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Achieving an extremely high hepatitis C treatment success rate in people who inject drugs in Hai Phong, Vietnam: Results of the ANRS 12380 DRIVE-C study

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Introduction

In order to achieve the WHO targets for elimination of hepatitis C (HCV), there is an urgent need to significantly increase screening and treatment. Oral interferon-free regimens with direct-acting antivirals (DAAs) allow for more effective, well-tolerated and shorter treatment. But despite this therapeutic revolution, only 20% of people living with HCV currently know their diagnosis, and of those whose HCV is known, only 15% have been treated. It should be noted that of the 58 million people affected by HCV worldwide, people who inject drugs (PWID) are highly affected, with over 50% exposure to HCV and limited access to HCV care. Demonstrating that simplified models can be effective, particularly with this hard-to-reach population, may be useful in expanding access to HCV to reduce the HCV burden.

The objective of the ANRS 12380 DRIVE-C study, conducted in Hai Phong, Vietnam, was to **evaluate the effectiveness and the impact of a community-based HCV mass screening strategy combined with simplified integrated hospital care**, which may have the potential to eliminate HCV among PWID. In the DRIVE-C study, PWID peers were involved in all stages of the strategy, including HCV screening, support for treatment adherence, social support, and harm reduction activities to prevent reinfection. Here, we evaluated the HCV treatment outcomes.

Materials and methods

From October 2018 to August 2019, PWID living in Hai Phong were screened for HCV serology, and HCV RNA when positive, during both a respondent-driven sampling (RDS) survey and cohort follow-up visits of the Drug use & Infections in Vietnam (DRIVE) study, a community-based research program.

PWID with detectable HCV RNA (≥ 10 IU/mL) were referred by members of community-based organisations (CBO) to one of the study clinics located in three public hospitals in Hai Phong.

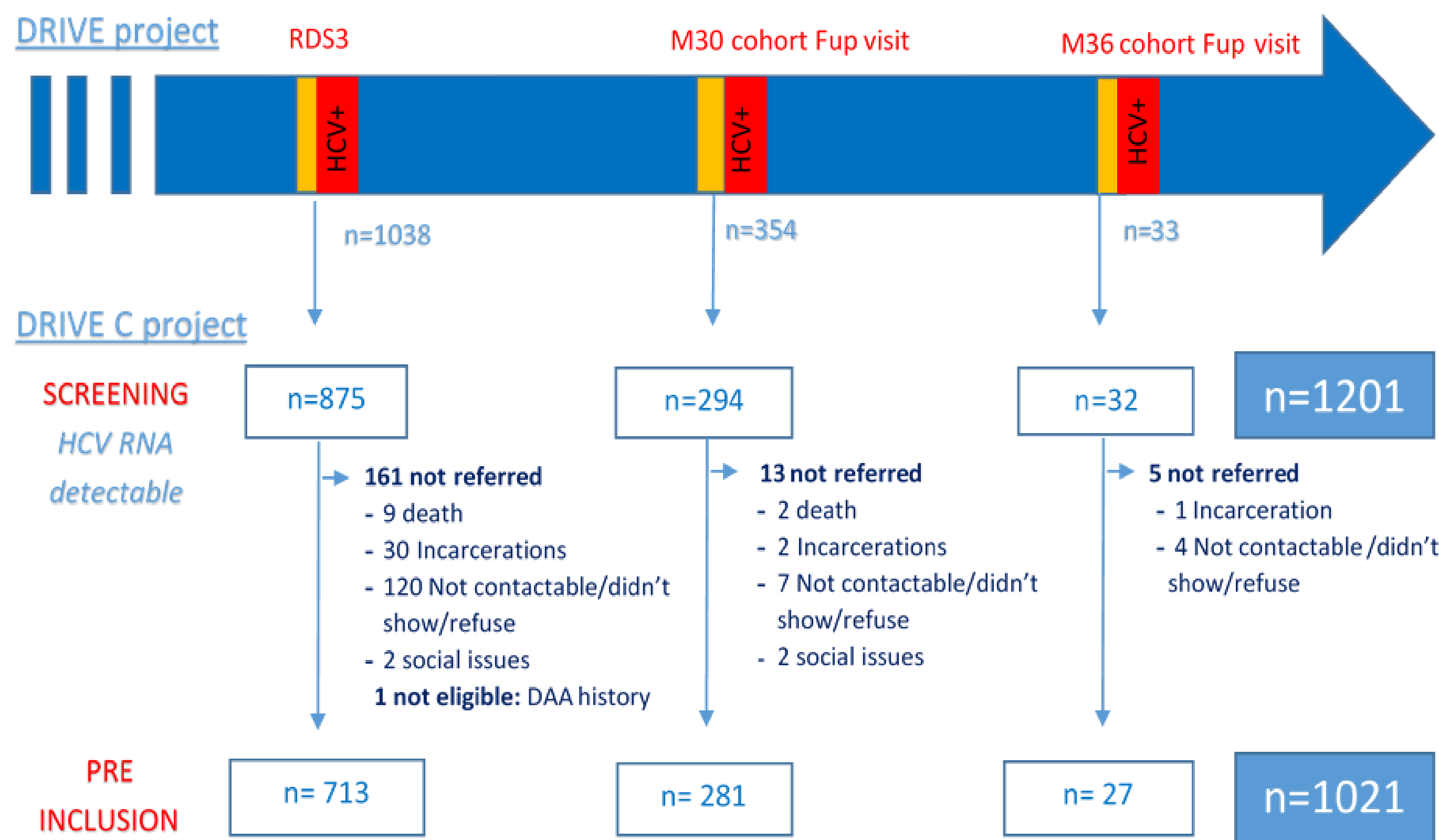
The free of charge pan-genotypic treatment consisted of a **12 weeks sofosbuvir-daclatasvir regimen**, with ribavirin if cirrhosis (Fibroscan[®]>12.5kPa).

