

4th HEPATITIS C
TECHNICAL ADVISORY
GROUP
TAG Meeting

Strengthening Blood Safety System in Georgia

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Tbilisi, Georgia



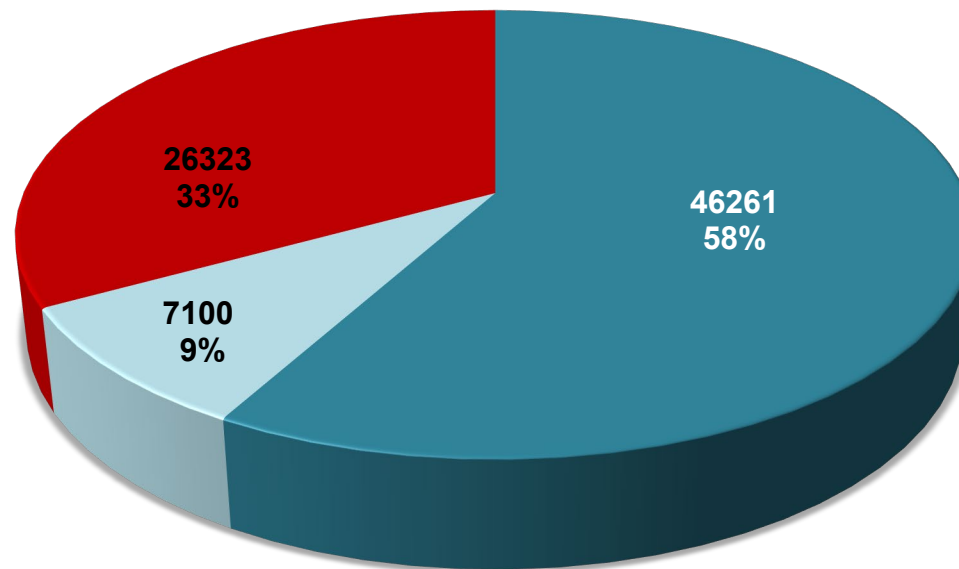
State Safe Blood Program

- 21 licensed blood establishments are functioning in Georgia (one was revoked)
- 16 blood banks are enrolled in the State Safe Blood Program, which provides the following activities:
 - Screening of blood donors for HIV, HCV, HBsAg and Syphilis
 - Provision of external quality control by Lugar Center
 - Professional Testing by Internationally accredited reference laboratories
 - Encouragement of regular unpaid blood donations
 - Confirmation testing of all screening positive donations in Lugar Center
 - Unified Electronic Donor Database
 - NAT testing (pending for adoption)



TTI screening in blood donations, 2019*

- n=79730 units produced totally
- Percentage of voluntary donations increased from 27% to 33% during the past two years.

