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NL Contribution Interim Report on ACTIVITY / 2.2.2

BASIC PROJECT INFORMATION

- **Twinning Number:** GE 18 ENI HE 01 19
- **Title:** Strengthening Blood Safety System in Georgia
- **Beneficiary Country:** Georgia
- **Member States:** Lithuania/Netherlands

ACTIVITY INFORMATION

2.1. Activity No. and Title: 2.2.2. Assessment of Blood Banks

2.2. Start date: 14-09-2020 **and end date of the Activity:** 18-09-2020

2.3. Experts of the Activity: **Martin Smid** (NL), Managing Director, Director of Academic Institute for International Development of Transfusion Medicine, Sanquin Blood Supply Foundation, **Wim de Kort** (NL), Professor of Donor Health Care, University of Amsterdam; **Daumantas Gutauskas** (LT), Director of National Blood Center of the Republic of Lithuania (*by teleconference*) **Laimute Stoniene** (LT), Head of Quality Assurance Department (NBC) (*by teleconference*), **Renata Poviliuniene** (LT), Deputy Director of Klaipeda branch of PI National Blood Center (*by teleconference*).

Resident Twinning Adviser: Algirdas Griskevicius

2.4. Tasks and description of the Activity:

- To prepare the questionnaire for the assessment of blood banks in Georgia with an aim to identify gaps in blood safety and blood products supply system.
- To visit Beneficiary institution administration as well as blood establishments located in Tbilisi and outside the capital;
- To meet with Georgian key experts involved in the blood safety program;
- To meet with Georgian experts and discuss a scope and specificity of questionnaire;
- To discuss with the Georgian counterparts' criteria and requirements for the selection of the organization that would conduct data processing

ACTIVITY RESULTS

3.1. Results

- Questionnaire for the assessment of blood banks in Georgia developed aiming at identifying gaps in blood safety and blood products supply system;
 - In cooperation with the Lithuanian experts, the Blood Bank Inspection Form –in itself a very good draft put forward by NCDC– was commented and restructured/rephrased. This led to a new BB Inspection Form to be used by inspectors in a later stage of this Twinning Project: Annex 1.
 - From the BB Inspection form a Self-Assessment Form was put together: Annex 2. This Self-Assessment Form is intended to set out among all existing blood banks in Georgia within two months as a 0-measurement. It was concluded that a would be more appropriate to do an actual assessment since data available from a self-assessment two years before may not be representative anymore. An additional advantage can be that the self-assessment can be a tool to sensitize the blood bank stakeholders to quality assurance and management compliant with the EU directives.
 - Later during Activity 2.2.2, when results are available, a report will be put together as to provide a basis for:
 - i. A gap analysis on EU-Directives and regulations
 - ii. Defining a Road Map for reforming the blood Supply in Georgia, which is part of Activity 2.3.1 and Activity 2.4.1.
- Assessment of the Blood Banks visited. Note that only shallow descriptives are presented, as the visits were not meant as detailed audits, but rather as visits giving a picture and overview of the present situation. In this first part of this Activity, five blood banks were visited.
- All blood banks visited made use of the national donor registration system. Due to the legislation a hardcopy donor dossier is kept in addition. Testing for TTI in general is done by semi-automated Elisa, samples for NAT testing are send to the centralized laboratory at NCDC. The blood banks report that they participate in national and/or international Equas program for TTI testing.
- a. “Gormedi” regional blood bank, Gormedi General Hospital, Gori
This former state-owned blood bank currently is a department of the Gormedi General Hospital. The first impression is a organized blood bank its premises showed tidy. Annually approximately 5000 whole blood donations are collected; no apheresis donations. Per month one to three units of platelets are produced by PRP method; recovered plasma that is not used for transfusion, is discarded (?). Blood products are supplied to about eighteen hospitals in the region the main customer being Goremedi hospital.

Testing is done by semi-automated Elisa method. The equipment in general was effective without high tech and seems in longer use and it gave the impression that is was well maintained and clean. Manual administration was well organized.

b. Blood bank of the Gori Military Hospital, Gori

The blood bank is a department of the Ministry of Defense of Georgia and located on the military hospital area. The blood bank area is spacious, well maintained, and clean. They perform 4000 to 5000 whole blood procedures per year mostly for the military hospital, but also to other, civilian hospitals; no apheresis; single-donor platelet units are performed on demand.

Laboratory applied mostly semi-automated elisa tests for TTI. Remarkable was that although automated blood grouping equipment (Autovue) was available, the blood grouping was done manually. Limited financial resources precluded using the automated equipment.

The blood bank reports that remaining, recovered plasma not used for transfusion, is very limited.

c. Blood bank of the Jo Ann Medical Center, Tbilisi

This blood bank is located in an old part of the Jo Ann pediatric hospital 3000 to 4000 whole blood procedures are performed per year. On demand platelet units are produced (up to about three per month). The possibility to produce apheresis units is available, but seldom used because of the high cost of apheresis sets. Management changed only days ago, with the former deputy manager being in charge now.

The blood bank is located in an old part of the hospital. The premises are tidy, the very small rooms appear to need refurbishment with broken carpeting and wall decoration.

The equipment in the laboratory and storage is state of art provided by an America NGO (Global Healing). The laboratory uses a Architect for Elisa testing. A platelet shaker is not in use. For blood grouping the use of cards was available, but limited financial resources precluded using the automated equipment.

