

4th HEPATITIS C
TECHNICAL ADVISORY
GROUP
TAG Meeting

STRENGTHENING BLOOD SAFETY SYSTEM IN GEORGIA

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Outline

- Background
- Statistical data
- Main challenges
- Progress achieved in 2018
- Future Activities

Distribution of Blood Banks in Georgia, 2018

22 blood establishments hold state license in blood production service, 15 blood banks out of them participate in the State Safe Blood Program

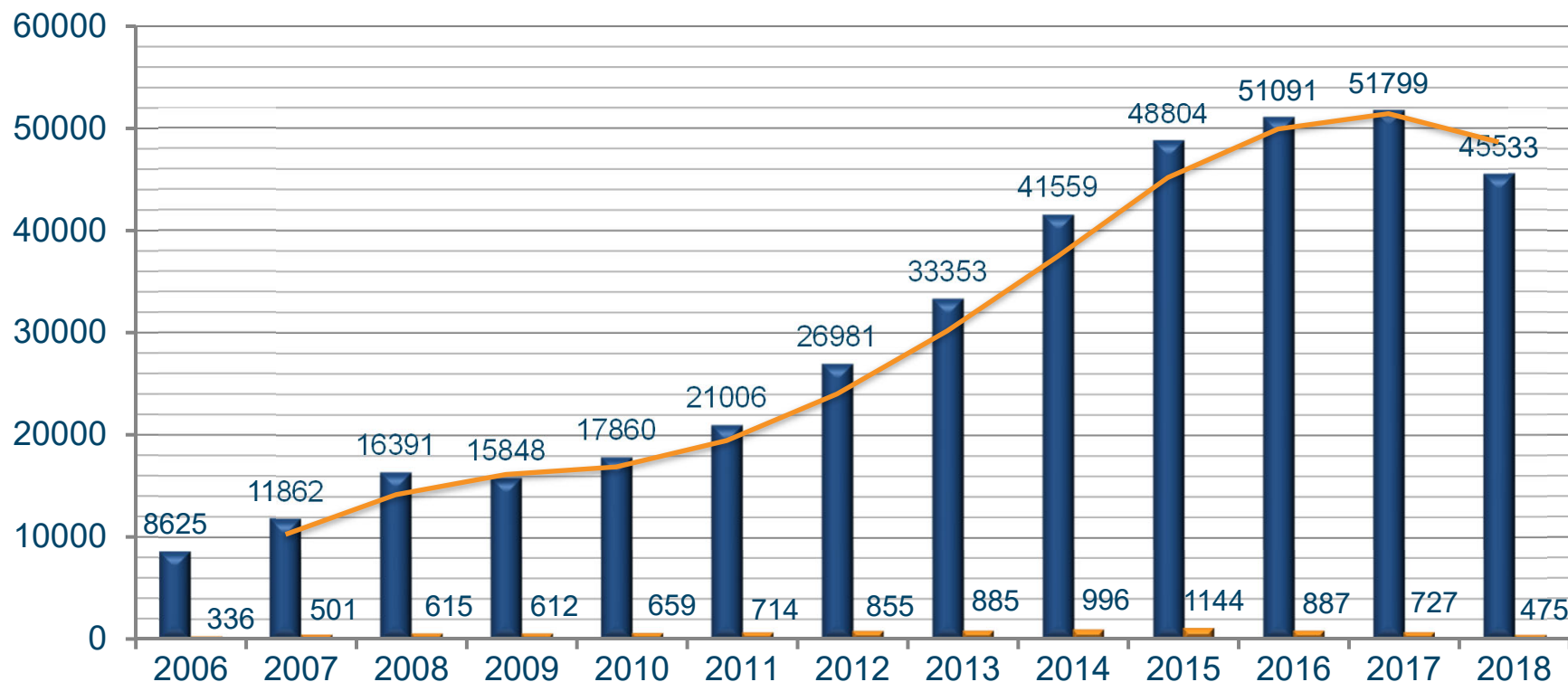


-  Participate in the state program
-  Blood banks involved since 2018
-  Do not participate in the state program

