# The Relationship Between HIV and HCV Adherence Among People Who Inject Drugs on Opioid Agonist Therapy

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Viral Hepatitis Research Symposium

2018

NYC

#### BACKGROUND

- 60% of PWID (People Who Inject Drugs) have HCV and 50-90% of HIV-infected PWID are co-infected with HCV.
- Data regarding the impact of HCV treatment on antiretroviral therapy (ART) adherence are conflicting, and have not been studied among PWID receiving direct acting antivirals (DAAs) on opioid agonist therapy (OAT).

#### RESULTS

- Mean adherence rates among HCV mono-infected and HIV/HCV co-infected PWID were 78% (SD=17) and 80% (SD=16), respectively (p=.56).
- There were no significant changes in ART adherence, CD4 counts, CD4%, or HIV viral loads among the pre-, during-, and post-HCV treatment periods.
- 71%, 71% and 87% had excellent HIV treatment adherence pre-, during-, and post-initiation of HCV treatment.
- Correlation between DAA and ART adherence was 0.18 (p=.49).

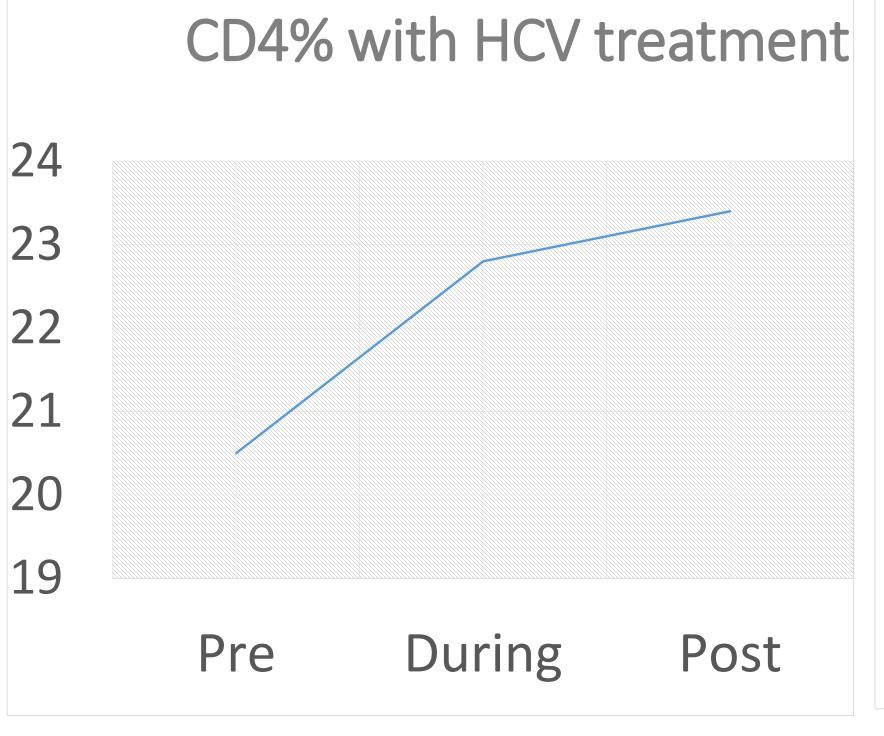
Daily Adherence							
Infection N Mean SD p							
HCV	126	78	17				
HCV/HIV	21	80	16	0.56			

