# Community-Based Approaches to HCV Treatment in San Francisco

Jennifer Price, MD, PhD
Associate Professor of Medicine
GI/Hepatology
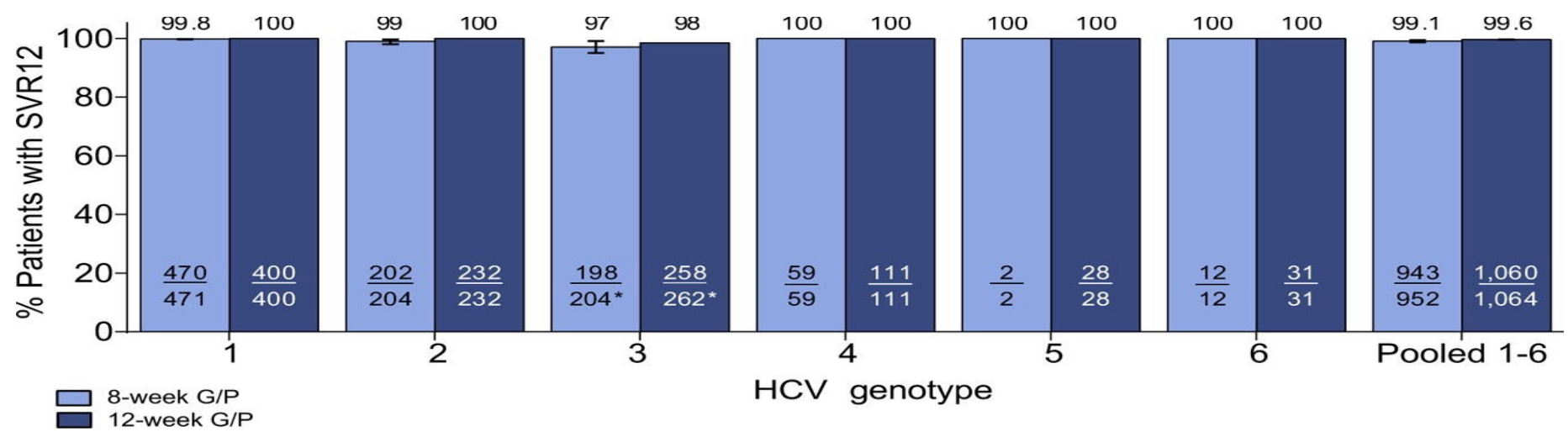Director, UCSF Viral Hepatitis Center

Disclosures

- Grant support: Merck, Gilead, AbbVie, Genentech, Zydus, VIR

Persons with HCV genotype 1, 2, 3, 4, 5, or 6 infection can be effectively treated with 1 tablet daily for 12 weeks

Sofosbuvir/Velpatasvir

Feld JJ et al. NEJM 2016; Foster G et al NEJM 2016
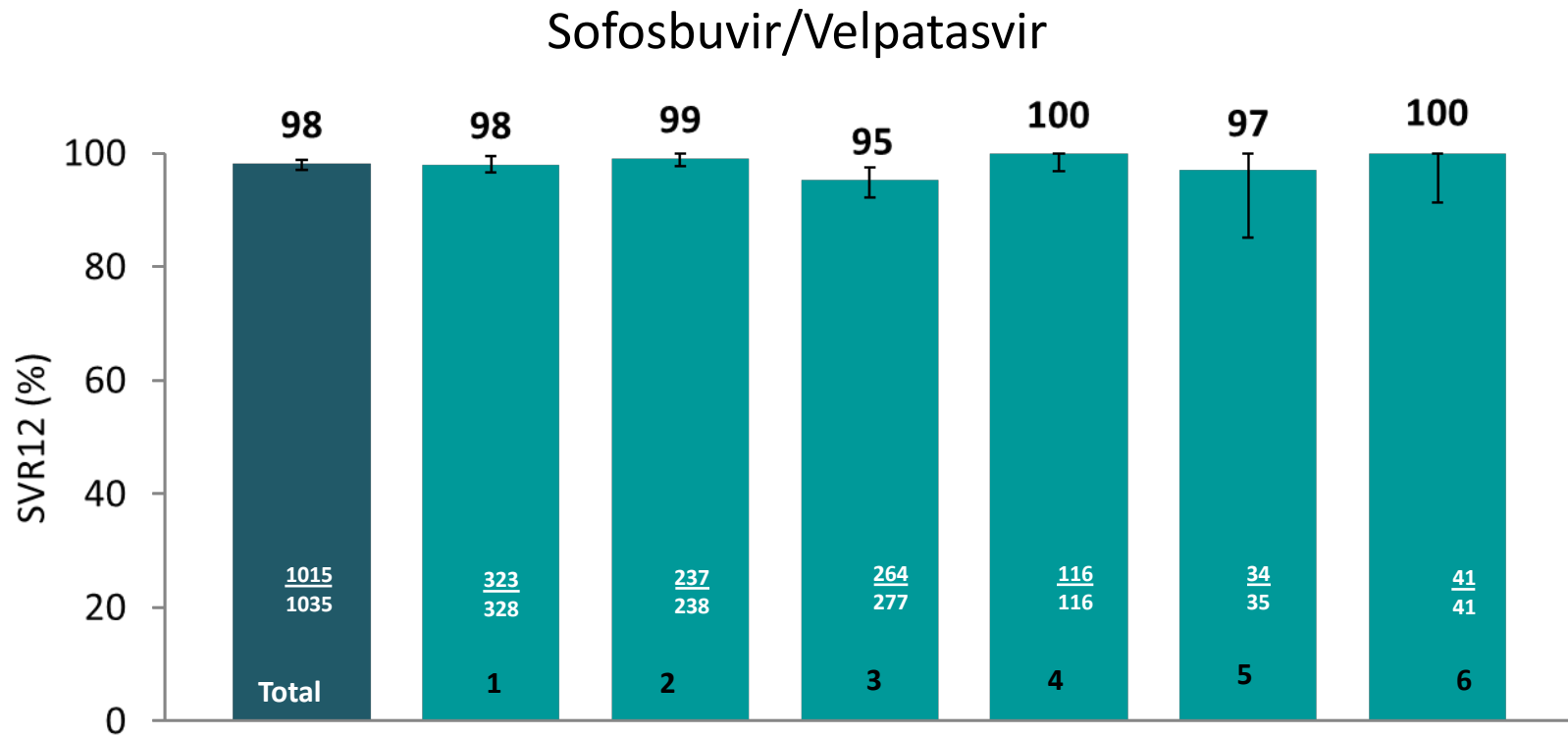
Persons with HCV genotype 1, 2, 3, 4, 5, or 6 infection can be effectively treated with 3 tablets daily for 8 weeks