CBO members intervened for RDS survey and cohort visits implementation, linkage and retention to care, drug delivery modalities in clinics, drug adherence counselling and harm reduction activities at community sites.

The sustained virological response (SVR) was assessed 12 weeks after the end of treatment.

Results

Recruitment of participants



Baseline characteristics of 1021 enrolled PWID

Category	Characteristic	n (%)
Socio-demographic	Age of the participant	41.89 [37 ; 48]
	Male	976 (96)*
	Current marital status	
	Single, Widowed, divorced/ separated	572 (56)*
Co-infection	Legally married or living in couple	447 (44)
	Valid health insurance	606 (59)*
	HIV positive	461 (45)
	Current ART	438 (95)
	HIV viral load (copies/mL)	
	<20	369 (80)
	[20-1000[50 (11)
	>=1000	42 (9)
	CD4 (cells/ μ L)	
	<200	39 (9) [§]
200-500	186 (41)	
>=500	227 (50)	
Drug use	HbsAg positif	51 (5)*
	Current drug use	635 (62)
	Drug used	
	Heroin use	585 (92)
Liver Assessment	Metamphetamine use	160 (25)
	Ongoing methadone treatment	730 (71)
	Classes of APRI score	
	<1	760 (75)
	1-2	179 (17)
	>=2	78 (8)
	Fibrosis stage (n=624)	
	F0-F1 (LSM \leq 7)	311 (50)
F2 (7.1 \leq LSM \leq 9.5)	146 (23)	
F3 (9.6 \leq LSM \leq 12.5)	84 (14)	
F4 (LSM>12.5)	83 (13)	
Biology	Classes of genotype (n=889)	
	1a	296 (33)
	1b	204 (23)
	2	12 (1)
	3	40 (5)
	6	337 (38)

* 1 missing value * 2 missing value # 4 missing value §9 missing value; Median[IQR], n(%)

HCV treatment initiation

Overall, 979/1021 (95.9%) participants initiated the treatment.