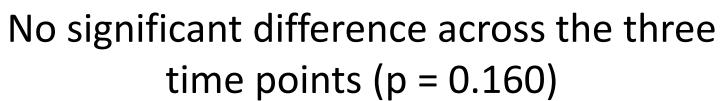
#### **PURPOSE**

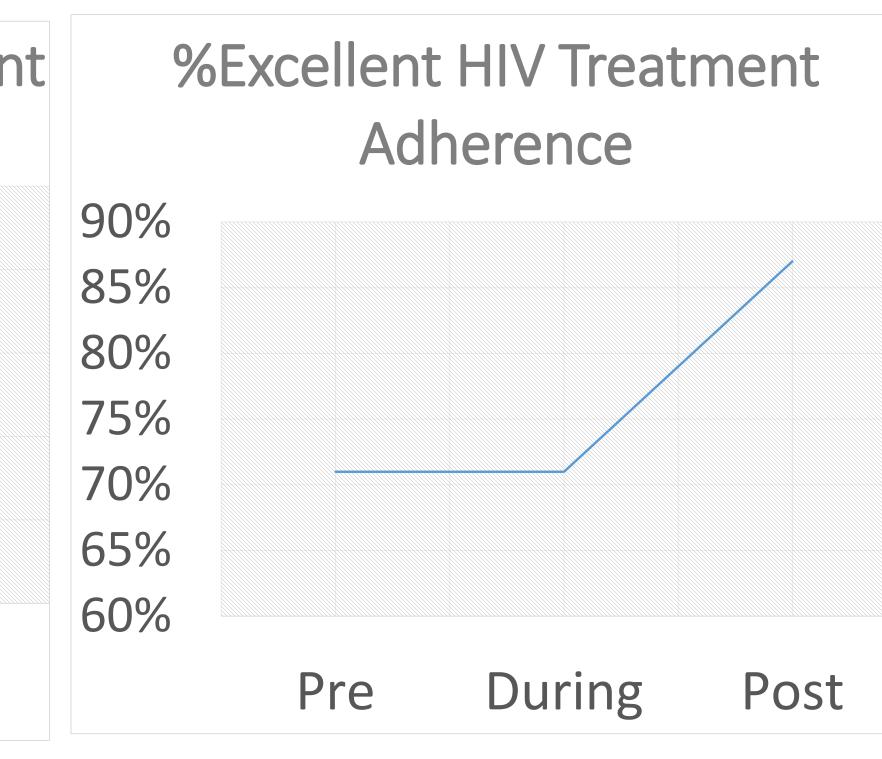
 We aimed to 1) compare adherence to DAAs among a cohort of HCV monoinfected (N= 129) and HIV/HCV co-infected (N=21) PWID, 2) assess for changes in ART adherence and HIV outcomes following HCV treatment initiation.

# METHODS

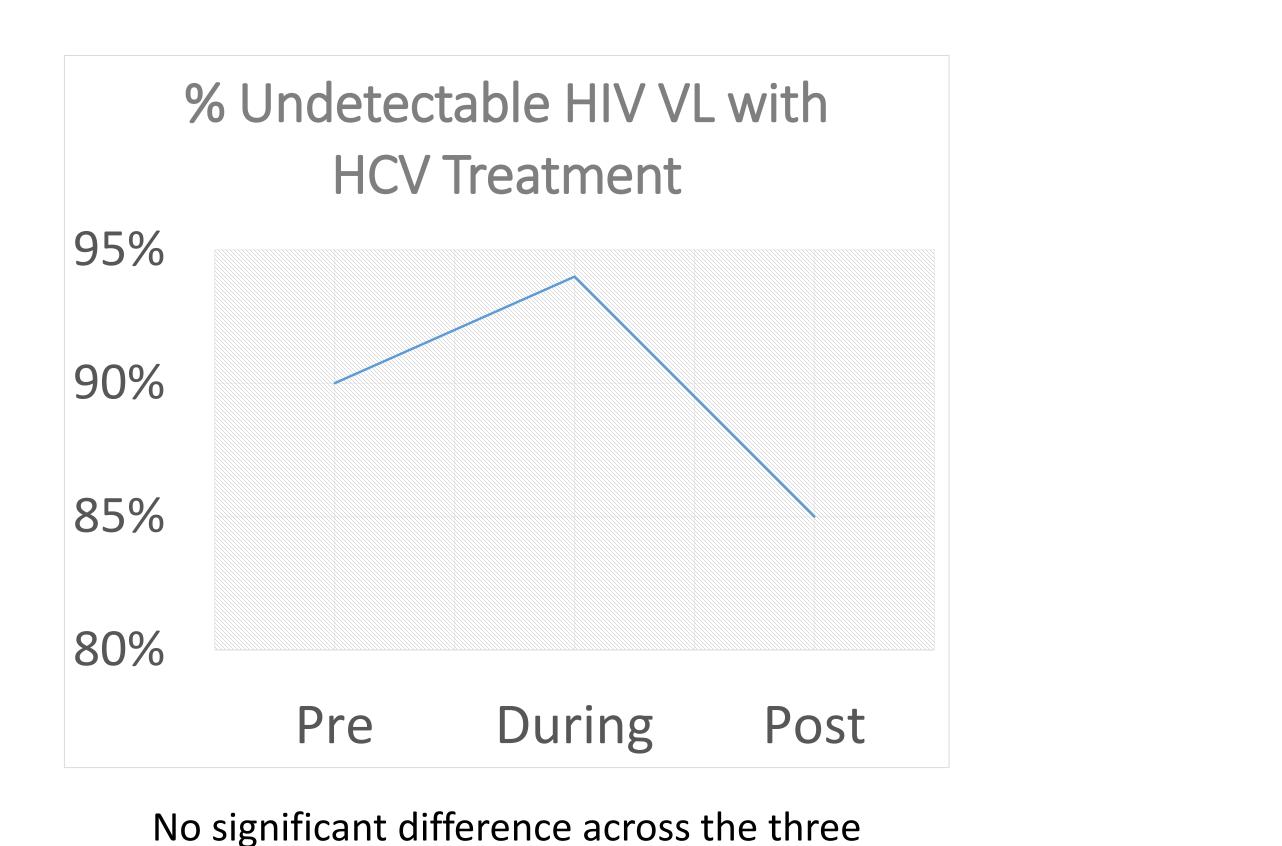
- HCV adherence was measured using electronic blister packs. Good adherence was defined as >80% of doses taken.
- ART adherence was measured using patient self-report and dichotomized to excellent or other based on clinician documentation.
- ART adherence, CD4 count, CD4%, and HIV viral load were identified 6-months prior to, during, and 6-months post HCV treatment.
- Statistical significance was assessed with ttests and mixed-effects regression models.
- The Pearson-correlation coefficient was calculated between DAA adherence and peri-ART adherence.







