



EUROPEAN COMMISSION

TWINNING PROJECTS

INTERIM QUARTERLY REPORT

TWINNING INTERIM QUARTERLY REPORT number: **1**

Project Title: **STRENGTHENING BLOOD SAFETY SYSTEM IN GEORGIA**

Partners: **Republic of Lithuania (LT; Lead Partner) – National Blood Center**
Netherlands (NL; Junior Partner) – Sanquin Blood Supply
Georgia (GE; Beneficiary Country) – National Center for Disease Control and Public Health

Date: **15-APRIL-2020**

Twinning Grant Contract number:

ENI/2019/411-554

Daumantas Gutauskas
Member State PL

[signature] _____

[date] _____

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[signature] _____

[date] _____

The **Interim Quarterly Report** for the project comprises the following parts:

- Section 0** Executive summary listing decisions needed to be taken by the Project Steering Committee
- Section 1** Basic data on the project
- Section 2** Content: progress achieved in the implementation of the Twinning project during the reporting period and schedule for the remaining period
- Section 3** Expenditure: actual expenditure in relation to budgeted expenditure
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List of Acronyms Used

BA	<i>Beneficiary Administration</i>
BC	<i>Beneficiary Country</i>
BC PL	<i>Beneficiary Country Project Leader</i>
CA	<i>Contracting Authority</i>
EU	<i>European Union</i>
EUD	<i>Delegation of the European Union</i>
IQR	<i>Interim Quarterly Report</i>
JPL	<i>Junior Project Leader</i>
LT	<i>Lithuania</i>
MS	<i>Member State</i>
NCDC&PH	<i>National Center for Disease Control and Public Health</i>
NL	<i>Netherlands</i>
PL	<i>Project Leader</i>
PSC	<i>Project Steering Committee</i>
PSCM	<i>Project Steering Committee meeting</i>
RTA	<i>Resident Twinning Advisor</i>
RTA-C	<i>Resident Twinning Advisor Counterpart</i>
STE	<i>Short-Term Expert</i>

Section 0: Executive summary

The overall objective of the EU Twinning Project "Strengthening Blood Safety System in Georgia" is to support public health policies and programmes to prevent the spread of communicable diseases, through promoting the safety of substance of human origin and ensuring the highest possible quality level of blood transfusion service in Georgia.

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The specific objectives of the Project are to 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.

The project consists of four components as follows:

- Component 1 : Approximation of Georgian primary and secondary legislation with the Union acquis on blood safety performed
- Component 2 : A well-organized, nationally coordinated blood transfusion system established and functioning in accordance with the provisions of the Association Agreement
- Component 3 : Blood transfusion services based on voluntary blood donation are able to ensure safe, adequate and sustainable blood supplies.
- Component 4 : Capacity of relevant state authorities and other key stakeholders strengthened to ensure safety and quality of blood transfusion service.

The Resident Twinning Advisor (RTA) Mr. Algirdas Griskevicius moved to Georgia and started working on the project on January 15, 2020, making that date the starting date of the implementation period of the EU Twinning Project "Strengthening Blood Safety System in Georgia".

As the Beneficiary Administration, the National Center for Disease Control and Public Health (NCDC&PH) of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia equipped the RTA office (RTA and RTA assistants) with 2 office rooms, 5 computers, internet and telephone connections, office supplies and ancillaries.

After the arrival of the RTA, Initial Work Plan (IWP) was drafted; the IWP Preparation Meeting was held on 28 March, 2019, and the Communication and Visibility Plan was developed.

The RTA assistants were selected through an official recruitment and selection procedure in February and March 2020. RTA Assistant and RTA Language Assistant started working on 25th of March.

The initial Project Steering Committee meeting (PSCM, so-called "zero Project Steering Committee meeting") was organized on 9 March 2020, during which the activities foreseen for the first six months were presented and the IWP and the Communication and Visibility Plan were adopted.

Georgia confirmed its first COVID-19 case on February 26. To halt further spread of the virus, on March 14 the Government of Georgia announced about the decision to suspend land travel with neighboring countries.

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On March 21, the President of Georgia issued Edict No 1 and declared the State of Emergency through the whole territory of Georgia until April 21. The GoG suspended all air movement and banned all foreign national from entering the country until at least May 10.

As a result of registered cases of internal disease transmission, Georgia announced nationwide lockdown and partial curfew starting from March 31. The new restrictions included observance of curfew between 21:00-06:00, suspension of public transportation, limiting the number of passengers in a single vehicle and banning of gathering of more than three people and observance a 2-meter distance.

To slow the spread of Coronavirus, by the decision of the Georgian Government, the state of emergency was extended until May 22, entailing a night curfew, suspension of public transport and a ban of gathering of more than three people.

The above restrictions, to some extent, affected the project implementation process and to ensure uninterrupted progress of the project, before the restrictions are gradually lifted, those activities have been planned that could be implemented remotely.

During the reporting period, Side Letter no.1 was drafted, signed and submitted, without reallocating resources.

