



FIND

Because diagnosis matters

Approaches to providing hepatitis C viremia testing to people who inject drugs in Georgia Study
HEAD-Start project (Hepatitis C Elimination through Access to Diagnostics) Georgia
Sonjelle Shilton, Deputy Head HCV Access
National Technical Advisory Group Scientific meeting;
18 Nov 2019, Tbilisi, Georgia



HEAD-Start Projects

Georgia:

Settings:

- Harm Reduction Sites
- National Reference Laboratory

Activities:

- Decentralization of testing
- Comparison study cAg as test of cure
- Simplification of testing algorithm
- Integration of HCV VL in existing decentralized testing platforms

India, Manipur:

Settings:

- Integrated Care Centers for ARV services in PWIDs

Activities:

- Decentralization of HCV care at community level

Myanmar:

Settings:

- Drug Treatment Center and community-based clinic
- National Reference Laboratories

Activities:

- Integration of testing (RDTs and POC) in decentralized settings
- Optimization of existing polyvalent central platforms

India, Punjab:

Settings:

- Secondary and primary facilities

Activities:

- Decentralization of HCV diagnosis at ART clinics

India, Delhi:

Settings:

- Primary facilities and district hospitals

Activities:

- Hub-spoke model with decentralized screening and centralized confirmation

Malaysia

Settings:

- Secondary and primary facilities to support DNDi phase 3 trial and MOH NHP
- National Reference Laboratory

Activities:

- Hub-spoke model with decentralized screening and centralized confirmation



FIND projects and studies in Georgia

FIND is working with NCDC regarding support to HCV program since 2016

COMPLETED

- FIND clinical evaluation on GeneXpert Fingerstick HCV cartridge in cooperation with Lugar center and Hepa+ HRS
350 persons provided with confirmatory testing
- HCV Rapid Diagnostic Test (RDT) evaluation – Lugar Center

ONGOING

- HEAD Start project (Phase 1)
- HEAD Start project (Phase 2)
Decentralization of integration project including NCDC Labs (total 15 sites)
- HCV cAg as a test of cure – Neo Lab clinic and Lugar center
- HCV DBS Validation study in Hepa+ HRS
- HCV Genedrive study of use in intended settings in Hepa+ HRS
- HCV National Data Base (Elim C) project – NCDC/MOH

PREPERATION

- Linkage project – NCDC



HEAD-Start Georgia

- HEAD-Start study looking at impact of point-of-care HCV confirmation on care cascade among PWIDs

- Objectives of the study:

- To determine whether the proportion of participants who receive results of HCV viremia testing differs between the Arms.
- To characterize the HCV care cascade for PWID identified through HRSs in Georgia, and quantify the proportion that go through each step in the cascade.

- Partners:

Georgia MoH, Georgia NCDC,
Georgian Harm Reduction Network,
Harm Reduction Sites



MINISTRY OF INTERNALLY DISPLACED
PERSONS FROM THE OCCUPIED
TERRITORIES, LABOUR, HEALTH AND
SOCIAL AFFAIRS OF GEORGIA



დაავადებათა კონტროლისა და
საზოგადოებრივი ჯანმრთელობის
ეროვნული ცენტრი
GEORGIAN NATIONAL CENTER FOR DISEASE
CONTROL AND PUBLIC HEALTH



Epidemiology

Population: 3.7 million
HCV (Gen Pop) seroprevalence 7.7% ¹
HCV (Gen Pop) chronic infection 5.4% ¹
PWID: ~50,000 ²
HCV prevalence among PWIDs ~66% ³