No significant difference across the three time points (p = 0.558)



time points (p = 0.661)

#### CONCLUSION

- This is the first assessment of the relationship between ART and DAA adherence among PWID.
- Our data demonstrate no effect of HCV treatment on ART adherence or HIV outcomes, and suggest concerns for worsening ART adherence HIV and outcomes due to increased pill-burden with HCV treatment are not warranted.

# LIMITATIONS

- Small sample size may limit generalizability
- May not be generalizable to HCVinfected patients not on OAT

# ACKNOWLEDGEMENTS

- National Institute of Drug Abuse (R01 DA034086)
- Gilead Sciences



# Improving Inpatient Screening for Hepatitis C: Lessons Learned from a Large Municipal Hospital

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#### BACKGROUND

- Hepatitis C virus (HCV) antibody positivity among the baby boomer birth cohort (born 1945-1965) in our hospital's emergency department was 7.3% in 2014-2015, over twice the national average.<sup>1</sup>
- Screening rates among eligible baby boomers admitted to the inpatient medicine service were only 19.4% (March-July 2017).
- We hypothesized that knowledge gaps among providers regarding HCV screening, and perceived barriers to initiating care for HCV-infected patients contributed significantly to screening failures.

#### METHODS

- We implemented a multimodal HCV screening campaign targeting inpatient internal medicine residents and faculty beginning August 2017.
- Inpatient internal medicine residents received monthly briefings on HCV screening.
- Informational flyers were placed in resident and faculty work areas.
- The role of HCV outpatient navigators and the infectious diseases consult service was expanded to address the care of HCVinfected inpatients.
- We compared inpatient screening rates among eligible baby boomers five months before and five months after initiation of these interventions.

# INFORMATIONAL FLYER

# Hepatitis <u>C</u> is <u>C</u>urable!

But first it needs to be diagnosed

Prevalence of Positive HCV Antibody
1.6 % in the U.S. population<sup>2</sup>
7.3 % in the Bellevue E.D.\*,<sup>1</sup>

Only 13.3 % of eligible Bellevue inpatients are screened\*3

\*1945-1965 Birth Cohort

Whom to

screen?

- Baby Boomers (1945 1965)
- Injection or intranasal drug use ever
- Transfusion/transplant before 1992
  Received clotting factor before 1987
- Unlicensed tattoo or piercing
- Ever incarcerated
- HCV+ sexual contacts
- HIV +
- On dialysis
- Born in or had invasive medical procedures or blood transfusions in areas of highest prevalence: Central and East Asia and North Africa/Middle East

# IF HCV AB+ CONTACT:

#### **HCV PATIENT NAVIGATORS:**

Name #1, Contact Information
Name #2, Contact Information

Please leave a message with the following information:

Patient name, location, MRN, co-infections (HBV or HIV), estimated date of discharge, and a call back number. Patient will be seen within 24 hours for Hepatitis education and linkage to care (inpatient treatment initiation or outpatient appointment).

No insurance? No Problem!