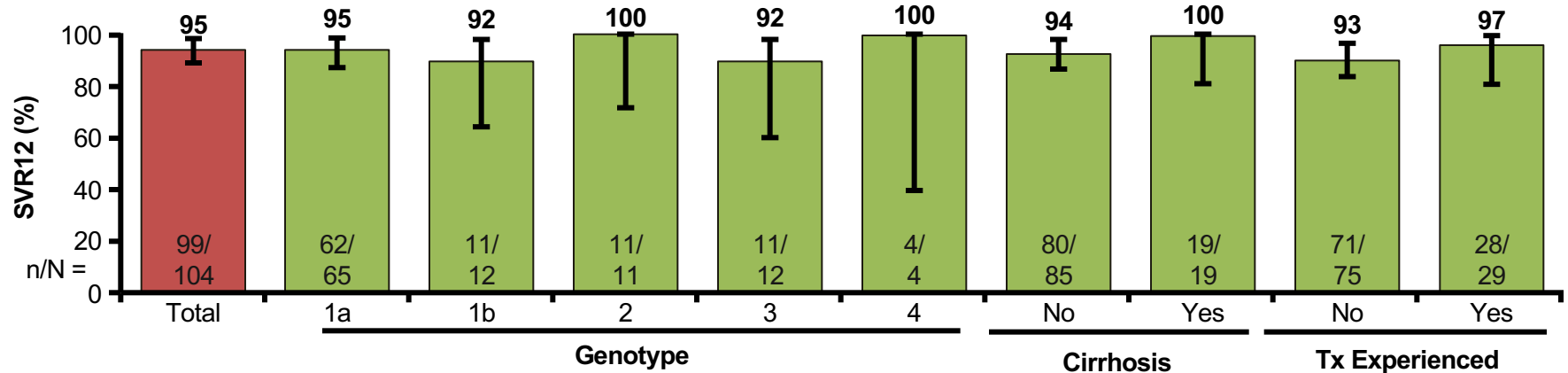## Glecaprevir/Pibrentasvir

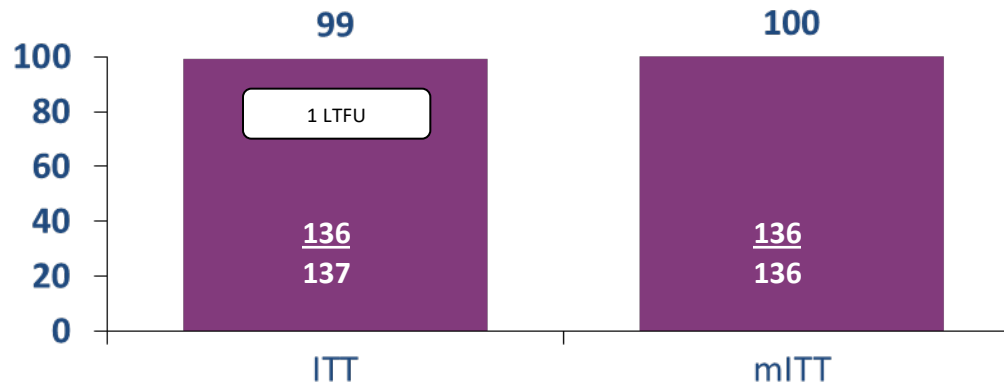

Puoti M et al. Journal of Hepatology (2018); Brown RS et al. Journal of Hepatology (2019)

Individuals with HIV/HCV Coinfected Have Similar Cure Rates

Wyles D, et al. EASL 2016. Abstract PS104. Reproduced with permission.
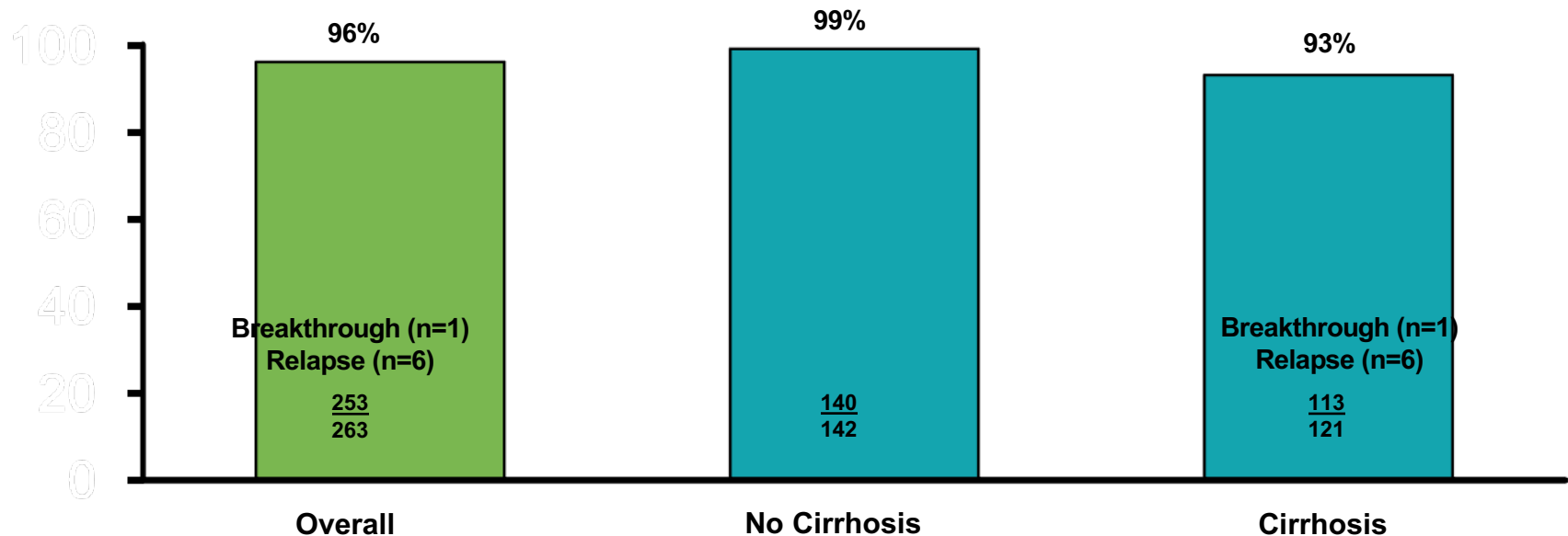
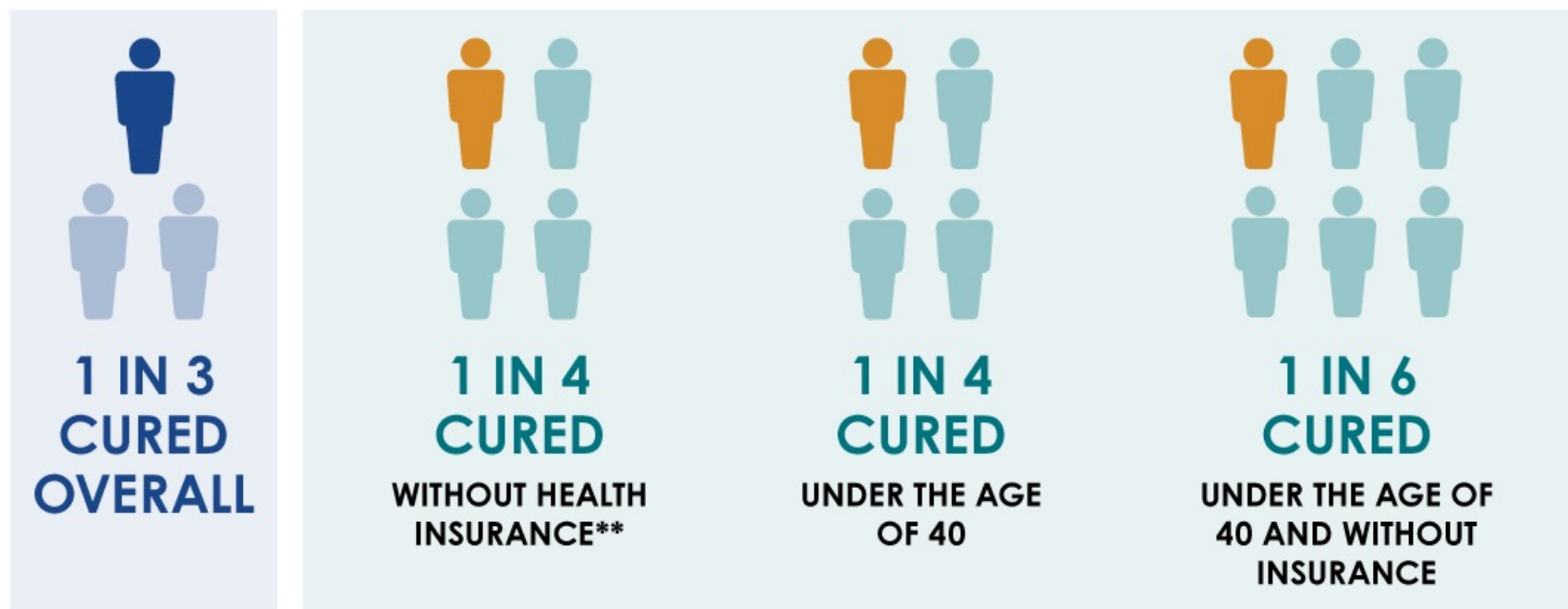# Overall Cure Rates in NS5A inhibitor – Experienced patients