Statistical Data, 2006-2018*

Total number of donors and anti HCV positive donors, 2006-2018*

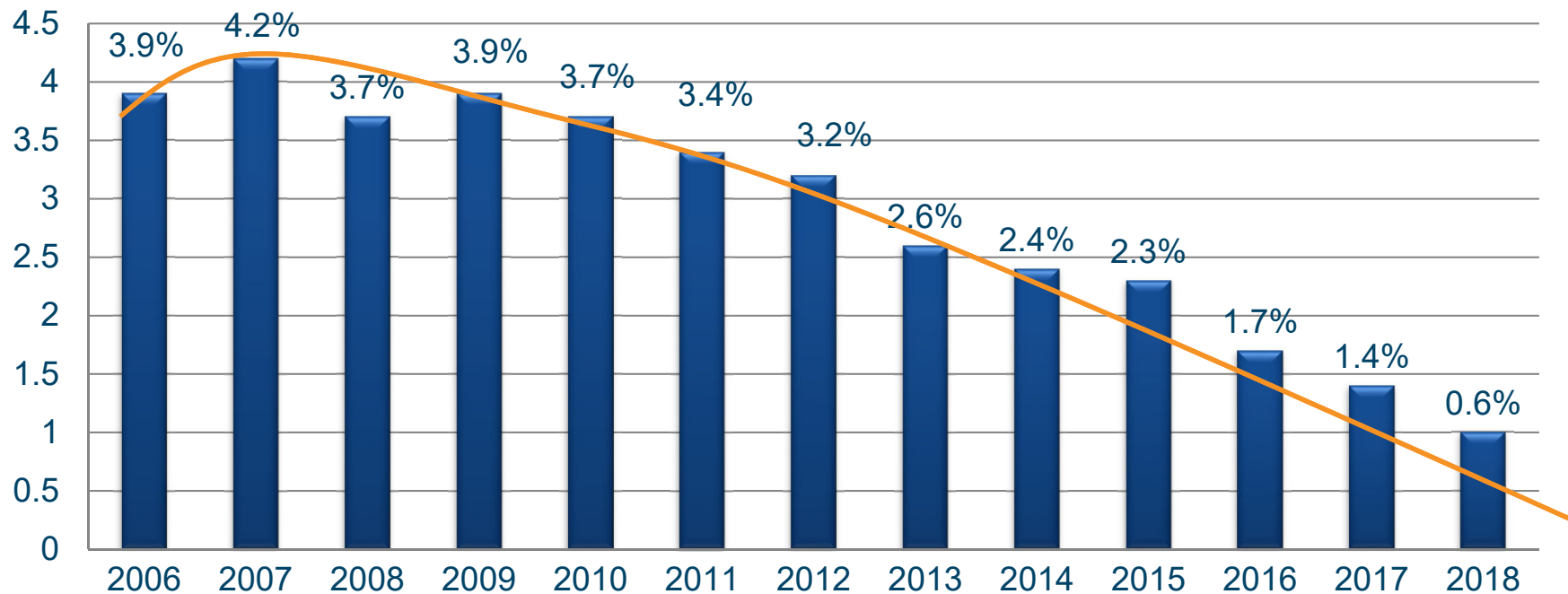
■ Total number of donors ■ Number of anti-HCV donors