#### RESULTS

Screening rates among baby boomers without a prior HCV antibody test admitted to the internal medicine service in 2017:

Prior to intervention period : 19.4% (187/962)

During intervention period: 18.1% (177/978)

P= 0.46, 95% CI -2.17 to 4.78

#### CONCLUSION

- Attempts at improving inpatient HCV screening rates using interventions focused on provider education and facilitation of linkage to care were ineffective.
- Low prioritization of screening interventions by providers caring for acutely ill patients may contribute more than knowledge gaps to screening failures.
- Despite administrative challenges, more effective error reduction strategies such as electronic medical record decision support tools should be implemented.<sup>4</sup>

Error reduction strategies<sup>5</sup>

Strategy	Power (leverage)
Fail-safes and constraints	11:
Forcing functions	High
Automation and computerization	<b>↑</b>
Standardization	
Redundancies	
Reminders and checklists	
Rules and policies	
Education and information	Low

Table reproduced from Cohen (2013)

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#### DISCLOSURES

No disclosures to report

# 2018 NIVC Viral Hepatitis Research Symposium

# Using Multifaceted and Multidisciplinary Care Coordination Techniques to Improve Linkage to Care and Treatment Success in Transient Populations

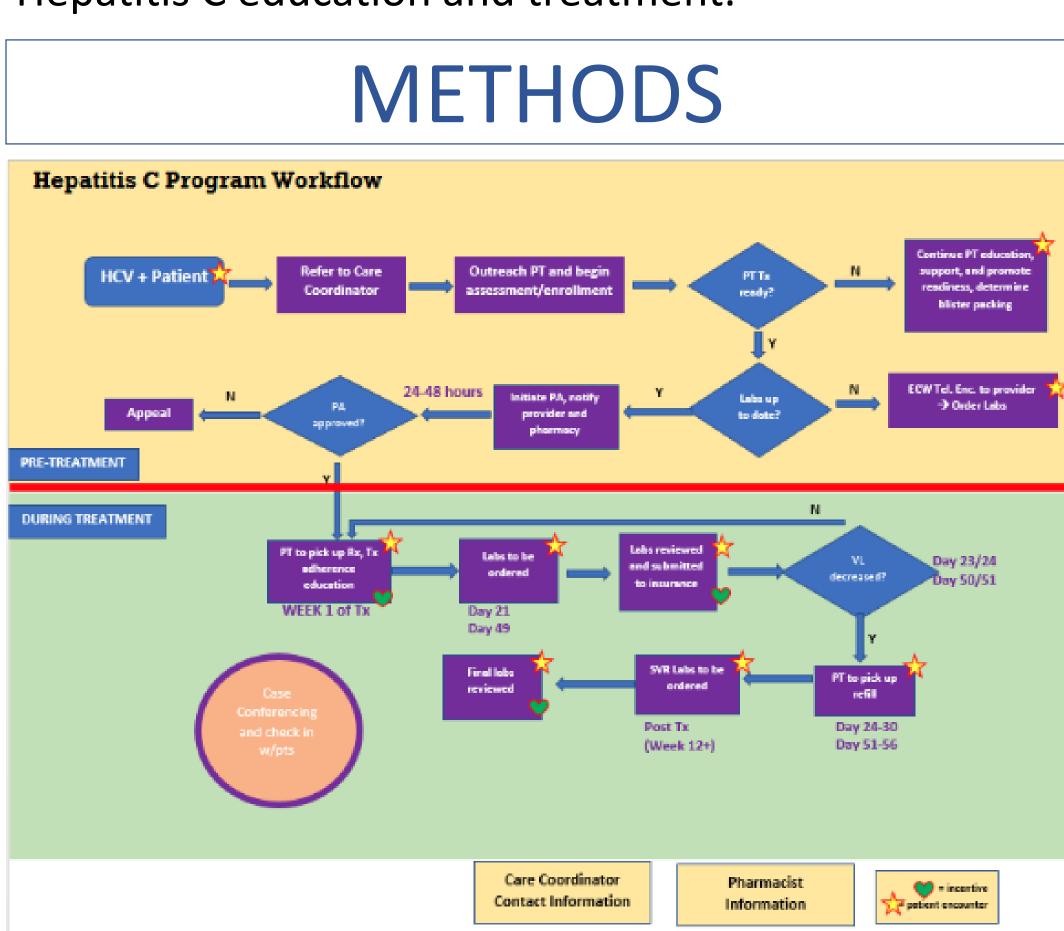
Medesa Garrett, LPN, HCV Program Coordinator; Lettice Maldonado, MPA, HCV/HIV Program Coordinator

#### BACKGROUND

Transient populations are often faced with several barriers, including, but not limited to, inadequate means of transportation, gaps in insurance coverage, and language and literacy barriers that ultimately contribute to health disparities that cannot be resolved through traditional health care systems. With the increasing number of diagnoses of Hepatitis C and the rising rates of Hepatitis C related deaths, it is imperative to take a holistic approach to engaging, educating, and providing treatment to the most vulnerable populations in New York City.