Sofosbuvir/Velpatasvir/Voxilaprevir (Genotypes 1-6)

No placebo patients achieved an SVR12.
*P<0.001 for superiority versus pre-specified goal of 85% for sofosbuvir/velpatasvir/voxilaprevir.

Bourlière M, et al. Hepatology. 2016;64(suppl S1):102A. Abstract 194.

ADULTS DIAGNOSED AND CURED* OF HEPATITIS C IN THE U.S., 2013-2022

1 IN 3 CURED OVERALL

1 IN 4 CURED
WITHOUT HEALTH INSURANCE**

1 IN 4 CURED
UNDER THE AGE OF 40

1 IN 6 CURED
UNDER THE AGE OF 40 AND WITHOUT INSURANCE

*Cured is defined as viral clearance, which is an undetectable hepatitis C virus ribonucleic acid (HCV RNA) after a prior test result of detectable HCV RNA.

**Referred to as Other (client or self-pay) in the analysis

Source: Centers for Disease Control and Prevention

Wester C et al, MMWR 2023.

Hepatitis C Epidemiology, US

ESTIMATED 2.4 MILLION (95% CI, 2.0−2.8 million) people living with hepatitis C (2016)

3,621 REPORTED ACUTE CASES (2018)

50,300 ESTIMATED ACUTE INFECTIONS (2018)

71% INCREASE in rate of acute cases (2014−2018)

AGES 20-39

INCREASES IN ACUTE HEPATITIS C INFECTIONS were most often among young people (aged 20−29 and 30−39 years) (2018)

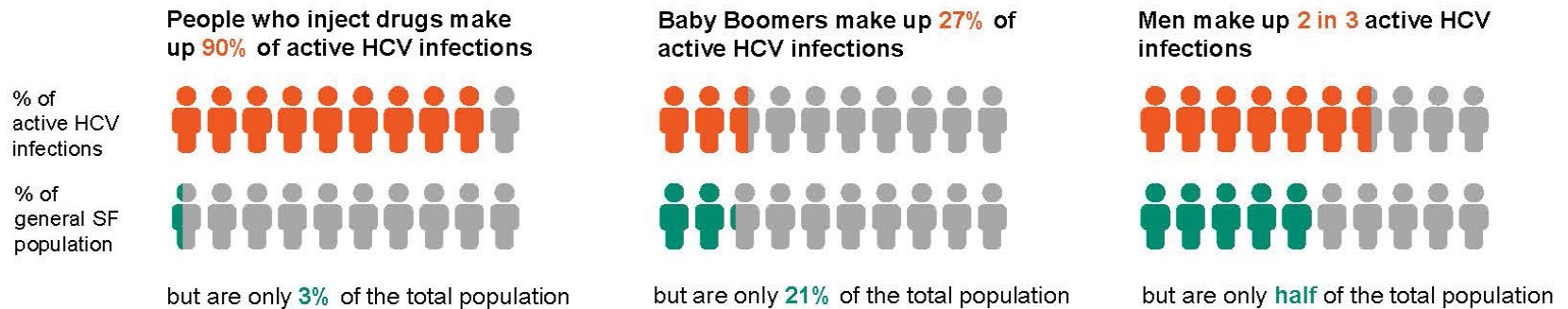**OF NEWLY REPORTED CHRONIC INFECTIONS,** 36% among people born 1981−1996 and 36% among people born 1945−1965 (2018)

Hepatitis C Virus Prevalence in San Francisco: Overall and by Subgroup

People who inject drugs make up 90% of active HCV infections

% of active HCV infections

% of general SF population

but are only 3% of the total population

Baby Boomers make up 27% of active HCV infections

but are only 21% of the total population

Men make up 2 in 3 active HCV infections

but are only half of the total population

Approximately 11,500 people are living with active, untreated hepatitis C virus (HCV) in San Francisco; an estimated 90% of those are people who inject drugs (PWID).
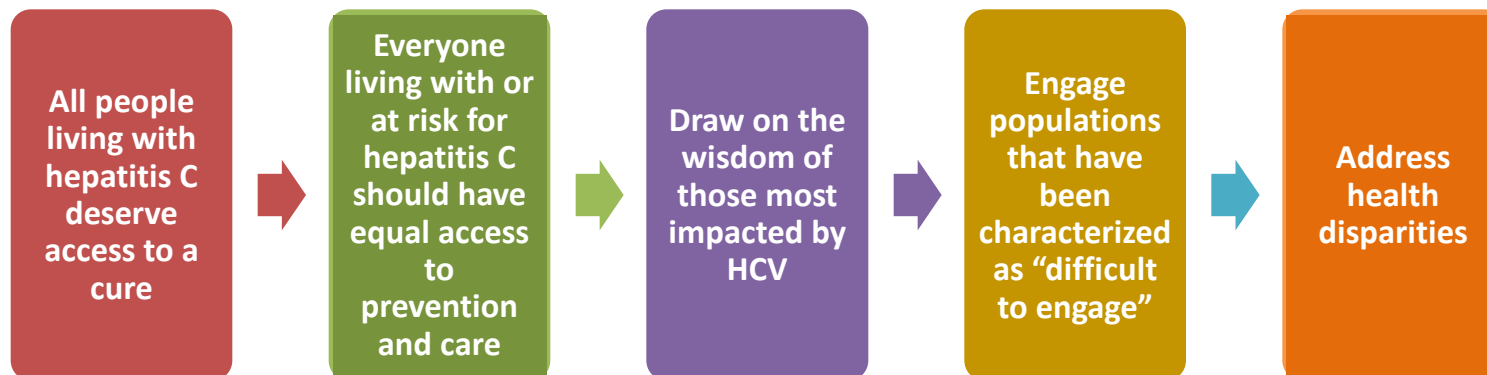
Facente SN et al, PLOS One, 2022

End Hep C SF: Multi-Sector Collective Impact Initiative

Mission

To support <u>all</u> San Franciscans living with and at risk for hepatitis C to maximize their health and wellness. We achieve this through prevention, education, testing, treatment, and linkage to reduce incidence, morbidity, and mortality related to hepatitis C.