The following decisions need to be taken at the upcoming PSCM1 in June 2020:

- Adoption of the PSCM1 agenda;
- Adoption of the minutes from the initial PSCM;
- Adoption of IQR1;
- Adoption of the rolling work plan for project implementation, months 6-9 (Q2 and Q3);
- Translation of guides and recommendations /*WHO Interim Guide, ABPN Rapid Brief Paper, AABB Outbreak Planning Checklist, AATM Recommendations, US/FDA Information, ECDC Technical Report*/ related to the activities of blood facilities during Coronavirus pandemic.
- Any other business.

Section 1: Project data

Twinning Grant Contract Number	ENI/2019/411-554
Project Title:	Strengthening Blood Safety System in Georgia
Twinning Partners (Member States and Beneficiary)	Lead partner – National Blood Center (NBC; LT) Junior partner – Sanquin Blood Supply (SBS; NL) Beneficiary administration – National Center of Disease Control and Public Health (NCDC&PH; GE)
Report Number:	1
Period covered by the report:	15 January 2020 – 15 April 2020
Duration of the project:	21 months
Reported by:	Edita Vilutyte, MS PL Amiran Gamkrelidze , BC PL Algirdas Griskevicius, RTA Eteri Kipiani, RTA-C

Section 2: Content

This section describes the activities of the project. It is divided in five following sections:

- 2A – BACKGROUND
- 2B – ACHIEVEMENT OF MANDATORY RESULTS/OUTPUTS
- 2C – ACTIVITIES IN THE REPORTING PERIOD
- 2D – TIMING AND DELAYS
- 2E – ASSESSMENT

2A - BACKGROUND

Overall objectives

Overall Objective and indicators of achievement (as in Log frame)	State of achievement/ problems encountered
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 	Related activities yet to start

Specific Objectives

Specific Objectives and indicators of achievement (as in Log frame)	State of achievement/ problems encountered
Project objective: 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	
Indicators of achievement: <ul style="list-style-type: none"> Level of compliance of blood establishments with the EU directive 2002/98/EC in terms of collecting, testing, processing, storing and 	Legal acts and draft laws in project components 1 and 2 are being translated during Q1. STE missions are postponed due to coronavirus pandemic and lockout of the countries.

<p>distributing of blood components</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 • Level of compliance of blood establishments' quality systems with EU Directive 2005/62/EC • Level of compliance of blood establishments' hemovigilance system for donor and patient adverse events with EU directive 2005/61/EC 	
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Policy and Sector Developments

To improve quality and safety of blood and blood components, a number of activities are ongoing in the country, in particular:

- Testing of donor blood for transfusion transmissible infections (TTI), such as hepatitis B and C, HIV, and syphilis, is performed on 100% of blood donations within the framework of the State Safe Blood Program.
- With support of the Global Fund, two nucleic acid testing (ID-NAT) systems were purchased (Procleix Panther System, Grifols), which will substantially improve the safety of blood components by reducing the “Window Period” for TTI detection.
- All blood banks enrolled in the state program participate in professional testing (PT) schemes which are implemented under agreements signed with reference laboratories with international accreditations (ESfEQA, RADNDOX/RIQAS). In addition, from December 2019, an external quality control pilot program was launched at the Lugar Center, which implies that blood banks will conduct control tests of professional panels prepared by the Lugar Center.
- By the end of 2019, a NAT laboratory has been put into operation at the Lugar Center.
- Since January 2020, a pilot of nucleic acid testing (NAT) of blood donations has been introduced at Lugar Center with current enrolment of 10 blood banks operating in Tbilisi. Countrywide scaling up of the pilot is planned by the end of 2020.
- An active communication campaign is underway to popularize non-remunerated, voluntary blood donorship.

The main policy changes are related to the draft law on quality and safety of blood and blood component, which will form the regulatory framework on blood safety for the blood transfusion service. The RTA-C must report whether working groups have been set up in relation to the project tasks. In addition, the RTA-C should facilitate the organization of telework with these working groups and stakeholders during the Coronavirus quarantine period.

Project Assumptions

- Full openness and support from the NCDC&PH have been given to the project in Q1 of its implementation.
- Adequate working conditions have been provided to the RTA upon his arrival.
- The cooperation between the Twinning partners is at a high professional level, with both partners demonstrating mutual respect and understanding.
- The state of achievements is affected by the current coronavirus situation.
- Both sides have anticipated activities, which can be taken or started remotely.

