procedures, infrastructure);
- Sound knowledge and working experience in BTS quality control, quality assurance and quality management;
- Sound knowledge and working experience in clinical transfusiology;
- Sound knowledge and particular skills in blood donor recruitment and popularization of regular voluntary non-remunerated donations;
- Experience in awareness raising, information campaigns and knowledge of different communication tools;
- Coaching, training and facilitator skills;
- Experience in developing of training modules and materials, good record in training delivery;
- Experience in network management, software development and database administration relevant to blood safety;
- Previous experience as an STE on an EU-funded Twinning Project would be an asset.
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Excellent computer literacy (word, excel, power point etc.).

Tasks:

- Contributing in drafting project related legal documents in accordance with the national rules for legislative development in their respective fields;
- Contributing in preparation of strategy documents, guidelines, operational procedures and manuals/instruction handbooks related to their field of expertise;
- Assistance with the preparation of trainings, study tours, conferences, workshops, seminars etc.;
- Supervision and on-site coordination of all activities related to their field of expertise and performed under this project;
- Contributing to the sustainability of the project by ensuring that aspects of the project related to their field of expertise are implemented timely and properly;
- Provision of legal and/or technical advice and consultations whenever needed in their respective fields;
- Preparing timely proposals for any corrective measures;
- Communicate with stakeholders and media;
- Liaise with RTA, Component leaders and BA counterparts.

The Project Leader/RTA are free to propose additional STEs as they see fit, based upon the needs of the project and in agreement with the beneficiary.

4. Budget

The budget for this grant is €1.300.000 (one million three hundred thousand Euro).

5. Implementation Arrangements

5.1 Implementing Agency

The EU Delegation to Georgia will be responsible for the tendering, contracting, payments and financial reporting and will work in close cooperation with the Beneficiary Administration. The person in charge of this project within the EU Delegation to Georgia is:

Ms. Nino Kochishvili
Programme Officer,
Delegation of the European Union to Georgia
38 Nino Chkheidze Street, 0102 Tbilisi, Georgia
Tel: + 995 32 2943763
E-mail: Nino.Kochishvili@eeas.europa.eu

5.2 Institutional framework

The direct beneficiary institution for the Twinning project will be NCDC (up to 15 persons) that will closely collaborate with the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia, State Regulation Agency for Medical Activities, line ministries and other stakeholders in the field. The NCDC is a key agency for public health in Georgia. Early detection and prevention of diseases is its core mandate. The NCDC has a significant role in development of a country's health care system and improvement of public health. NCDC implements prevention of communicable and non-communicable disease, performs laboratory diagnostic activities, responds to public health emergencies caused by environmental and other behavioral risk factors and carries out implementation of state public health programs in the fields of disease early detection and screening, immunization, epidemiological surveillance, blood safety, maternal and child health, prevention of occupational diseases, management of HIV/AIDS, tuberculosis and hepatitis C, and health promotion.

Furthermore, the NCDC is responsible for developing and managing health-related databases and registries (such as blood donor database, birth registry, cancer registry, hepatitis C screening database, immunization module) and integrates the R. Lugar Center for Public Health Research, a BSL-3 facility which represents the referral laboratory for the public health system of Georgia.

Within the State Safe Blood Program, some of the functional responsibilities are split across several departments and divisions of NCDC:

- a) State Programs Department/Programs Administration Division – is responsible for the implementation of the State Safe Blood Program;
- b) R. Lugar Center – conducts external quality control at blood banks enrolled in the state program;
- c) Department of Communicable Diseases conducts epidemiological surveillance of communicable diseases;
- d) Legal Division – prepares legal and administrative documents and participates in the law making processes within the competencies;
- e) Department of Non-communicable Diseases/Health Promotion Division – plans and implements activities for popularization of voluntary unpaid donations, including organization of World Blood Donor Day.

All above mentioned departments/divisions will be involved in the implementation of the Twinning project within the scope of their competencies.

It is anticipated that the results of the project will strengthen NCDC's laboratory capacities for providing effective quality control mechanisms of blood establishments. The project envisages establishment of the National Competent Authority, reference laboratory, centralized testing laboratory and upgrading of blood transfusion system which will entail number of institutional (functional or/and structural) changes in the health care sector.

5.3 Counterparts in the Beneficiary administration

Project Leader Counterpart:

Mr. Amiran Gamkrelidze
Director General of the National Center for Disease Control and Public Health
Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
Kakheti Highway 99, Tbilisi 0198, Georgia
E-mail: a.gamkrelidze@ncdc.ge

RTA Counterpart/Contact Person:

Ms. Eteri Kipiani
Head of Programs Administration Division
State Programs Department
National Center for Disease Control and Public Health
Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
Kakheti Highway 99, Tbilisi 0198, Georgia
E-mail: e.kipiani@ncdc.ge

6. Duration of the project

The duration of the project is 24 months.

7. Management and reporting

7.1 Language

The official language of the project is the one used as contract language under the instrument (English). All formal communications regarding the project, including interim and final reports, shall be produced in the language of the contract.

7.2 Project Steering Committee

A project steering committee (PSC) shall oversee the implementation of the project. The main duties of the PSC include verification of the progress and achievements *via-à-vis* the mandatory results/outputs chain (from mandatory results/outputs per component to impact), ensuring good coordination among the actors, finalizing the interim reports and discuss the updated work plan. The Project Leaders, the RTA, the RTA counterpart, the EU Delegation and Programme Administration Office representatives will meet regularly (quarterly) to discuss and coordinate the progress of the project implementation. Other details concerning the establishment and functioning of the PSC are described in the Twinning Manual.

7.3 Reporting

All reports shall have a narrative section and a financial section. They shall include as a minimum the information detailed in section 5.5.2 (interim reports) and 5.5.3 (final report) of the Twinning Manual. Reports need to go beyond activities and inputs. Two types of reports are foreseen in the framework of Twinning: interim quarterly reports and final report. An interim quarterly report shall be presented for discussion at each meeting of the PSC. The narrative part shall primarily take stock of the progress and achievements *via-à-vis* the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

Monitoring and Evaluation of the project will be conducted using the project-specific logical framework, to be encoded in the EU projects monitoring system OPSYS. The contractor should report on the results at

impact, outcome and output levels, linked to sources of verification presented in the logical framework. Reporting will be carried out through Progress, Interim and Final Reports as laid down in the terms of reference / project description and general conditions. For the better quality of the log frames and indicators, the contractors are encouraged to get familiar with DG NEAR guidelines on Indicators - P. 45 and the EU Results Framework. Wherever an indicator set out in the project log frame is also reflected in the EU Results Framework, project reporting will also cover it.

8. Sustainability

The mandatory results and outcomes of the project are in full compliance with the state policy priorities in public health. The project will have an impact on Georgian health care system. It envisages institutional changes through the establishment of new structures or/and integrating new functions into existing structures (such as competent authority, centralized/referral laboratory, etc.) at both central and regional levels, both public and private sectors, that based on sectoral policy, relevant legislation and their own structural provisions will ensure institutionalization of project results after completion of the project.

Furthermore, financial sustainability of the project outputs will be guaranteed by the state budgetary assignments allocated for the State Safe Blood Program and the institutional sustainability of the project achievements will be embedded in the routine functions and works of the Ministry and its subordinated agencies.

9. Crosscutting issues (equal opportunity, environment, climate etc...)

The project will be implemented by NCDC, the beneficiary administration, where more than 70% of the employees are women with equitable engagement in the organizations management, impartial access to decent work for women of all ages and equal opportunity to participate in the organizational policy, decision making and governance processes. The project declares equal health opportunities as its specific objective aims at “equal safety standards of blood components across the nation” which means that project outcomes will ensure equity and equality in the access to quality preventive and curative health care and will benefit Georgian population irrespective of gender, disability, racial, religion, belief, ethnic or social origin.

The principles of equal opportunities will be applied to all involved parties and stakeholders through the project implementation process as well as will be reflected in all documents developed during the project.