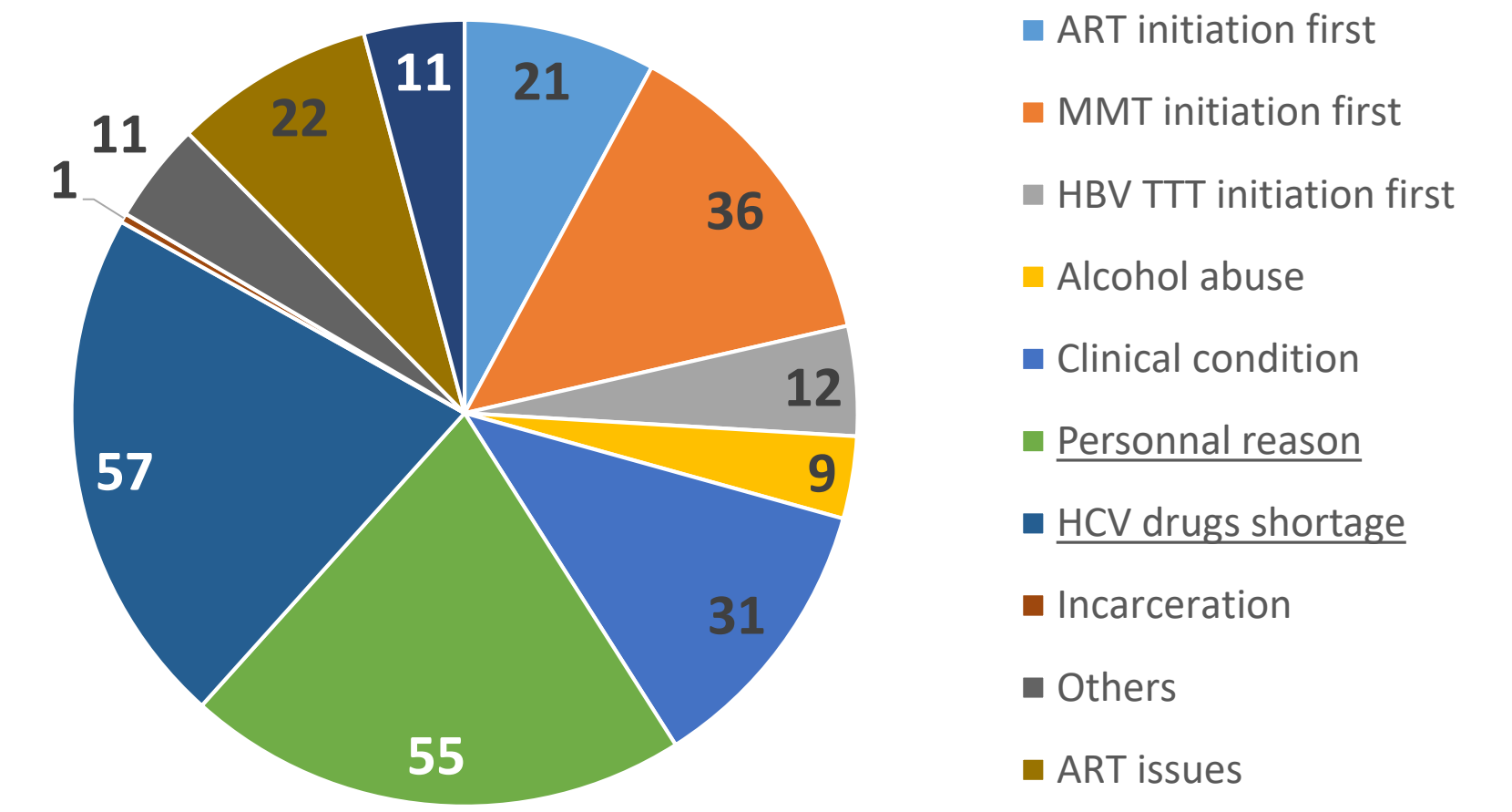
Of the 42 participants who did not initiate, **9 died**, 10 withdrew consent, 5 Lost to follow-up, 6 were incarcerated, **8 had tuberculosis** and 4 were non eligible (1 deprived of freedom, 1 had a severe associated disease, 2 had renal failure).

Time of treatment initiation

713/979 (73%) participants initiated the HCV treatment within 15 days after the pre-inclusion visit.

For the other 266 participants (27% of the total), the mean time of treatment initiation was 53 days [16-308] after pre-inclusion.