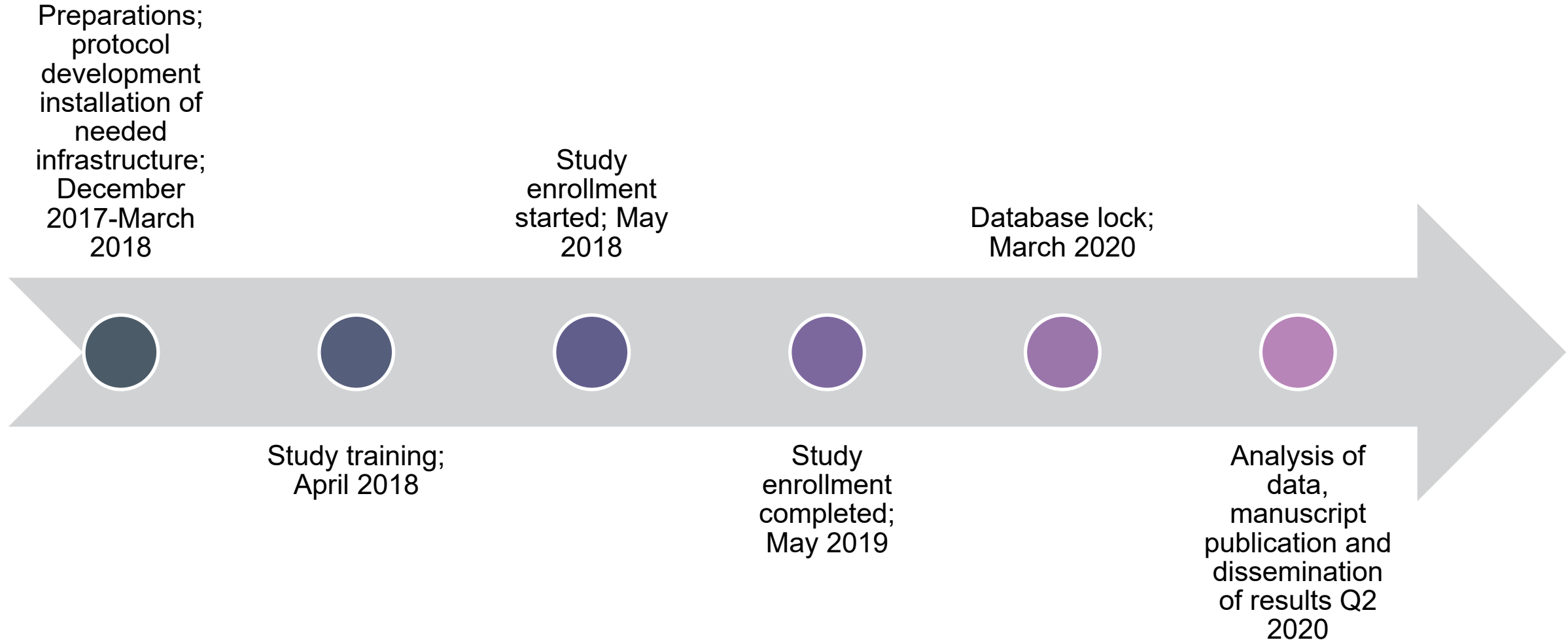
1 NCDC, National Survey, 2015

2 Addiction Research Development in Georgia Project, Drug situation in Georgia 2015, report

3 Bio-Behavioral Surveillance Survey, 2014 - 2015

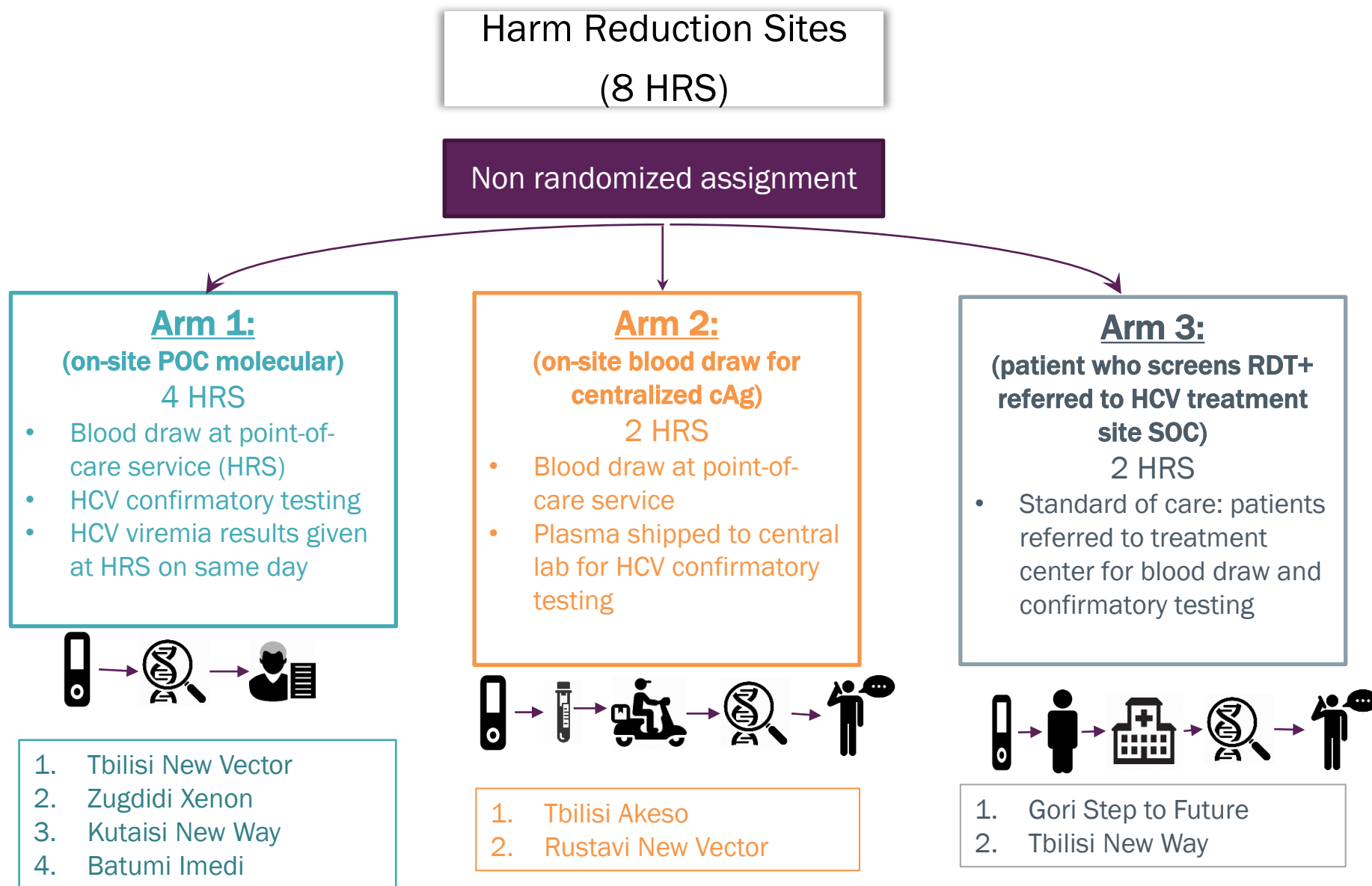


