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Trends in new hepatitis C virus infections among repeat blood donors – Georgia, 2017–2023

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Abstract

BACKGROUND AND OBJECTIVES: Blood donor cohorts are an underappreciated resource for surveillance and public health programming for infectious diseases. The incidence of hepatitis C virus (HCV) infection was evaluated in repeat blood donors in Georgia.

MATERIALS AND METHODS: Using data from the national hepatitis C screening registry, we calculated overall hepatitis C incidence for 2017–2023 and annual incidence during 2017–2022 among adults who donated blood at least twice and had a nonreactive HCV antibody (anti-HCV) test result upon first screening and a subsequent anti-HCV test conducted in any location. Rates of anti-HCV seroconversion and current infection were calculated by year, sex, age group, and location of last HCV screening and expressed per 100,000 person-years (PY).

RESULTS: Of 101,443 blood donors with ≥ 2 anti-HCV results, 775 (0.8%) seroconverted to anti-HCV reactive, of whom 403 (52.0%) had current infection. Incidence of anti-HCV seroconversion

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S.S and D.B acquired and analyzed the data and wrote the first draft of the manuscript; E.M.B. and R.A.T. supervised the research and reviewed and edited the manuscript. M.A., V.G., I.S.S, S.S., and S.H contributed to data collection, interpretation of findings, review and editing of final draft of the manuscript.

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decreased from 408 per 100,000 PY in 2017 to 218 per 100,000 PY in 2022 and incidence of infection decreased from 172 per 100,000 PY in 2017 to 118 per 100,000 PY in 2022. Males, persons aged 18–39 years, and people last tested for HCV in prisons had the highest incidence rates for anti-HCV seroconversion and HCV infection, while persons last screened in blood banks and during antenatal care had the lowest.

CONCLUSION: Despite the observed decline, incidence of HCV infection among repeat blood donors remains high in specific subgroups. Hepatitis C prevention, screening and treatment interventions need to particularly focus on incarcerated populations and young adults in Georgia.

Keywords

Blood transfusion; Blood Donors; Hepatitis C; Epidemiology; Incidence; Georgia (Country)

1.0 Introduction

In 2015, Georgia initiated the world's first national hepatitis C elimination program[1]. History of blood transfusion has been associated with hepatitis C virus (HCV) infection in Georgia[2, 3]. Therefore, blood transfusion safety was prioritized in the hepatitis C elimination program, through complete overhaul of blood transfusion services, spanning national policy and the regulatory framework pertaining to blood donor selection, blood collection, laboratory-based donor screening and clinical transfusion practices[4].

A high proportion of donors in Georgia are either paid or friends/family members of the intended transfusion recipient, all of whom are at higher risk of transfusion-transmitted infections (including HCV) than voluntary donors[4, 5]. Efforts are underway to refine donor recruitment in Georgia, with a transition to exclusive voluntary non-remunerated blood donors by 2025. All blood donations in Georgia are screened routinely for hepatitis C (anti-HCV), in addition to syphilis, hepatitis B (hepatitis B surface antigen, HBsAg), and HIV. Anti-HCV reactive donations are subsequently referred for HCV RNA or HCV core antigen testing to assess current HCV infection. Those with evidence of current infection are referred for treatment with direct acting antivirals, which are provided free of charge. Prompted by the hepatitis C elimination program, routine nucleic acid testing (NAT) was also implemented in 2020 using a centralized model in which all donor samples are sent to Tbilisi (the capital city) for testing, with results distributed to blood collection sites within 24 hours[6]. Blood donors with a positive screening result are permanently deferred from blood donation; this information is recorded in a national blood donor database and a hepatitis C screening registry. The screening registry captures data from all screening venues nationwide, which enables tracking of hepatitis C among previous blood donors when they undergo HCV testing in other settings, such as a hospital or outpatient clinic. We sought to estimate temporal trends in new HCV infections among repeat blood donors who were retested for hepatitis C at various locations.