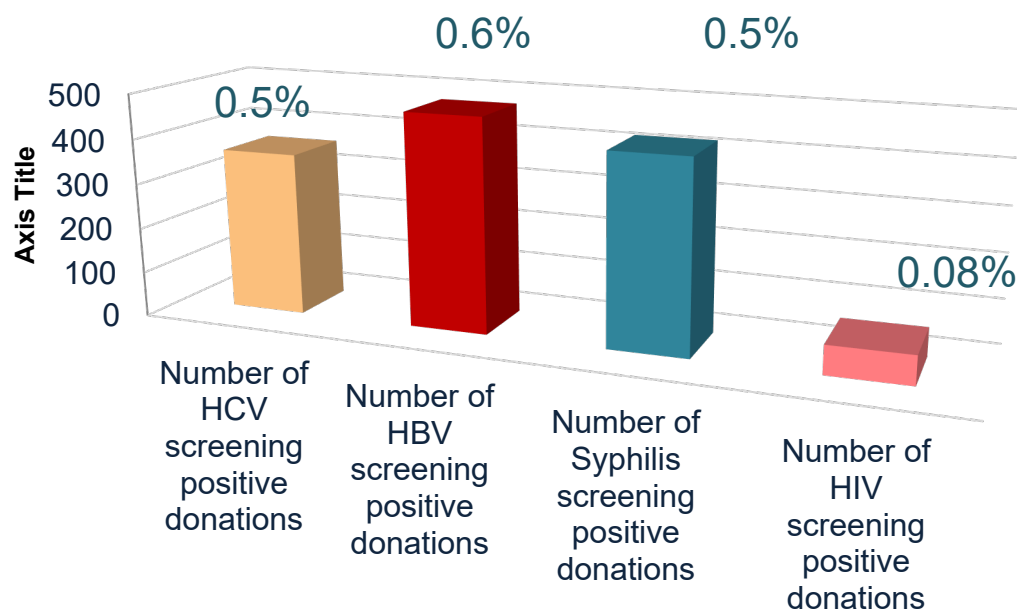


■ Paid ■ Replacement ■ Voluntary

* 2019 data include 10 months period from 1st January to 1st November



TTI screening in blood donations, 2019*



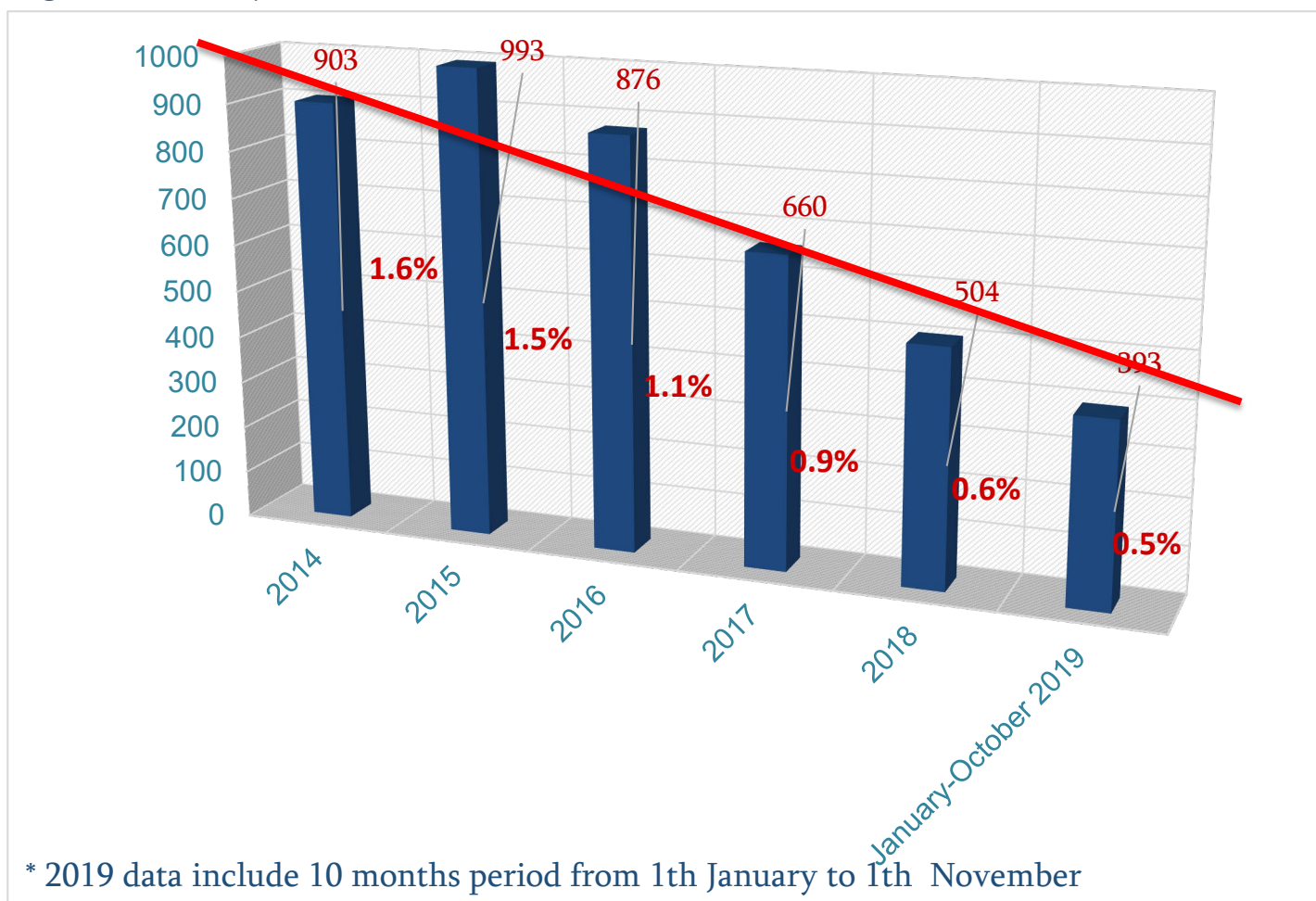
	Number of HCV screening positive donations	Number of HBV screening positive donations	Number of Syphilis screening positive donations	Number of HIV screening positive donations
■ Series 1	362	474	422	64

