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Advancing blood transfusion safety using molecular detection in the country of Georgia

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Abstract

Background: In 2015, the country of Georgia initiated its hepatitis C virus (HCV) elimination program. Given a high background incidence of HCV infection, centralized nucleic acid testing (NAT) of blood donations was prioritized for implementation.

Study design and methods: Multiplex NAT screening for HIV, HCV and hepatitis B virus (HBV) was launched in January 2020. An analysis was conducted of serological and NAT donor/donation data for the first year of screening (through December 2020).

Results: A total of 54,116 donations representing 39,164 unique donors were evaluated. Overall, 671 donors (1.7%) tested positive for at least one infectious marker by serology or NAT, with the highest prevalence among donors aged 40–49 years (2.5%; n = 200), male (1.9%; n = 524), replacement (2.8%; n = 153) and first time (2.1%; n = 642) donors. Sixty donations were seronegative but NAT positive, and therefore would not have been found by traditional serology testing alone. These were more likely among female vs. male (adjusted odds ratio [aOR] 2.06; 95% confidence interval [95%CI]: 1.05–4.05), paid (aOR 10.15; 95%CI: 2.80–36.86) or voluntary (aOR 4.30; 95%CI: 1.27–14.56) vs replacement, and repeat vs. first time (aOR 13.98; 95%CI: 4.06–48.12) donors. On repeat serological testing (including HBV core antibody [HBcAb] testing), 6 HBV + donations, 5 HCV + donations and 1 HIV + donations were deemed NAT yield

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

(detected through the implementation of NAT, and would have otherwise been missed by serology screening alone).

Conclusion: This analysis offers a regional model for NAT implementation, demonstrating the feasibility and clinical utility in a nationwide blood program.

Keywords

Hepatitis C; Blood donor; Screening; Blood transfusion; Public health; Georgia (Country)

1. Introduction

In 2015, the country of Georgia initiated the world's first national hepatitis C virus (HCV) elimination program. Blood transfusion has been identified as a risk factor for both hepatitis B virus (HBV) and HCV infections in Georgia [1–3]; in a national serosurvey, about one-fifth of HCV- and one-tenth of HBV seropositive respondents reported a history of blood transfusion. From the outset, blood transfusion safety was prioritized for intervention in the HCV elimination program [4,5]. Despite having a longstanding State Safe Blood Program since 1997, Georgia's blood transfusion services do not meet international standards; suboptimal practices span blood donor selection (e.g., large numbers of first-time, paid and replacement donors), testing (e.g., non-standardized serological testing, lack of repeat and confirmatory testing) and quality oversight [1]. Coupled with a high background prevalence of the major transfusion transmissible viruses (notably HBV and HCV), there is a risk of transfusion-associated infection.

The HCV elimination program's Technical Advisory Group and the European Union (EU)-funded Technical Assistance and Information Exchange (TAIEX) and twinning programs provided recommendations to address blood transfusion safety [1,2]. One of the key recommendations was implementation of nucleic acid testing (NAT) to address the high prevalence of HCV infection in the blood donor population [6]. NAT shortens the time to detection of infection; for HCV infection, the median time to seroconversion is 5–6 weeks, whereas the time to nucleic acid detection is approximately 6–10 days [1,7–12]. Therefore, NAT can provide information on individuals who have been recently infected, allowing for characterization of contemporary acute infections [13,14]. NAT can also identify occult infections caused by HBV, which can escape detection when screening for hepatitis B surface antigen (HBsAg) alone [15]. Collectively, NAT has proven enormously beneficial to blood transfusion safety [16]. Nonetheless, it has not been widely adopted outside of high-income settings due to its higher cost compared to serology and the infrastructure and technical expertise required for implementation [17]. We evaluated the feasibility and incremental benefit of implementing NAT in Georgia by assessing yield in seronegative samples.

