COLLOCATION OF HCV TREATMENT, BUPRENORPHINE, AND PrEP TO REDUCE HARM IN PWID WITH HCV: **THE ANCHOR STUDY**

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DISCLOSURE

- **The ANCHOR study is supported by an investigator initiated research grant from Gilead Sciences paid to the institution (IHV/UMD)**

OBJECTIVES

- **Understand the efficacy of using direct acting antivirals to treat HCV infected individuals with ongoing injection drug use.**
- **Evaluate HCV treatment as an anchor to engage PWID in harm reduction strategies**
  - **Opioid agonist therapy**
  - **Pre-exposure prophylaxis (PrEP)**
  - **Needle and syringe programs**
  - **Naloxone**

BACKGROUND

- **PWID have high interest in treatment for HCV[1]**
- **PWID treated with IFN based therapy had comparable rates of SVR and treatment adherence to non-drug users[2]**
- **In clinical trials, PWID on opioid agonist therapy demonstrated high rates of SVR when treated with DAAs[3]**
- **For PWID not on opioid agonist therapy, there are increasing data indicating high rates of SVR in PWID with recent IDU[4]**

[1]Doab, 2005; Grebely, 2008; Stein, 2001; Strathdee, 2005
[2]Cunningham, 2017
[3]Dore, 2016
[4]Grebely, 2017

BACKGROUND

- If the goal is to improve morbidity and mortality in PWID
  - HCV cure is not enough
- Even after HCV cure, PWID are at risk for:
  - HCV reinfection
  - HIV acquisition
  - Opioid overdose
- To positively impact this population and the HCV epidemic, we must address all three potential harms.

HARM REDUCTION IN PWID

- Opioid agonist therapy (buprenorphine or methadone)[1]
- Needle and syringe programs[2]
- Pre-exposure prophylaxis for HIV with tenofovir[3]
- Naloxone distribution[4]

[1]Tsui, 2014
[2]Martin, 2013
[3]Choopanya, 2013
[4]Walley, 2013

METHODS

THE ANCHOR STUDY

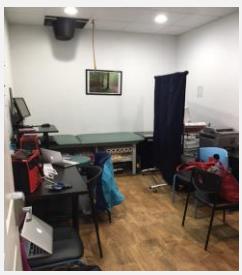
- **Single center study**
- **Evaluates a model of care to provide targeted, comprehensive care utilizing HCV treatment to engage PWID in harm reduction strategies.**

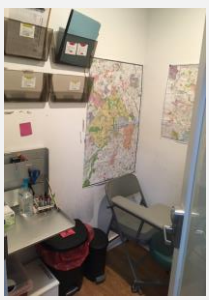
PARTICIPANTS

- N = 100
- Inclusion
  - Chronic HCV infection
  - Opioid use disorder
  - Injection of an opioid within 3 months
- Exclusion
  - Decompensated cirrhosis
  - Prior DAA therapy
  - CrCl <30

METHODS

- Patients are treated at HIPS, a harm reduction organization drop-in center in Washington, DC
  - Community health workers
  - Transportation provided as needed





METHODS

- All patients receive sofosbuvir/velpatasvir x12 weeks
  - Access to needle and syringe program
  - Access to naloxone
- On-treatment MD Visits
  - Day 0
  - Week 4
  - Week 8
  - Week 12
- Medication
  - 1 bottle (28 pills) dispensed on-site during treatment visit
  - Delivered by CHW if patient doesn't come to visit

METHODS

- Eligible patients are offered
  - Initiation of opioid agonist therapy with buprenorphine/naloxone
  - Initiation of PrEP with tenofovir/emtricitabine
- Patients are followed prospectively for 2 years
  - HCV reinfection, HIV acquisition
  - Risk behaviors
  - HCV-PRO

OUTCOMES OF INTEREST - HCV

- Long-term efficacy of direct acting antiviral therapy in PWID
  - Adherence to visits and medication
  - Sustained virologic response
  - HCV reinfection

OUTCOMES OF INTEREST – HARM REDUCTION

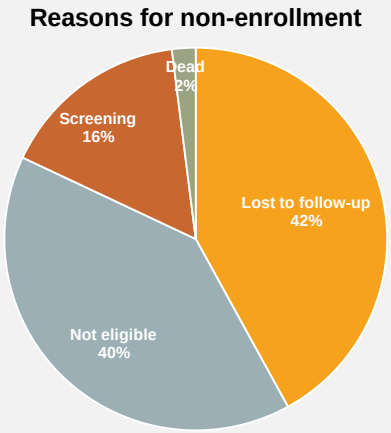
- Impact of embedded HCV care on uptake of harm reduction services
  - Initiation of and adherence to buprenorphine/naloxone
  - Initiation of and adherence to PrEP
  - Engagement in needle and syringe program
  - Frequency of opioid overdose and naloxone administration
  - Change in risk behaviors over time

RESULTS

RESULTS – ENROLLMENT

- 97 patients screened
- 53 patients enrolled

- Reasons not eligible
  - 10 HCV VL UD
  - 4 Medical contraindication
  - 3 No active IDU
  - 1 No venous access
  - 2 Other