Values

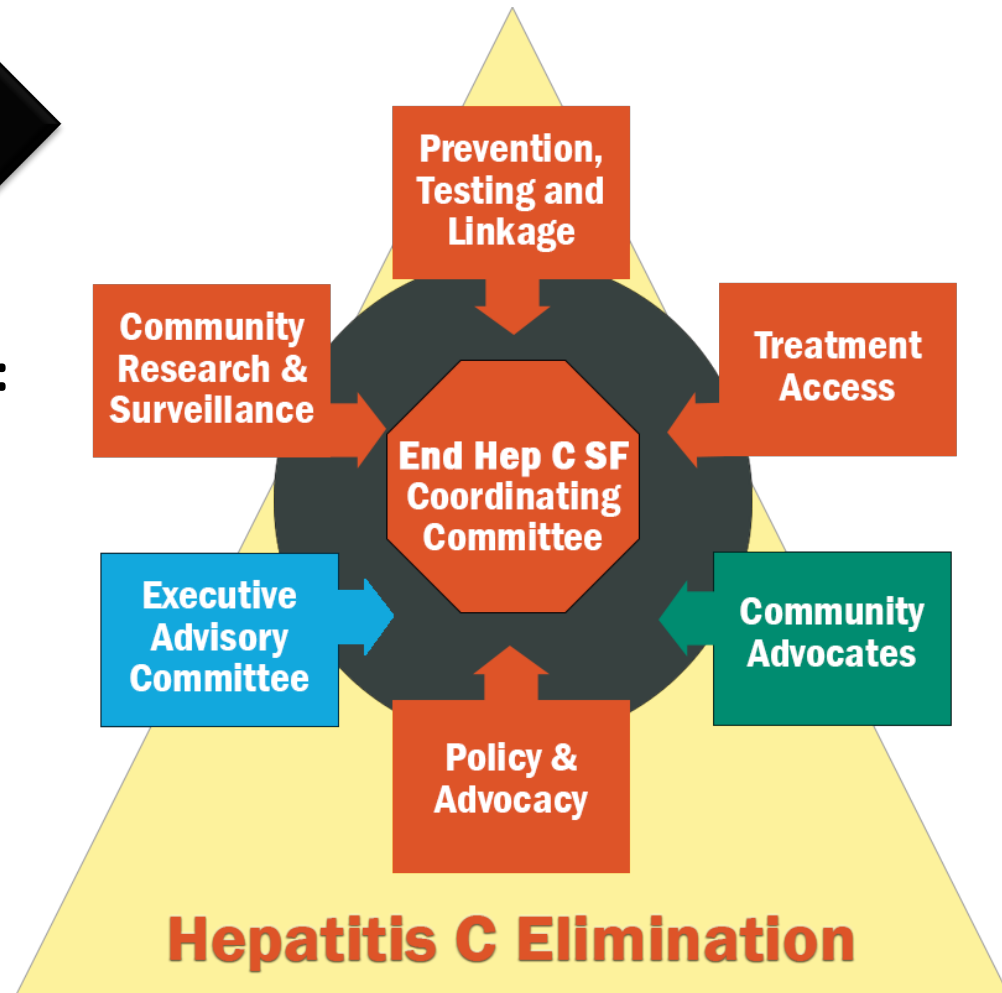|				
All people living with hepatitis C deserve access to a cure	→ Everyone living with or at risk for hepatitis C should have equal access to prevention and care	→ Draw on the wisdom of those most impacted by HCV	→ Engage populations that have been characterized as "difficult to engage"	→ Address health disparities

The End Hep C SF Collective Impact Model

Pillars of Collective Impact Model:

- Common Agenda
- Common Progress Measures
- Mutually Reinforcing Activities
- Continuous Communication
- Backbone Support

Prevention, Testing and Linkage

Community Research & Surveillance

Treatment Access

End Hep C SF Coordinating Committee

Executive Advisory Committee

Community Advocates

Policy & Advocacy

Hepatitis C Elimination

Addressing Gaps in Hep C Care Cascade in San Francisco

END HEP C SF

Barriers:

- Reaching at-risk persons for screening

- Linkage from diagnosis to HCV provider

- Paucity of HCV providers
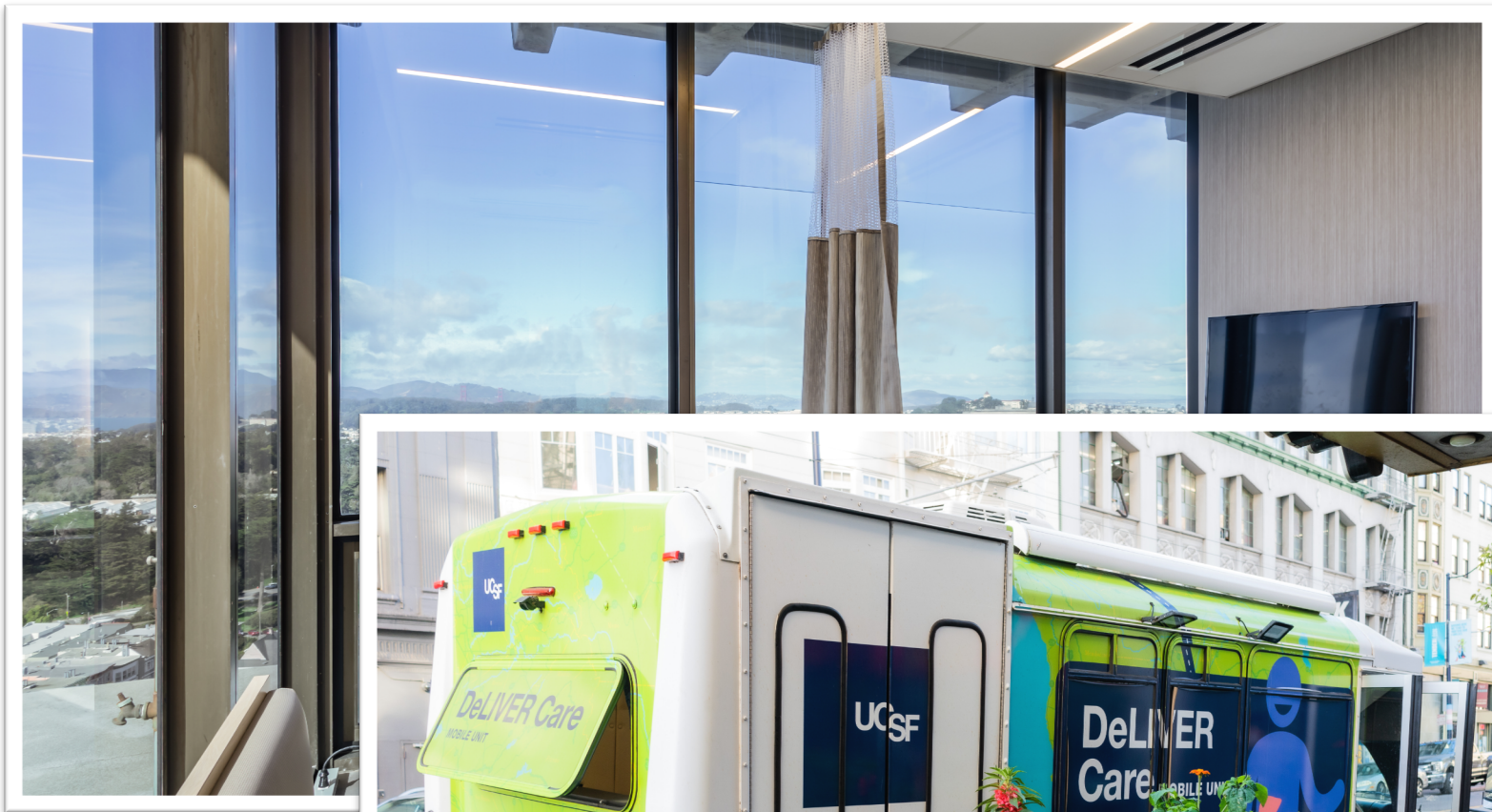
- Competing priorities