The project objectives reflect the principles of The Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine imposing prohibition of financial gain and disposal of a part of the human body, including blood.

Whilst environmental requirements are not immediately applicable to the implementation of the project, if any such situation arises, both partners are required to comply with the environmental requirements of the EU.

10. Conditionality and sequencing

The main concepts of the project are based on current successful cooperation with EU instruments. In particular, project activities are conditional to the EU TAIEX instrument that took place in June 2018 and reflect recommendations set by European experts for Georgian health authorities on one side and on the other comply with the main dimensions of state health policy and the ongoing public health reforms.

The project will be implemented through close collaboration with the EU technical assistance allocated to the Ministry, which fills and echoes the goals of this project and aims at harmonization of national legislation with the EU directives in the quality and safety of human tissues, organs and cells. Synergies between these two projects will ensure improvement of quality and safety of human substances through the establishment of the joint controlling body, introduction of coordinated supervision mechanisms and development of institutional capacities.

The success of the project also depends on macroeconomic factors such as understanding of external conditions and identifying the binding constraints that guide selectivity of activities that spur and sustain healthcare reforms. The project outcomes will be stemmed from the sequencing of institutional adjustment and structural reforms and could therefore be initiated early on, in particular:

- a) Establishing more stringent licensing requirements for blood establishments and introducing of the accreditation system;
- b) Creating a competent authority/controlling body/inspectorate and developing institutional capacities;
- c) Introduction of quality control mechanisms;
- d) Upgrading of blood transfusion services based on GMP and GLP principles.

11. Indicators for performance measurement

The project MS and BC partners will ensure the smooth implementation of project activities and assess performance measurement in line with the logical framework. Through the project operation phase the project counterparts will meet regularly to ensure consistency of project implementation and achievement of the results.

Performance Indicators to Component 1

Sub-Result 1.1:

- Amendments to the Georgian primary and secondary legislation on blood safety prepared in an inclusive and evidence based process using the unified LA methodology;
- Availability of the Tables of Concordance.

Performance Indicators to Component 2 (Sub-Result 2.1):

- Status of normative acts related to the establishment of the NCA;

Sub-Result 2.2.:

- Number of blood banks participating in the assessment;
- Status of the functional review/assessment report of the blood establishments;

Sub-Result 2.3.:

- Status of written normative documents required to implement all legal, structural and functional changes for BTS reorganization;
- Status of the BTS reorganization strategy and its action plan;
- Number of preliminary memoranda with EU member states to ensure sufficiency of blood supplies during and after reorganization process;

Sub-Result 2.4.:

- Status of legal and political documents required to implement legal, structural and functional transition from for-profit to non-profit organizational arrangements;
- Share of blood establishments with non-profit organizational status;

Sub-Result 2.5.:

- Availability of legal and political documents required to establish centralized TTI testing laboratory;
- Number of blood donations that underwent TTI testing at centralized laboratory(s);

Sub-Result 2.6.:

- Availability of approved documents required to establish centralized National Reference Laboratory;

Sub-Result 2.7.:

- Availability of approved documents required for introduction of NAT methodology and other high sensitive technologies;
- Share of blood units among total donations screened by NAT;

Sub-Result 2.8.:

- Share of blood banks that have implemented external and internal quality assessment and control systems in accordance with EU blood directives;
- Share of blood banks that have developed blood processing quality standards and standard operating procedures in accordance with EU blood directives;
- Share of blood banks that use documentation/ SOPs in accordance with EU blood directives;
- Availability of guidelines, protocols related to the quality systems developed in accordance with EU directives and submitted to Georgian health authorities;
- Share of blood establishments that comply with GMP and GLP standards;

Sub-Result 2.9.:

- Availability of manuals, guidelines, ToRs;
- Number of health professionals trained in the operation of the upgraded donor database;
- Share of blood establishment that manage data according to the updated guidelines;
- Share of hospitals enrolled in the upgraded database;

Sub-Result 2.10.:

- Availability of a system for traceability, reporting, monitoring and investigating adverse events and reactions in clinical transfusion and blood donation;
- Share of blood establishments and hospitals engaged in national and/or international haemovigilance initiatives;
- Availability of programmes for vigilance, rapid alert and information sharing for emerging infections at regional, national and international levels;
- Availability of a collaboration mechanism with public health agencies in surveillance of diseases that have impact on blood safety and supplies;
- Status of approved normative act(s), guidelines, and manuals required for establishing and functioning the national haemovigilance system;
- Share of blood establishments with an accurate labeling system, identification procedures and record maintenance;
- Share of blood banks and hospitals that report adverse events and reactions to the Competent Authority;

Sub-Result 2.11.:

- Share of hospitals that apply national guidelines on the appropriate clinical use of blood and blood products;
- Share of hospitals having functional hospital transfusion committees;
- Share of hospitals that have conducted trainings on appropriate clinical use of blood and blood products.

Performance Indicators to Component 3

Sub-Result 3.1:

- Availability of a communication strategy for enhancing voluntary, non-remunerated donations from at low risk population including education, motivation, attraction, mobilization, recruitment and retention;
- Availability of thematic courses on societal benefits of blood donations for secondary schools and higher educational institutions and status of their integration into the educational curricula of secondary schools and higher educational institutions;
- Availability of collaboration platforms between governmental entities, public and private institutions to promote a positive social image of blood donors and to create a culture of voluntary unpaid donations;
- Availability of an implementation plan for the introduction of obligatory non-remunerated blood donations;

Sub-Result 3.2.:

- Share of blood banks with designated recruitment services;
- Availability of blood donor recruitment and retention guidelines, SOPs.

Performance Indicators to Component 4

Sub-Result 4.1:

- Availability of training needs analyses;
- Number of NCA inspectors trained and skilled to perform blood bank inspection/audits (including collection of evidences, identification and classification of non-conformities, assessment of risks, writing reports, imposing corrective measures and other relevant aspects of quality control);
- Number of administrative/public health professionals of the beneficiary organization and other stakeholders with full knowledge of updated legislation and EU standards;

Sub-Result 4.2:

- Availability of training needs analyses;
- Number of laboratory specialists trained and skilled in NAT methodologies and other high technologies for TTI testing;
- Availability of Reference Laboratory specialists capable to conduct QC, QA and QM in accordance with EU standards;
- Number of healthcare professionals (blood bank, clinical personnel) trained in application of new legislation, guidelines, standards and information management technologies for blood production, clinical use and haemovigilance.

The Quarterly Project Steering Committee meetings will also facilitate the coordination and monitoring of project development to assess project implementation against performance measurement and address any emerged issue.

Strong coordination with other stakeholder organizations, donors or interested parties related to the field of operation of the NCDC will also safeguard successful performance of the Twinning project.

12. Facilities available

The Beneficiary commits itself to deliver the following facilities:

- Adequately equipped office space for the RTA and the RTA assistant(s) for the entire duration of their secondment;
- Supply of office room including access to computer, telephone, internet, printer, photocopier;
- Adequate conditions for the STEs to perform their work while on mission;
- Provide suitable venues for the training sessions and meetings that will be held under the Project;
- Security related issues will be assured according to the standards and practices applicable for all Georgian public institutions.

ANNEXES TO PROJECT FICHE

1. Simplified Logical Framework
2. NCDC Organizational Chart
3. Distribution of Blood Banks in Georgia, 2019
4. TAIEX Expert Report

Annex 1
Simplified Logical Framework

Project Title: Strengthening Blood Safety System in Georgia				Programme name and number: EU support for the Implementation of the EU-Georgia Association Agreement, ENI/2018/041-415, Direct Management	
Beneficiary Institution: National Center for Disease Control and Public Health, Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia				Total budget: 1, 300,000 €	EU ENI financing (100%)
	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	Support public health policies and programmes to prevent the spread of communicable diseases, through promoting the safety of substances of human origin and ensuring the highest possible quality level of blood transfusion service in Georgia	<ul style="list-style-type: none"> • Prevalence of blood borne infections (HIV, HCV indicative) reduced in general population Baseline: 2017 - HIV - 400 per 100,000 (0.40%) HCV – 5% of general population Target: 2022 - HIV prevalence - <500 HCV prevalence - 0.5%	HIV-National SPECTRUM files HCV-National Population Survey (has to be conducted in every 5 years)	Widespread high-risk practices, patterns of high mobility specific to key populations. Change in political situation in Georgia	Government commitment on the fulfillment of AA/DCFTA requirements continued; Strong support and proactive cooperation of Twinning partner(s); Successful implementation of activities envisaged by National Hepatitis C Elimination and HIV/AIDS Strategic Plans.