Georgia HEAD-Start study timelines



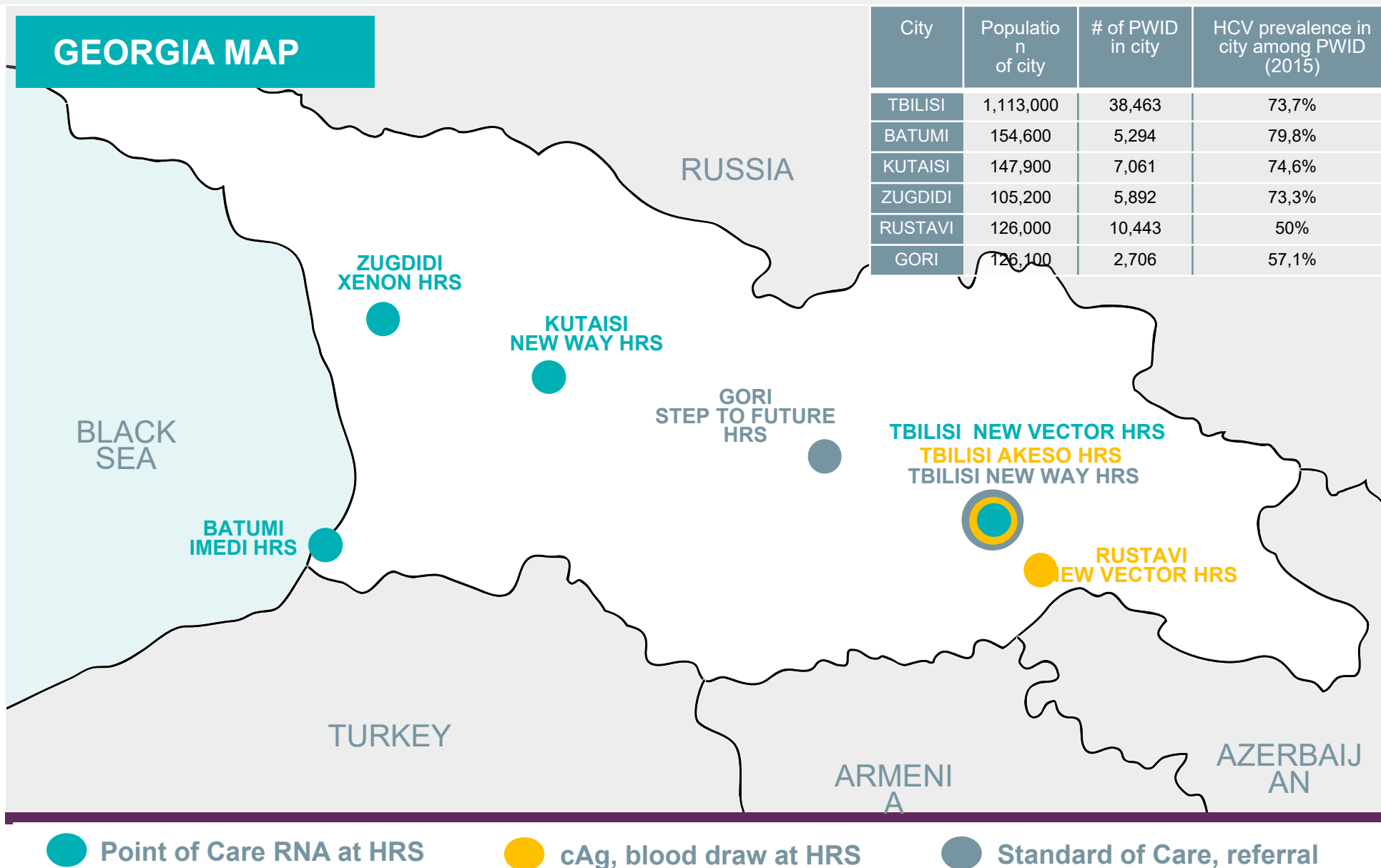


HEAD-Start Georgia study design



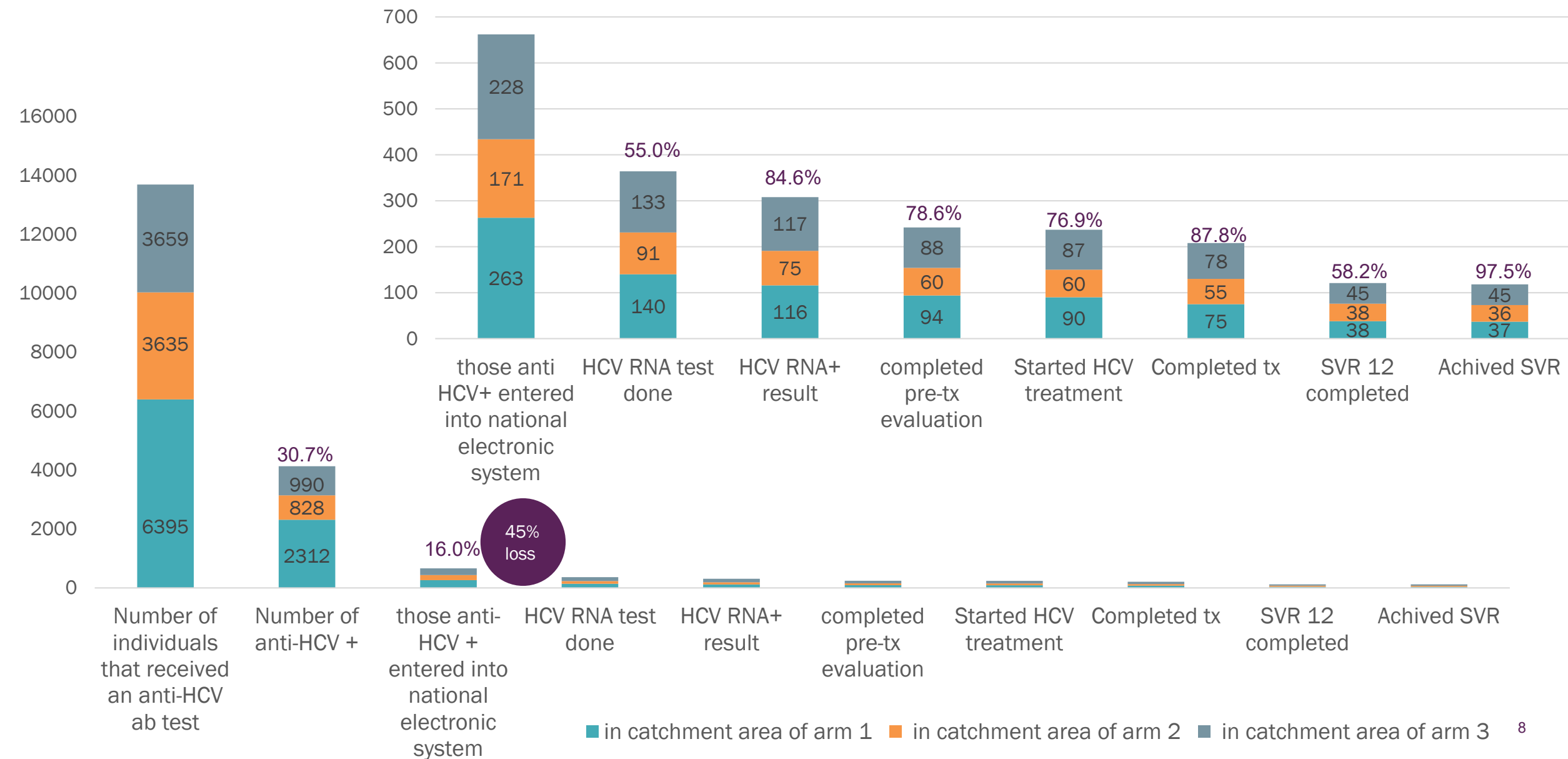


HEAD-Start study map; Georgia





Baseline data April 2017-April 2018 (before study start)





Timeline of changes in national program during study duration

Lugar cAg testing started
as standard of care in
Georgia (as an option)
since
1 Dec 2017

Change to treatment
committee process.
1 Aug 2018.