2. Materials and methods

2.1. Overview of population and setting

Blood transfusion services in Georgia were privatized in the 1990 s, following the dissolution of the Soviet Union. Currently, a total of 23 blood centers collect blood as

part of the State Safe Blood Program. A donor history questionnaire (DHQ) is used to determine eligibility to donate based on medical and socio-behavioral risk factors for transfusion-transmitted infections (TTIs). While certain elements (e.g., history of hepatitis or jaundice, receipt of blood transfusion) of the DHQ are shared across the blood centers in Georgia, the DHQ form is not standardized across all sites. Policies pertaining to blood donation eligibility and deferral are current being revised in to align with European Union (EU) standards. At time of writing, male to male sexual encounter (i.e., MSM) incurs a 10-year deferral, while medical intervention and intravenous drug use each carry a 1-year deferral. Following collection, the blood products are quarantined while awaiting TTI testing results. Prior to implementation of NAT, donor screening for HBV, HCV, HIV and *T.pallidum* was conducted using serological tests alone (i.e. HBsAg, anti-HCV, anti-HIV and Treponemal specific antibodies). The methods and quality of serological testing vary across sites (Table 1), with differences spanning the assays used (i.e., kit manufacturers), their levels of automation (i.e., semi- vs fully-automated), and extent to which repeat and confirmatory testing is undertaken. Hepatitis B core antibody (HBcAb) testing is not routine, nor is repeat, confirmatory, or supplementary testing for the other serological tests, likely given the additional cost (e.g., reagents) and labor of testing.

Only blood products from donors who test negative for all four TTIs are allowed to be used. Donors who screen positive for any infectious marker are not permitted to donate again. All blood centers have access to a national donor registry and are required to cross-check this database at the time of donation. At time of writing, there is no hemovigilance system in Georgia; this is being actively addressed as part of overhaul of its blood safety program. Following the introduction of NAT, donors must test negative by both NAT and serology before their blood can be used. Blood collection from paid and replacement donors (i.e., friends or family of the intended transfusion recipient) is allowed in Georgia, in addition to unpaid, voluntary donations [1]. Under the former Soviet system, all donors were compensated for blood donation, whereby, paid—rather than voluntary donation— was the norm. Many paid donors donate regularly and are contacted during blood shortages. Nonetheless, there have been concerted efforts to increase the proportion of unpaid, voluntary donations since inception of the HCV elimination program. Similarly, family replacement donation is common. When applied, friends or relatives of the intended transfusion recipient are expected to donate blood or recruit individuals who can donate, in order to replenish blood that has been used for the patient.

2.2. Implementation of NAT

Multiplex NAT screening was launched in January 2020 in 3 blood centers in Tbilisi. As planned, testing was expanded in subsequent months, first to other blood centers in Tbilisi followed by regional blood centers. By September 2020, 22 of the 23 blood centers in the State Safe Blood Program were included. NAT was centralized, whereby all testing was performed exclusively at the Richard Lugar Center for Public Health Research at the National Center for Disease Control and Public Health (NCDC), Tbilisi, Georgia with the support of the Global Fund [1]. One small hospital blood collection site in Tbilisi was not included.

2.3. Description of the testing algorithm

Primary serological testing was performed on whole blood samples by the individual blood centers in accordance with their routine testing procedures. Second donor samples were collected for NAT and shipped daily to Lugar Center. These samples were screened individually using the Procleix® Ultrio Elite Assay (Grifols, Spain) by the manufacturer instructions. The Procleix® Ultrio Elite Assay is an FDA-approved and CE-marked multiplex NAT assay for blood donor screening. The assay detects HBV DNA, HCV RNA, HIV-1 and HIV-2 RNA using transcription-mediated amplification but does not provide virus-specific results; The sensitivity (95% CI) of the Procleix Ultrio Elite Assay is 100 % for HIV-1 and HBV, and 98.86% for HCV when applied to individually- tested (i.e. rather than pooled) known-positive samples [18]. While the assay can be used for "mini-pool (MP)" testing, individual testing (ID-NAT) was performed in the program. In the event of a discordant result between the Procleix® Ultrio Elite Assay NAT and serology (i.e., NAT multiplex positive, serology negative), additional discriminatory testing with the Procleix® Ultrio Elite Assay for HBV, HCV, and HIV (sensitivity (95% CI) 100 % for HIV, HBV and HCV) was performed to ascertain which infectious marker was responsible. Concordant samples (i.e., serology positive, NAT positive) were not subjected to discriminatory testing. A subset of the discordant samples was retested at the Lugar Center using ARCHITECT i2000SR immunoassay (Abbott, USA) for HBsAg, HBcAb, antibody to HCV (anti-HCV), and HIV 1/2 Ab and Ag. In order to integrate NAT into routine workflow, the average time from donation to availability of test results had to be within 24 hours. Samples that were detected through NAT and would have otherwise been missed by serology screening alone were deemed NAT yield.