<p>Specific (Project) Objective(s)</p>	<p>Upgrade national blood safety legislation in accordance with European regulations and strengthening national institutional capacities in Georgia with the aim to provide equal safety standards of blood components across the nation, assure safety of blood related services and prevent the spread of blood borne infections by blood transfusion</p>	<p>Level of compliance of blood establishments with the EU directive 2002/98/EC in terms of collecting, testing, processing, storing and distributing of blood components</p> <p>Baseline: 2019 - limited compliance</p> <p>Target: 2022 - full compliance</p> <ul style="list-style-type: none"> Level of compliance of blood establishments with EU Directive 2004/33/EC in terms of producing blood components <p>Baseline: 2019 - limited compliance</p> <p>Target: 2022 - full compliance</p> <ul style="list-style-type: none"> Level of compliance of blood establishments` quality systems with EU Directive 2005/62/EC <p>Baseline: 2019 limited compliance</p> <p>Target: 2022 - full compliance</p> <ul style="list-style-type: none"> Level of compliance of 	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Project documentation: legal analysis reports, institutional analysis reports, training needs assessments, recommendations etc; AA implementation report</p>	<p>Difficulties related to the implementation of the upgraded legislation (blood bank technical capacities, human resources, infrastructure, culture)</p> <p>Lack of commitment from respective actors Delays in adopting new/or amended legislation</p>	<p>Government commitment on the fulfillment of AA/DCFTA requirements continued;</p> <p>Strong support and proactive cooperation of Twinning partner(s);</p> <p>The Blood Safety Working Group established at the Ministry of Internally Displaced Persons, Labour, Health and Social Affairs will cooperate with the project staff on the upgrading of the national legislation</p>
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		<p>blood establishments` hemovigilance system for donor and patient adverse events with EU directive 2005/61/EC</p> <p>Baseline: 2019 - limited compliance</p> <p>Target: 2022 - full compliance</p>			
Mandatory results/outputs by components	Mandatory result 1: Approximation of Georgian primary and secondary legislation with the Union acquis on blood safety (Annex XXXI) performed	<ul style="list-style-type: none"> Status of normative acts approximating Georgian primary and secondary legislation with the Union acquis on blood safety <p>Baseline: 2019 – Amendments not elaborated</p> <p>Target: 2022 - Normative acts adopted by the GoG or respective ministries</p>	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Analysis reports of the relevant Georgian legislation</p> <p>Legislative Amendments</p> <p>AA implementation report.</p> <p>Project quarterly and final reports</p> <p>STE Mission reports</p>	<p>Difficulties related to the implementation of the upgraded legislation (blood bank technical capacities, human resources, infrastructure, culture)</p>	<p>The Blood Safety Working Group established at the Ministry of Internally Displaced Persons, Labour, Health and Social Affairs will cooperate with the project staff on the upgrading of the national legislation</p>
	Mandatory result 2: A well-organized, nationally coordinated blood transfusion system established in accordance with the provisions of the Association Agreement	<ul style="list-style-type: none"> Share of blood banks with non-profit legal status <p>Baseline: 2018 -14% (3 BB out of 22) of blood establishments have non-profit organizational status</p> <p>Target: 2022 - 100% of blood establishments have non-profit legal status</p> <ul style="list-style-type: none"> Share of blood processing and blood collection centers 	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Project quarterly and final reports</p> <p>STE Mission reports</p> <p>AA implementation report</p> <p>Operational plans and procedures, implementation manuals and guidelines</p>	<p>Blood bank resistance</p> <p>Lack of appropriate human resources</p> <p>Lack of material-technical resources</p> <p>Need for additional financial interventions</p>	<p>Strong advocacy at high political level ensured</p>

		<p>Baseline: 2019 - 22 (100%) of blood establishments collect blood and process blood components</p> <p>Target: 2025 - No more than 3 blood banks produce blood and blood components across the country and the rest of the licensed blood establishments operate as blood collection centers</p> <ul style="list-style-type: none"> Share of blood donations that underwent NAT at centralized TTI testing laboratories <p>Baseline: None</p> <p>Target: 2019 – 3% (3000) of total donations; 2020 – 50% (50 000) of total donations; 2021 – 70% (70 000) of total donations; starting from 2022 – 100% (100 000) of total donations</p>			
	<p>Mandatory result 3: Blood transfusion services based on voluntary blood donation are able to ensure safe, adequate and sustainable blood supplies</p>	<ul style="list-style-type: none"> Share of blood centers that collect 100% of blood donations from voluntary non-remunerated donors <p>Baseline: 2018 – 0</p> <p>Target: 2025 – at least 90% of</p>	<p>National blood registry (Unified Electronic Blood Donor Database)</p> <p>Supporting documents: guidelines, instructions, rules, operational plans</p>	<p>Law public awareness on needs and benefits of voluntary blood donations</p> <p>Delays in project implementation process</p>	<p>Strong collaboration and involvement at all levels including media, governmental, educational, donor, non-governmental and private organizations ensured</p>

		<p>blood establishments</p> <ul style="list-style-type: none"> • Share of unpaid voluntary donations among total number of donations <p>Baseline: 2018 – 28% of total donations</p> <p>Target: 2025 – at least 90% of the total donations</p> <ul style="list-style-type: none"> • Share of repeat donors among total donor pool recruited within the year <p>Baseline: 2018 – 12% of total donations</p> <p>Target: 2025 – at least 50% of total donations</p> <ul style="list-style-type: none"> • Share of educational institutions with specific awareness raising program on blood transfusion and unpaid voluntary donations <p>Baseline: 2018 - 0</p> <p>Target: 2022 – at least 50% of educational institutions</p>	Project quarterly and final reports		
	<p>Mandatory result 4: Capacity of relevant state authorities and other key stakeholders strengthened to ensure safety and</p>	<ul style="list-style-type: none"> • Number of NCA personnel capable to perform blood bank inspections in accordance with EU 	Project documentation (list of various meetings, list of participants from various meetings, training programmes,	Lack of human resources with basic education and experience in the relevant fields	Collaboration between all stakeholders in training needs identification and trainees/resource