- Insurance restrictions

Solutions

- Increased community-based HCV screening >300%

- Initiated ZSFG in-hospital HCV routine opt-out testing

- Developed community peer navigation program, inpatient navigation program

- Increased PCP HCV treatment capacity >100%

- Supported HCV treatment outside specialty clinics: shelters, drug treatment programs, street medicine teams, harm reduction centers

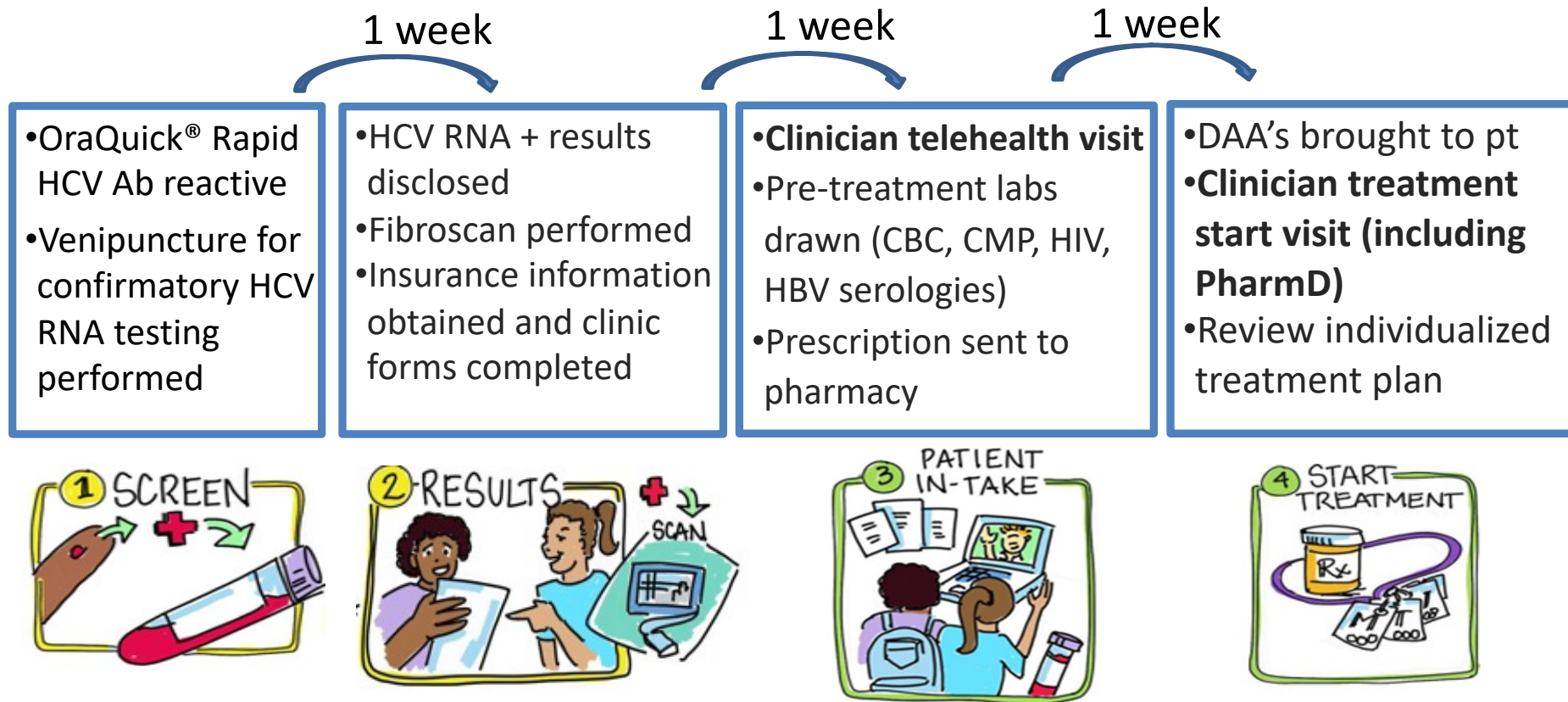- Successfully advocated for removal of DAA payer restrictions

No genotype requirement
No PA's for simplified treatment!

Mobile Hepatitis C Screening and Treatment via Telemedicine

1 week   **1 week**   **1 week**

•OraQuick® Rapid HCV Ab reactive •Venipuncture for confirmatory HCV RNA testing performed	•HCV RNA + results disclosed •Fibroscan performed •Insurance information obtained and clinic forms completed	•**Clinician telehealth visit** •Pre-treatment labs drawn (CBC, CMP, HIV, HBV serologies) •Prescription sent to pharmacy	•DAA's brought to pt •**Clinician treatment start visit (including PharmD)** •Review individualized treatment plan

Mobile Hepatitis C Screening and Treatment via Telemedicine

DeLIVER Care

Community-based
- Meet people where they are

> "I think this is a fantastic program. I don't think I would have sought it out…. To be cured is huge."

> "I liked it. It was convenient and normally when I go to a doctor's office I wait an hour or 45 minutes, but I am seen sooner at the van."

> "I was touched that UCSF has come to me because I would have not been able to go to them…"
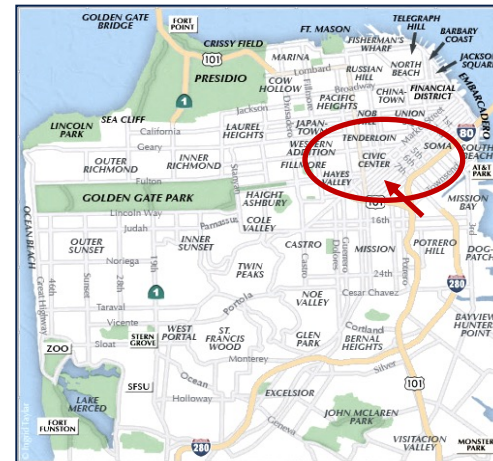
Staff-assisted collaboration with medical team

Support patients on treatment

PRE-TREATMENT

MRN:
- **Medication info:** TBD-weeks | weekly pu | RX:
- **Contact info:** Billie Holiday Reentry Navigation (6th & Mission St)
- **Navigation support:**
  - Referral POC: (Jail Services Navigator)
  - Navigation Center POC:
    - (program manager)
    - (case manager)
- **Visit summary:**
  - **Today:** 6/8- visit is pushed to next week
  - **Next:** 6/15-new patient visit + pre-tx BD + fibroscan
  - **Action Items:**
    - @Rosaura- FibroScan + reminder call + email check in
    - @Jaz/Yesenia-insurance check
    - @Jaz- schedule new patient visit w/clinician on 6/15 @9:30am