Dates HRSs started
treatment

1. Zugdidi Xenon
2 Nov 2018
2. Batumi Imedi
5 Nov 2018
3. Tbilisi New Vector
5 Nov 2018

All diagnostics and doctors
visits now free to patients
2 Sept 2019



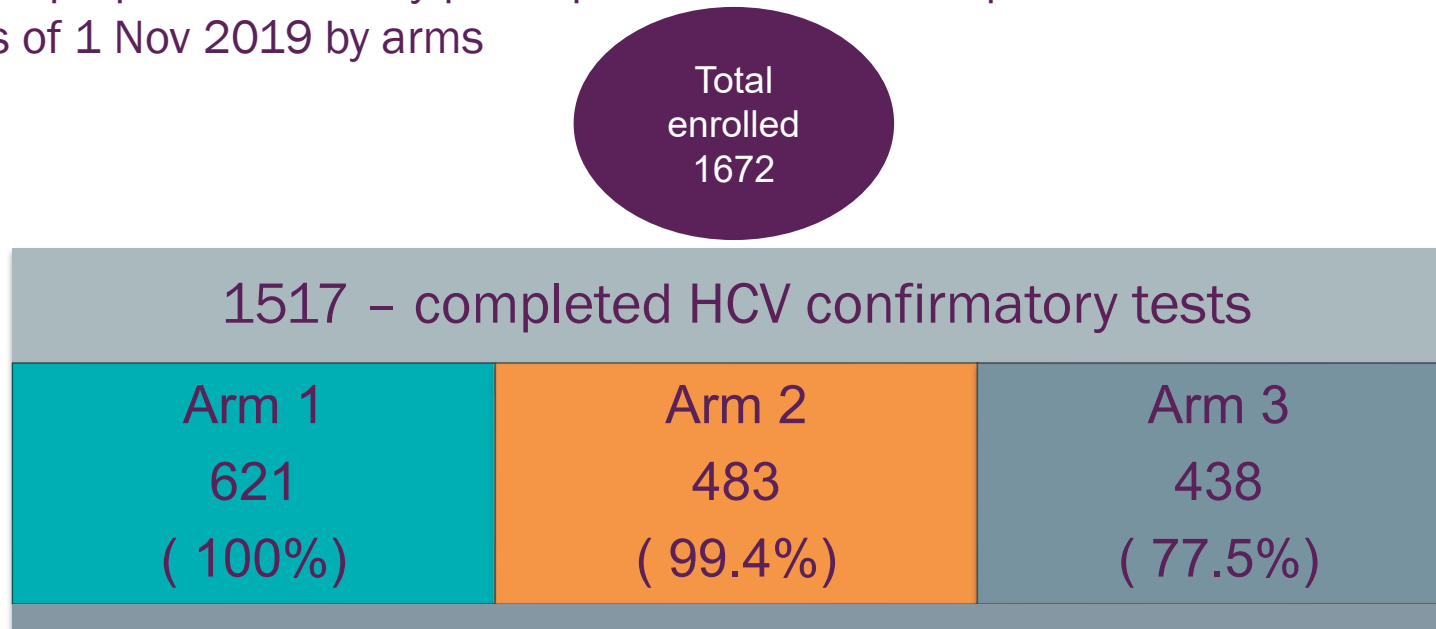
HEAD-Start inclusion criteria

- 18 years of age or older
- Eligible for Georgian National HCV program
- Current or past PWID
- Confirmatory test never done since April 2015
- Never treated for HCV in national program since April 2015
- Willing to return to HRS
- Not pregnant
- Venous access
- Living within catchment area of HRS



Proportion of participants receiving HCV confirmatory test by arms, preliminary data

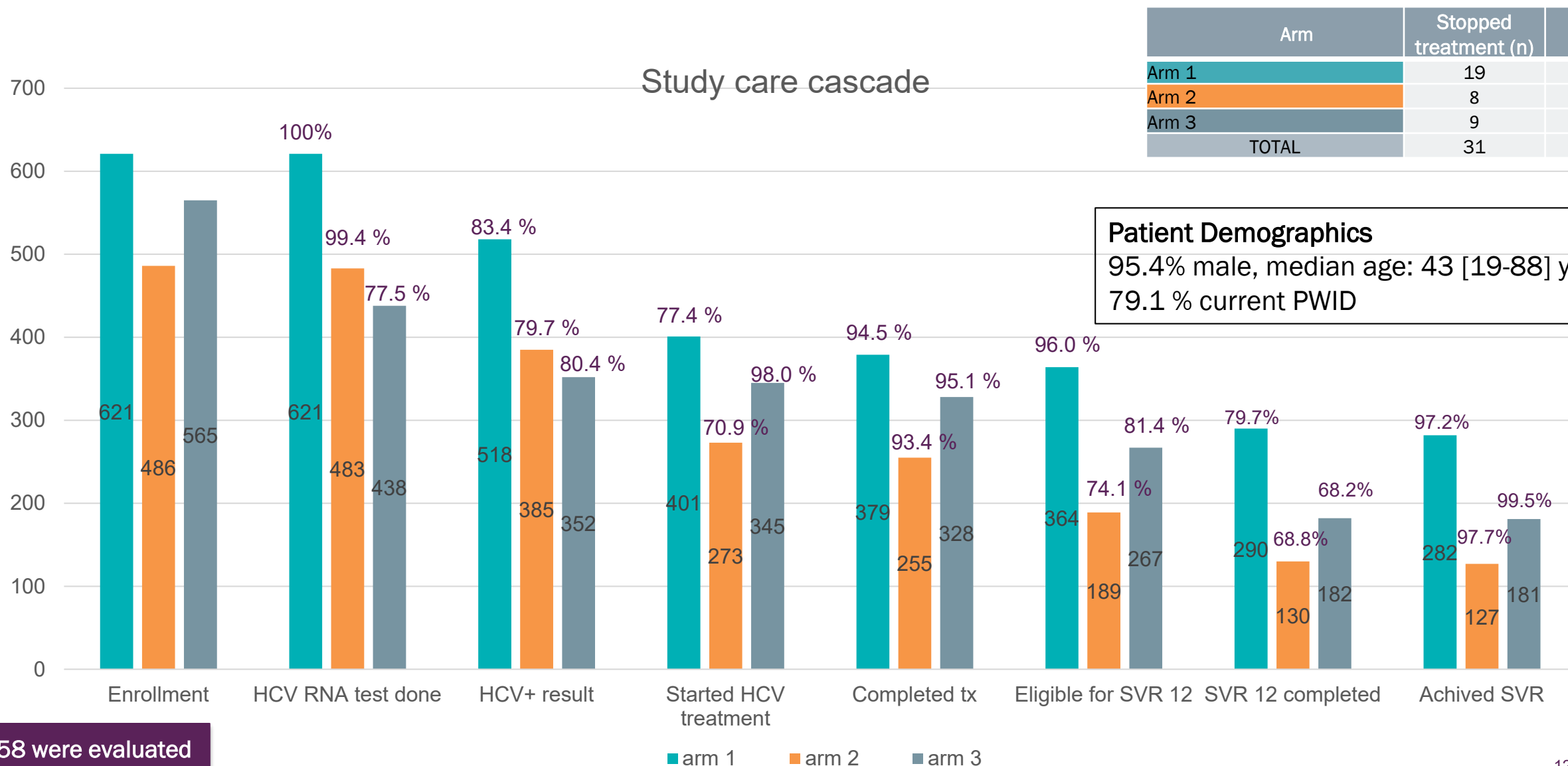
The proportion of study participants who have completed HCV viremia test as of 1 Nov 2019 by arms