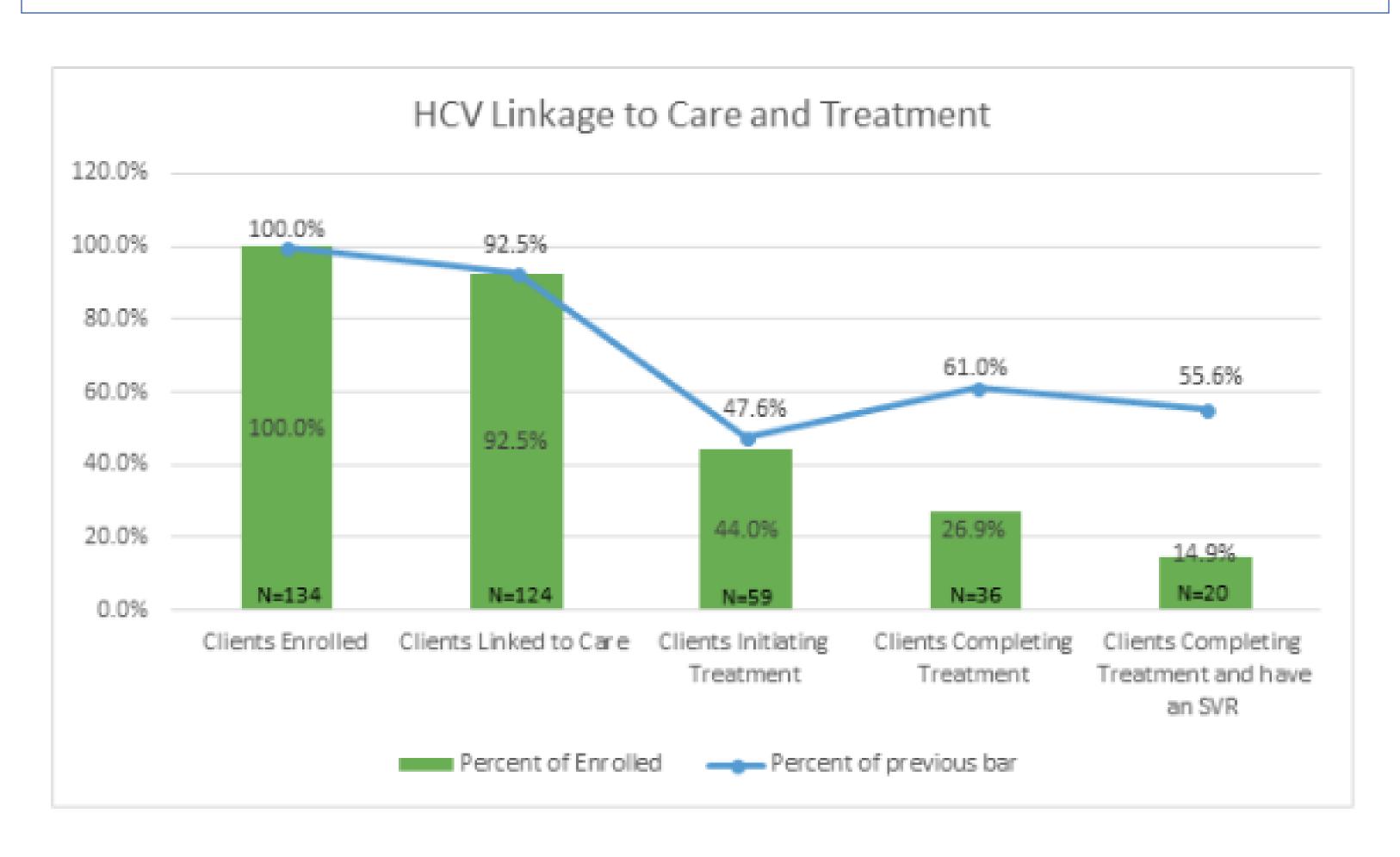
# PURPOSE

By employing a robust care coordination model with intensive outreach efforts, the goal is to improve health literacy, and increase rates of testing and linkage to care to ultimately eliminate Hepatitis C in transient populations. Through a comprehensive program, Brightpoint Health strives to empower clients to become advocates in their communities for Hepatitis C education and treatment.



**Fig 1.** A robust care coordination program focusing on intensive outreach, patient education, integrated workflows that put patients at the center of a multidisciplinary care team, and incentives aligned with important treatment milestones.