MRN:
- **Medication info:** TBD-weeks | weekly pu | RX:
- **Contact info:** 415-879-4693 | Tahanan #520
- **Navigation support:**
  - LEA:
- **Visit summary:**
  - **Today:** 6/8- did not check in
  - **Next:** 6/15- Fibroscan + pre tx BD + new patient visit
  - **Action items:**
    - @Rosaura: print requisitions + FibroScan + reminder call
    - @Jaz: schedule new pt visit w/Jeff on 6/1 @11am

ON TREATMENT

MRN:
- **Medication info:** Epclusa 12 weeks | monthly pu |
- **Contact info:** no ph# | Jail Services Referral
- **Navigation support:**
  - Referral POC: (Jail Services Navigator)
  - Navigation Center POC:
- **Visit summary:**
  - **Today:** 6/8- pick up doses 29-56 + week 4 blood draw
  - **Next:** 7/6- pick up doses 57-84 (final month)
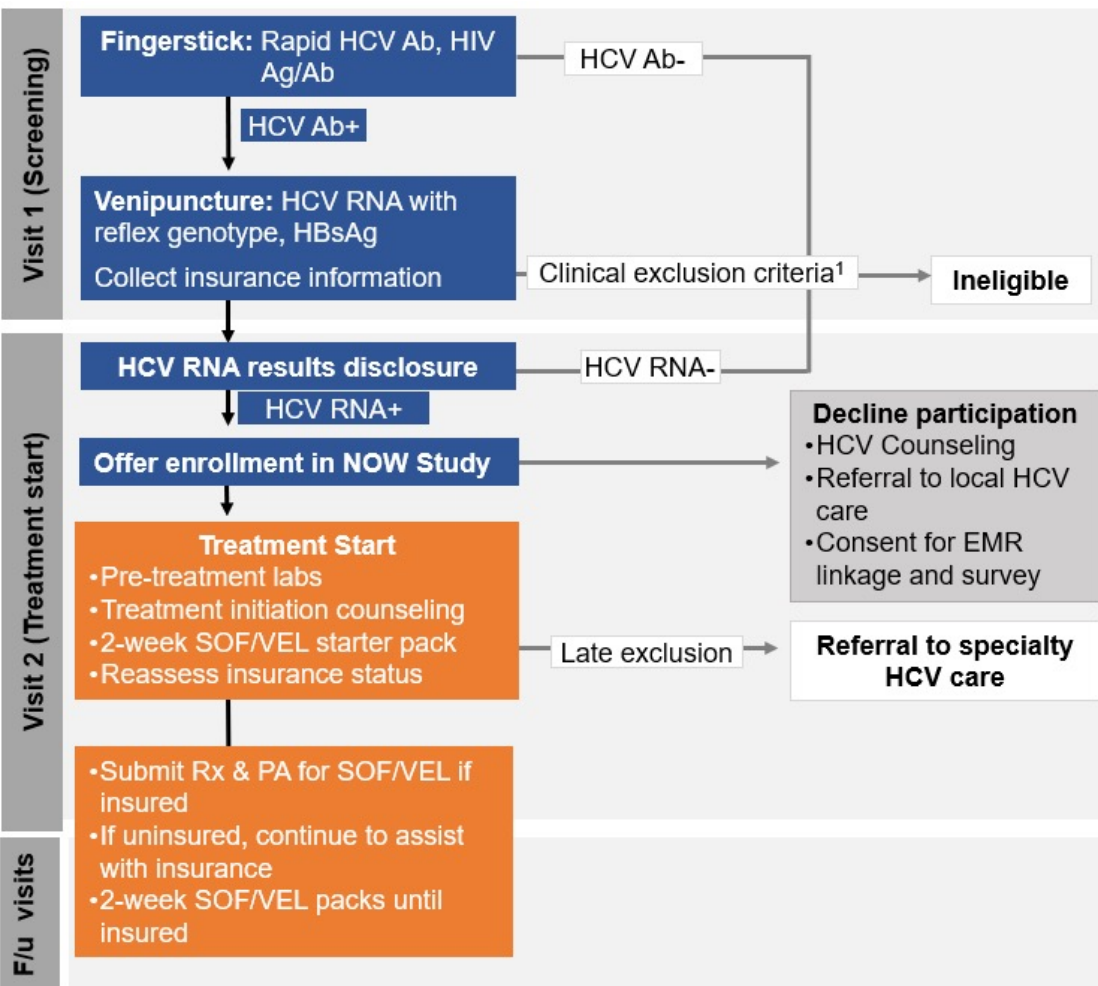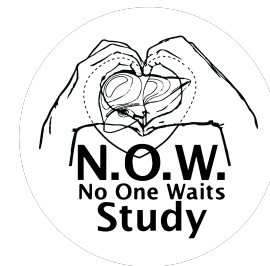 - **Action items:**

No One Waits (NOW) Study: Community-Based Point-of-Diagnosis Hepatitis C Treatment
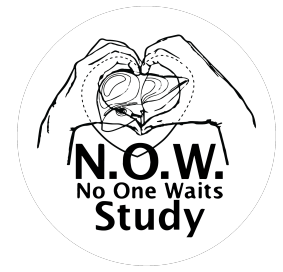
Primary objective: Establish the feasibility, acceptability and effectiveness of an accelerated on-site HCV point-of-diagnosis treatment model in which 2-week starter packs of SOF/VEL are provided at the time of active HCV confirmation

No One Waits (NOW) Study Design

Visit 1 (Screening)

Fingerstick: Rapid HCV Ab, HIV Ag/Ab
→ HCV Ab-

HCV Ab+

Venipuncture: HCV RNA with reflex genotype, HBsAg
Collect insurance information
→ Clinical exclusion criteria[1] → **Ineligible**

Visit 2 (Treatment start)

HCV RNA results disclosure
→ HCV RNA-

HCV RNA+

Offer enrollment in NOW Study
→ **Decline participation**
- HCV Counseling
- Referral to local HCV care
- Consent for EMR linkage and survey

Treatment Start
- Pre-treatment labs
- Treatment initiation counseling
- 2-week SOF/VEL starter pack
- Reassess insurance status
→ Late exclusion → **Referral to specialty HCV care**

F/u visits

- Submit Rx & PA for SOF/VEL if insured
- If uninsured, continue to assist with insurance
- 2-week SOF/VEL packs until insured