* January-October, 2018

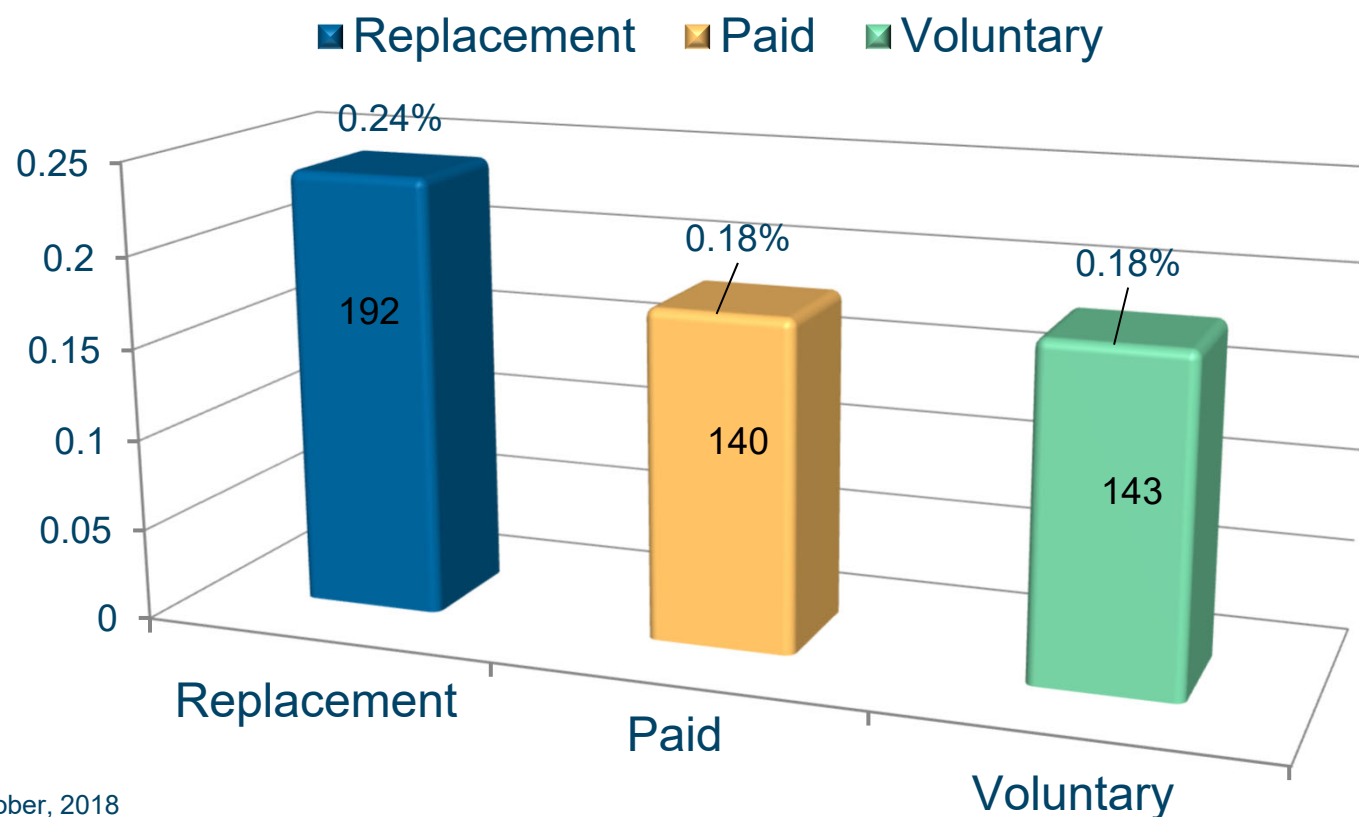
HCV screening prevalence in blood donors 2006-2018*