2.0 Materials and methods

We included adults (age ≥ 18 years) who provided ≥ 2 blood donations with a nonreactive first anti-HCV test result followed by at least one subsequent anti-HCV test, dated >12

days later to limit misclassification from data entry errors. The analysis included HCV tests performed at all venues (hospitals, antenatal care clinics, blood banks, prisons, harm reduction sites), so testing could have been performed for reasons other than blood donation. Using data from Georgia's national hepatitis C screening registry, we calculated overall anti-HCV seroconversion rates during January 1, 2017 to December 31, 2023. To minimize exclusion of repeat donors, data from 2015–2016 were incorporated for classification purposes only; final incidence analysis did not include screening data for these two years due to incomplete reporting. Seroconversion was defined as a nonreactive anti-HCV test followed by a reactive result on subsequent testing. The overall seroconversion rate was calculated by dividing the number of seroconversions by total person-time and expressed per 100,000 person-years (PY) with 95% confidence intervals (95%CI). Person-time was the summation of each individuals' number of days from the first anti-HCV test to either the last nonreactive test (for consistently nonreactive individuals) or the first reactive test (for individuals who seroconverted). To calculate annual incidence rates, for the numerator we assumed uniform distribution of the seroconversion probability from the date of the last negative to the first reactive anti-HCV test. For the denominator, persistently nonreactive persons contributed the full amount of time between their first and last anti-HCV test, while for seroconverters, time between multiple non-reactive tests contributed in full, while the daily person-time contribution between a non-reactive and reactive test was equal to the time between each day and the date of the reactive test divided by the full seroconversion interval. Similar methods to calculate annual incidence in other populations are described elsewhere[7, 8]. An observed effect of this methodology was an artificial increase in annual incidence in the most recent year, caused by right censoring. Thus, 2023 annual incidence results have been suppressed, but 2023 data are incorporated in the overall analysis. Overall seroconversion rates were estimated by year, sex, age group, and screening venue. Among individuals who seroconverted, 72% underwent testing for HCV RNA or HCV core antigen. To limit underestimation of current HCV infections, multiple imputations method was used to impute missing HCV RNA or core antigen results for anti-HCV reactive persons who were not tested for infection, controlling for spontaneous clearance rates by age, sex, region, and venue. The rate of new current HCV infections was calculated using the same methodology described above.

3.0 Results

3.1 Overview and incidence of anti-HCV seroconversion

During 2017–2023, a total of 235,807 blood donors were tested for anti-HCV, of whom 101,443 (43.0%) were repeat blood donors with a nonreactive anti-HCV result followed by another anti-HCV test in any setting. Among those repeat donors, 71,906 (70.9%) were male, and 64,397 (63.5%) were aged 18–39 years. After a median follow-up of 43 months (IQR 24–61 months), 775 (0.8%) seroconverted to anti-HCV reactive (Table 1). The overall anti-HCV seroconversion incidence rate during 2017–2023 was 218 (95%CI: 203–234) per 100,000 PY; 253 (95%CI: 234–273) per 100,000 PY among males and 138 per 100,000 PY among females (95%CI: 118–162) (Table 2). Seroconversion rates were highest in those aged 18–29 years (228, 95%CI: 201–259) and 30–39 years (235, 95%CI: 208–265). Persons last tested in prisons had the highest rate of 13,541 (95%CI: 7862–

23,319) per 100,000 PY while those last tested in antenatal clinics (150 [95%CI: 48–464] per 100,000 PY) and blood banks (165 [95%CI: 150–182] per 100,000 PY) had the lowest seroconversion rates compared to other settings (Table 2). Annual rates of seroconversion decreased by 46.6% from 408 (95%CI: 336–497) per 100,000 PY in 2017 to 218 (95%CI: 182–261) per 100,000 PY in 2022. The lowest anti-HCV seroconversion rate was observed in 2020 with increases in 2021 and 2022 (Figure).

