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C-FREE
Eliminate Hep C

Moving Towards Microelimination with C-FREE: An Effective Community-based Model of Care for Hepatitis C in People who Use Drugs and their Partners in Thailand

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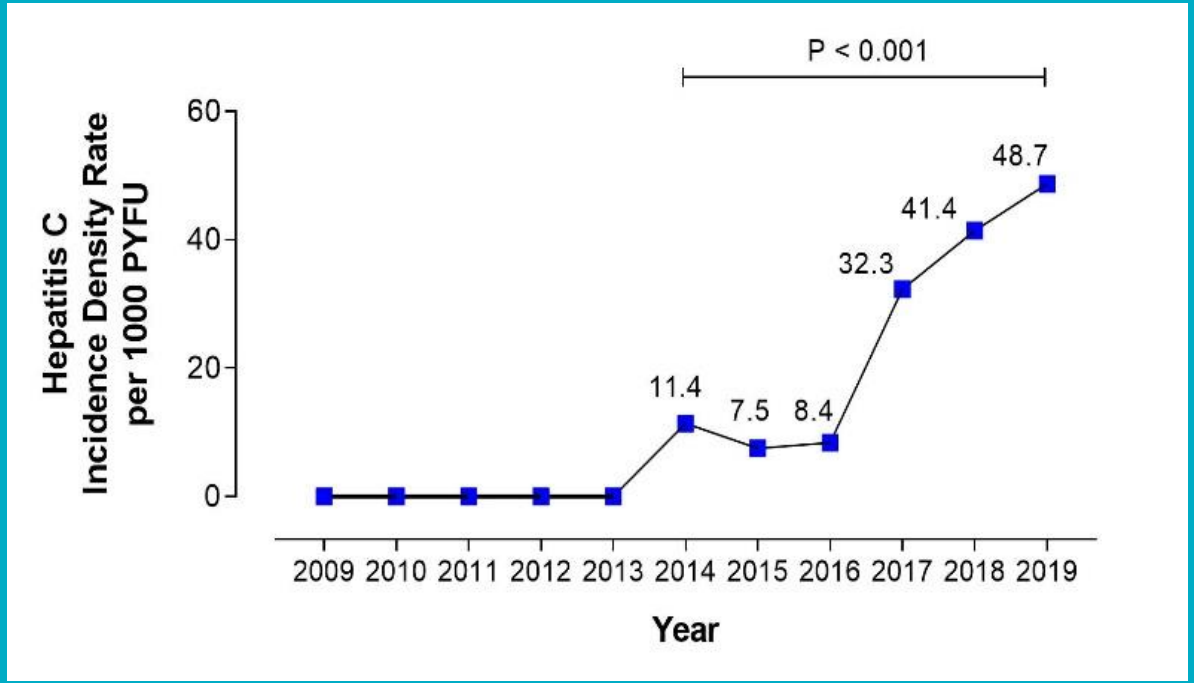
No conflict of interest to report

HCV among key populations: PWID/PWUD and MSM

- Among PWID, global HCV antibody prevalence reported at 52.3% (95% CI 42.4-62.1%). Recent WHO estimates for PWID in Thailand are near 60%.
- PWID account for 50-60% of all HIV/HCV coinfections worldwide
- MSM identified as emerging KP for HCV infection with multiple outbreaks and increasing incidence noted globally.
  - Methamphetamine use, group sex, syphilis co-infection identified as key risk factors for HCV acquisition.



- Degenhardt et al, Lancet Global Health, 2017
- Wansom et al, JAIDS, 2020

C-Free Study : Primary Objectives

Among people who use drugs and their sexual/life partners:

1. Evaluate uptake of HIV, HBV, and HCV testing
2. For people living with HIV (PLHIV), measure engagement in care and rates of viral suppression
3. Assess effectiveness of community-based HCV treatment using DAA

Emphasis on delivering integrated diagnosis and treatment within community centers offering harm reduction services

C-Free: Study Design

First study in Thailand to offer community-based integrated HCV treatment to active and former drug users and their partners

Currently conducted at six clinical sites in four Thai cities embedded in community centers run by partner organizations that provide outreach and harm reduction services.