Percentage of anti-HCV positive donors, 2006-2018*



* January-October, 2018

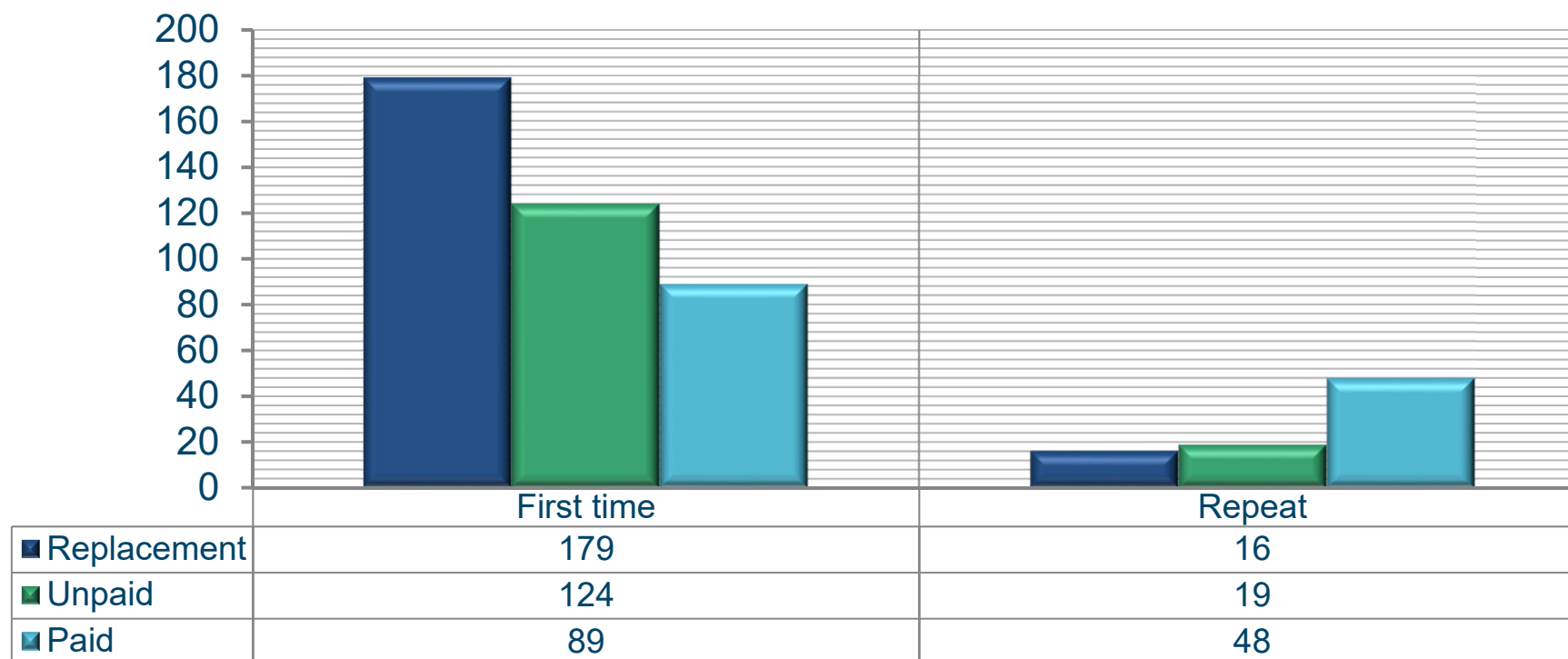
HCV prevalence by donor type (paid, relative, unpaid), 2018*



