Community-based testing and treatment of HIV and viral hepatitis for key populations in Thailand: the C-FREE-2 study

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BACKGROUND

- Despite proven high efficacy of direct-acting antivirals (DAA), key populations disproportionately affected by HCV face multiple barriers to accessing treatment services.
- Real-world evidence on community-based HCV treatment in LMIC settings remains scarce.
- C-FREE-1 (2019–2023), demonstrated 95.1% per-protocol SVR with SOF/VEL among PWUD and partners, *Wansom et al., Bull World Health Organ 2026;104:71–81*.
- C-FREE-2 extends this model with sofosbuvir/ravidasvir (SOF/RDV), added to the WHO Essential Medicines List in 2023, for which real-world programmatic data are very limited.

OBJECTIVES

Primary

Assess effectiveness and safety of SOF/RDV in a decentralised community model of care:

- 12-week course for non-cirrhotic participants (APRI < 1.5)
- 24-week course for compensated cirrhosis (APRI ≥ 1.5)

METHODS

Study design

- Ongoing observational and treatment cohort study since March 2023. Current analysis contains cohort data up to August 2025.
- 11 community drop-in centres (DiC) across 9 provinces

Participants

- PWUD/PWID, MSM, transgender persons, and partners
- Recruited and treatment supported by peer-led CBOs

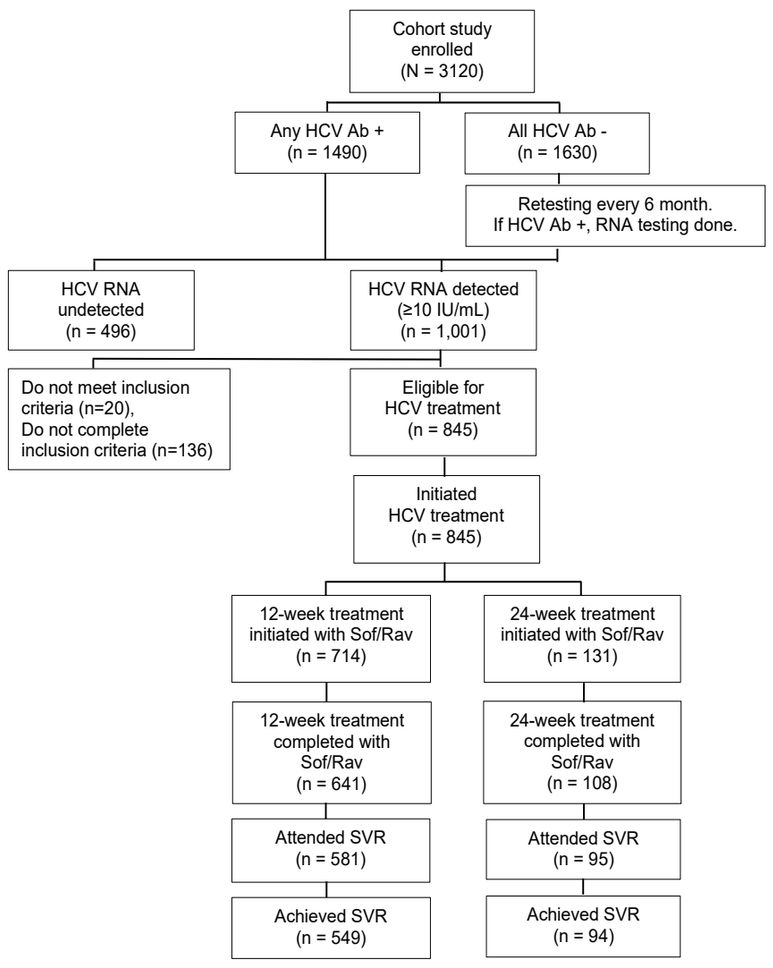
Integrated on-site services

- Rapid serology tests (HCV, HBV and HIV),
- POC molecular testing for those with reactive Ab/Ag testing
- HBV vaccination
- Linkage to ART, PrEP, TB preventive therapy

Analysis

- SVR12 by GeneXpert RNA · ITT and per-protocol analyses
- Logistic regression for predictors of SVR