2.4. Data analysis

All blood donor and donation screening data are housed in a national database. Analysis was confined to one year of data (1 January – 31 December 2020). The database identifies unique individuals using their national identification numbers, which were encrypted prior to analysis; this provides access to donor demographics, donation date(s), remuneration type, donor status (i.e., first-time vs. repeat), seropositivity for HBV, HCV, HIV, and *T.pallidum*, multiplex NAT screening and follow-up discriminatory testing results for HBV, HCV and HIV. Given the focus of this analysis, *T.pallidum* serology results have been excluded.

Statistical analysis was performed using SAS version 9.4 (Cary, North Carolina, USA). Bivariate analysis was performed using chi-square tests to determine statistically significant associations of demographic characteristics and donor status with infectious marker positivity as well as serology/NAT result concordance. Odds ratios were computed for serology/NAT test discordance from multivariable analysis and adjusted for age, sex, remuneration, and first/repeat donor status. A probability (P) of less than 0.05 was used as a threshold for statistical significance.

2.5. Human subjects

The study was deemed to be exempt by the IRB at the NCDC of Georgia. NAT was permissible under routine consent for blood donation.

3. Results

3.1. Overview

During the first month of the NAT study (January 2020), 303 donations were tested; the number of tested donations increased over the following months, and from October to December 2020, an average of 6,521 donations were tested per month, representing > 99% of all donations in that period. A total of 54,116 donations (63.3% of all donations in 2020), representing 39,164 unique donors, were tested by both serology and NAT, and thus included in this analysis (after excluding 591 donors due to invalid or missing identification numbers). Of those who were included, 71.8% (n = 28,106) were male, 35.9% (n = 14,068) were age 18–29 years, and 30.4% (n = 11,909) were 30–39 years of age (Table 2). More than half (53.6%; n = 20,997) were voluntary and 79.1% (n = 30,988) were first-time donors. The majority donated in Tbilisi (58.3%; n = 22,838), followed by the regions of Adjara (17.9%; n = 7,016) and Kvemo Kartli (14.9%; n = 5,835). Among 8,176 repeat donors, the majority (76.5%; n = 6,251) were paid donors, 22.0% (n = 1,797) were voluntary, and 1.6% (n = 128) were replacement donors.

3.2. Infectious marker positivity

A total of 671 (1.7%) donors tested positive for at least one infectious marker (HBsAg, HCV, or HIV), including 611 identified by serology and an additional 60 by NAT (Fig. 1). Of the seropositive donations, 331 (54.2%) were positive for HBsAg, 252 (41.2%) for anti-HCV, and 40 (6.5%) for antibody to HIV; 12 (2.0%) were positive for more than one marker. Of the 60 identified through NAT, 53 (88.3%) were positive for HBV DNA, 6 (10.0%) for HCV RNA, and 1 (1.7%) for HIV-1 RNA. The overall donor prevalence by serology and/or NAT for HBV, HCV, and HIV was 1.0% (n = 384), 0.7% (n = 258), and 0.1% (n = 41), respectively. In bivariate analysis, any-marker positivity was significantly associated with age, sex, region, remuneration, and first/repeat donor status, with the highest prevalence among those aged 40–49 years (2.5%; n = 200), males (1.9%; n = 524), replacement (2.8%; n = 153) and first time (2.1%; n = 642) donors. Donations in the region of Samegrelo (4.2%; n = 25) had the highest prevalence, followed by Adjara (2.0%; n = 138) and Tbilisi (1.7%; n = 395). Among repeat donors, 18 (0.2%) had a positive NAT result following a previous negative test, among whom 72.2% (n = 13) were male and 83.3% (n = 15) were paid donors.