* January-October, 2018

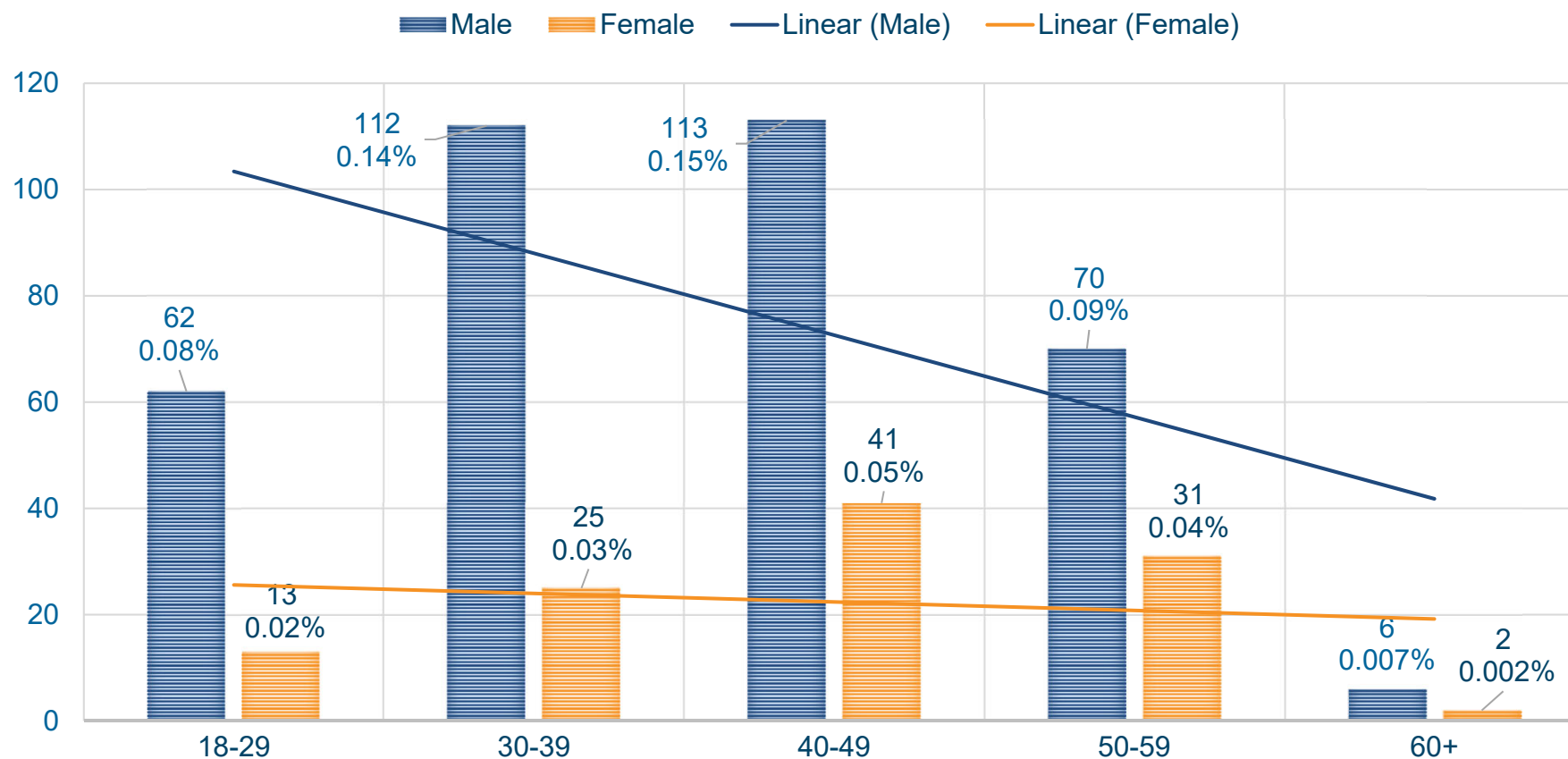
HCV screening prevalence by donor status (first time/repeat donors), 2018*