	<p>quality of blood transfusion service</p>	<p>standards</p> <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 4 inspectors and 2 administrative personnel</p> <ul style="list-style-type: none"> • Number of TTI testing laboratory specialists capable to perform NAT testing <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 6 laboratory specialists and 2 administrative personnel</p> <ul style="list-style-type: none"> • Number of Reference Laboratory specialists capable to conduct QC, QA and QM in accordance with EU standards <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 6 laboratory specialists and 2 administrative personnel</p> <ul style="list-style-type: none"> • Number of public health professionals at BA and relevant governmental organizations with special 	<p>training materials, list of trainees); STE mission reports; Project quarterly and final reports etc.</p>	<p>Lack of sufficient support and/or means of relevant institutions</p>	<p>(training space, equipment) mobilization ensured</p>
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		<p>knowledge and well understanding of new requirements and updated regulations in blood safety</p> <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 10 public health professionals (BA, MoIDPLHSA and other relevant governmental entities)</p>			
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<p>Sub-results per component (optional and indicative)</p>	<p>1.1 National regulatory framework in blood safety revised and upgraded in accordance with Union acquis on blood safety</p>	<ul style="list-style-type: none"> Amendments to the Georgian primary and secondary legislation on blood safety prepared in an inclusive and evidence based process using the unified LA methodology <p>Baseline: 2019 – Amendments not elaborated</p> <p>Target: end of 2021 – Amendments/new normative acts adopted by the GoG or respective ministries:</p> <ul style="list-style-type: none"> - Law of Georgia on Donation of Blood and Blood Components - Law of Georgia on Licenses and Permits - Resolution of the Government of Georgia №385, 17.12.2010 - Decree of MoIDPLHSA №14/N, 14.01.2002 - State Safe Blood Program - Resolution of the Government of Georgia №74, 15.01.2014 - Decree of MoIDPLHSA №241/N, 05.12.2005 - Resolution of the Government of Georgia №539, 05.09.2014 - Decree of MoIDPLHSA №110/N, 14.03.2001 - Decree of MoIDPLHSA №01-26/N, 25.03.2019 <ul style="list-style-type: none"> Availability of the Tables of 	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Tables of concordance</p> <p>Project documentation: legal analysis reports, institutional analysis reports, training needs assessments, recommendations etc;</p>	<p>Difficulties related to the implementation of the upgraded legislation (technical capacities, human resources, infrastructure, culture)</p> <p>Blood bank resistance</p> <p>Insufficient human recourses</p>	<p>The Blood Safety Working Group established at the Ministry of Internally Displaced Persons, Labour, Health and Social Affairs will cooperate with the project staff on the upgrading of the national legislation</p>
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		<p>Concordance</p> <p>Baseline: 2019 – Draft documents elaborated by Ministry’s working group:</p> <ul style="list-style-type: none"> - Standards for blood testing - Standards for blood processing - Standards for donor selection - Standards for collection, storage and distribution of blood and blood components <p>Target: end of 2021 - amendments for approximation with following EU legal acts elaborated:</p> <ul style="list-style-type: none"> - Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 - Commission Directive 2004/33/EC of 22 March 2004 - Commission Directive 2005/62/EC of 30 September 2005 - Directive 2005/61/EC of 30 September 2005 			
	2.1 National Competent Authority established and fully functional to take the role, tasks and responsibilities required by EU Blood Directives	<ul style="list-style-type: none"> • Status of normative acts related to the establishment of the NCA <p>Baseline: 2019 - Not established</p> <p>Target:</p> <ul style="list-style-type: none"> - End of 2020 – legal bases for the establishment developed, 	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Reports on administrative/ institutional assessments, including legal basis for a fully</p>	<p>Need for additional financial, technical, human resources</p> <p>Delays in project implementation process</p> <p>Low motivation of blood banks for participation in the assessment</p>	<p>NCA empowered to perform its duties with sufficient number of qualified and competent personnel and implemented quality system appropriate for the tasks it performs.</p>

		<p>including structure, functions, budget, organizational chart, planning, inspection program, JAS, standard operating procedures (SOP), check-lists for inspectors, training plan, registries</p> <p>- 2021 - NCA established and fully functional to provide overall surveillance of blood transfusion service from blood selection to clinical use of blood and blood products (including accreditation, designation, authorization or licensing of blood establishments as well as Inspections and control measures)</p>	<p>functional blood transfusion service surveillance system</p> <p>Supporting documents: operational plans and procedures, manuals and guidelines</p>	<p>Blood Bank resistance</p> <p>Possible deficit of blood products at initial stage of system reorganization</p> <p>Lack of experience in this specific field</p> <p>Complicated logistical mechanism</p> <p>Need for building new infrastructure and equipment</p> <p>Need for high skilled personnel</p> <p>Need for additional financial resources for establishing of a new functions/infrastructure/equipment/human resources</p> <p>High cost of NAT methodology</p> <p>Need for new infrastructure and equipment</p> <p>Lack of skilled personnel capable to perform QM,</p>	<p>Strong advocacy at high political level ensured</p> <p>Additional financial, logistical and human resources mobilized</p> <p>Additional financial resources mobilized to ensure structural, functional and logistical issues and develop sufficient pool for competent human resources</p> <p>National reference laboratory established either as a single standing structure or its functions integrated within the centralized testing laboratory or one of the state owned blood bank.</p> <p>High involvement and trainings of all users (hospitals, blood banks, NCDC) ensured</p> <p>Strong collaboration between blood establishments, hospitals and public health centers ensured</p>
	<p>2.2 Assessment of blood banks performed</p>	<ul style="list-style-type: none"> Number of blood banks participating in the assessment <p>Baseline: 2018 - 4 blood establishments</p> <p>Target: 2020 - 22 blood establishments</p> <ul style="list-style-type: none"> Status of the functional review/assessment report of the blood establishments <p>Baseline: 2018 - TAIEX expert report available</p>	<p>Assessment report Project quarterly and final reports</p>		

		<p>Target: 2020 - comprehensive assessment of all (22) licensed blood establishments conducted, gaps identified, recommendations for improvement prepared and submitted to Georgian health authorities</p>		<p>QC and QA Lack of control mechanisms to provide day-to-day monitoring of the donor database and data accuracy</p>	
	<p>2.3 Reorganization of blood transfusion service (BTS) performed</p>	<ul style="list-style-type: none"> Status of written normative documents required to implement all legal, structural and functional changes for BTS reorganization <p>Baseline: 2019 – N/A</p> <p>Target: end of 2020 - Legal bases for BTS reorganization developed including BTS optimization plan, recommendations for effective statutory models, contingency plan etc.</p> <ul style="list-style-type: none"> Status of the BTS reorganization strategy and its action plan <p>Baseline: 2019 – N/A</p> <p>Target: end of 2020 - BTS development (reorganization) strategy and its action plan endorsed by the GoG</p>	<p>RAMA licensing data</p> <p>Plans for improvement of legal, structural and functional bases of BTS</p>	<p>Possible low interest and motivation of blood banks and hospitals to participate in the national hemovigilance system</p> <p>Difficulties related to the implementation of the upgraded legislation (hospital low motivation, insufficient capacities, lack of skilled human resources)</p>	

		<ul style="list-style-type: none"> • Number of preliminary memoranda with EU member states to ensure sufficiency of blood supplies during and after reorganization process <p>Baseline: 2019 - none</p> <p>Target: end of 2020 – memoranda with at least two EU Member States</p>			
	<p>2.4 Transition to the mandatory non-profit organizational form for blood establishments initiated</p>	<ul style="list-style-type: none"> • Status of legal and political documents required to implement legal, structural and functional transition from for-profit to non-profit organizational arrangements <p>Baseline: 2019 – N/A</p> <p>Target: end of 2020 - Legal bases for BTS transition from profit based to non-profit organizational form developed including BTS transition plan</p> <ul style="list-style-type: none"> • Share of blood establishments with non-profit organizational status <p>Baseline: 2019 - 14% (3 BB out of 22) of blood establishments are based on non-profit organizational status</p> <p>Target: 2022 - 100% of blood establishments have non-profit</p>	<p>RAMA licensing data</p> <p>STE mission reports</p> <p>Project quarterly and final reports</p> <p>Assessment reports</p>		

		legal status			
	2.5 Centralized TTI testing laboratory(s) established	<ul style="list-style-type: none"> Availability of legal and political documents required to establish centralized TTI testing laboratory <p>Baseline: 2019 – N/A</p> <p>Target: end of 2020 - centralized TTI testing laboratory established</p> <ul style="list-style-type: none"> Number of blood donations that underwent TTI testing at centralized laboratory(s) <p>Baseline: N/A</p> <p>Target: 2022 – 100% of donations</p>	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>National Blood Registry (Unified Electronic Donor Database)</p>		
	2.6 National reference laboratory established	<ul style="list-style-type: none"> Availability of approved documents required to establish centralized National Reference Laboratory <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – Appropriate legal act approving establishment of the National Reference laboratory (including organizational structure, functions and related issues) endorsed by the GoG.</p>	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>Supporting documents: guidelines, instructions, rules, operational plans</p>		