Flowchart of HCV screening, treatment and SVR



Catchment areas and density of Cohort participants

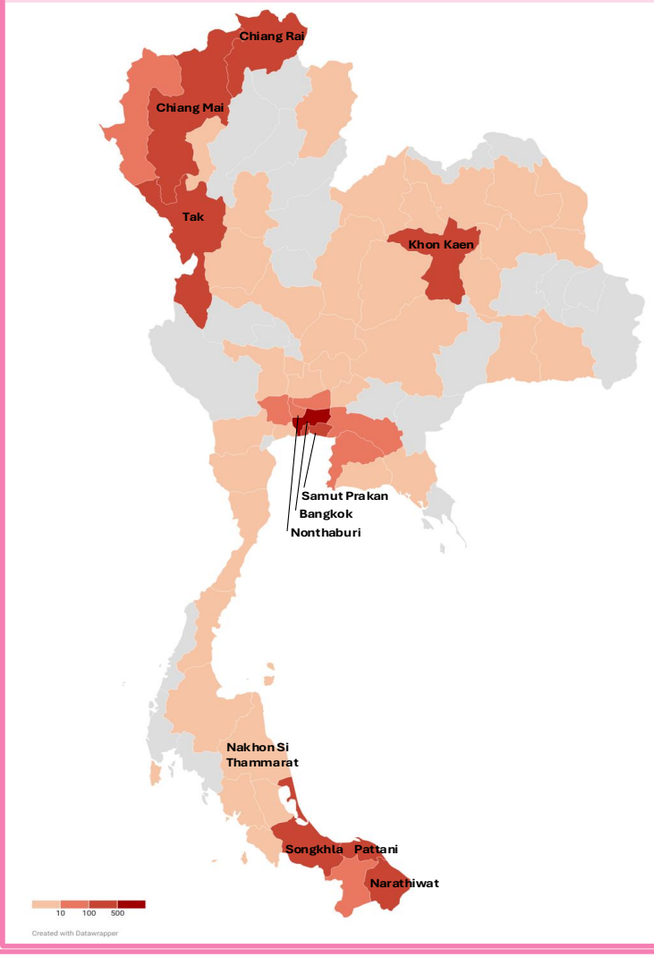


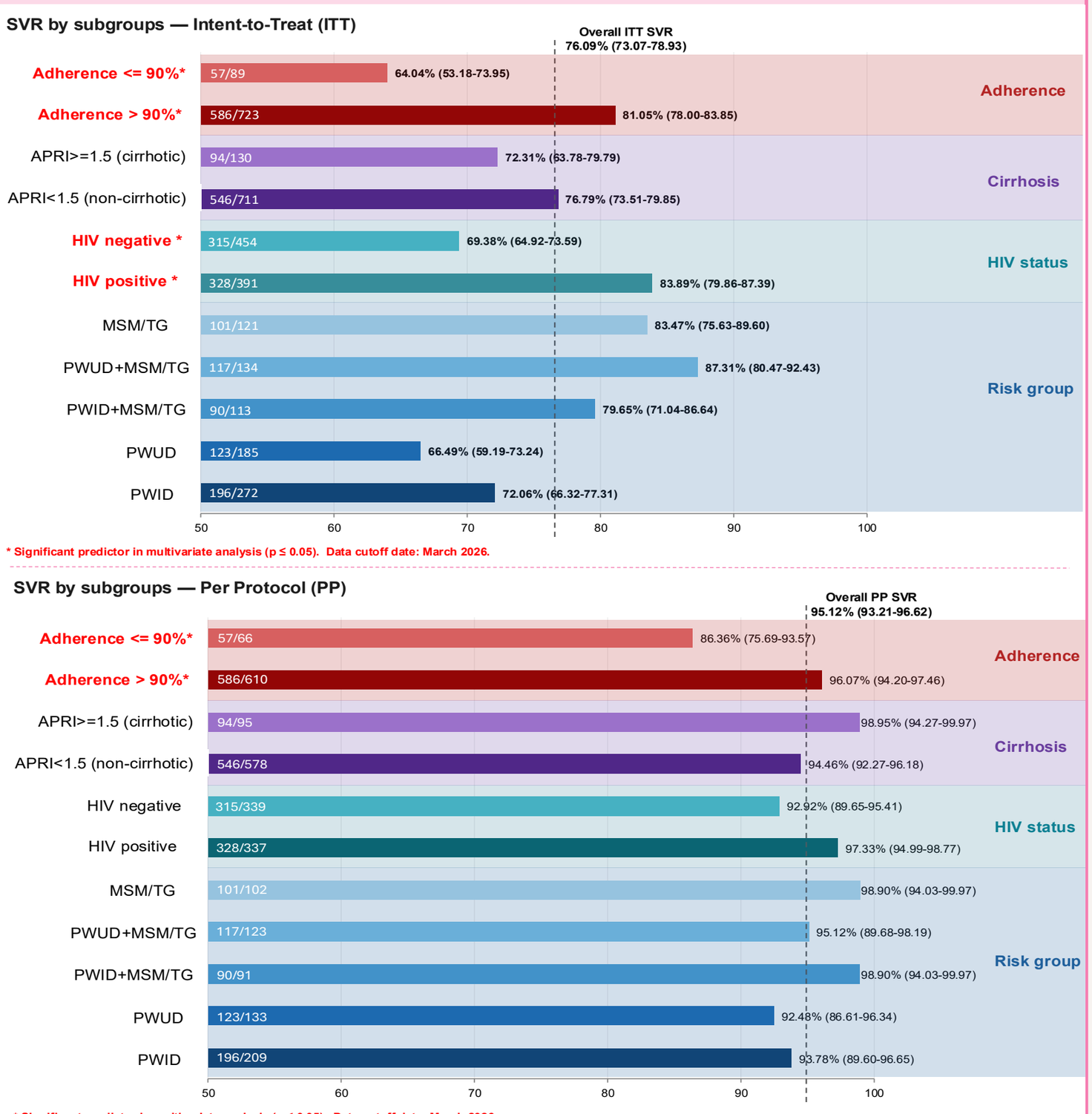
Table 1: Demographics of Cohort and HCV study participants at baseline