Reasons for postponing HCV treatment initiation



Treatment distribution (n=979)

SOF/DCV 60 521 (53%)
SOF/DCV 90 380 (39%)
SOF/DCV 60/RBV 54 (5.5%)
SOF/DCV 90/RBV 24 (2.5%)

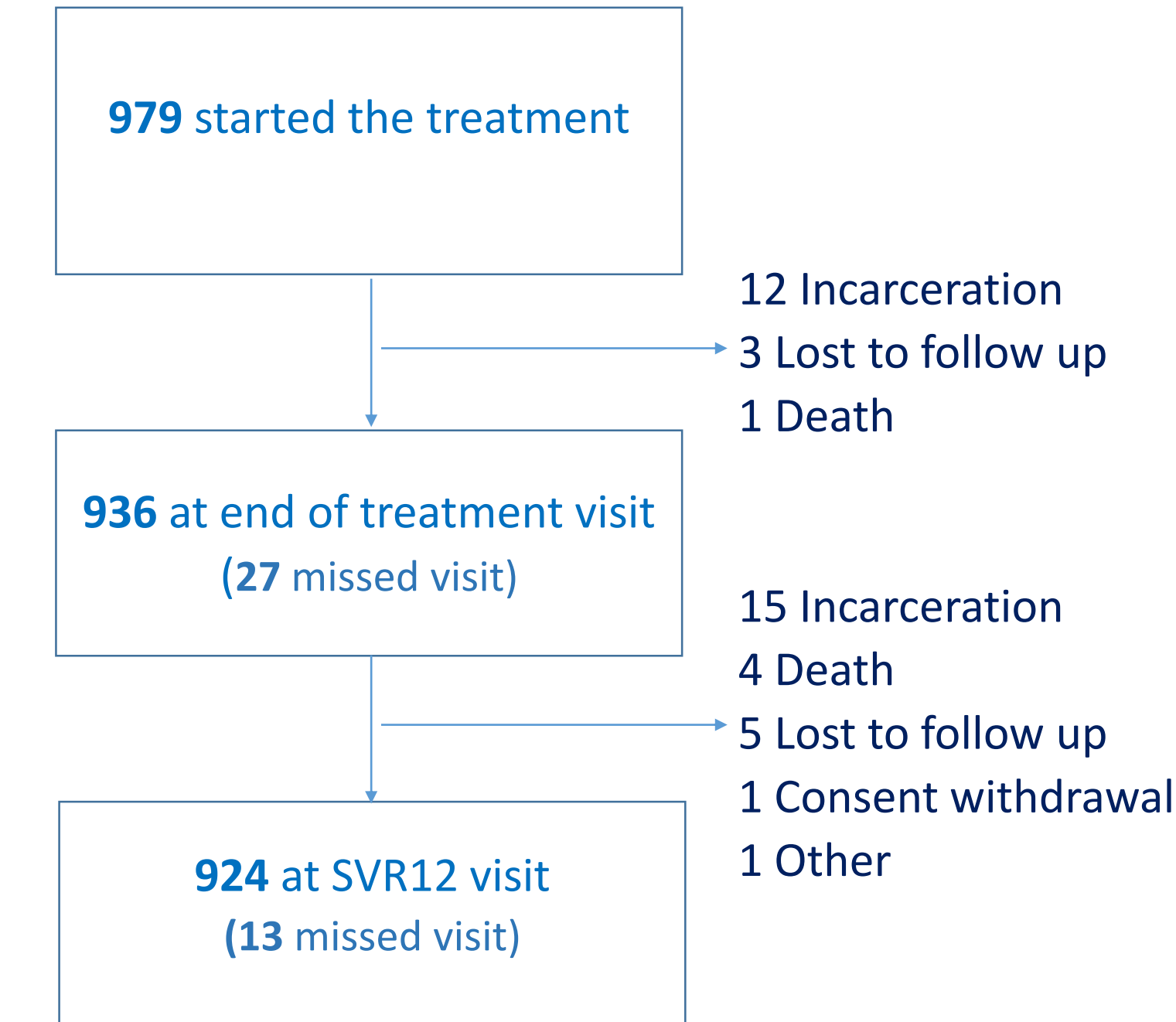
No adverse event with sofosbuvir and daclatasvir

Only 1 adverse event leading to stop ribavirin and switch to 24 weeks SOF/DCV

264 participants were not on methadone treatment during the HCV treatment

Treatment completion 966/979 (98%)

Follow up of participants (n=979)