3.3. NAT vs serology

Of the 54,116 donations, 487 (0.9%) screened positive by multiplex NAT, of which 60 (12.3%) were seronegative. NAT discordant donations were associated with age, sex, region, remuneration, and first/repeat donor status. Among all NAT-positive donations, discordance (negative serology result) was most prevalent among donors who were female (20.8%; n = 20), aged ≥50 years (21.7%, n = 15), paid (28.4%, n = 27), and repeat (72.2%, n = 13) donors. After adjusting for these in multivariable analysis, the likelihood of having discordant results was higher among donors aged ≥ 50 years vs. 18–29 years of age (adjusted odds ratio [aOR] 3.05; 95% confidence interval [95% CI]: 1.05–8.88), female vs. male (aOR 2.06; 95% CI: 1.05–4.05), paid (aOR 10.15; 95% CI: 2.80–36.86) or voluntary (aOR 4.30; 95% CI: 1.27–14.56) vs. replacement, and repeat vs. first time (aOR 13.98; 95% CI: 4.06–48.12) donors (Table 3). Additionally, 184 donations were seropositive but NAT

negative, of which 116 (63.0%) were positive for anti-HCV, 44 (23.9%) for HBsAg, 21 (11.4%) for anti-HIV, and 3 (1.6%) were positive for more than one marker (Fig. 1). Among multiplex NAT positive samples that were retested by discriminatory NAT, all 60 (100%) tested positive for an infectious marker.

3.4. Repeat serology testing and NAT yield

Among the 53 NAT-positive samples for HBV, 44 underwent repeat testing for HBsAg and 42 for HBcAb (Fig. 1). Of those, 5/44 (11.0%) were HBsAg positive and 36/42 (85.7%) were found to be HBcAb positive. Three samples were positive for both HBsAg and HBcAb. All 6 NAT-positive samples for HCV and 1 positive for HIV underwent repeat serology testing, and 1 tested positive for anti-HCV. The remaining 6 HBcAb negative, 5 anti-HCV negative, and 1 anti-HIV negative sample are considered true NAT yield. Among the 12 NAT yield cases, 66.7% were male and they were equally divided among age groups. Two-thirds donated blood in Tbilisi, were first time donors, and were paid donations. Out of the total 54,116 donations, the final NAT yield rate was 1 in 9,019 for HBV, 1 in 10,823 for HCV, and 1 in 54,116 for HIV.

4. Discussion

We demonstrate the feasibility and clinical utility of implementation of NAT in a national blood program in Georgia, thus offering a regional model for other countries with high prevalences of TTIs. Within 10 months, nearly all donations in Georgia were screened centrally using NAT, with a timely turn-around of results. Sixty seronegative donations were interdicted by NAT, which would otherwise have escaped detection and could have led to new infections. On repeat serological testing (including addition of HBcAb testing, which is not routinely used in Georgia), 6 HBV + donations, 5 HCV + donations, and 1 HIV + donation were deemed to be NAT yield, possibly representing donations collected during the “window period” prior to seroconversion. The overwhelming majority (88%) of the NAT discordant donors were those with HBV infection. Of the 44 HBV DNA-positive samples that were initially reported as HBsAg negative, 5 were positive on HBsAg repeat testing. Additionally, 36 of 42 HBsAg negative samples were HBcAb positive. Male sex and first-time donor status were significantly associated with overall NAT reactivity. This is unsurprising: first-time donors are high risk for TTIs [9]. By contrast, repeat donors through sequential testing and deferral of marker positive donors, are lower risk. Male sex has previously shown to be associated with significantly higher prevalence of HCV, HBV and HIV seropositivity among blood donors in Georgia [1].

Spurred by its national HCV elimination program, Georgia committed to improving blood transfusion services to align with international (i.e., EU) standards. This ongoing transformation has been informed by on-site assessments of the participating blood centers in the State Blood Safety Program and represents a complete revision and reassessment of the blood safety value chain. Examples include revision of the regulatory framework pertaining to blood transfusion with a goal to transition to an exclusive voluntary donor pool, development of a hemovigilance system and implementation of standardized laboratory testing, including the adoption of NAT. Paired with results from a previous study [1], our

findings suggest improvements. Infectious marker positivity declined from 2017 – 2020 for HBsAg (1.1% to 0.8%) and anti-HCV (1.4% to 0.6%), further confirming a trend that was previously reported [1]. No changes were observed for HIV prevalence, which was already low at the baseline (0.1%). A known selection bias exists among blood donors, in which individuals who donate tend to be healthier than the general population [19,20]. This is evident by reporting in the general population: a national prevalence study of adults that was conducted in Georgia in 2015, reported HBcAb, HBsAg and HCV RNA positivity of 25.9%, 2.9% and 5.4%, respectively [3]. Based on separate reporting, the estimated prevalence of HIV in Georgia is 0.5% [21].