Those who are 18 and over, provide informed consent, and have a past/current history of drug use or are sexual/life partners of former/current drug users are eligible to participate.

C-Free Study :

Testing and Diagnosis

- Prospective cohort study
- HIV, HBV, HCV every 3 mos.

HCV Treatment

- Nested open-label treatment study
- 12 weeks of sofosbuvir/velpatasvir, direct acting antiviral (DAA) that treats ALL genotypes of HCV, for eligible participants with active HCV.

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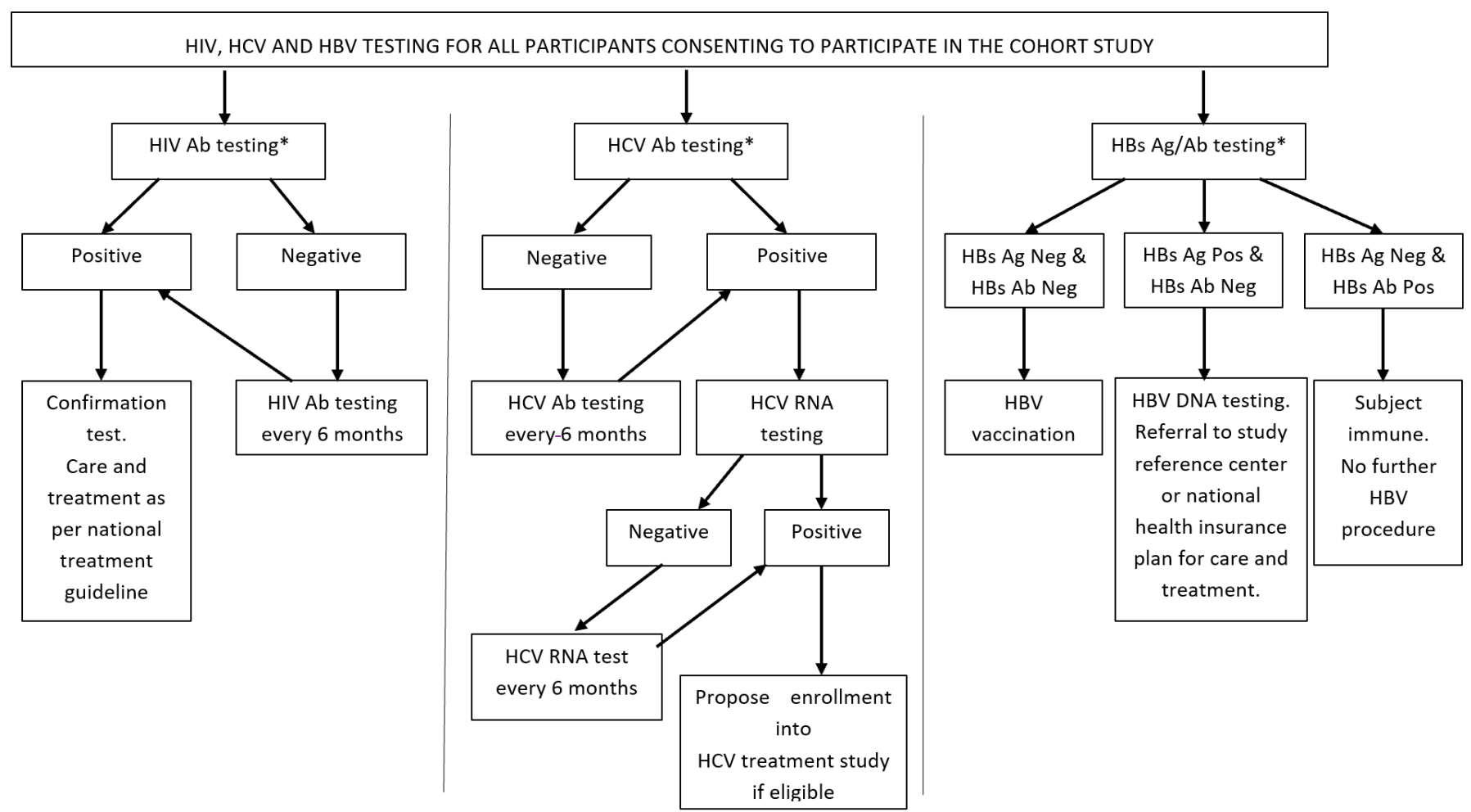
C-Free Cohort: Methods



* Participants with prior evidence of results for these tests may not need to repeat them. For details, refer to narrative of section 6.