3.2 Incidence of current HCV infection

Of 775 blood donors who seroconverted, 556 (71.7%) were tested for HCV RNA or HCV core antigen, 291 (52.3%) of whom were positive. An additional 112 cases were imputed for a total of 403 persons with current HCV infection. During 2017–2023, the overall incidence rate of current infection was 113 (95%CI: 103–125) per 100,000 PY, which was higher among males (153 [95%CI: 138–169] per 100,000 PY) than females (22 [95%CI: 15–33] per 100,000 PY). Persons aged 18–29 years (153 [95%CI: 131–179] per 100,000 PY) and 30–39 years (138 [95%CI: 118–161] per 100,000 PY) had the highest rates of current infection (Table 2). There were also regional differences, from 43 (95%CI: 21–86) per 100,000 PY in Shida Kartli to 467 (95%CI: 117–1869) per 100,000 PY in Racha Lechkhumi/Kvemo Svaneti. Persons last screened in a prison setting had the highest incidence rate of current HCV infections (12,492 [95%CI: 7,094–21,996] per 100,000 PY), while those last screened in a blood bank had the lowest (78 [95%CI: 68–90] per 100,000 PY). Overall annual rates of new current infections decreased by 31.4% from 172 (95%CI: 128–232) per 100,000 PY in 2017 to 118 (95%CI: 92–151) per 100,000 PY in 2022. The lowest rates were observed in 2020 and 2021 with an increase in 2022 (Table 2).

4.0 DISCUSSION

Our findings indicate the incidence of HCV infection has decreased among repeat blood donors in Georgia, with a nearly two-fold decline in anti-HCV seroconversion rate and a 1.5-fold decline in the rate of current HCV infection during 2017–2022. Previous analysis has also shown decreasing anti-HCV prevalence among Georgian blood donors from 2.3% in 2015 to 1.4% in 2017⁴. The current findings afford insight into the contemporary epidemiology of HCV infection among repeat donors, highlighting the disproportionate incidence rates among males, younger persons, and incarcerated populations, as well as regional differences.

The World Health Organization (WHO) has established a target incidence rate of ≤ 5 new annual chronic HCV infections per 100,000 PY in the general population and ≤ 2 per 100 PY among people who inject drugs (PWID) for validation of hepatitis C elimination[9]. Walker et al. reported a modeled estimated incidence rate of current HCV infection in the total population in Georgia (as of March 2022) to be 66 (95% credible interval [CrI] 34–131) per 100,000 PY, with a 58% (95% CrI 52–67%) decrease since 2015[10]. Among PWID, the incidence rate was estimated to be 1.14 (95% CrI 0.08–6.4) per 100 PY, similarly representing a 57% (19–68%) decrease since 2015¹⁰. The substantial decline in incidence rates per 100,000 PY among repeat blood donors (from 408 in 2017 to 218 in 2022) observed in our study is proportional to that reported by Walker et al. in the general

population. However, the modeled estimates and our findings are dissimilar for multiple reasons: (1) Our study was restricted to the adult population, while the modeling estimates included children; (2) Our analysis is confined to persons with ≥ 2 blood donations. In our study, persons last tested in a blood bank had lower incidence rates of anti-HCV seroconversion and current infection compared to those last tested in other settings. Blood donation is intended to select for a healthier subset of the population, specifically those who are at low risk of HCV infection and other transfusion-transmissible infectious diseases. Repeat donors are regarded as the safest subset of the donor population[5], and have a significantly lower prevalence of anti-HCV than first-time donors in Georgia (0.8% vs. 4.0% in 2017)⁴.

This study has limitations. A variety of different methods for anti-HCV testing, including both laboratory-based and rapid diagnostic tests are used in various screening sites. Further, repeat and confirmatory anti-HCV testing is not undertaken uniformly. Unfortunately, information on the individual test types (e.g. rapid diagnostic tests) and testing algorithms (i.e. repeat or confirmatory testing) was not captured rigorously, precluding analysis of the associated effect on the study's findings. For example, it is possible that a negative anti-HCV result during the first test represented a false negative, and a subsequent positive test would be erroneously counted as a new case, thus overestimating incidence. Standardization of serological testing is being prioritized in Georgia, regarding assays as well as testing algorithms. Second, a slight increase in annual incidence was observed in 2022. This may be an overestimation due to right censoring; there could be a higher proportion of seroconversion cases in the latest years because there is insufficient time for follow-up, e.g. persons non-reactive for the first time in 2023 would not contribute person-time until they are retested. Annual incidence for 2023 was suppressed for this effect but it may still artificially inflate 2022 results. Finally, some regions and venues had few seroconversions, leading to wide confidence intervals that should be interpreted with caution.