	<p>2.7 Nucleic Acid Testing for screening of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and HCV introduced at centralized testing laboratory(s)</p>	<ul style="list-style-type: none"> Availability of approved documents required for introduction of NAT methodology and other high sensitive technologies <p>Baseline: 2019 – N/A</p> <p>Target: 2020 – Appropriate normative acts/amendments to the current regulations introducing NAT methodology for TTI testing (State Safe Blood Program, technical requirements) endorsed by the GoG</p> <ul style="list-style-type: none"> Share of blood units among total donations screened by NAT <p>Baseline: 2019 - 0</p> <p>Target: 2019 – 3% (3000) of total donations; 2020 – 50% (50 000) of total donations; 2021 – 70% (70 000) of total donations; starting from 2022 – 100% (100 000) of total donations</p>	<p>National Blood Registry (Unified Electronic Donor Database)</p> <p>Supporting documents: guidelines, instructions, rules, operational plans</p>		
	<p>2.8 Requirements for a quality systems to maintain the highest possible standards in all aspects of blood transfusion developed and</p>	<ul style="list-style-type: none"> Share of blood banks that have implemented external and internal quality assessment and control systems in accordance with EU blood directives 	<p>Routine monitoring data</p> <p>STE mission reports</p> <p>Project quarterly and final reports</p>		

	implemented	<p>Baseline: 2019 – N/A</p> <p>Target: 2022 – at least 95% of blood establishments</p> <ul style="list-style-type: none"> Share of blood banks that have developed blood processing quality standards and standard operating procedures in accordance with EU blood directives <p>Baseline: 2019 – N/A</p> <p>Target: 2022 – at least 95% of blood establishments</p> <p>Share of blood banks that use documentation/SOPs in accordance with EU blood directives</p> <p>Baseline: 2019 – N/A</p> <p>Target: 2022 – at least 95% of blood establishments</p> <ul style="list-style-type: none"> Availability of guidelines, protocols related to the quality systems developed in accordance with EU directives and submitted to Georgian health authorities <p>Baseline: 2019 – current quality regulations (Minister’s Decree №14/N, 14.01.2002, GoG resolution №74, 15.01.2014,</p>			
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		<p>GoG №539, 05.09.2014)</p> <p>Target: end of 2021 – amendments to the current quality regulations and/or new normative documents developed in accordance with EU directives and adopted by the GoG</p> <ul style="list-style-type: none"> • Share of blood establishments that comply with GMP and GLP standards <p>Baseline: 2019 – N/A</p> <p>Target: 2025 - at least 95% of blood establishments comply with GMP and GLP standards</p>			
	<p>2.9 Unified Electronic Donor Database upgraded</p>	<ul style="list-style-type: none"> • Availability of manuals, guidelines, ToRs <p>Baseline: 2019 – N/A</p> <p>Target:</p> <ul style="list-style-type: none"> - ToRs for upgrading of Donor Database developed within 9 months from the beginning of the project - 2020 – operational guidelines / manuals in place <ul style="list-style-type: none"> • Number of health professionals trained in the operation of the upgraded donor database 	<p>National Blood Registry (Unified Electronic Donor Database)</p> <p>Supporting documents, including operational guidelines/manuals, ToRs STE mission reports Project quarterly and final reports</p>		

		<p>Baseline: 2017 – 425 trainees (blood bank and hospital staff)</p> <p>Target: 2021 – at least 50 blood bank professional and 400 hospital data operators</p> <ul style="list-style-type: none"> • Share of blood establishment that manage data according to the updated guidelines <p>Baseline: 2019 – N/A</p> <p>Target:</p> <ul style="list-style-type: none"> - 2021 – 100% of blood establishments operate in the upgraded database - Upgraded database ensures vein-to vein traceability, accountability, and hemovigilance related to blood donations <ul style="list-style-type: none"> • Share of hospitals enrolled in the upgraded database <p>Baseline: 2019 – 60% of hospitals performing blood transfusion</p> <p>Target: 2021 – 100% of hospitals performing blood transfusion</p>			
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	<p>2.10 National Hemovigilance Network established</p>	<ul style="list-style-type: none"> • Availability of a system for traceability, monitoring and investigating adverse events and reactions in clinical transfusion and blood donation <p>Baseline: 2019 – N/A</p> <p>Target: 2022 – a robust national hemovigilance system established enabling monitoring of all aspects of transfusion practice, including adverse events occurring in the vein-to-vein chain</p> <ul style="list-style-type: none"> • Share of blood establishments and hospitals engaged in national and/or international hemovigilance initiatives <p>Baseline: 2019 – N/A</p> <p>Target: 2022 – 100% of blood establishments and at least 70% of hospitals are engaged in the national and/or international hemovigilance programs</p> <ul style="list-style-type: none"> • Availability of programmes for vigilance, rapid alert and information sharing for emerging infections at regional, national and international levels 	<p>Legislative Herald of Georgia, LEPL www.matsne.gov.ge</p> <p>National Blood Registry (Unified Electronic Donor Database)</p> <p>Assessment reports Project quarterly and final reports Supporting documents including guidelines, manuals</p>		
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		<p>Baseline: 2019 – N/A</p> <p>Target: 2022 – vigilance, rapid alert and information sharing program(s) in place at regional, national and international levels</p> <ul style="list-style-type: none"> • Availability of a collaboration mechanism with public health agencies in surveillance of diseases that have impact on blood safety and supplies <p>Baseline: 2019 – N/A</p> <p>Target: 2021 – collaboration platforms with 64 public health centers established</p> <ul style="list-style-type: none"> • Status of approved normative act(s), guidelines, and manuals required for establishing and functioning the national hemovigilance system <p>Baseline: 2019 – N/A</p> <p>Target: Normative acts adopted by the GoG or relevant ministries/governmental agencies</p> <ul style="list-style-type: none"> • Share of blood establishments with an accurate labeling system, 			
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		<p>identification procedures and record maintenance</p> <p>Baseline: 2019 – data N/A</p> <p>Target: 2021 – 100% of blood establishments</p> <ul style="list-style-type: none"> Share of blood banks and hospitals that report adverse events and reactions to the Competent Authority <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 - 100% of blood establishments and at least 95% of hospitals performing blood transfusion</p>			
	<p>2.11 Unnecessary blood transfusion at clinical settings reduced</p>	<ul style="list-style-type: none"> Share of hospitals that apply national guidelines on the appropriate clinical use of blood and blood products <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 - at least 80% of hospitals have implemented national standards on clinical use of blood and blood products</p> <ul style="list-style-type: none"> Share of hospitals having functional hospital transfusion committees <p>Baseline: 2019 – N/A</p>	<p>Universal healthcare reporting system</p> <p>Routine monitoring data</p> <p>Project quarterly and final reports</p>		

		<p>Target: end of 2021 - At least 80% of hospitals have functional hospital transfusion committees</p> <ul style="list-style-type: none"> Share of hospitals conducted trainings on appropriate clinical use of blood and blood products <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 - at least 80% of hospitals have conducted trainings in the appropriate clinical use of blood and blood products</p>			
	3.1 Awareness of the general population and specific target groups on blood transfusion increased	<ul style="list-style-type: none"> Availability of a communication strategy for enhancing voluntary, non-remunerated donations from at low risk population including education, motivation, attraction, mobilization, recruitment and retention <p>Baseline: Findings from 2016 focus group survey (94 interviewees)</p> <p>Target: end of 2020 – communication strategy for popularization unpaid voluntary donations developed</p> <ul style="list-style-type: none"> Availability of thematic 	<p>Communication strategy and an appropriate normative document adopting the strategy</p> <p>Educational/promotional materials</p> <p>Operational plans, procedures, implementation manuals and guidelines</p>	<p>Law public awareness on needs and benefits of voluntary blood donations;</p> <p>Social problems, donation stress</p> <p>Lack or depreciation of important information</p> <p>Lack of positioning of the problem</p> <p>Incorrect messages, rumors and myths, mistrust to blood banks;</p> <p>Lack of stimulation of unpaid voluntary repeat donations</p>	<p>Strong collaboration and involvement at all levels including media, governmental, educational, donor, non-governmental and private organizations ensured</p>