Eligibility criteria for HCV treatment

- Inclusion criteria: HCV RNA positive
- Key exclusion criteria
  - Prior history of treatment failure with sofosbuvir-containing regimen
  - Decompensated liver cirrhosis (Child Pugh B and above)
  - Hepatocellular carcinoma
  - eGFR<30 ml/min
  - Pregnancy
- Cirrhosis assessed by APRI score
  - If 2.0 and above, referred for abdominal ultrasound to rule out HCC
  - Specialty labs: AFP, PT/INR, albumin
- Sof/vel cannot be taken concomitantly with:
  - Efavirenz
  - Rifampin/rifampicin
  - If patients on these meds, asked to switch or wait until therapy completed prior to HCV treatment

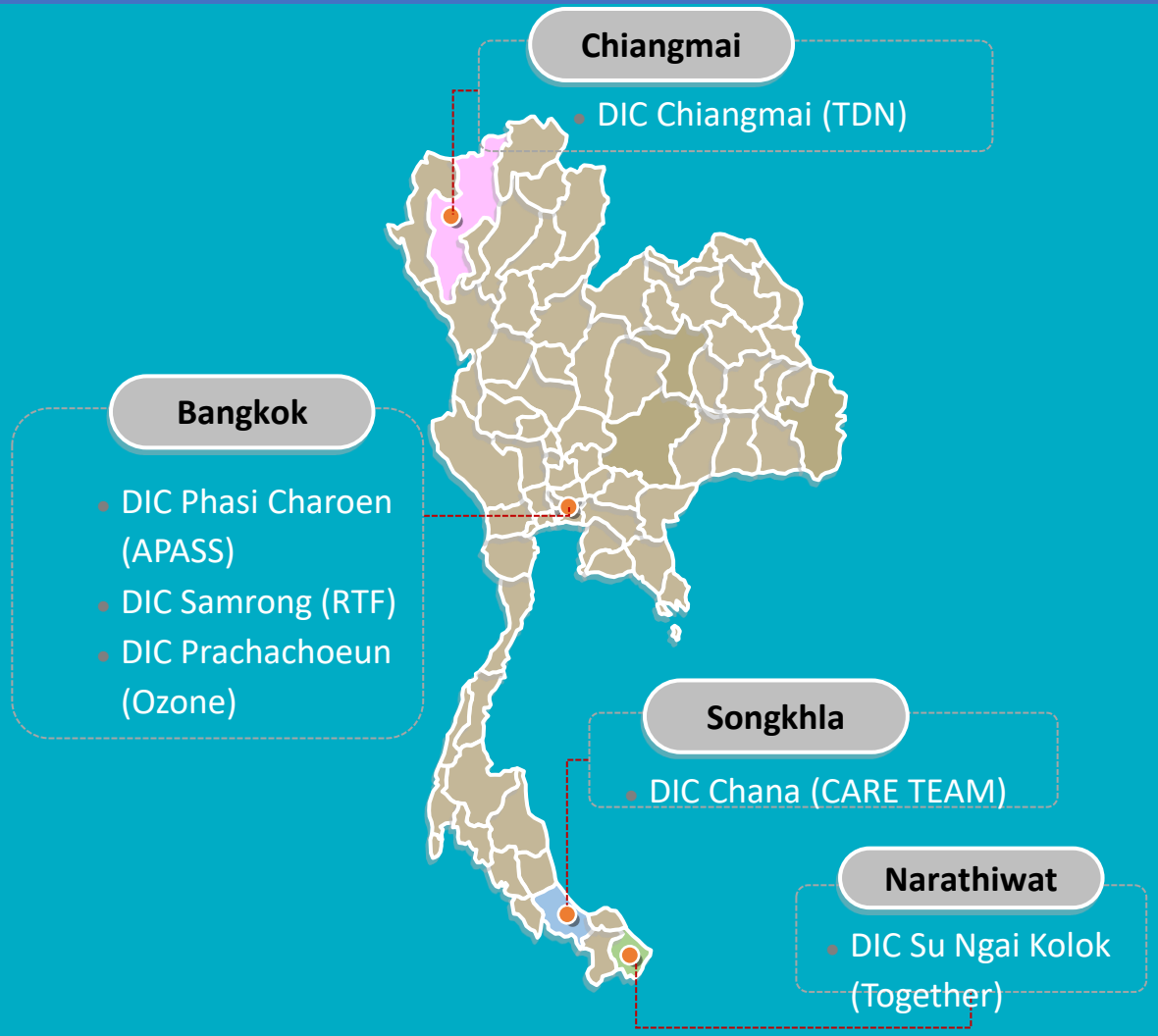
C-Free Cohort Results

Cohort Study:

1322 participants

- 36% from Southern provinces