Inclusion criteria:
- ≥18 years
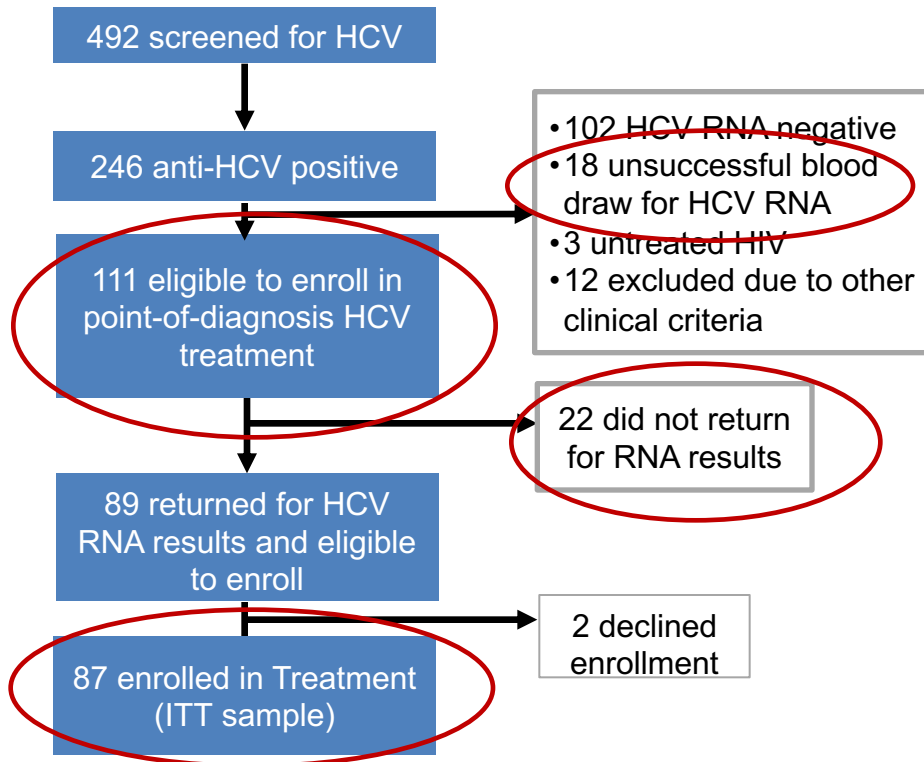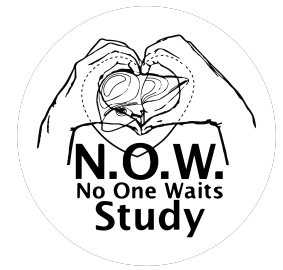- History of ever injecting drugs or receiving blood transfusion before 1992

Exclusion criteria:
- DAA experienced
- Untreated HIV
- HBsAg+
- Decompensated cirrhosis

Pre-treatment labs:
- CBC, CMP, INR
- Anti-HBc, anti-HBs
- Sample for NS5A RAS testing if FIB-4 >3.25 and genotype 3

N.O.W. No One Waits Study

Morris MD, et al. AASLD 2022. Abstract 3495.

HCV Screening and Study Enrollment

492 screened for HCV

↓

246 anti-HCV positive

→
- 102 HCV RNA negative
- 18 unsuccessful blood draw for HCV RNA
- 3 untreated HIV
- 12 excluded due to other clinical criteria

↓

111 eligible to enroll in point-of-diagnosis HCV treatment

→ 22 did not return for RNA results

↓

89 returned for HCV RNA results and eligible to enroll

→ 2 declined enrollment

↓

87 enrolled in Treatment (ITT sample)

- 18/246 (7%) of HCV Ab+ unable to get confirmatory HCV RNA testing

- 111/126 (88%) of HCV RNA+ potentially eligible for modified simplified HCV tx
    - 5 DAA experienced
    - 3 untreated HIV
    - 3 insufficient blood draw (HBsAg)
    - 1 HBsAg+
    - 1 high dose PPI
    - 2 started treatment outside of study

- 22/111 (20%) of HCV RNA+ LTFU between visits 1 and 2

- 87/89 (98%) of HCV RNA+ with results disclosure enrolled in same-day treatment

Morris MD, et al. AASLD 2022. Abstract 3495.

NOW Study Population
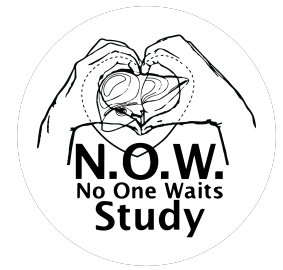
	N=87
Median years of age (IQR)	48 (37, 58)
Male	71%
Race and ethnicity	
African American and Black	25%
Latino/a/e/x	10%
Asian, Native Hawaii, Pacific Islander, Mixed	6%
White	56%
Not specified	2%
Slept outside or in vehicle in past 12 months	61%
Current housing	
Outdoors or vehicle	43%
Shelter	9%
SRO or hotel	17%
With friend or family	3%
Treatment or transitional	10%
Rent or own	17%
Income below the national poverty line	97%
Any injection drug use in past 3 months	80%

	N=87
Insured at time of enrollment	94%
Type of insurance	
Medi-Cal/SFHP	95%
VA	1%
Blue Cross	3%
Kaiser	1%
Primary care provider	48%
Time it took to get to study location	
Less than 15 min	52%
15 min - 30 min	29%
More than 30 minutes	17%

Morris MD, et al. AASLD 2022. Abstract 3495.

# No One Waits (NOW) Study: Community-Based Point-of-Diagnosis Hepatitis C Treatment
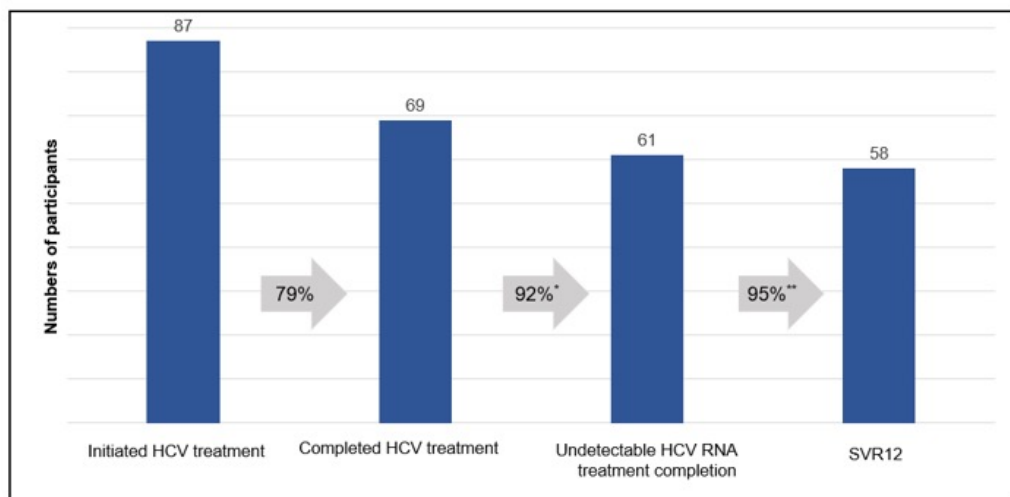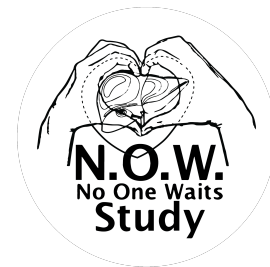
*excludes 3 people with incomplete blood draws at end of treatment
**includes 2 people with presumed reinfection post-treatment