		<p>courses on societal benefits of blood donations for secondary schools and higher educational institutions and status of their integration into the educational curricula of secondary schools and higher educational institutions</p> <p>Baseline: 2019 – N/A</p> <p>Target: 2020 – educational curricula for secondary schools and higher educational institutions developed / endorsed and their piloting started in at least 10 public schools and 2 higher educational institutions across the country</p> <ul style="list-style-type: none"> • Availability of collaboration platforms between governmental entities, public and private institutions to promote a positive social image of blood donors and to create a culture of voluntary unpaid donations <p>Baseline: 2019 – N/A</p> <p>Target: 2020 – Memorandum of Understanding with the Ministry of Education, Science,</p>		<p>Insufficient human resources Delays in project implementation process</p>	
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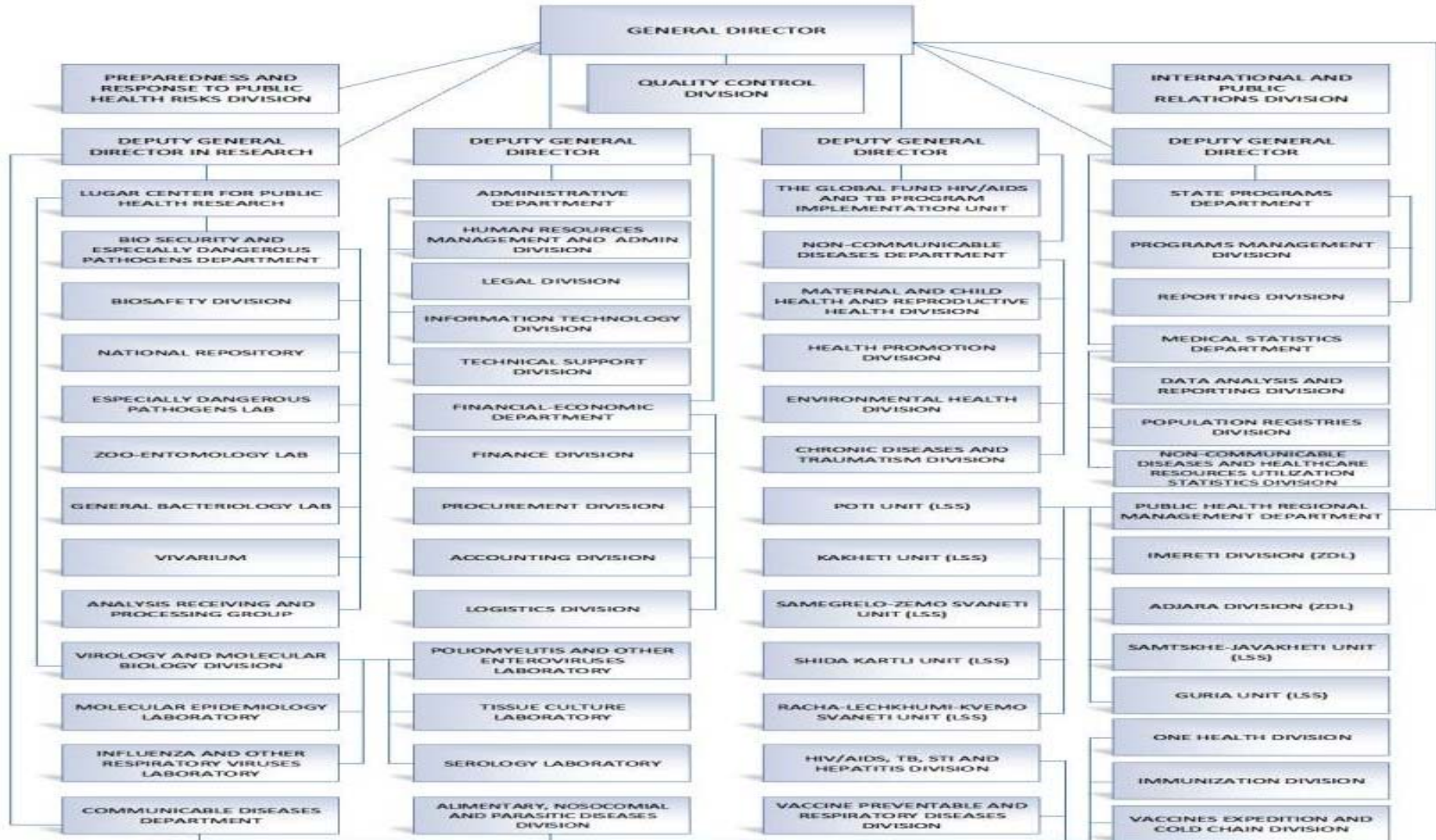
		<p>Culture and Sport of Georgia signed; Intersectoral working group established</p> <ul style="list-style-type: none"> • Availability of an implementation plan for the introduction of obligatory non-remunerated blood donations <p>Baseline: 2019 – N/A</p> <p>Target: 2020 – legal bases and implementation plan for introduction of obligatory non-remunerated donations developed including contingency plans to response possible blood shortage and ensure country’s self-sufficiency</p>			
	<p>3.2 Donor recruitment services strengthened at blood centres</p>	<ul style="list-style-type: none"> • Share of blood banks with designated recruitment services <p>Baseline: 2019 – 70% of blood establishments have person(s) specifically assigned for donor recruitment</p> <p>Target: 2022 – 100% of blood banks have a well organized recruitment services</p> <ul style="list-style-type: none"> • Availability of blood donor recruitment and retention 	<p>National Blood Registry (Unified Electronic Donor Database) Monitoring report Guidelines, manuals, SOPs</p>		

		<p>guidelines, SOPs</p> <p>Baseline: 2019 – N/A</p> <p>Target: Guidelines, SOPs developed</p>			
	<p>4.1 Capacities of the National Competent Authority and Beneficiary Administration strengthened</p>	<ul style="list-style-type: none"> • Availability of training needs analyses <p>Baseline: 2019 – N/A</p> <p>Target: Training needs identified, training plans developed within 6 months from project initialization</p> <ul style="list-style-type: none"> • Number of NCA inspectors trained and skilled to perform blood bank inspection/audits (including collection of evidences, identification and classification of non-conformities, assessment of risks, writing reports, imposing corrective measures and other relevant aspects of quality control) <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 4 inspectors and 2 administrative personnel</p> <ul style="list-style-type: none"> • Number of administrative/public health 	<p>Training programs, reports, materials, list of training participants, training evaluations</p> <p>STE mission reports</p> <p>Study visits' report</p>	<p>Lack of human resources with basic education and skills either trainers or trainees</p> <p>Delays in project implementation process</p>	<p>Collaboration between all stakeholders in training needs identification and trainees/resource (training space, equipment) mobilization ensured</p>

		<p>professionals of the beneficiary organization and other stakeholders with full knowledge of updated legislation and EU standards</p> <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 10 public health professionals (BA, MoIDPLHSA and other relevant governmental entities)</p>			
	<p>4.2 Capacities of the centralized laboratory and healthcare institutions (blood establishments, hospitals) strengthened</p>	<ul style="list-style-type: none"> • Availability of training needs analyses <p>Baseline: 2019 – N/A</p> <p>Target: Training needs analysis developed, needs identified and training plans developed with 6 month of project inception.</p> <ul style="list-style-type: none"> • Number of laboratory specialists trained and skilled in NAT methodologies and other high technologies for TTI testing <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 6 laboratory specialists and 2 administrative personnel</p> <ul style="list-style-type: none"> • Availability of Reference Laboratory specialists capable to conduct QC, QA 	<p>Training programs</p> <p>Project documentation (list of meeting/trainings, participants, recommendations)</p> <p>Project quarterly and final reports</p> <p>STE mission reports</p> <p>Study visits' report</p>		

		<p>and QM in accordance with EU standards</p> <p>Baseline: 2019 – N/A</p> <p>Target: end of 2021 – at least 6 laboratory specialists and 2 administrative personnel</p> <ul style="list-style-type: none"> • Number of healthcare professionals (blood bank, clinical personnel) trained in application of new legislation, guidelines, standards and information management technologies for blood production, clinical use and hemovigilance <p>Baseline: 2019 – N/A</p> <p>Target: 2021 - at least 50 blood bank professional and 400 hospital personnel</p>			
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Annex 2
NCDC Organizational Chart



Annex 3
Distribution of Blood Banks in Georgia, 2019



Annex 4

**EXPERT REPORT**

EVENT TITLE: TAIEX EXPERT MISSION ON THE APPROXIMATION OF NATIONAL BLOOD SAFETY LEGISLATION TO EU REGULATIONS

ID: 66143

DATE: 18TH-20TH JUNE 2018

PLACE: TBILISI

Please fill in this report in detail and return it electronically to nais.habermacher@ec.europa.eu within two weeks of the completion of your mission. For reasons of coherence, teams of experts are invited to draft joint reports.