#### RESULTS



**Fig 2**. 134 patients, both mono- and dually-infected (HIV), were enrolled in a period of twelve months. Of these 134 patients, 124 (92.5%) were linked to care, of which 59 clients (47.6%) initiated treatment, with 36 of these 59 (61.0%) successfully completing treatment.

# BRIGHTPOINT HEALTH

# CONCLUSION

The results observed over the 12-month period confirm that multidisciplinary and intensive care coordination is advantageous to the retention and treatment of transient patients. Milestone incentives effectively promote appointment and treatment adherence, subsequently improving patient-care team relationships and treatment success rates. Through community engagement, education, and treatment advocacy, we can end the viral hepatitis epidemic within New York City's vulnerable populations.

# LIMITATIONS

The cohort for this study is limited to patients receiving services at Brightpoint Health Bronx based clinics. Thus, the population is not representative of all NYC boroughs.

# ACKNOWLEDGEMENTS

Thank you to our Brightpoint Health interdisciplinary team- care coordinators, primary care and behavioral health providers, health home staff, Grants department and Leadership Team.

Thank you to the following for supporting our efforts:

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HepCure Dashboard, Montefiore Medical Center,
Rockefeller University

Author(s): Jasmine Muniz-Cadorette, Lettice Maldonado, Medesa Garrett

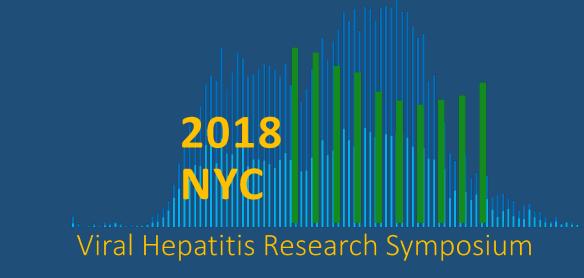
#### DISCLOSURES

None.

# A Model for Patient-Centered Hepatitis C Treatment within Primary Care

2018 NYC

Dr. Russell Perry, Jared Smith, Courtney Dower
BronxCare Health System



# BACKGROUND

As medical treatment options for Hepatitis C have advanced tremendously in recent years, now virtually all infected patients qualify for treatment. With such a broad population in need of treatment, added focus on identifying and eliminating potential treatment barriers has become increasingly more important. The Department of Family Medicine at BronxCare Health System has incorporated a teambased, Patient-Centered Group Treatment Model (PCGTM) to its Hepatitis C care that combines a group model with community health workers (CHW's) partnering directly with Hepatitis C primary care providers.

### PURPOSE

The Hepatitis C treatment team at BronxCare Health System seeks to improve upon the "treatment cascade" as it relates to Hepatitis C treatment by identifying and eliminating barriers to cure for patients at the individual level while systematically implementing changes to eliminate such barriers for current and future patients.

# METHODS

- Monthly Hepatitis C group meetings: allows patients to be connected with previously cured patients ("Proven Peers"), offering inspiration and support from patients with similar life experiences while also serving as a time to educate patients on treatment options, risk factor modification, and health implications of being cured.
- CHW-PCP partnership: provides HepC patients with a dedicated team to assist with appointment adherence, medication compliance, Hepatitis education, and non-health-related barriers to care. This includes a dedicated Hepatitis C Community Health Worker, partnering with a dedicated Hepatitis B and/or HIV Community Health Worker when applicable.
- Hepatitis C Outreach Liaison: meets with patients and their Methadone Maintenance Treatment Program (MMTP) counselors to discuss Hepatitis C treatment and potential barriers to care.
- Linkage Hybridization: training MMTP Counselors to identify clients infected with HCV.