2B - ACHIEVEMENT OF MANDATORY RESULTS/OUTPUTS

Results under components:

Results and indicators of achievement (as in Log frame)	State of achievement/ problems encountered
RESULT 1- Approximation of Georgian primary and secondary legislation with the Union acquis on blood safety (Annex XXXI) performed	
Status of normative acts approximating Georgian primary and secondary legislation with the Union acquis on blood safety	<p>Activity 1.1.1. Translation of draft law on Quality and Safety of Blood and Blood Components of Georgia Translation of concomitant law package</p> <p>Activity 1.1.2. (Extra activity according to the Side Letter) Translation of the recommendations and guidelines applied to blood collection and supply centers and public health facilities developed for the use in coronavirus emergency situations.</p>
RESULT 2 - A well-organized, nationally coordinated blood transfusion system established and functioning in accordance with the provisions of the Association Agreement.	
Share of blood banks with non-profit legal status	<p>Activity 2.1.1 Meeting with the State Regulation Agency for Medical Activities and arrangement to set up a working group to establish NCA as required by EU Blood Directives.</p>
Share of blood processing and blood collection centers	

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Share of blood donations that underwent NAT at centralized TTI testing laboratories	<p>Activity 2.3.2. Translation of legal acts related to licensing requirements for blood establishments</p> <p>Other activities have not been yet started</p>
RESULT 3 - Blood transfusion services based on voluntary blood donation are able to ensure safe, adequate and sustainable blood supplies.	
<p>Share of blood centers that collect 100% of blood donations from voluntary non-remunerated donors</p> <p>Share of unpaid voluntary donations among total number of donations</p> <p>Share of repeat donors among total donor pool recruited within the year</p> <p>Share of educational institutions with specific awareness raising program on blood transfusion and unpaid voluntary donations</p>	<p>- Activities have not been yet started</p>
RESULT 4 - Capacity of relevant state authorities and other key stakeholders strengthened to ensure safety and quality of blood transfusion service.	
<p>Number of NCA personnel capable to perform blood bank inspections in accordance with EU standards</p> <p>Number of TTI testing laboratory specialists capable to perform NAT testing</p> <p>Number of Reference Laboratory specialists capable to conduct QC, QA and QM in accordance with EU standards</p> <p>Number of public health professionals at BA and relevant governmental organizations with special knowledge and well understanding of new requirements and updated regulations in blood safety</p>	<p>Activities have not been yet started</p>

2C - ACTIVITIES IN THE REPORTING PERIOD

Note: The terms “Result” and “Component” shall mean the same.

INITIAL WORK PLAN (IWP) PREPARATION

Soon after arrival, the RTA liaised with the RTA-C in order to develop the Initial Work Plan (IWP), which is the basis for the effective and timely implementation of the whole Project. To accelerate the preparation of the IWP, IWP Preparation meeting with all PLs, as well as relevant experts was held between 4-6th of February, 2020. All parties involved have underlined the overall importance of the project, as well as discussed in general the key project results foreseen in the Twinning proposal. The IWP outlining the activities within the initial 6-month period, as well as the calendar of upcoming activities, including PSC meetings and the kick-off meeting, was drafted.

Reference number / Title of activity	Names of MS STEs	Number of BC experts and their departments of origin	Duration of activity
<i>Initial Work Plan Preparation</i>	1. Ms. Edita Vilutyte, MS PL (LT) (2WD) 2. Mr. W. Martin Smid, MS Junior PL (NL) (3WD)	BC PL, NCDC&PH RTA-C, NCDC&PH 4 BC Comp. Leaders, NCDC&PH	4-6 th of February 2020

ACTIVITY 0.3 - The Initial Project Steering Committee Meeting (so-called "Zero PSCM")

The Initial Work Plan was drafted on the basis of agreed schedule of activities. In the meantime, the Communication and Visibility Plan was also developed. After these two documents were agreed by the contracting parties and approved by the Contracting Authority, the initial Project Steering Committee meeting (so-called "Zero PSCM") was organized on 9 March 2020, during which the activities foreseen for the first six months of project implementation were presented and the IWP and the Communication and Visibility Plan were adopted.

Reference number / Title of activity	Names of MS STEs	Number of BC experts and their departments of origin	Duration of activity
<i>Activity 0.3 Initial Project Steering Committee meeting (Zero PSCM)</i>	1. Ms. Edita Vilutyte, MS PL (LT) (participated by telecommunication) 2. Mr. W. Martin Smid, MS Junior PL (NL) (participated by telecommunication)	BC PL, NCDC&PH RTA-C, NCDC&PH, other 18 stakeholders	9 th of March 2020

	3. Mr. Klemensas Mazeika, Project Manager (LT) (participated by telecommunication)		
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2D. TIMING AND DELAYS

Adherence to time schedule

See attached file.

2E. ASSESSMENT

Overall Assessment of progress

The progress made is in line with the given time frame. The cooperation with the beneficiary is efficient and discussions are constructive, thus the benchmarks are expected to be met as stated in the contract. The RTA and the Twinning team received valuable support and information from the officials of the BC Institution.

Other Issues

In consequence of Coronavirus pandemic worldwide, the Georgian Government and the respective EU Member States declared the State of Emergency and put in place the restrictive measures. At the international level all air movement was suspended, while inside the country the nationwide lockdown and partial curfew was announced. This have had a direct impact on project performance. Some activities envisaged in the project have been postponed for certain period of time. Due to the restrictions announced in the country, the RTA and project assistants were allowed to proceed with the Twinning activities in remote mode until the restrictions mentioned above are lifted.

Section 3: Expenditures

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See attached financial report

Mission Reports and Attendance Sheets should be annexed to the IQR.