REPORT

1) Please describe the overall aim of your mission:

The aim of the expert mission is to provide technical consultation on the upgrading of blood safety in Georgia through approximation of the national blood safety legislation with the standards set forth by EU directives 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC as well as to share the information on statutory models and best practice of the organization of Blood Transfusion Service (BTS) in EU countries. The mission will include discussions on transition from paid donation practice to a voluntary, non-remunerated donation system and provide recommendations on blood establishment (BE) licensing, as well as quality management, quality assurance, and quality improvement requirements.

2) **State of play – analysis (indicative length: 1 page)**

Please list key issues and developments in the area covered by your mission, e.g. legislation, policies, statistics, resources and infrastructure available, best practices and shortcomings which explain the current and the future need for assistance. This section is particularly important for defining our future activities as well as for the European Commission and the EU Delegation.

The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the European Union. Neither the European Union institutions and bodies nor any person acting on their behalf may be held responsible for the use which may be made of the information contained therein.

Main demographic and economic indicators for Georgia

Population: 3 719 300

Life expectancy at birth: 72.7

GDP per capita (at current prices), (2016): 3852 USD

Government expenditure on health as % of GDP: 3%

General Government expenditure on health per capita: 116 USD

Regulation in the Blood field

Legislation covering the field of blood exists in Georgia. It is a complex set of different legally binding documents overarched by “Law On Donation of Blood and Blood Components”(from 1995, amended 2004 and 2006):

- Law On Donation of Blood and Blood Components
- Resolution Of the Government of Georgia №385 approving Provisions on the Rules and Terms of Issue of a Medical Practice License and an In-patient Facility Permit
- Decree of the Minister №14/N on Approval of Rules for the Preparation, Reservation and Usage of blood and blood components (14.01.2002)
- Decree of the Minister №241/N on Determining of Blood and Blood Components Donation Contraindications (05.12.2000)
- Resolution of the Government of Georgia № 74 approving Technical Regulations - Obligatory Norms for Functioning Blood Transfusion Centers (15.01.2014)
- Resolution of the Government of Georgia №539 on Approval of Technical Regulations for Blood Establishments (05.09.2014)
- Decree of The Minister №110/N on Transfusion Centers further development (14.03.2001)

Legislation allows voluntary, unpaid, non-remunerated donation as well as family, replacement and remunerated donations.

Serological testing is required by national regulations, but sensitivity of tests is not a requirement, so that rapid tests are in use.

Although procedure for licensing of blood establishments exists, system is complicated, specifically for suspension or revocation of license. Requirements for obtaining the license are basic and not targeting the specific topics of transfusion service. They covers only issues of personal hygiene and cleaning of the premises, medical waste management, general disinfection and sterilization, storage of the blood and blood components, water and electricity supply, medical records and qualification of the medical staff.

There is no competent authority for blood fulfilling the functionalities according to the EU Directives, particularly inspection and haemovigilance (SARE management) role.

No inspection and control measures are carried out routinely.

No algorithms for TTI testing are in place.

There are no updated national guides on quality and safety of blood components.

Donation

Only 28% of total donations come from non-remunerated voluntary unpaid donors.

Donors deferral criteria are set by the Minister's decree, but no common Donor Questionnaire exists. KAP survey on the voluntary donor motivation factors has been conducted.

Organisation

There are 22 blood establishments that are licensed for collection of blood and production of blood components. Each BE is autonomous, there is no functional network for management of blood supply.

86% of them are for-profit organizations.

17 blood establishments out of them participate in the State Safe Blood Program.

Quality System

Since 2005 common national IT system - an Electronic Donor Database is in use. It contains information on donors-demographic and testing records and allocates the unique ID number to the donor. System does not allocate the unique number to the each donation.

During the mission 4 blood establishments were visited:

- City Station of Blood Transfusion, Ltd , Tbilisi,
- Institute of Hematology and Blood Transfusion, Ltd, Tbilisi
- Kvemo Kartli Regional Blood Bank Station, Ltd., Rustavi
- Blood Bank and Clinical Transfusion Department of High Technology Medical Center, University Clinic, Ltd., Tbilisi.

Neither visited establishment has quality system applicable to their activities implemented. Except in the Kvemo Kartli Regional Blood Bank Station, no control of sterility of the components is performed.

Since 1997 under the State Safe Blood Program 15 blood establishments are provided with resources for

- Screening of blood donors for Hepatitis B and C, HIV by means of EIA method and Syphilis (using TPHA method) as well as blood group and rhesus determination
- Confirmatory testing for HIV (AIDS Center) and Hepatitis C (Lugar Center)
- Provision of external quality control by Lugar Center of NCDC with voluntary participation of all blood banks.

From 2018 hepatitis C screening-positive samples confirmatory tested at the Lugar Center for Core-Ag.

Unpaid donation and NAT testing is mandatory for blood donors with high behavioral risk (MSM, persons with unprotected sexual contacts or multiple partners).

Most of the blood is processed by outdated techniques due to lack of equipment, poor condition of the premises or unfavourable organisational aspects (e.g. platelets processed from PRP, extraction done manually, low number of filtered components, no irradiated components...)

3) Recommendations (indicative length: 1 page)

Please list i) your main conclusions; ii) your recommendations (legal/institutional/operational dimensions) and iii) if applicable possible areas for further TAIEX assistance.

i) Main conclusions

- a. Ratio of non-paid to paid blood donations of 30:70 cannot guarantee desired level of safety of the blood components.
- b. Situation where majority of blood establishments are running on pro-profit base causes risks for decreased quality and safety of the blood components.
- c. There is no Competent Authority performing tasks of authorization and surveillance of blood establishments creates environment, inspections are not performed regularly.
- d. There is significant level of incompatibility of National legislation with EU Blood Directives; highlighting here requirements for voluntary unpaid donation, donor testing, quality system for blood establishments, inspection.
- e. There is no functional national transfusion network allowing sustainable and self-sufficient blood supply.
- f. No quality system relevant for blood components processing is implemented in blood establishments to assure quality and safe blood, particularly meaning SOPs, equipment qualification, processes validation.
- g. There is no system for allocation of unique donation number.
- h. Premises and equipment are seriously outdated resulting in a processing of obsolete or low quality components. Majority of the processes observed are performed manually.
- i. There are dramatic differences between the condition of the BEs visited. Neither fully complies with the contemporary standards, but some are in a so poor condition, not meeting even the minimal requirements.

ii) Recommendations

- a. We underline the priority of shifting the actual situation of 70% paid blood donation to a 100% voluntary blood donation within the shortest time period possible.
To achieve that goal strong commitment of health authorities is of crucial importance. National Blood Policy needs to be developed together with the program and plan of intensive promotion of VUD covering simultaneously the whole country. In the designing of the promotional campaigns, to reach the targeted group and achieve the best results PR professionals should be engaged. Sufficient financial and human resources should be allocated for that purpose. All professional working in transfusion should be involved, as well as all relevant and appropriate NGOs.
- b. Human blood is a precious resource, especially given within altruistic, voluntary donation act, that should be managed by a public entity in order to guarantee to the entire population, through a network of transfusion services, timely access to the blood components of the same safety and quality.
Transfusion services should be organized and managed on the principles of voluntary, solidary and repetitive blood donation, processing of safe and quality blood products, proper use of blood, hemovigilance and transfusion safety.
- c. It is strongly recommended to establish as soon as possible National Competent Authority for blood, fully functional to take the role, tasks and responsibilities required in EU Blood Directives. NCA should be constituted as new public/state body or specialized unit within the existing larger body, empowered to perform its duties, with sufficient number of qualified and competent personnel and implemented quality system appropriate for the tasks it performs.
Training plan for the inspectors should be developed and inspectors trained in conducting inspection of BE, collection of evidences, identification and classification of nonconformities, writing reports, imposing corrective measures and all other relevant aspects of inspection.
NCA should design inspection programme and start on-site inspections in a shortest possible time.
- d. Actual Georgia legislation should be minutely reviewed and revised to represent correct

transposition of EU Directives' requirements.

