

4th HEPATITIS C
TECHNICAL ADVISORY
GROUP
TAG Meeting

**BLOOD BANK ASSESSMENTS
AND RECOMMENDATIONS**

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Overview: Blood Bank Assessments

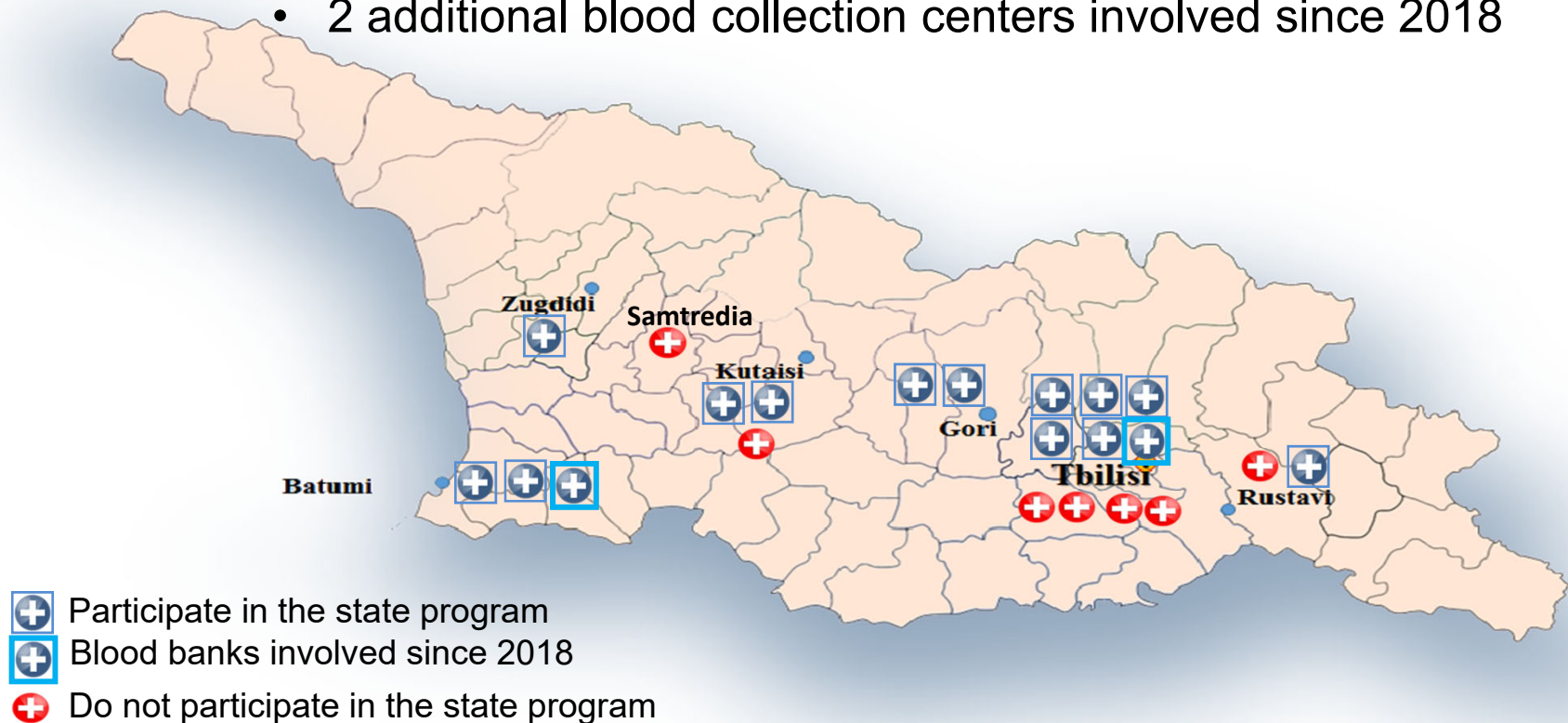
- **On-site visits to blood collection facilities/transfusion services that participate in the blood safety program**
- **Format:** Tour of facility with targeted questions of key personnel about major elements of **blood safety value chain**
 - Policy, standards and regulations
 - **Donor recruitment**/selection (incl. compensation)
 - Collections
 - Processing
 - **Testing** (incl. mode of testing and algorithms in use)
 - Clinical transfusion practice and blood utilization
 - Post-transfusion surveillance
 - **Quality oversight** (incl. proficiency testing)



Status Blood Banks in Georgia: 2018

22 facilities hold state license for blood collections/manufacture

- 15 (68%) participate in the State Safe Blood Program
- 2 additional blood collection centers involved since 2018



1

Blood center licensing and accreditation

Variable quality and lack of standardization of practice

- **Assign task team to review current licensing requirements**
 - Update to align with similar frameworks in US and EU
 - Train teams of inspectors to conduct assessments
- **Blood safety program**
 - Mandate participation by all blood centers
 - Strive to be broadly inclusive: remove requirement for minimum number of collections
- **Phased/structured implementation of accreditation system**
 - There are groups e.g. AABB that can assist
 - Mandatory participation with regular (q2yrs) assessments

Over time, inability to maintain quality standard with low volume collections will tend toward closure of small centers

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Donor selection and recruitment

High proportion (57%) of paid donors

- **Phased implementation (e.g. 5 years)** of exclusive voluntary non-remunerated blood donation
 - National awareness campaign: community education and outreach
 - Replace payment with small incentives e.g.. Grocery vouchers, T-shirts, movie tickets of fixed value that can't be exchanged for money
- Ultimate passing of **legislation and enforcement** against paid donation