Because of the small size of the premises, that are tidy, the impression is that it seems less well organized, this is reinforced because cables run loosely along walls and ceilings; in one instance, a clear a short circuit damage is visible with unprotected cable endings. The mainly US equipment requires a different voltage.

d. Blood bank of the Iashvili Hospital, Tbilisi

The blood bank is located in premises of the Iashvili Hospital, only several hundreds of meters from the Jo Ann Blood Bank (and again within walking distance of a third blood bank in the same hospital area).

The blood bank is located in the basement, is well maintained, tidy and has some elements of the logic routing for donors that for production is less clear. The equipment is fit for purpose and for apheresis state of the art. For laboratory and processing the equipment is older but well maintained.

This is the largest blood bank we visited in terms of donations amounting 25,000 whole blood collections per year, including approximately 5000 performed in their affiliated collection site; 200 platelet apheresis procedures per month; also, through apheresis (preferably double) red cells are produced.

There is also a special room for therapeutic apheresis with 2 Cobe Spectra, however, this is not used very often. Red cells are supplied to about fifteen hospitals, including the pediatric hospital in the same building.

A specific finding for the blood bank is that apheresis platelet units are supplied nation-wide.

e. Natalya Kvantaliani blood bank, Tbilisi

In square meters by far the largest (estimated to be several hundreds of square meters), privately owned blood bank, performs 5000 to 7000 whole blood donations per year. We note that ‘just around the corner’, another state-owned blood bank is located.

f. The NK blood bank is a commercial blood bank that works closely together with adjacent hospital’s departments, from which staff (mainly medical doctors from the departments of cardiology and [hemato-]oncology) are detached on a part-time basis. Through apheresis red cells and at times platelets are produced. They supply about 80 hospitals. Freezers are packed with recovered plasma units, for which they seek purchasers (e.g. in Ukraine and Belarus).

There are six beds, and separate rooms for transfusion procedures (performed on an irregular basis) and apheresis procedures exist.

The laboratory has several semi-automated testing machines, which in part are used for the adjacent hospital departments, but less often/rarely for the blood bank itself.

Equipment in the donation area is fit for purpose and with state-of-the-art apheresis equipment. For the storage of recovered plasma a large variety of freezers is used, with manual temperature monitoring.

The blood bank is exploring the possibilities of starting plasmapheresis activities.

- General assessment of blood establishments visited.

On the positive side, we note:

- A strong motivation to do things right, presenting a good starting point to reach a high level of quality management.
- Eagerness to learn more.
- Each blood bank visited showed their strengths. Some on the level of quality management, others on the general management; thoroughness of the quality assurance and quality control; or PR-activities. Moreover, others showed a high level of blood banking knowledge, including donor management and clinical transfusion.
- The atmosphere is positively influenced by the management style of the director.
- In summary all blood banks were different in their strengths that probably reflected the competences of the directors. For example, some blood banks directors clearly had a more entrepreneurial approach especially a director with a

non-medical background, but with an ambition to grow and provide quality products. Others showed a greater focus on content, either more donor oriented or more technical. This situation brings opportunities to blood banks to learn from each other and cooperate more closely.

- In Georgia there is a national donor data base with data on the donor and his/her donation history and laboratory testing results. This data base is online accessible at each location visited.

Unfortunately, we did not have the time to fully assess its content completely, e.g. on deferrals and reasons for deferrals.

Regarding points for improvement in order to comply with the EU directives we noted:

- The percentage of paid (voluntary) donors varied from approximately 10 percent via thirty and 70 percent up to more than 90 percent.
- An important organizational factor to be improved, was the difference in type of organization: a blood bank could be state owned; private; for profit or not for profit; being a department of a hospital or independently operating. The difference in organization type seemed to impact the blood banks possibilities on e.g. investing into new techniques.
- Competition for the donor. In one instance there were three blood banks within one square kilometer, which results in looking for donors in the same neighborhood/city/region.
- Donor privacy was not always guaranteed, e.g. several times the donor interview could easily be overheard by others. In one instance even by other donors that could be present in the same room.
- The route of the donor and the product showed so-called crossing lines, giving rise to mistakes and/or cross-contamination.
- In close to every situation, data were registered and copied by hand, and apparently not double checked.
- Although mostly correctly noted, not every equipment in use had a clear quality control, or calibration.
- Methods and its equipment appeared outdated, however, not necessarily wrong. The apparent reason for that was a lack of financial resources. E.g. several blood banks owned modern automated equipment which regrettably was not in use for this reason.

In summary, the five blood banks with two more that were visited in February, show a high variety of individual strengths, that seem to be related with the competences of the director in charge. In each blood bank elements of a quality system are visible. For a demonstrable quality system that complies with the EU directives and the Good Practices Guide of the CoE the implementation of such a system is a required and will be a priority. A centrally coordinated blood system supports the introduction of such a quality system, with in addition possible economies of scale.

- Preliminary assessment of the degree of incompliance of blood establishments with EC directives and EU standards evaluated, gaps analyzed and areas and need for future interventions prioritized.
- i. This item is best worked out when data on the blood bank survey using the self-assessment form –developed during this Activity– is available.

3.2. Documents

- Report of the visit to blood establishments in Georgia: see above.
- Annex 1: Blood Bank Inspection Form
- Annex 2: Self-Assessment Form

Date: 25-09-2020