A total of 77250 donations were performed in 2018 and 475 tested positive by HCV markers, among them 392 (82%) were first time donors and 84 (18%) were repeat donors. ■ Replacement ■ Unpaid ■ Paid



* January-October, 2018

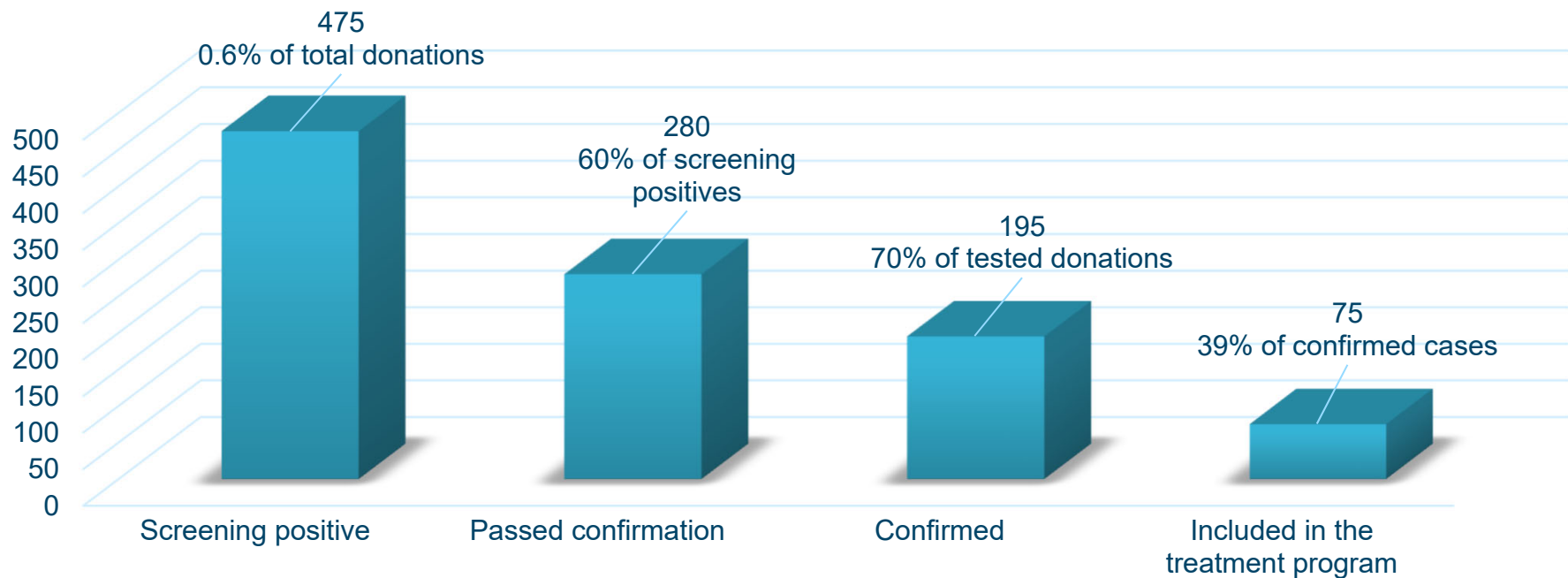
HCV prevalence by gender and age, 2018*



* January-October, 2018

Linkage between screening and treatment, 2018*

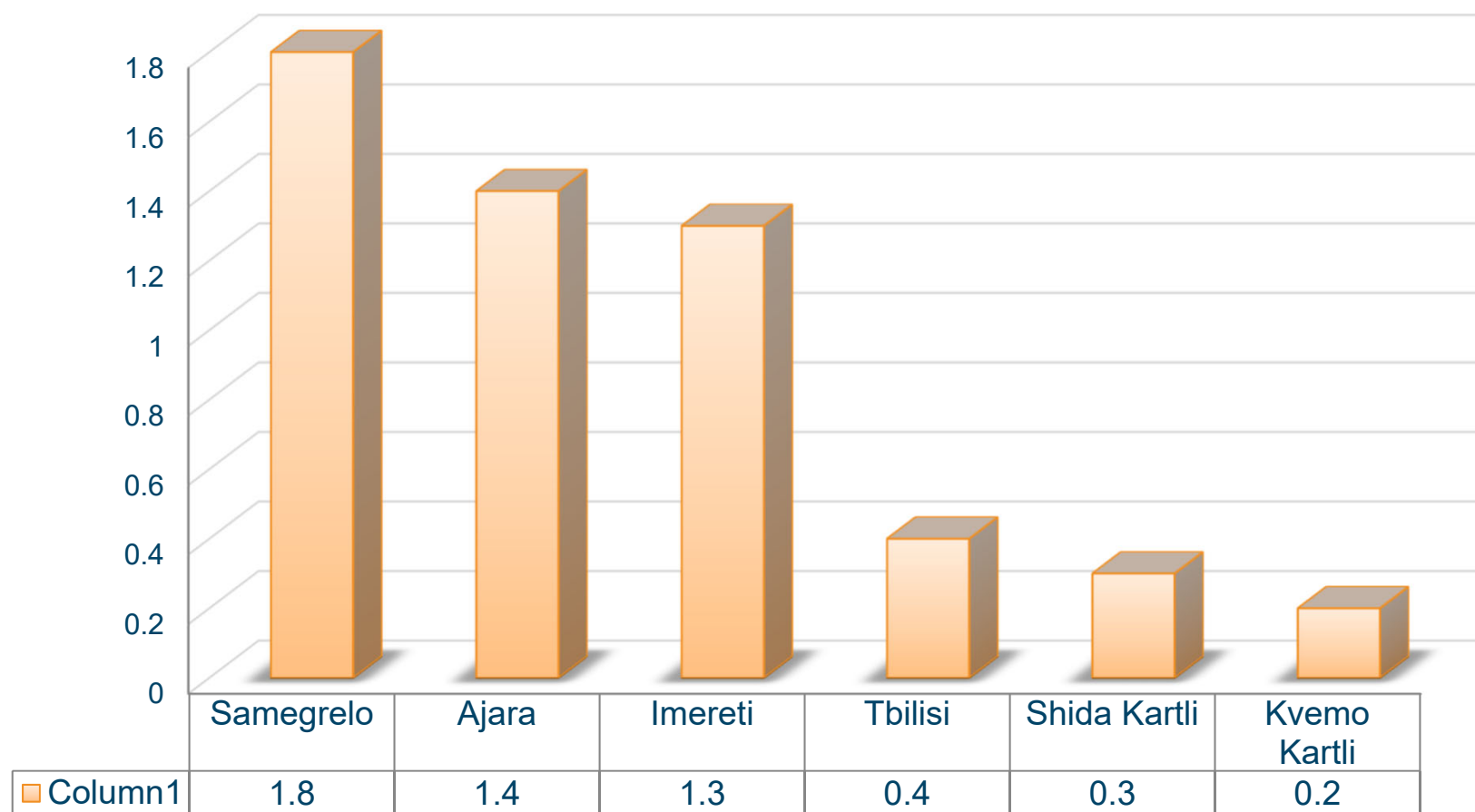
Number of screening positive donors, confirmed cases and included in the treatment program