A total of 60 seronegative donations were interdicted during the first year of NAT. Two other studies may be used to contextualize these findings. In a study in South Africa, which is highly endemic for HIV, the rates of HIV, HBV, and HCV ID-NAT yield donations were 1:45,765, 1:11,810, and 1:732,200, respectively [22]. In Poland, a moderately endemic country for HBV, the HBV NAT yield rates were 1 in 108,800 donations using MP and 1 in 1:11,900 when ID-NAT was applied [23]. In low-endemic countries, NAT rates are markedly lower, accounting for estimates being reported per million donations [24–26]. By contrast, the true NAT yield rates in Georgia were 1 in 54,116 for HIV, 1 in 9,019 for HBV, and 1 in 10,823 for HCV. The number of “yield” cases is substantially higher than those observed in high-income settings like the US [27] (where routine HBcAb screening likely reduces the HBV yield). As in our study, NAT can detect both early as well as occult infections. This is particularly useful where the background incidence is high, as is the case in Georgia for both HBV and HCV. Transfusion is a highly efficient mode of transmission: most (e.g. 90% in the case of HIV) recipients of blood from NAT-positive donors will become infected [28]. Further, given that parent donations are used to produce components, multiple transfusion recipients may be at risk from a single infectious donor [9]. NAT has also supported the broader programmatic objectives. For example, first-time donors were overwhelmingly (97.5%) responsible for NAT-positive donations, highlighting the need to establish a stable repeat donor pool.

NAT studies in other settings have similarly shown that occult HBV rather than true NAT-yield cases (e.g., pre-seroconversion infections) account for most HBV NAT discordant (NAT+/seronegative) results. In a NAT study of 1,011,857 donation samples in Poland, all NAT positive were evaluated further with repeat testing [23]. Of the total index donations, 28 cases were HBV NAT (i.e., DNA) positive yet HBsAg negative; on further follow-up testing, 12 (43%) of the cases were HBcAb positive representing either chronic or resolved “occult” HBV infection. In Croatia, there were 51 NAT yield donations in the first 3 years of ID-NAT (i.e. out of 545,463 donations), representing 1 window period HIV-1 and 50 occult HBV infections [29]. Germane to our study, our data have identified deficiencies in current serological testing practices. Specifically, a proportion of discordant donations (11% in the case of initial HBsAg; 86% in the case of HBcAb) resolved on repeat testing. There is an opportunity for improvement, either through repeat (i.e., on the same assay) or confirmatory serological testing (e.g., using a different assay), neither of which is routine practice in Georgia.

The major argument against NAT is cost, which can strain transfusion services, particularly in low and middle-income countries (LMICs) [30]. The vast majority of infections will be detected using serology alone, particularly in a blood donor population that selects for low-risk individuals (i.e., absent medical or socio-behavioral risk factors for infection). Therefore, the incremental cost-effectiveness ratio (using serology as a base comparator) is high and driven by the incidence of the prevailing pathogen in the blood donor population. NAT yield donations, even in highly or moderately endemic countries are variable, yet collectively rare. This was the case for Georgia: although 60 infections were detected by NAT, most were not ultimately shown to be true NAT-yield cases and could otherwise have been detected by repeat or high-quality serological testing, (e.g., repeat anti-HCV) or addition of HBcAb. If attempting to conserve resources where NAT has been adopted, addition of HBcAb would be viewed as redundant.

Selected groups that were observed to have a higher likelihood of discordant results (individuals ≥ 50 years of age, females, paid and voluntary, and repeat donors), were not the same as those traditionally considered high-risk for TTIs. These results must be interpreted with caution as they do not indicate that these groups pose higher risk of being infected, but rather when infected, are more likely to be detected with NAT. In the case of repeat donors, one can surmise that an individual who has donated previously, and thus been serology negative, is more likely to be in the “window period”. Also, more frequent donation, and thus screening, would increase chances of being detected early in infection, whereas someone who is donating for the first time, and potentially chronically infected for a while, would be more likely to be detected through serology.