### RESULTS

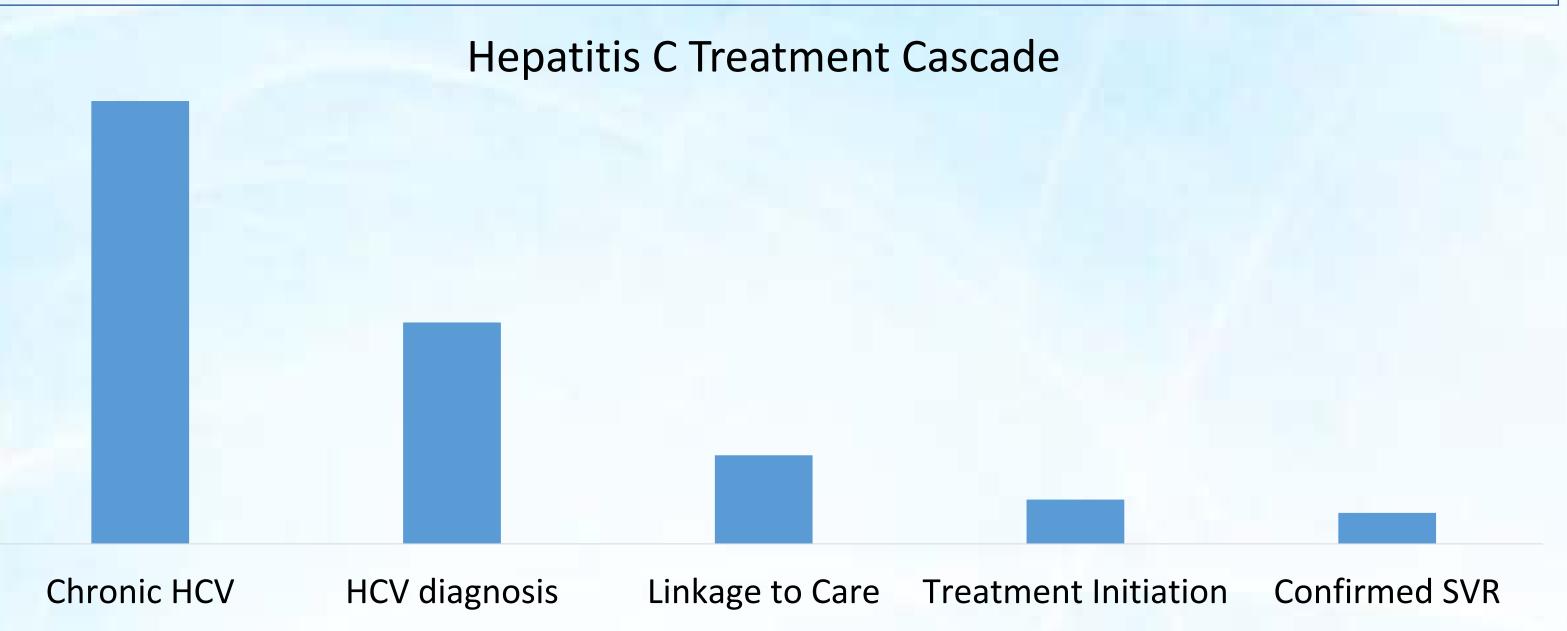


Fig. 1: An example of what has been traditionally accepted as the cascade of treatment for Hepatitis C. As depicted above, roughly 20% of HCV patients are connected to care. Of that 20%, roughly 10% begin therapy, and roughly 7% of that 10% completed therapy and attain SVR.