- 56% enrolled at Bangkok sites
- Approximately 15% travel from other provinces
- 7.9% from Chiang Mai (site initiated in Nov 2020)

Close to 75% are referred by community outreach workers



Key Cohort Demographics

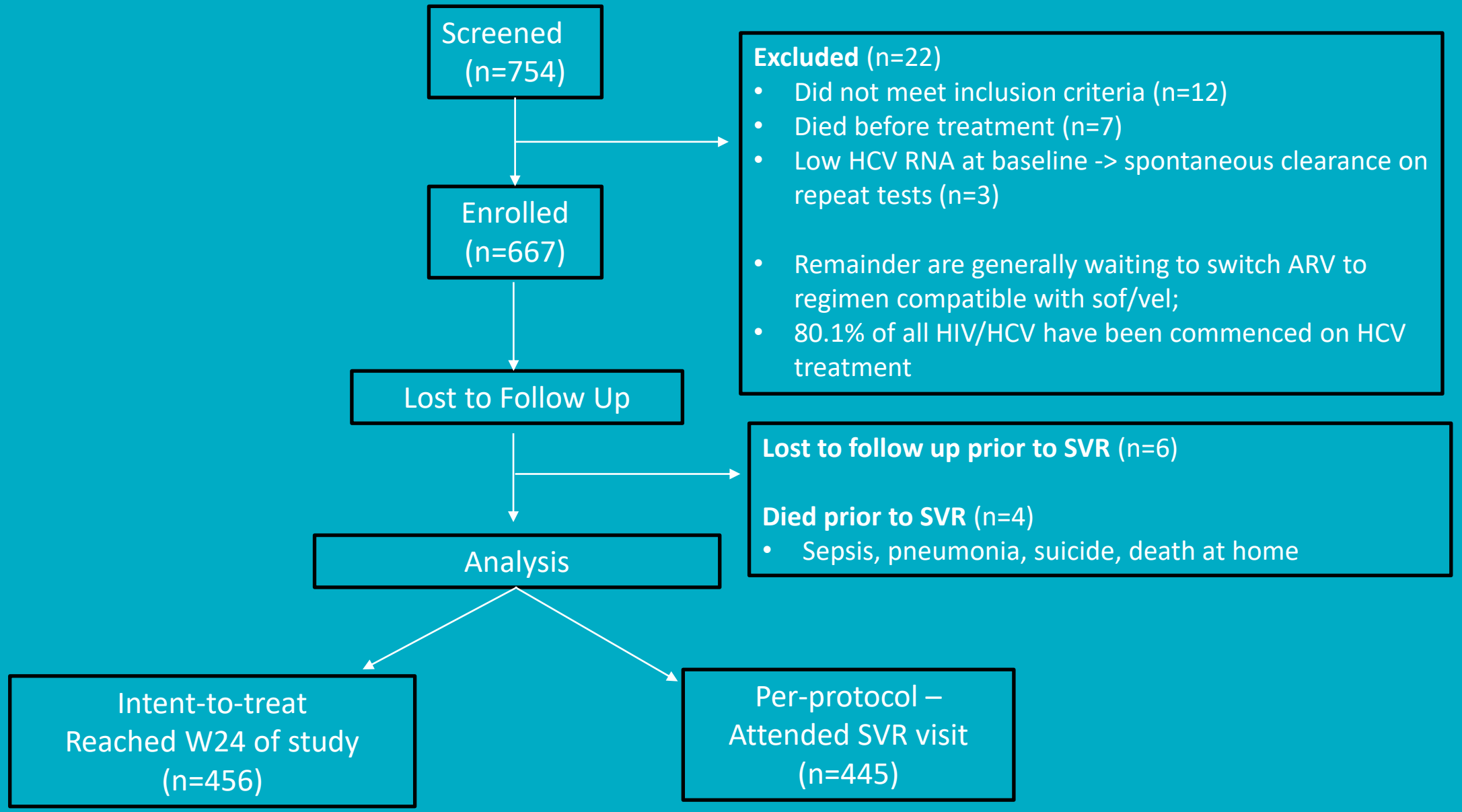
Baseline Characteristic	Cohort Study (n=1322)
Median age in years (range)	42 (18-73)
Female sex at birth, n (%)	192 (14.5%)
Transgender	14 (1.1%)
Men who have sex with men	166 (12.5%)
Highest education level completed	
Primary school	381 (28.8%)
Secondary school	329 (24.9%)
High school	194 (14.7%)
Injecting drug use	
Current	471(35.6%)
Previous	512 (38.7%)
Age at first injection (median, IQR)	20 (17, 24)
Alcohol use	
Current	475 (35.9%)
Previous	664 (50.2%)
History of incarceration	581 (44.0%)