This study has limitations. Foremost are the sample size and relatively short observation period of one year, given the rarity of true NAT yield cases after accounting for repeat and/or confirmatory testing. NAT is now routine in Georgia, whereby prospective testing will enable continued accumulation of cases. There are also plans to better characterize these cases both with other biomarkers (e.g., alanine aminotransferase [ALT]) to refine the clinical interpretation as well as risk factor inquiry to understand whether there are contributing factors that might inform interventions. Ideally, one would stratify the data between confirmed reactive (i.e., ‘positive’) samples and those non-confirmed designated as ‘reactive’. The algorithm in use precluded this. Second, not all HBV discordant samples were available for repeat serological testing. It is possible more true HBV NAT yield cases would have been identified in those unresolved cases; this would strengthen our findings. Third, while NAT HBV-only positive results likely reflect a window period infection if HBcAb is negative and occult infection if HBcAb is positive, there are exceptions. Furthermore, cases of HBV infection that have been missed by NAT have been documented [31]. Fourth, the number of HCV RNA positive only cases was very high, yet only one of them seroconverted to anti HCV. Similarly, the only HIV RNA positive, anti-HIV negative donor did not seroconvert to anti-HIV. This detracts from their classification as true NAT-yield cases, further highlighting the importance of repeat and confirmatory testing. Fifth, pooled testing was not evaluated during our study. Future endeavors will include evaluation of individual donor vs. mini-pool approaches; the latter may be used to contain cost at marginal reduction to sensitivity. Sixth, less than two-thirds of all samples in 2020 underwent NAT. While the sample may be viewed as incomplete, this reflected the

implementation plan rather than a source of bias; once a blood center began participating, all samples were tested from that site. Finally, a formal economic analysis was not undertaken as that falls outside the scope of this study. Quantification of cost-effectiveness (i.e., unit cost per averted TTI) would be valuable for other countries that are considering implementation of NAT. This would ideally be undertaken ahead of implementation. Ultimately the value of NAT and other interventions is informed by societal willingness to pay. Historically, this has dissuaded its adoption in LMICs [17]. In summary, the lack of standardization of serological testing —by approach as well as inconsistent repeat and/or confirmatory testing—limits the extent to which one can draw meaningful conclusions regarding association of a particular methodology with false reactivity. Further, while not systematically investigated, some of the discrepant results could be ascribed to clerical —rather than laboratory—errors such as mislabeling of specimens. These considerations detract from a designation of true NAT yield. The highlighted deficiencies are being actively addressed with a view to improve the program.

5. Ethics

The project activities were conducted in the frame of the Georgian State Blood Safety Program (Government Resolution #674, 2020). Main Aim of the program was improving public health and was focused on the health of donors and recipients. The program is not punitive in nature, It serves only to detect deficiencies of the blood system, timely detection of errors and prevention of the spread of infection. All Human rights are protected, Donors are signing ICF(form is build in e-database) before each donation, Quality of blood products are checked regularly by the reference Lab (LugarCenter) as discribed in the Govermental resolution. As a public Heath program, it does not need special IRB approval. Confidentiality is protected according to the requirements of the Law of Georgia on personal data protection.

6. Conclusions

In conclusion, the project has advanced blood safety in Georgia while aligning directly with the HCV elimination program to mitigate the spread of HCV infection. While many of the cases (particularly of HBV) were not true NAT yield, this does not diminish the impact. Germane to HCV infection, 75% of those who acquire HCV will proceed to chronic infection [12]. NAT is an important technology, particularly in countries with high incident rates of TTIs. While the contribution of NAT to the HCV elimination program is modest, the contribution of NAT to the safety of the blood supply is significant.