Challenge: Currently operating at a deficit whereby rapid transition could strain ability to contend with transfusion demand



Low standing inventory and limited product diversity

- **Need formal assessment of services and concomitant projected needs**
 - Increase platelet collection proximal to high-need settings e.g. oncology
 - Increase RBC collections (contingent on needs assessment)

Challenge: lack of standing inventory curtails practice and impedes adoption of high complexity services e.g. transplant, hematology oncology, cardiac surgery

Multiple areas of deficiency

■ Infectious marker testing

- Exclusive serological testing
- Reliance on semi-automated and rapid platforms
- Deficient testing algorithms e.g. no repeat testing
- Lack of confirmatory testing
 - **Shift to automated testing using standardized processes and algorithms**
 - **Implementation of NAT**

■ ABO testing

- Manual testing
- Limited to no capacity to perform complex work-up of non-ABO red cell antibodies

Challenge: logistics and turn around time impact plans for regional/centralized NAT

Currently unable to tolerate long turn-around; blood utilization and clinical practice needs evaluation

Unable to meet transfusion demand

- **Comprehensive assessment of practice needed**
 - **Disconnect between collections, low inventory and reports of being unable to meet demand**
 - “Patient blood management” programs have improved efficiency in US and Europe, optimizing outcomes while containing costs
 - Clinical guidelines, standardization of practice
- **Medical education in transfusion medicine**
 - Outdated practices e.g. exclusive reliance on Group specific blood is inefficient
 - Change in practice needs a substantial investment in education

**Challenge: change in clinical practice is not rapid;
suggest targeting medical school curricula**

Post-transfusion surveillance

If one doesn't look, one doesn't find anything

Gross under-reporting based on expected incidence of TTIs and adverse events

- **Need to implement lookback**

- Assign responsibility i.e. transfusing institution brings recipients back, blood center assumes cost of testing and referral, state protection against litigation (cover in informed consent for blood transfusion)

- **Improve communication between blood centers and transfusing institutions**

- Develop reporting systems e.g. CDC hemovigilance criteria
- Education needed

Challenge: initial reporting could erode confidence in blood supply and collection agencies



Multiple levels: a few examples listed

- **Revisits licensing and accreditation**
 - **Difficult to address without standardization**
 - Need bar coding of labels and automation of processes where possible
 - Document control, SOPs and internal and external blood center audits
 - Monitoring of product outdating and usage
- **EQA program at Lugar center**
 - Need for refinement
 - SOP at blood centers to standardize collection and storage of EQA aliquots; currently burdensome on blood centers (storage suboptimal) and challenging for Lugar center given the state of receipt

The donor-donation database: preliminary findings

Exceeds minimum recommended collections

Table 1: Overview of Blood collections by year

	2015	2016	2017	Total
Number of Collections	79,383	84,755	87,881	252,019
Donor Status				
First Time	18,503	19,235	19,725	57,463
Repeat	30,301	31,856	32,074	94,231

22.8% first time donors

WHO recommends 10 per 1000 population

For a population of 3,7 million (2017): **minimum** collections: **37,000**

Table 2: Donor infectious marker positivity by year

	2015 n (%)	2016 n (%)	2017 n (%)
Hepatitis C	1144 (2.3)	887 (1.7)	727 (1.4)
Hepatitis B	744 (1.5)	615 (1.2)	574 (1.1)
HIV	75 (0.2)	86 (0.2)	71 (0.1)
T. Pallidum	515 (1.1)	375 (0.7)	376 (0.7)
Total	2,478	1,963	1,748

28% of total donations from VNRBDs

Testing: External quality assurance

Randox PT program for TTI testing

- **From Sept 2015 to Oct 2016:** 5 rounds where proficiency testing panels distributed to blood banks (n=12)
 - 5 samples each for HBV/HCV/HIV and 3 samples for T. pallidum

Marker	Range of overall error rates	Average overall error rate for 12 labs	# False Positive Results	# False Negative Results	# of Inconcl. Results	# of results Not Reported
HBsAg	0%-28%	5.2%	0/254	4/254	0	11
Anti HCV	0%-16%	2.4%	1/280	0/280	0	6
Anti HIV 1/2	0%-24%	5.8%	5/267	0/267	2	10
Syphilis	0%-25%	5.8%	0/132	2/132	3	3

Comments

- 3 of 12 labs had **NO** errors for all 4 TTI markers
- 1 lab had 3 of the 4 FN for HBsAg; and 3 of the 5 FP results for HIV
- 2 of the 12 labs accounted for majority of cases where no results reported

Summary: challenges in Georgia

1 **Licensing and accreditation**

- I.e. incomplete capture of blood centers, suboptimal regulation

2 **Donor selection and recruitment**

- I.e. paid donors constitute majority of donor pool

3 **Collections**

- I.e. low standing inventory and limited product diversity

4 **Laboratory Testing**

- Exclusive serological testing, reliance on semi-automated and rapid platforms, deficient testing algorithms, lack of confirmatory testing etc..

5 **Blood utilization and clinical practice**

- Unable to meet demand, clinical guidelines and compliance

6 **Post-transfusion surveillance**

- No lookback, virtual absence of reporting to blood centers

7 **Quality assurance**

- Linked to lack of standardization, SOPs etc..

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