5.0 Conclusions

This study highlights the broader utility of blood donor populations to advance our understanding of infectious diseases and to support public health programming[11]. Ease of longitudinal follow-up, laboratory testing, and data capture render donor populations an invaluable, albeit underappreciated, sample for research and surveillance. The donor-donation infrastructure can be leveraged to study emerging and neglected pathogens, independent of whether the agents pose risk to blood transfusion safety[11, 12]. There has been an observed decline in hepatitis C prevalence since the inception of the HCV elimination program in Georgia³. Nonetheless, incidence remains high in a subset of repeat donors, particularly among young men and incarcerated populations. To achieve hepatitis C elimination, interventions need to target higher incidence populations to prevent transmission and diagnose and treat those with current HCV infection.

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Conflict of interest

EMB reports personal fees and non-financial support from Grifols, Abbott, UpToDate, Tegus and Health Advances outside of the submitted work. EMB is a co-investigator on a US government funded clinical trial evaluating Mirasol Pathogen Reduction Technology.

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Highlights

- A national hepatitis C elimination program is underway in the country of Georgia
- Blood transfusion safety has been prioritized as part of the elimination program
- Incidence of Hepatitis C virus infection has decreased among repeat blood donors
- Selected subgroups of the population remain at risk
- Blood donors are an important resource to support public health programming