HIV, HBV, and HCV

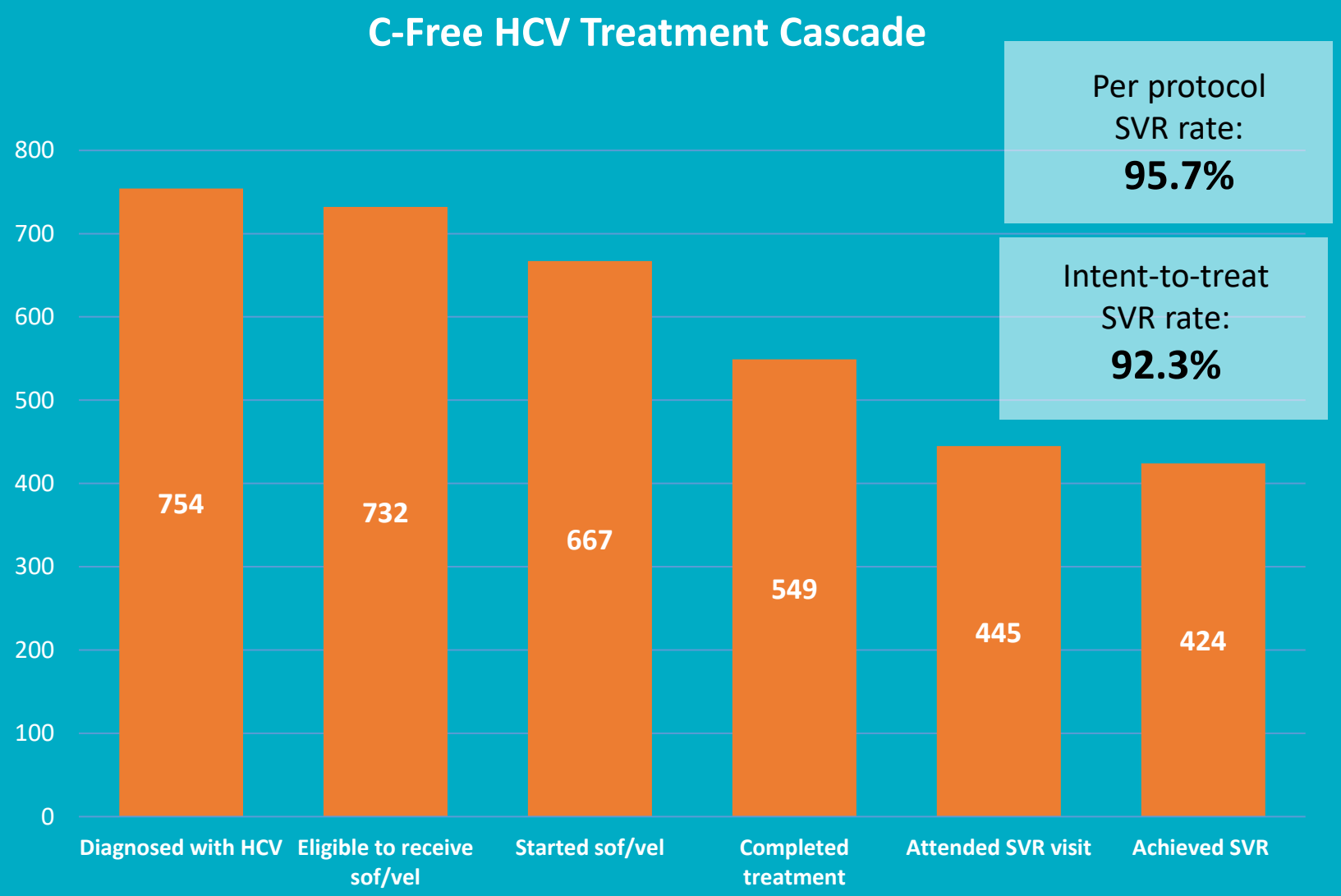
HIV	Cohort Study (n=1332)
HIV infection, n(%)	502 (38.0%)
On ART	483 (94.3%)
Undetectable HIV RNA (<40 copies/ml)	377(75.1%)
Hepatitis B	
Chronic HBV (HBsAg positive)	73(5.5%)
Hepatitis B immune (HbsAb positive)	351(26.6%)
Hepatitis C	
HCV Antibody positive	900(68.1%)
Chronic HCV (HCV RNA>LLOD) +	754(83.4%)
Cirrhosis (APRI 2.0 and above) §	69 (9.2%)
Coinfection	
HIV/HCV*	358 (71.3%)
HIV/HBV*	11(2.2%)
HIV/HBV/HCV	17
HBV/HCV	15