1,255 (81.4%)	– Positive HCV Confirmatory results
262 (18.6%)	– Negative HCV Confirmatory results



HEAD-Start Georgia study care cascade; preliminary data: May 2018 to 1st Nov 2019 (from clinics)





Demographics, preliminary data

	Total	Arm 1	Arm 2	Arm 3
Age (range, average)	Range 19-88 Average 44 n=1671	Range 19-71 Average 44 n=620	Range 20-72 Average 43 n=486	Range 22-88 Average 45 n=566
Gender	Male 95.4%, n=1594 Female 4.6%, n= 77	Male 96.0%, n=595 Female 4.0%, n= 25	Male 92,4%. n=449 Female 7.6% n=37	Male 97.3% n=550 Female 2.7% n= 15



Demographics, preliminary data

	Total	Arm 1	Arm 2	Arm 3
Currently injecting drugs	Yes 79.1%, n=1289 No 24.9%, n=382	Yes 75.6%, n=469 No 22.4%, n=141	Yes, 95.1%, n=462 No 4.9%, n=24	Yes 71.6%, n=348 No 44.4%, n=217
Age started injecting drugs?	Range 13-48 yr Average 21 yr	Range 13-48 yr Average 21 yr	Range 15-42 yr Average 21 yr	Range 13-35 yr Average 21 yr



Demographics, preliminary data

	Total	Arm 1	Arm 2	Arm 3
Highest grade completed	Primary 0.6% n=10 Secondary 59.2% n=989 Post secondary college 40.2%, n=672	Primary 0.2% n=1 Secondary 54.2% n=336 Post secondary college 45.6%, n=283	Primary 0.8%, n=4 Secondary 61.5%, n=299 Post secondary college 37.7%, n=183	Primary 0.9%, n=5 Secondary 62.7%, n=354 Post secondary college 36.5%, n=206
Current employment status	Employed: 20.0%, n=335 Self-employed: 14.7%, n=245 Un-employed: 64%, n=1061 Temp-employed: .7%, n=11 Retired: 1%, n=17 Student: 3%, n=2	Employed: 19.8%, n=123 Self-employed: 11.6%, n=72 Un-employed: 67.6%, n=419 Temp-employed: 6%, n=4 Retired: 0.3% , n=2 Student:0	Employed: 21.8%, n=106 Self-employed: 18.1%, n=88 Un-employed: 58.1%, n=282 Temp-employed: 0.8%, n=4 Retired: 1%, n=5 Student: 0.2%, n=1	Employed: 19%, n=106 Self-employed: 14%, n=85 Un-employed: 64%, n=360 Temp-employed: 1%, n=3 Retired: 2%, n=10 Student: 0.2%, n=1



Co-infections preliminary data

	Total	Arm 1	Arm 2	Arm 3
HBsAg (rapid test)	Negative 97.7% n=1563 Positive: 2.3% n=37	Negative 97.8% n=542 Positive 2.2% n=12	Negative 97.6% n=479 Positive 2.4% n=12	Negative 97.8% n= 542 Positive 2.2% n= 3
HIV (rapid test)	Negative 99.2% n=1675 Positive: 0.8% n=13	Negative 99.7% n=603 Positive 0.3% n=5	Negative 98.8% n=484 Positive 1.2% n=6	Negative 99.7%)n= 588 Positive 0.3% n= 2



Preliminary Data _ Behavior factors

	Total
Attending harm reduction programme?	44.0% yes n=743, arm 1 67.0% n=436; arm 2 15.5% n=76; arm 3 60.6% n=231 56.0% no n=944, arm 1 33.0% n=190; arm 2 84.5% n=414; arm 3 39.4% n=355
If yes, what programme (NSP, OST, Peer ed, Case management)	672 engaged in single HRS services, the most popular being NSP (n=457) followed by OST (n=175) Of the 66 that engage in multiple services NSP and OST was the most common (n=52)
Method of use	Of the 1648 who reported using opioids, 1632 reported the main method of use injecting. Of the 512 who reported using amphetamine 503 reported the main method of use injecting