- ITT SVR12: 67%
- PP SVR12: 84%
- Lower SVR12 in people experiencing homelessness over past 12 months (55% vs 85%)
- No adverse events causing premature tx discontinuation
- No alterations in treatment based on pre-treatment labs drawn day of SOF/VEL start
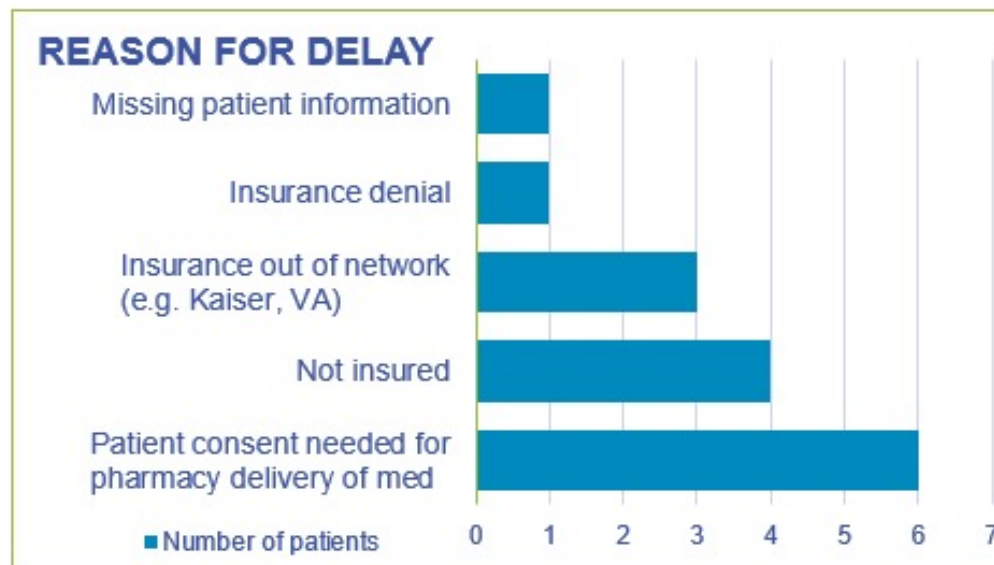
Morris MD, et al. AASLD 2022. Abstract 3495.

Transition from Study-Provided to Insurance-Provided DAA*
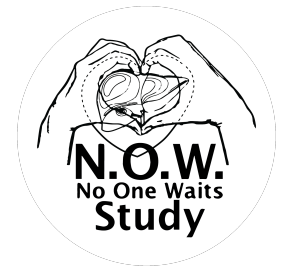
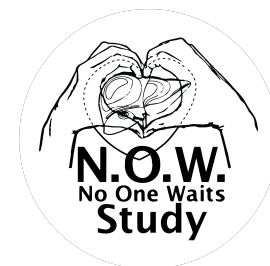## Transition to Insurance-covered Medication

91% transitioned to insurance-covered DAAs during the 12-week course.

• 77% transitioned after the 2-week starter pack
• 9% remained on study drug throughout treatment

REASON FOR DELAY

Reason	Number of patients
Missing patient information	1
Insurance denial	1
Insurance out of network (e.g. Kaiser, VA)	3
Not insured	4
Patient consent needed for pharmacy delivery of med	6

■ Number of patients

*Among first 64 participants July 2020 to July 2021

Ung D et al. AASLD 2022. Abstract 984.

Role of the Pharmacy Team in Point-of-Diagnosis HCV Treatment

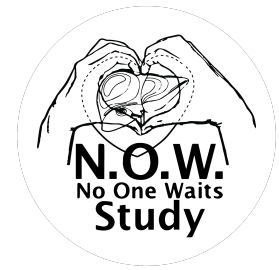| Collaboratory Steps		1. Patient intake	2. Prescription sent to pharmacy team	3. Benefits investigation	4. Prior authorization submission	5. Insurance approval	6. Medication dispensed/delivered

Details		• Gather baseline participant information
		  • Identification card
		  • Health insurance
		  • Bloodwork
		  • Income/ household size
			• CL E-prescribes SOF/VEL
			• CL notifies PH/PT via secure message
			• *Participant given 2-week starter pack (14 pills of study donated SOF/VEL) at study visit*
				• PT verifies participant's insurance coverage
				• PT and RT communicate to troubleshoot hurdles
					*Prior authorization for prescription approval is required by insurance plans except Medi-cal.
					• PT compiles information needed for PA (Step 1)
					• PT submits Prior Authorization request to IC
					• PT/RT respond to appeals as needed
						• IC approves prescription authorization request
						• PT/PH receives notification of approval
						• PT/RT enrolls participant in **Copay Assistance as needed OR study pays copay
							• RT and PT coordinate medication pick-up from pharmacy
							• RT picks up medication from pharmacy
							• RT dispenses medication to patient at community research site visit

Time		30 min	10 min	5 min – 7 days	30 min	24 -72 hrs.	15 min -1 hr.
Team member involved	Research Team (RT)	██		██			██
	Clinician (CL)		██				
	Pharmacist (PH)		██			██	
	Pharmacy technician (PT)			██	██	██	██
	Insurance Company (IC)			██	██	██	

*Prior authorization requirements
- Clinical notes to support HCV diagnosis
- Cirrhosis status, genotype, previous treatment history

**Copay Assistance Program requirements
-Program-specific eligibility
-Proof of income
-Household size

Ung D et al. AASLD 2022. Abstract 984.

HCV Medication Security Strategies for People Experiencing Homelessness

- 63% of surveyed participants reported concerns about **safely storing** their DAAs

- 33% reported missed doses due to **medication loss/theft**

  - 70% reported multiple instances of medication loss over 12 week treatment course

(A) Necklace (B) Modified Fanny pack (C) Modified pillbox

Type		MATERIAL I	MATERIAL II	TOTAL COST PER CONTAINER
A	Necklace	Baggies used to organize the supply of harm reduction materials. These baggies were purchased as a pack of 1,000 for $20 USD. 2 cents x 7 units = $0.14 for 7 day supply.	Necklace - The necklace chain was from a free lanyard from an individual's clothing donation to our study's free clothing supplies. However online the median price from a large online retailer was 50 for $10.00. 1 unit = $0.20	$0.34
B	Fanny pack	A passport belt/fanny pack was purchased from a major online retailer. 1 unit = $14	Travel pill organizer was purchased from a major online retailer and sewed into the passportbelt/fannypack. 1 unit = $17 USD	$31.00
C	Modified Pillbox	A Pillbox was purchased from a local drug store. 1 unit = ~$4.00	Carabiner - the carabiner was taken from the top of a donated metal reusable water bottle. However online the median price at a major online retailer was ten for $9.00. 1 unit = $1.11	$5.11

2021 prices in US Dollars

Morris MD et al, Clinical Liver Disease, 2023

Key Themes for Success

Shorten the steps from HCV diagnosis to treatment
- Minimize obstacles, blood draws, insurance barriers

Community-based
- Meet people where they are
- Close to where participants live/congregate, public transit

Staff-assisted collaboration with medical/pharmacy team
- Utilize technology in way to address needs of population
- Maximize specialty resources

Provide support through treatment
- Regular check-ins
- Safe medication storage

N.O.W.
No One Waits
Study

Thank you!

DeLIVER Care Van

NOW Study

UCSF

Lisa Catalli, NP

Jeff McKinney, NP

Diana Ung, PharmD

Mackenzie Clark, PharmD

Vivian Lian, PharmD

Philip Kong, PharmD

Martha Delos Reyes, Pharm Tech

Claire Mcdonell

Rebecca Kim, MD

Annie Luetkemeyer, MD

Meghan Morris, PhD

USC

Norah Terrault, MD

NOW Study participants

End Hep C SF

Yesenia Laguardia

UCSF DeLIVER Care Project Manager

Pauli Grey

UCSF DeLIVER Navigation Coordinator and Harm Reduction Specialist

Jordan Ackerley

End Hep C SF Strategic Director