* 2019 data include 10 months period from 1th January to 1th November



Dynamic of HCV screening positive donations by years 2014-2019*

Up to 70% decrease was observed in the hepatitis C screening positive donations during the last 5 years



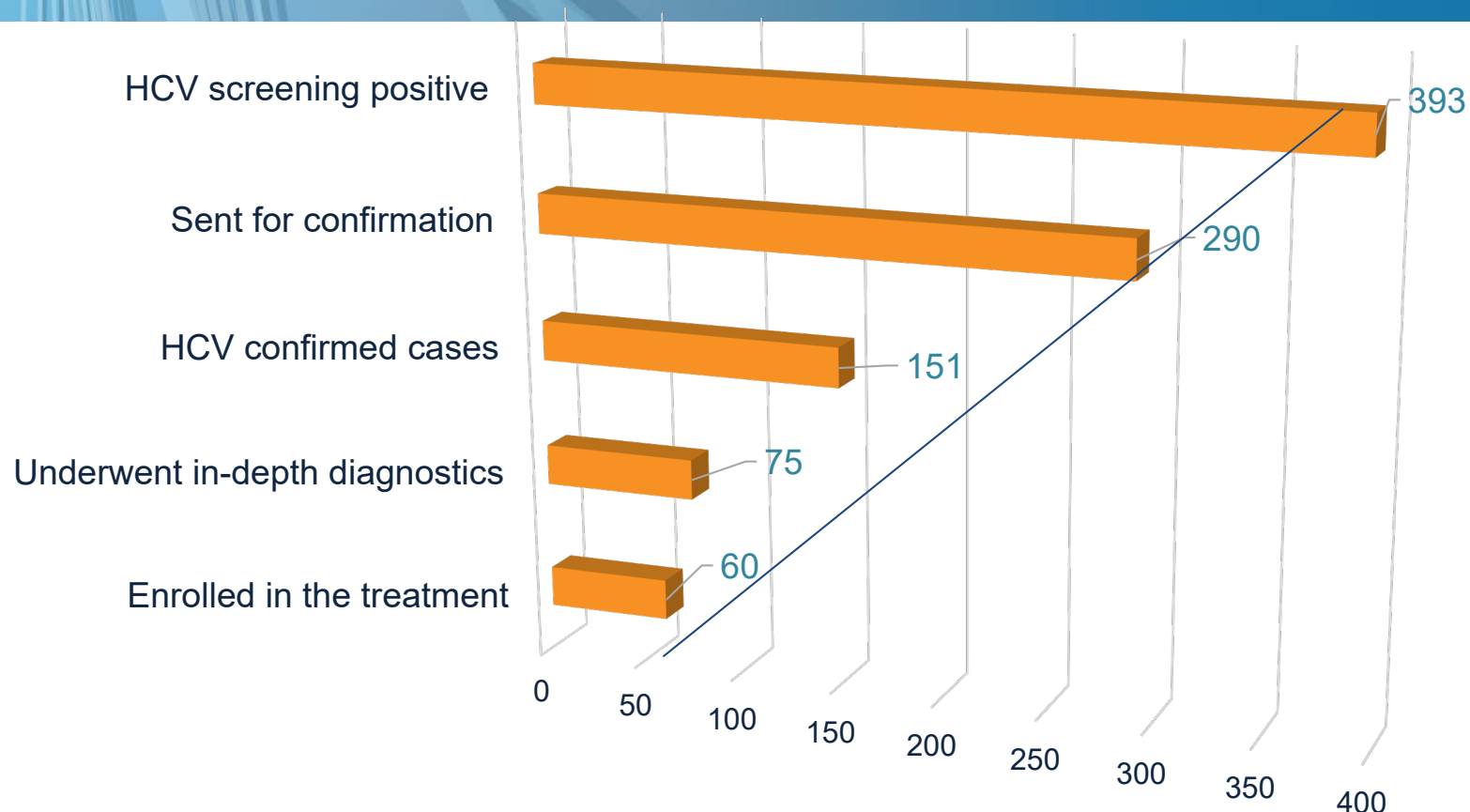
Twinning Activities, 2020-2021

Four EU blood directives will be implemented by the Twinning Project, covering the following aspects:

- Law approximation
- Competent authority
- BTS reorganization
- Haemovigilance system
- NAT scaling up
- National Reference Laboratory (NRL)
- Quality systems
- Unpaid voluntary donations
- Clinical transfusion
- Capacity building



Linkage to Care in Blood Donors, 2019*



* 2019 data include 10 months period from 1st January to 1st November



Progress, 2019

- Two multiplex ID-NAT machines (Procleix Panthers, Grifols) purchased
- Lugar Center's lab specialists trained
- NAT SOPs developed
- Linkage between laboratory information systems of NAT apparatus, LIMS and Donor Database is under way
- Training of blood bank personnel has started
- Centralized NAT piloting will launch at 12 Tbilisi blood banks in December, 2019



Progress, 2019 (cont.)

- Implemented new syphilis screening algorithm (TPHA or ELISA)
- Elaborated draft Law on Quality and Safety of Blood and Blood Components
- Developed draft Standards for donor selection, blood collection, processing, testing, labeling, storing and distribution



Progress, 2019



- EU Twinning Project on Strengthening Blood Safety System in Georgia will launch in January, 2020
- Consortium of Lithuania and Netherlands will cooperate with NCDC



Main Challenges, 2019

- Profit based status of blood establishments
- Predominantly paid donation practice
- Lack of central supervision