Characteristics	Cohort study (N = 3120)	HCV study (N = 845)
Age (Years)		
Mean (SD)	39.26 (11.51)	39.56 (11.36)
Median (Q1, Q3)	39 (30, 47)	38 (30 , 48)
Min, Max	18 , 77	18 , 74
Gender, n (%)		
Male	2624 (84.10%)	788 (93.25%)
Female	476 (15.26%)	49 (5.80%)
Transgender	20 (0.64%)	8 (0.95%)
Risk Behaviours		
PWID	897 (28.75%)	272 (32.19%)
PWUD	1436 (46.03%)	185 (21.89%)
MSM *	221 (7.08%)	117 (13.85%)
TG *	7 (0.22%)	4 (0.47%)
Partner of drug user	114 (3.65%)	20 (2.37%)
PWID and (MSM or Transgender)	203 (6.51%)	113 (13.37%)
PWUD and (MSM or Transgender)	242 (7.76%)	134 (15.86%)
Methadone		
Yes	1021 (32.72%)	300 (35.50%)
No	2099 (67.28%)	545 (64.50%)
Drug Use		
Current	2483 (79.58%)	635 (75.15%)
Former	432 (13.85%)	142 (16.80%)
Drug Injection		
Current	952 (30.51%)	331 (39.17%)
Former	741 (23.75%)	246 (29.11%)

Table 2: Co-infections among study participants

Reactive /Positive Result	Cohort study (N = 3120) n (%) (95% CI)	HCV study (N = 845) n (%) (95% CI)
HIV Ab	718 (23.01) (21.55-24.53)	391 (46.27) (42.87-49.70)
HBs Ag	154 (4.94) (4.20-5.76)	30 (3.55) (2.41-5.03)
HCV Ab	1482 (47.50) (45.73-49.27)	838 (99.17) (98.30-99.67)
Coinfections		
HIV/HBV	8 (0.26) (0.11-0.50)	-
HIV/HCV	580 (18.59) (17.24-20.00)	371 (43.91) (40.53-47.33)
HBV/HCV	47 (1.51) (1.11-2.00)	14 (1.66) (0.91-2.76)
HIV/HBV/HCV	33 (1.06) (0.73-1.48)	16 (1.89) (1.09-3.06)

Comparison of Sustained Virological Responses ITT and PP by Subgroups (from multivariate analyses)



SVR OUTCOMES (PER PROTOCOL)

95.1%	94.5%	98.9%
Per-protocol overall	PP 12-week	PP 24-week

SVR OUTCOMES (INTENT-TO-TREAT)

76.1%	76.9%	71.8%
Intent-to-treat overall	ITT 12-week	ITT 24-week

ADVERSE EVENTS AND SAES

146 (17%)	34 (4%)	9 (1%)
at least one grade 3/4 of AE/SAE	SAEs on/after medication	Deaths during study period

- Zero SOF/RDV-related SAEs confirms favourable safety in real-world conditions.
- 9 deaths during study period with none attributed to study medication.

CONCLUSIONS

- SOF/RDV was **safe and highly effective** in a **community model** with **76.1% intent-to-treat SVR** and **95.1% per-protocol SVR**, comparable to clinical trial outcomes.
- High-yield population: Of those tested on-site, **47.5% HCV Ab+**, and **5% chronic HBV**, confirming substantial unmet need in key populations.
- **Integrated community model** can deliver **effective HCV care** at scale and **accelerate national HCV elimination goals** in Southeast Asia.

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