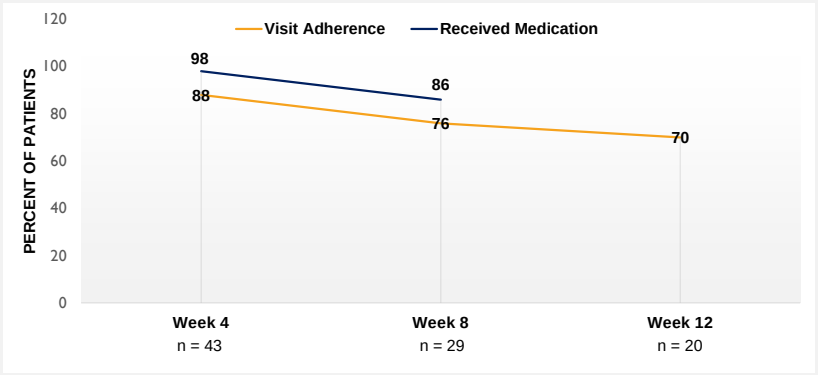
RESULTS - DEMOGRAPHICS

Baseline Characteristics	Total Cohort n=53
Median Age, years	57
Men, n (%)	40 (75)
Race, n (%)	
Black	51 (96)
White	1 (2)
More than one race	1 (2)
Frequency of opioid injection	
Once a day or more	34 (64)
More than once a week	10 (19)
Once a week or less	9 (17)
Cirrhosis, n (%)	16 (30)
HIV co-infection, n (%)	1 (2)

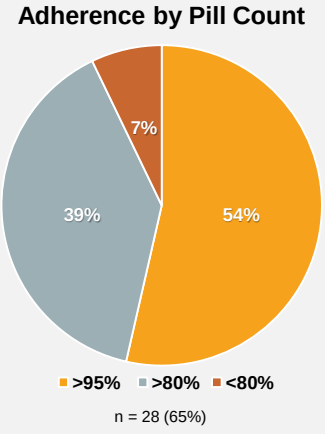
RESULTS – OVERDOSE BASELINE

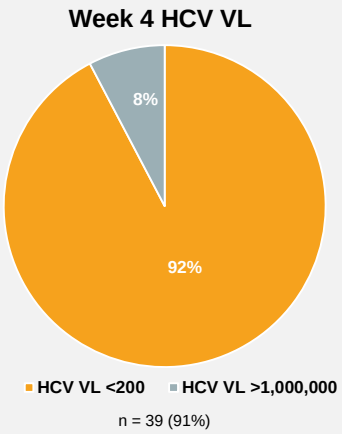
- 33 (62%) have ever overdosed on an opioid
- 49 (93%) have ever witnessed another person overdose on an opioid
- 15 (28%) currently carry naloxone
- 29 (76%) are interested in getting naloxone

RESULTS - ADHERENCE



RESULTS – ADHERENCE WEEK 4





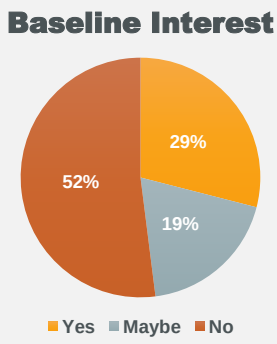
RESULTS – OPIOID AGONIST THERAPY

- 35 (63%) patients not on opioid agonist therapy at screening
  - 35 (100%) interested in opioid agonist treatment
  - 22 (63%) started buprenorphine/naloxone
  - 18 (82%) retained in buprenorphine/naloxone

RESULTS - PrEP

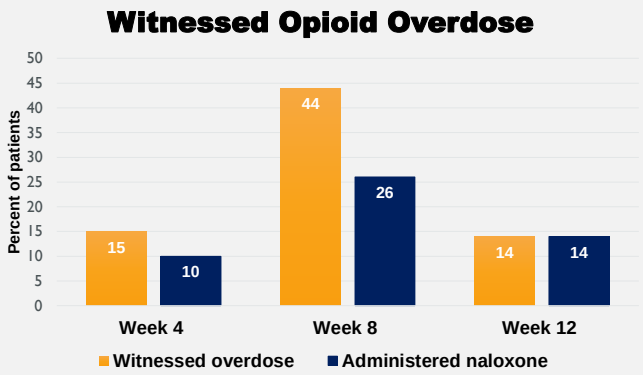
Of 52 (98%) non-HIV infected patients

- 0 patients on PrEP at screening
- 28 (55%) eligible for PrEP by CDC criteria
- 10 (19%) started on PrEP



RESULTS – OVERDOSE ON TREATMENT

- No enrolled patients have reported overdose after HCV treatment day 0



RESULTS - INCARCERATION

- 48 (91%) ever incarcerated
- Median of 9.6 years since last incarceration
- 5 (9%) known to be incarcerated after Day 0
  - 4 incarcerated before completing HCV treatment

CONCLUSIONS

CONCLUSIONS

- **Preliminary results of the ANCHOR study support that PWID with HCV have:**
  - **Good adherence to DAA treatment**
  - **High interest in buprenorphine treatment**
  - **Moderate interest in PrEP**
  - **High risk of overdose or witnessing an overdose**
- **Collocating HCV therapy with buprenorphine, PrEP, and naloxone may provide an opportunity to initiate harm reduction strategies in PWID**
- **Frequent incarceration may be a challenge in the continuity of HCV treatment in these individuals**
- **We continue to acquire long-term outcomes regarding SVR, reinfection, and other measures.**

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