* 1 January- 1 September, 2018

Distribution of HCV screening positive cases by regional blood banks

Percentage of anti-HCV positive cases by regions



External Quality Control

Analysis of blood bank PT results from Sept 2015-Oct 2016 was performed with the support of the U.S. CDC South Caucasus Office

- 12 blood banks participated in the Randox PT program for TTI testing
- Some banks switched testing platforms for some markers over the 1 year time period.
- Majority of banks participated in all 5 rounds of the PT program
- BioRad and Diagnostic BioProbes are most common platforms
- 3 of 12 blood banks had 0 errors for all 4 TTI markers
- 2 of the 12 banks accounted for the majority of the No Result Reported error

- 1 blood bank located in West Georgia had 3 of the 4 false negatives for HBsAg; the same lab had 3 of the 5 false positives for HIV 1/2 and 1 inconclusive, another BB had 1 false negative for HBsAg and one BB, not currently functioning, demonstrated 1 false positive result for HIV
- 1 blood bank in capital city had 2 false negatives for syphilis and another 1 false positive for HIV

Main challenges

National competent authority not established

86% of blood establishments are running on for-profit base

There is no functional national transfusion network

There is significant level of incompatibility of national legislation with EU Directives

No quality system is implemented in blood establishments

Premises and equipment are outdated resulting in processing low quality components

Ration of non paid to paid donations is 30:70

Single serological testing is applied for TTI testing

TAG Recommendations

Recommendations	Progress Status
Recruit first time donors with low risk for HCV infection	<ul style="list-style-type: none"> • Information campaign implemented within State Safe Blood Program • Financial Stimulation of repeat voluntary donors
Continue development of systems for hemovigilance in blood banks and hospitals	Updated Donor Database enables BB and hospitals to follow donations from blood donor to blood recipient
Train providers to reduce the number of unnecessary transfusions	Development of the transfusion guidelines is planned in the working group format
Establish systems at blood banks to ensure linkage of HCV seropositive donors to care and treatment	Linkage of screening and diagnostic modules has been established, linkage of diagnostic and treatment modules is under way
Add HCV RCR or core antigen testing to reduce the number of HCV contaminated blood donations missed by laboratory testing in blood banks	All seropositive donations are transferred from blood banks to Lugar Center to undergo Cor-Ag testing, all core antigen negative samples are tested by HCV PCR method

TAIEX Expert Recommendations

Recommendations	Progress Status
Establish National Competent Authority for BTS	Not established
Shift the actual situation of 70% paid blood donation to a 100% voluntary blood donation within the shortest time period possible	In progress
Review actual Georgian legislation to represent correct transposition of EU Directives requirement	In progress
Improve existing national IT system of traceability and hemovigilance	In progress
Conduct comprehensive assessment of all BB including all aspects: personnel, premises, equipment and QS	Planned within the Twinning Project
Optimize and centralize existing BTS to maximum 2 blood processing establishments and a numerous collection centers (either fixed and mobile sites for the reasons of accessibility)	Requires strategic decision
Develop training plan for blood transfusion professionals to increase their technical level, particularly in the processing, testing, hemovigilance and QC aspects	The process of development of standards and guidelines is underway

Progress achieved in 2018

Confirmatory testing was introduced for all anti-HCV positive blood donations within the State Safe Blood Program

All blood banks and hospitals were enrolled in the Donor Database

Technical Assistance and Information Exchange project (TAIEX) was implemented

A principal decision was signed by the European Commission to grant Georgia a Twinning Assistance in Blood Safety

Revision of national blood regulations has been started by the Ministry's working group

EU Twinning instrument



Approximate national legislation on blood safety to EU Directives and their implementation in order to strengthen blood safety system in Georgia, ensure safety and quality of blood and blood components and reduce the burden of diseases caused by TTI infections

Establishment of National Competent Authority

Revision of relevant legislative acts and bring them in line with EU Directives

Assessment of blood establishments

Transposition of blood establishments from for-profit to non-profit organizational form

Introduction of NAT testing

Development of the regular non-remunerated donorship institute



Thank you for your attention!