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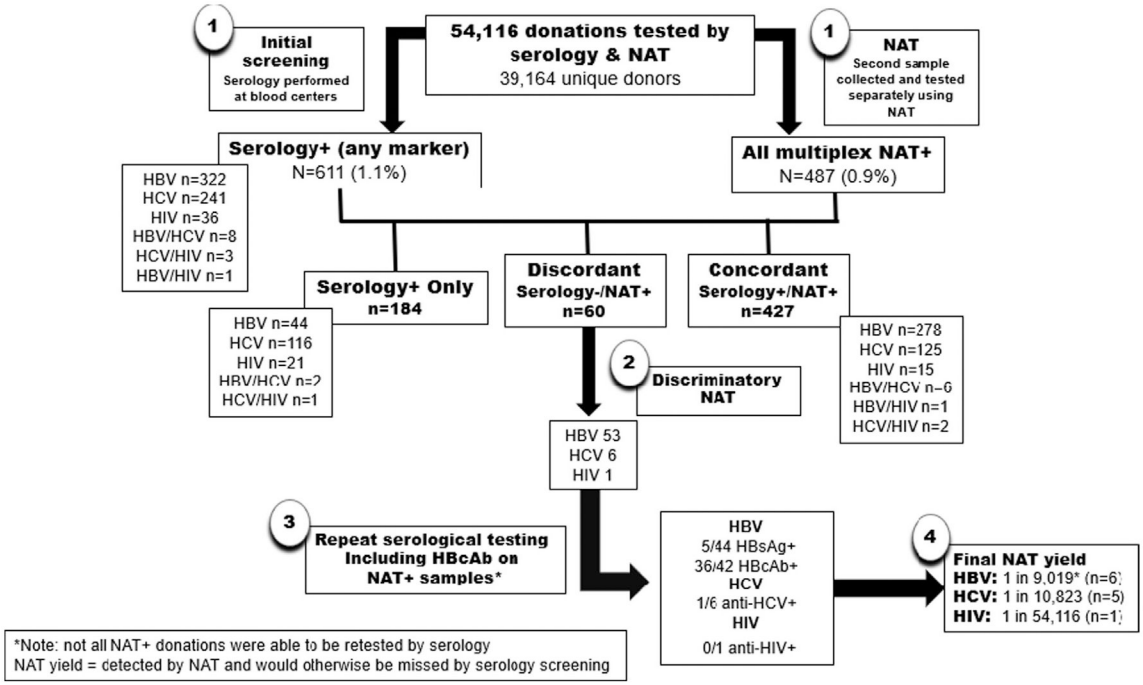

Fig. 1.

Study overview of testing and composition and results.

Table 1

Equipment and Methods used by blood banks for HCV, HIV and HBV serological screening.

Equipment used by Blood Banks		**Kit manufacturers**	
Fully-Automated	**Semi-Automated**	**Methods**	**Names**
ADVIA Centaur XPT Immunoassay System, Siemens	Stat fax 2100 microplate reader	Chemiluminescent immunoassay [CLIA]	ADVIA Centaur HIV Ag/Ab Combo (CHIV), HBsAgII(HBsII) and HCV(aHCV) Assays, Siemens USA
Abbott Architect i2000 SR, Abbott VITROS® ECiQ Immunodiagnostic System, Ortho Clinical Diagnostic Cobas 411, Roche diagnostics Maglumi 800, Snibe	Human Reader HS iMark™ Microplate Absorbance Reader Bio-Rad Mindray MR-96A	Electro Chemiluminescent immunoassay [ECLIA] Chemiluminescence microparticle assay [CMIA] Enzyme-linked immunosorbent assay [ELISA]	Elecsys A-HCV II, Elecsys HBsAg II and Elecsys HIV combi PT, Roche Diagnostics, Germany Anti-HCV, HBsAg and HIV Ag/Ab Combo Abbott assays, Abbott Diagnostic, USA VITROS Anti HCV, HBsAg and HIV Combo, Ortho Clinical Diagnostic, UK Monolisa anti HCV Plus, Monolisa HBS Ag Ultra and Monolisa Ultra HIV Ag-Ab Bio Rad, France HCV Ab, HBs Ag one Version Ultra and HIV Ab &Ag, Dia. pro, Italy

notes: HBsAg = HBV surface antigen; anti-HCV = antibody to HCV; HIV Ab/Ag = antibody to HIV and HIV antigen;

Table 2

Demographic characteristics and testing results among blood donor population tested by serology and NAT, Georgia, January – December 2020.