- Lack of sustainable and self-sufficient blood supply
- Outdated premises and equipment at blood banks
- Lack of automated processes at blood establishments
- Incompatibility of national blood regulations with EU directives
- Lack of effective quality systems
- Neither of blood banks fully complies with the contemporary standards



TAG Recommendations

TAG recommendations for 2019	Current Status
Mandate participation of ALL blood collection sites in blood safety program	16 out of 21 blood banks participate
Continue to develop regulatory oversight such as licensing and accreditation of blood transfusion facilities	Not implemented
Conduct Comprehensive assessment of ALL blood banks	Not implemented
Assess and ensure high quality testing at all sites including standard testing algorithms, and implementation of repeat and confirmatory testing	HCV and HIV confirmatory testing has implemented
Conduct comprehensive survey of blood bank practices, including parallel HCV Ab and NAT	NAT yield will be assessed along with NAT implementation
Conduct pilot testing to inform NAT strategy implementation in blood banks; if implemented, NAT should be centralized	NAT piloting will start in December , 2019



Future plans

- Eliminate inclusion criteria to allow enrollment of all 21 blood banks in the State Safe Blood Program
- In 2019 start centralized NAT piloting at 12 blood banks located in Tbilisi
- In 2020, countrywide scale up NAT testing
- Increase share of unpaid voluntary donations by at least 10% by 2021
- Develop and implement Twinning program plan for 2019 in collaboration with partner Member States
- Include estimation of hemoglobin (Hb), hematocrit (HCT) and thrombocyte concentration into the current EQA schemes



Thank you!