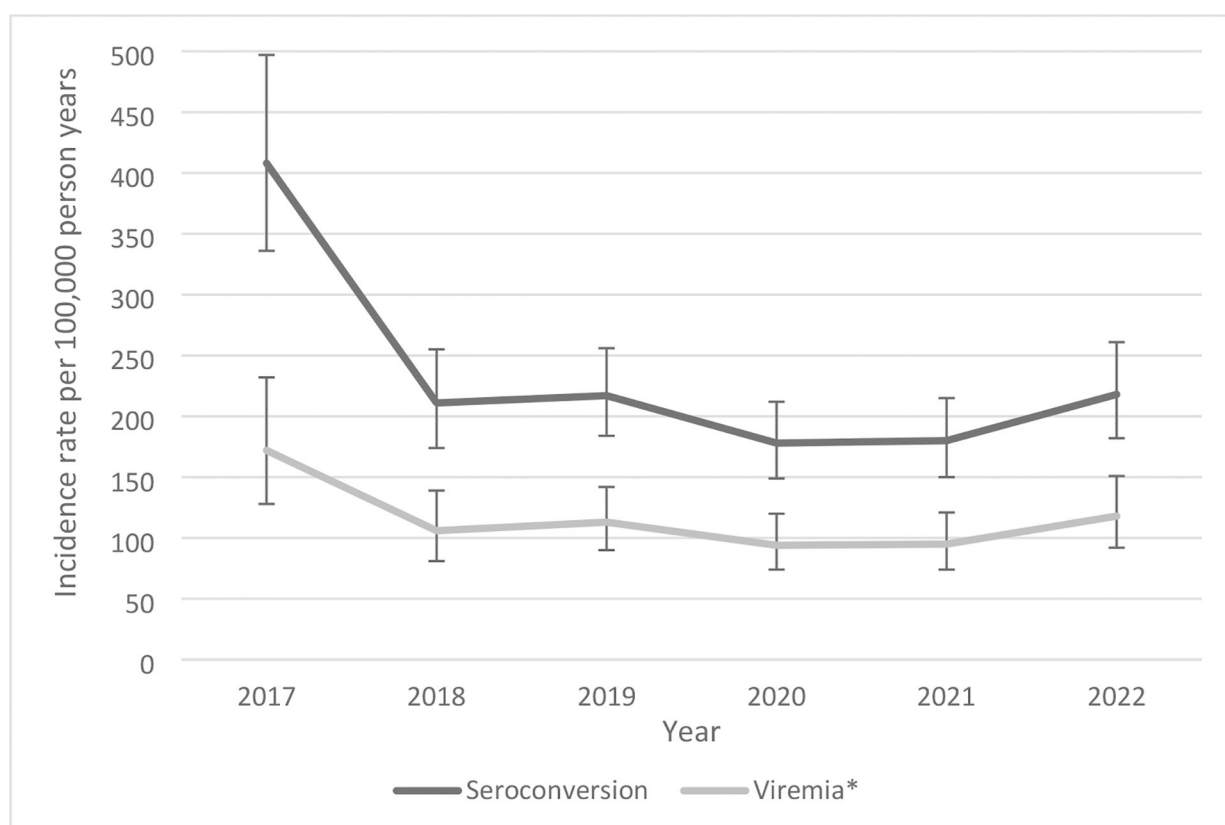


Figure 1.
Annual incidence rates of hepatitis C (per 100,000 PY; 95% CI) among repeat blood donors with ≥ 2 hepatitis C antibody tests, Georgia, 2017–2022
* Including imputed cases

Table 1.

Overview of study population and anti-HCV seroconversions among repeat blood donors with ≥ 2 hepatitis C antibody tests in any setting, Georgia, 2017–2023

	Repeat Blood Donors n (column %)	Anti-HCV Seroconversion n (row %)	No Seroconversion n (row %)
Overall population	101,443	775 (0.8)	100,668 (99.2)
Sex			
Male	71,906 (70.9)	626 (0.9)	71,280 (99.1)
Female	29,537 (29.1)	149 (0.5)	29,388 (99.5)
Age			
18–29	33,245 (32.8)	237 (0.7)	33,008 (99.3)
30–39	31,152 (30.7)	262 (0.8)	30,890 (99.2)
40–49	21,895 (21.6)	177 (0.8)	21,718 (99.2)
50–59	12,066 (11.9)	80 (0.7)	11,986 (99.3)
≥ 60	3,085 (3.0)	19 (0.6)	3,066 (99.4)
Region of the first screening			
Tbilisi	50,562 (49.8)	397 (0.8)	50,165 (99.2)
Kakheti	867 (0.9)	6 (0.7)	861 (99.3)
Shida Kartli	4,821 (4.8)	44 (0.9)	4,777 (99.1)
Kvemo Kartli	1,665 (1.6)	12 (0.7)	1,653 (99.3)
Mtskheta Mtianeti	300 (0.3)	3 (1.0)	297 (99.0)
Imereti	7,897 (7.8)	59 (0.7)	7,838 (99.3)
Guria	826 (0.8)	9 (1.1)	817 (98.9)
Adjara	20,570 (20.3)	152 (0.7)	20,418 (99.3)
Samegrelo	4,548 (4.5)	46 (1)	4,502 (99)
Racha Lechkhumi Kvemo Svaneti	119 (0.1)	2 (1.7)	117 (98.3)
Samtskhe Javakheti	450 (0.4)	2 (0.4)	448 (99.6)
Missing	8,818 (8.7)	43 (0.5)	8,775 (99.5)
Venue of first screening			
Antenatal care	1,213 (1.2)	4 (0.3)	1,209 (99.7)
Blood bank	69,391 (68.4)	574 (0.8)	68,817 (99.2)
Inpatient/Outpatient	23,965 (23.6)	146 (0.6)	23,819 (99.4)
Prison	275 (0.3)	3 (1.1)	272 (98.9)
Other (including GHRN)	6,379 (6.3)	47 (0.7)	6,332 (99.3)
Missing	220 (0.2)	1 (0.5)	219 (99.5)
Venue of latest screening			
Antenatal care	595 (0.6)	3 (0.5)	592 (99.5)
Blood bank	73,658 (72.6)	408 (0.6)	73,250 (99.4)
Inpatient/Outpatient	25,835 (25.5)	282 (1.1)	25,553 (98.9)
Prison	50 (0.0)	13 (26.0)	37 (74.0)
Other (including GHRN)	1,301 (1.3)	69 (5.3)	1,232 (94.7)

	Repeat Blood Donors n (column %)	Anti-HCV Seroconversion n (row %)	No Seroconversion n (row %)
Missing	4 (0.0)	0 (0.0)	4 (100.0)
Time from first to latest test, months			
Median (interquartile range)	43 (24, 61)	25 (12, 42)	43 (24, 62)

GHRN: Georgian harm reduction network

Table 2.