- e. Improvements of existing national IT system should be done, especially in terms of allocation of traceability (unique donation ID number), proper blood component labeling, automatically transmission of test results from the serology and immunohematologic lab.

Already existing information on the donors in the IT should be kept and maintained for the purpose of the traceability and haemovigilance but also as a core of the future only voluntary non-paid donors' pool.

- f. Having in mind size of population and country it is recommended for Transfusion service to be centralized. Activities of blood testing and processing, and distribution of blood components should be performed in maximum 2 BEs - one in Tbilisi and another in western part of the country. Collection sites should be numerous and spread over the country, either as mobile or fixed sites for the reasons of accessibility. Centralization will have positive effects on, at minimum, uniformity of the components' quality, increase of quality, lower cost of service, decrease of need for competent personnel.

Prior to development of the reorganization plan due diligence of the existing BEs should be performed assessing all aspects: personnel, premises, equipment and QS.

In reorganization of the service care should be taken on the requirements for the competences of the personnel-especially responsible person of the BE shall be medical professional, expert in transfusion medicine.

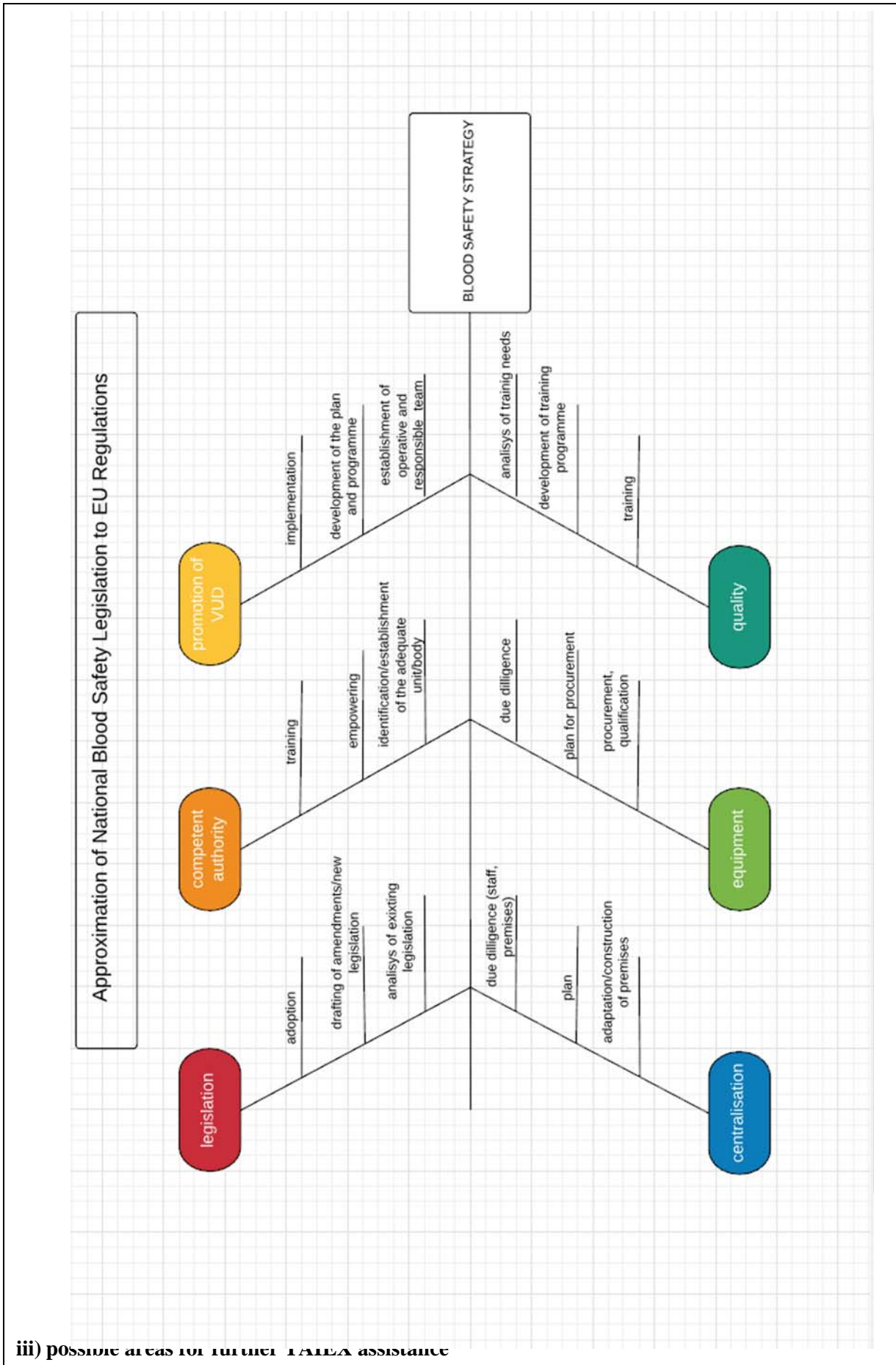
The other most prominent aspect that should be taken into account is the fact that automatization of the processes is current golden standard in transfusion medicine, preventing different types of errors. Particularly processes such as TTI testing and immunohaematology testing should not be performed manual as they are in observed BEs. Centralization will enable that improvement also.

- g. Technical level of the transfusion professionals should be increased.

In that aim access to international guidelines or publications should be assured. Initial efforts should be done in terms of organizing the translation into Georgian language of most relevant of them.

Training needs should be assessed and training plan developed including initial and continuous training. Practical training should be performed particularly in the processing, testing, haemovigilance and QC aspects.

Structured view of the recommendations is presented graphically in fishbone diagram as follows:



iii) possible areas for future TA/EA assistance

We recommend following areas to be targeted by TAIEX event:

- a. Establishment of competent authority for blood
 - study visits to explore different organizational models and functions of CA
- b. Organization of the Transfusion Service
 - study visits to explore different organizations of functional Transfusion Service assuring full self-sufficiency through VUD of quality and safe blood components
- c. Strategies and tools for the implementation of a voluntary blood donation
 - workshop supporting preparation of development of the plan for the VUD promotion
- d. Quality system in the blood field
 - series of workshops covering QM, QA and QC in transfusion
 - study visit(s) to cover identified training needs in specific topics
- e. Establishment of the inspectorate for the blood field
 - series of workshops covering issues of establishment of the inspectorate: QS (SOPs, check-lists, planning, risk assessment) , personnel, training programme
 - expert mission(s) to exercise the inspection under supervision of experienced inspectors
 - study visit(s) to observe inspection performance

4) Gender equality

In line with the EU Gender Action Plan 2016-2020, the European Commission aims to strengthen girls' and women's rights, to give them a stronger voice and to improve their participation as well as empower them in all the areas in which we provide assistance. In this regard, how do you assess the progress of policy or the institutional set-up in the country and/or in the area covered by your mission?

The participation as well as the empowerment of women in the area cover with this TAIEX event was very high. In the most of the activities beneficiary country was presented by well-trained women, with knowledge and decision capacity in the fields they work.

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