+ Percentage of HCV Ab positive
§ Percentage of chronic HCV
*Percentage of HIV infected

CONSORT diagram: HCV Study



Excellent HCV Cure (SVR) Rate



Per protocol SVR rate: **95.7%**

Intent-to-treat SVR rate: **92.3%**

- Study is ongoing.
- 12 weeks is the time of the treatment course.
- SVR (cure) is measured at least 12 weeks after completion of treatment.
- The majority of participants in between these visits are in the process of completing treatment or awaiting SVR.

Data as of 10 June 2021

Safety of Community-based HCV Treatment

- SAEs recorded on study treatment:
- Hospitalizations (n=19, 2.9%)
  - Only two hospitalizations resulted in treatment interruption.
  - Motorcycle accidents
  - Viral illness and/or pneumonia
  - Septic arthritis
  - Leptospirosis
  - Overdose
  - COVID-19
- Deaths while on study treatment (n=2)
  - Death at home after head trauma
  - Variceal bleeding
    - Pt had compensated cirrhosis prior to starting treatment with sof/vel

Adapting to COVID-19

- Reduced hours or closure of community sites
- Decreasing number of in-person visits during HCV treatment due to lockdowns and travel restrictions
- Mail or community worker delivery of medications
- Remote physician and nurse visits
- Use of phone/social media applications (LINE) to check in on participants
- Implementation of protocols regarding infection control, procurement of PPE for study staff

Key Messages

Community-based diagnosis and treatment for HIV, HBV, and HCV is in high demand among PWID/PWUD

- The model of care allows improved packaging of harm reduction services, within comprehensive model of care for PWID.
- Engaging them in HIV & HBV care.

Sofosbuvir/ velpatasvir is safe and effective in community-based settings, including among:

- PWID (people who inject drugs, including active users and injectors)
- People Living with HIV/AIDS (PLHIV)
- National programs should reimburse and support community-based diagnosis and care

Future Plans and Expansion

- Inclusion of STI (syphilis, gonorrhea, chlamydia) testing and treatment will be implemented within 2021
- Seeking funding to expand to PrEP, latent TB diagnosis and treatment
- Integration into Bangkok (government funded) OST, comprehensive HIV/PrEP/STI sites (n=3)
- Expansion to other provinces and CBOs within Thailand
- Continued advocacy to ensure access to HCV treatment nationally

- Regional plans: C-Free CSEA (Central and Southeast Asia)

THANK YOU

Acknowledgments