	All Donors	Infectious Marker Positivity			Serology/NAT Test Concordance		
	n (column %)	Serology or NAT Positive n (row %)	Serology and NAT Negative n (row %)	Chi-square *P*-Value	Serology negative/NAT Positive n (row %)	Serology and NAT Positive n (row%)	Chi-square *P*-Value
Donations	**54,116**	671 (1.2)	53,445 (98.8)	–	60 (12.3)	427 (87.7)	–
Unique donors	**39,164**	671 (1.7)	38,493 (98.3)	–	60 (12.3)	427 (87.7)	–
Age group							
18–29	14,068 (35.9)	118 (0.8)	13,950 (99.2)	<0.001	9 (13.6)	57 (86.4)	0.008
30–39	11,909 (30.4)	249 (2.1)	11,660 (97.9)		14 (7.0)	187 (93.0)	
40–49	8162 (20.8)	200 (2.5)	7,962 (97.5)		22 (14.6)	129 (85.4)	
50+	5025 (12.8)	104 (2.1)	4,921 (97.9)		15 (21.7)	54 (78.3)	
Sex							
Female	11,058 (28.2)	147 (1.3)	10,911 (98.7)	<0.001	20 (20.8)	76 (79.2)	0.005
Male	28,106 (71.8)	524 (1.9)	27,582 (98.1)		40 (10.2)	351 (89.8)	
Region							
Tbilisi	22,838 (58.3)	395 (1.7)	22,443 (98.3)	<0.001	35 (12.4)	247 (87.6)	<0.001
Adjara	7016 (17.9)	138 (2.0)	6,878 (98.0)		11 (11.0)	89 (89.0)	
Imereti	1588 (4.1)	16 (1.0)	1,572 (99.0)		6 (42.9)	8 (57.1)	
Kvemo Kartli	5835 (14.9)	90 (1.5)	5,745 (98.5)		5 (6.6)	71 (93.4)	
Samegrelo	589 (1.5)	25 (4.2)	564 (95.8)		0 (0.0)	9 (100.0)	
Shida Kartli	1298 (3.3)	7 (0.5)	1,291 (99.5)		3 (50.0)	3 (50.0)	
Remuneration status *							
Paid	12,668 (32.3)	122 (1.0)	12,546 (99.0)	<0.001	27 (28.4)	68 (71.6)	<0.001
Voluntary	20,997 (53.6)	396 (1.9)	20,601 (98.1)		30 (10.6)	252 (89.4)	
Replacement	5493 (14.0)	153 (2.8)	5340 (97.2)		3 (2.7)	107 (97.3)	
Donor Status							
First	30,988 (79.1)	642 (2.1)	30,346 (97.9)	<0.001	47 (10.0)	422 (90.0)	<0.001
Repeat	8176 (20.9)	29 (0.4)	8,147 (99.6)		13 (72.2)	5 (27.8)	

Abbreviations: HBV = hepatitis B virus; HCV = hepatitis C virus; HBsAg = HBV surface antigen; anti-HCV = antibody to HCV; anti-HIV = antibody to HIV; NAT = nucleic acid amplification test.

*Missing values not shown.

Table 3

Odds ratios for serology and NAT test discordance among blood donor population, Georgia, January – December 2020.

	Serology negative/NAT positive n = 60 n (row %)	Serology and NAT positive n = 427 n (row %)	Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
Age Group				
18–29	9 (13.6)	57 (86.4)	1	1
30–39	14 (7.0)	187 (93.0)	0.47 (0.20, 1.15)	1.12 (0.40, 3.14)
40–49	22 (14.6)	129 (85.4)	1.08 (0.47, 2.49)	2.09 (0.78, 5.64)
50+	15 (21.7)	54 (78.3)	1.76 (0.71, 4.36)	3.05 (1.05, 8.88)
Sex				
Female	20 (20.8)	76 (79.2)	2.31 (1.28, 4.17)	2.06 (1.05, 4.05)
Male	40 (10.2)	351 (89.8)	1	1
Remuneration Status				
Paid	27 (28.4)	68 (71.6)	1	1
Voluntary	30 (10.6)	252 (89.4)	3.34 (1.86, 5.99)	2.36 (1.18, 4.73)
Replacement	3 (2.7)	107 (97.3)	0.24 (0.07, 0.79)	0.23 (0.07, 0.79)
Donor Status				
First	47 (10.0)	422 (90.0)	1	1
Repeat	13 (72.2)	5 (27.8)	23.35 (7.97, 68.37)	13.98 (4.06, 48.12)

Abbreviations: NAT = nucleic acid amplification test; CI = confidence interval.

*Model includes age, sex, donor type, donor status.