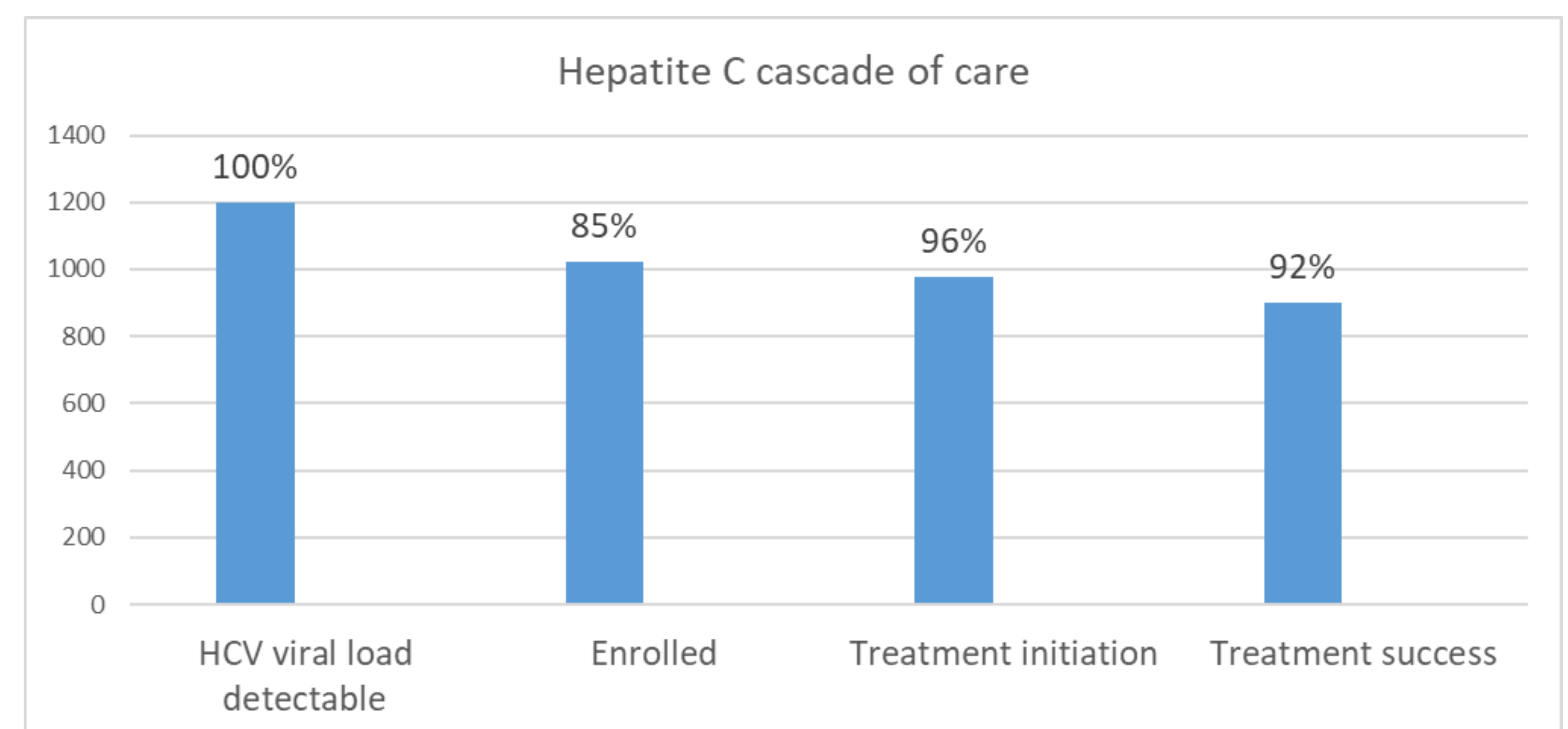
SVR12 was achieved in 901/979 (92.0%) participants.

- Among failures, 55/979 (5.6%) participants did not attend the SVR12 visit, including 5 deaths, 8 lost to follow-up, 1 withdrawal, and 27 incarcerations.

- Of the 23/979 (2.3%) participants with detectable HCV RNA, 10 had a different genotype from the baseline one, strongly suggesting early reinfection.

ITT success rate: 92%

HCV cascade of care



Conclusion

Extremely high HCV treatment success rate can be achieved among the hard-to-reach population of PWID when optimized and tailored CBO support is implemented. Beside free access to treatment, CBO involvement is pivotal to reach elimination of HCV among PWID.