Incidence of hepatitis C among repeat blood donors with ≥ 2 hepatitis C antibody tests in any setting, Georgia, 2017–2023

DEMOGRAPHIC CHARACTERISTICS	Total N	Anti-HCV Seroconversion		Cases of current infection (HCV RNA or core antigen positive) *	
		Seroconversions (n)	Incidence per 100,000 PY (95% CI)	Current Infection (n)	Incidence per 100,000 PY (95% CI)
Total population	101,443	775	218 (203–234)	403	113 (103–125)
Sex					
Male	71,906	626	253 (234–273)	379	153 (138–169)
Female	29,537	149	138 (118–162)	24	22 (15–33)
Age					
18–29	33,245	237	228 (201–259)	159	153 (131–179)
30–39	31,152	262	235 (208–265)	154	138 (118–161)
40–49	21,895	177	218 (188–253)	71	88 (69–110)
50–59	12,066	80	175 (141–218)	15	33 (20–54)
≥ 60	3,085	19	143 (91–225)	4	30 (11–80)
Region of the first screening					
Tbilisi	50,562	397	216 (196–238)	229	124 (109–142)
Kakheti	867	6	179 (80–398)	2	60 (15–238)
Shida Kartli	4,821	44	236 (175–317)	8	43 (21–86)
Kvemo Kartli	1,665	12	181 (103–319)	4	60 (23–161)
Mtskheta Mtianeti	300	3	289 (93–895)	1	96 (14–683)
Imereti	7,897	59	205 (159–265)	33	115 (82–161)
Guria	826	9	297 (155–571)	4	132 (50–352)
Adjara	20,570	152	200 (171–235)	71	94 (74–118)
Samegrelo	4,548	46	262 (196–350)	29	165 (115–237)
Racha Lechkhumi Kvemo Svaneti	119	2	467 (117–1869)	2	467 (117–1869)
Samtskhe Javakheti	450	2	126 (32–504)	1	63 (9–447)
Missing	8,818	43	291 (215–392)	19	128 (82–201)
Venue of latest screening					
Antenatal care	595	3	150 (48–464)	2	100 (25–399)
Blood bank	73,658	408	165 (150–182)	193	78 (68–90)
In/Outpatient	25,835	282	274 (244–308)	148	144 (122–169)
Prison	50	13	13,541 (7,862–23,319)	12	12,492 (7,094–21,996)
Other (including GHRN)	1,301	69	1,866 (1,474–2,363)	48	1,296 (976–1,719)
Missing	4	0	--	0	--
Annual incidence **					
2017	40,767	101	408 (336–497)	43	172 (128–232)
2018	61,021	103	211 (174–255)	52	106 (81–139)
2019	75,873	138	217 (184–256)	72	113 (90–142)

DEMOGRAPHIC CHARACTERISTICS	Total N	Anti-HCV Seroconversion		Cases of current infection (HCV RNA or core antigen positive) *	
		Seroconversions (n)	Incidence per 100,000 PY (95% CI)	Current Infection (n)	Incidence per 100,000 PY (95% CI)
2020	78,418	124	178 (149–212)	66	94 (74–120)
2021	75,095	119	180 (150–215)	63	95 (74–121)
2022	65,655	118	218 (182–261)	64	118 (92–151)

* Including imputed cases, accounting for spontaneous clearance of infection

** N = number of persons that contributed person-time to a given year. Since some persons contributed person-time to multiple years, the total sum in this variable exceeds the actual number of persons included in the analysis.

GHRN: Georgian Harm reduction Network