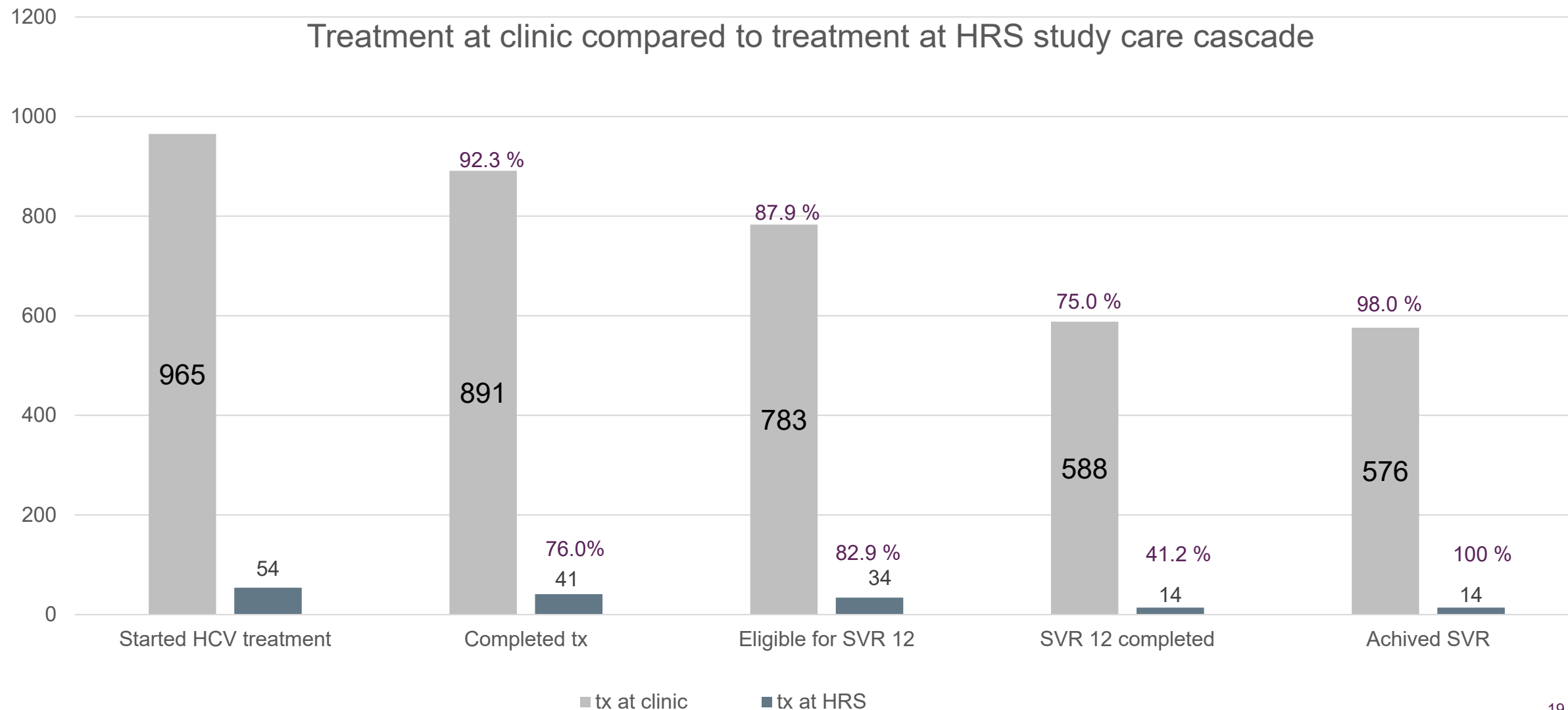
Preliminary Data _ Risk factors

	Total
- Of all the times you have injected in the past 6 months, how often were you injecting with other people?	15% report never, 20% less than half, 10% more than half, 21% always, 34% cannot recall
- Of all of the times you injected with other people in the last 6 months, how often did you inject with syringes that had been used before by someone else, even if the syringe was cleaned first?	74% reported never sharing needles, 25% reported sharing needles at least sometimes 1% declined to answer



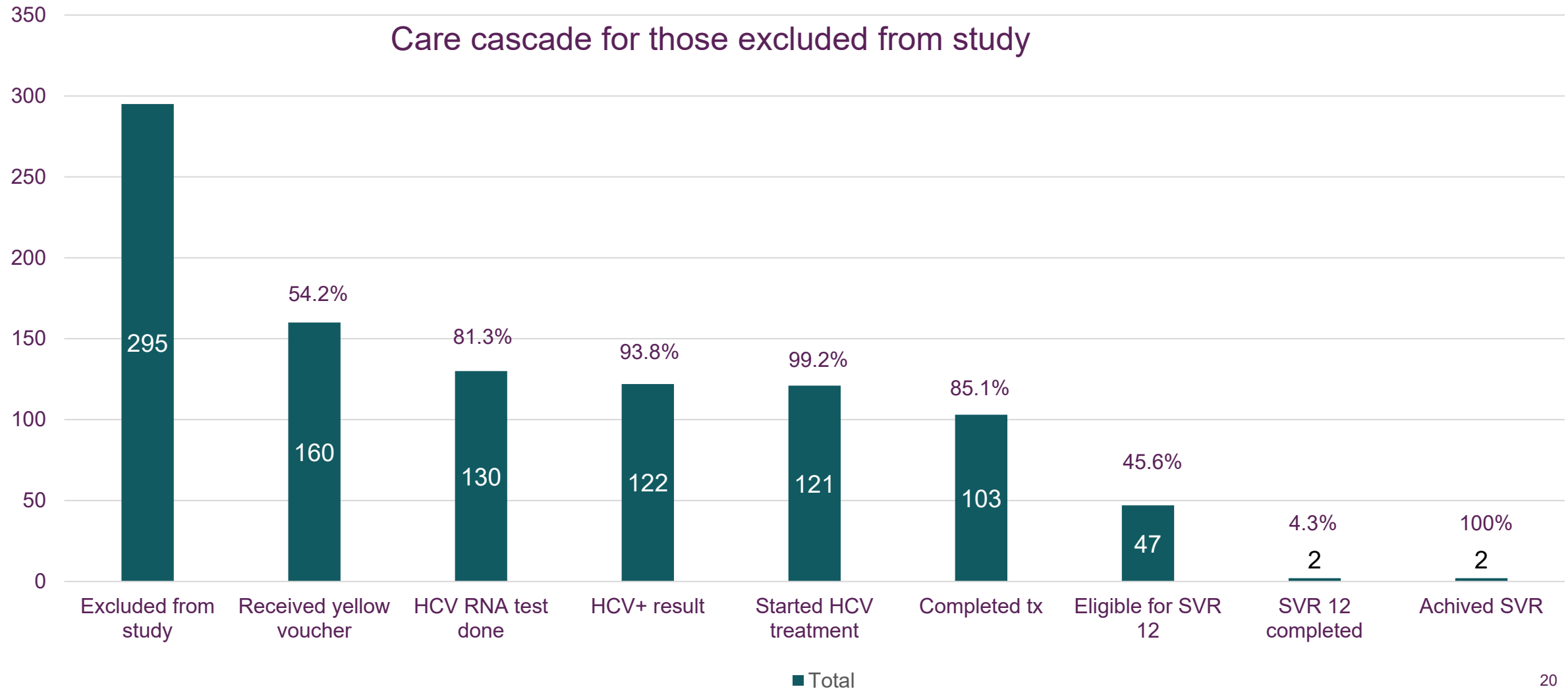
HEAD-Start Georgia study care cascade; preliminary data: May 2018 to 1st Nov 2019

Treatment at clinic compared to treatment at HRS study care cascade





Patients excluded from study care-cascade preliminary data: May 2018 to 1st Nov 2019





LTFU for study and program perspectives as of 1 Nov 2019

➤ LTFU for study

	Steps	Arm 1	Arm 2	Arm 3
130	Between enrollment and confirmatory test	0	3	127
81	For second interview (after 2 – 4 weeks from enrollment day)	4	3	74
225	For third interview (after 6 months from enrollment day)	7*	77*	141*
	TOTAL	11	83	215

Grand total – 309*

➤ LTFU project / program perspectives

	Steps	Arm 1	Arm 2	Arm 3
130	Between enrollment until confirmatory test	0 (0 %)	3 (1%)	127 (22%)
238	Between conf test and treatment initiation	117 (23%)	112 (29%)	7 (2%)
26	During the treatment	19 (5%)	8 (2.9%)	9 (2.6%)
65	For SVR 12/24 completion	59 (16%)	30 (16%)	25 (9%)
	TOTAL	180	139	149

Grand Total - 469



Early treatment cessation _ 1 Nov 2019

Arm	Started treatment (n)	Stopped treatment (n)	%
Arm 1	401	19	4.7
Arm 2	273	8	2.9
Arm 3	345	9	2.6
TOTAL	1019	36	3.5

Cities	Arm	Started treatment (n)	Stopped treatment (n)	%
Tbilisi HRS	1, 2, 3	336	12	3.6
Zugdidi HRS	1	88	10	11.4
Kutaisi HRS	1, 2	224	0	0.0
Batumi HRS	1	85	3	3.5
Rustavi HRS	2	147	6	4.1
Gori HRS	3	139	5	3.6
Total		1019	36	3.5



Turn around time by arms, preliminary data _ 1 Nov 2019

Time between (mean) Arm		HCV screening and sample collection for confirmation test	Sample collection and completion of sample testing	Completion of sample testing and result entered into National Database	Result entered into database and result delivered back to patient	Total Time
Arm 1	n=621	Same day (same day- next day)	1 hr 51 min (1 hr 27 min – 4 hr 15 min)	19 hr 12 min (same day- 21 days)	25 minutes* (same day- 4 days)	2 hr 45 min (same day- 4 days)
Arm 2	n=483	Same day (same day-21 days)	6.3 days ** (1 day- 32 days)	4.0 days (same day- 43 days)	10.0 days (same day- 118 days)	20.7 days (5 days- 164 days)
Arm 3	n=432	5.1 days (same day- 170 days)	5.4 days (same day-38 days)	2.4 days (same day – 84 days)	4.0 days (same day – 97 days)	19.6 days (1 day to 131 days)

* time between completion of sample testing and result delivered back to patient

** It is included the time that are spent for repeated test of PCR in case of cAg test result is negative or it is in grey zone.

Preliminary conclusions*

- On location based approaches to blood sample collection resulted in a larger proportion of participants receiving their confirmatory test results;
- The turnaround time was shortest where POC service was performed.

* Please note the feasibility/acceptability/costing data is not yet compiled and will be forthcoming



Special thanks to our partners in this endeavor!



We are grateful for the input and feedback of many of the organizations also doing great work in the area of HCV elimination in Georgia



Thank you !



■ Natalie can you please put a good Georgia picture here?



Enrollment per site

Arm	Site	# of enrollees	Total sample size	% completion
1	Tbilisi New Vector	155	155	100%
	Zugdidi Xenon	156	155	101%
	Kutaisi New Way	155	155	100%
	Batumi Imedi	155	155	100%
2	Tbilisi Akeso	223	310	72%
	Rustavi New Vector	264	310	85%
3	Gori step to future	251	310	81%
	Tbilisi New Way	313	310	101%