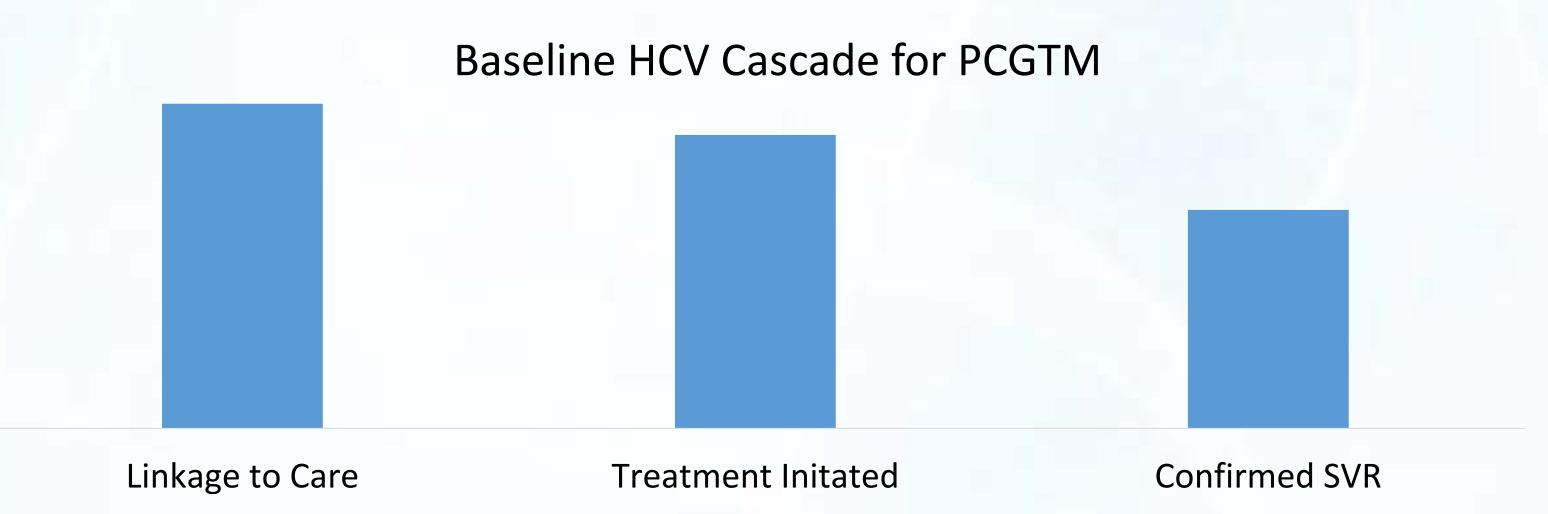


Fig. 2: In years 2016-2017, there were 53 patients linked to care with this provider for treatment of Hepatitis C. Of those, 47 went on to begin treatment. 35 of those 47 patients were later confirmed to have attained SVR.

# Traditional Model Cured Unknown

Fig. 3: According to the currently accepted HCV treatment cascade, 20% of HCV patients will be linked to care, and 7% of those 20% will go on to attain SVR.

# PCGTM 2016-2017 Cured Unknown

Fig. 4: Patients connected to care 2016-2017- At time of documentation, 35 of the 53 patients linked to this provider had attained SVR. Of the remaining 17 patients, 5 were either currently being treated or awaiting test of cure via SVR.

# Traditional Model PCGTM

Linkage To Cure

Fig. 5: Comparing outcomes of the Traditional HCV Treatment Cascade (35% cured) to the PCGTM (74.5% cured). For the sake of comparison, the 5 patients currently on treatment or awaiting SVR testing were omitted.

As previously mentioned, the implementation and data analysis of this model as it pertains to collaborating with Methadone Treatment Programs is ongoing. As such, the full results of this recent addition to the project are yet to be analyzed. The data presented is an analysis of data from patients of this program years 2016 and 2017.

#### CONCLUSION

It is our belief that our Patient-Centered Group Treatment Model for Hepatitis C can be utilized in a wide variety of clinical settings throughout New York City and beyond as we continue to fight toward a "Hep Free NYC." While this model had previously been implemented in a program treating patients only on a physician referral or walk-in basis, the BronxCare Health System has teamed up with three local Methadone Treatment Centers in order to reach their high-risk population. While this branch of our program has yet to yield many quantifiable results given it's recent implementation, it should be noted that our Hepatitis C treatment team has noticed a marked decrease in patients being lost to follow-up with these patients. Since the beginning of 2018, there has yet to be a single patient from one of our partnering Methadone Programs to be lost to follow-up.

# LIMITATIONS

Each of the three methadone programs we've been working with since January have 300+ patients actively infected with Hepatitis C. Connecting patients at such a scale has presented itself as a barrier of sorts in terms of scheduling. To solve this, the Department has implemented a full-scale capacity building project by ramping up the Hepatitis education of its faculty and working to incorporate residents, junior attendings, and seasoned attendings into this program.

# ACKNOWLEDGEMENTS

Dr. Russell Perry, Associate Chairman of the
Department of Family Medicine
Jared Smith, Hepatitis C Outreach Liaison
Courtney Dower, Program Manager, HIV/HepB/HepC
Mandeep Kataria, Ross University School of Medicine
Stephen Sebastian, Ross University School of
Medicine

# DISCLOSURES

The Hepatitis Community Health Worker is graciously funded through the City Council Viral Hepatitis Initiative - Check Hepatitis C program (run through the NYCDOMH).



# "The Test": An Educational Comic Book **Encouraging Hepatitis B Screening**



Janice Lyu, MS<sup>1</sup>; Michelle Yan<sup>2</sup>; Rachelle Ocampo, EdM<sup>1</sup>; Matthew Chin<sup>1</sup>; Amy Tang, MD<sup>1</sup>; Perry Pong, MD<sup>1</sup>

1. Charles B. Wang Community Health Center, New York, NY

2. Brandeis University, Waltham, MA

#### Background

Approximately one-third of the world's population has been infected with hepatitis B virus (HBV) and two-thirds do not know their status. HBV screening and understanding one's HBV status is a critical step towards hepatitis B elimination—it prevents new infections in those susceptible, identifies those who are at risk of reactivation, and links infected persons to essential care and treatment to prevent serious liver complications.

To encourage HBV testing in at-risk populations, we developed a culturally appropriate educational comic book, "The Test" in English and Chinese.

The Charles B. Wang Community Health Center (Health Center) is a Federally Qualified Health Center that serves a primarily low income and low health literate Asian population in Greater New York with a high burden of HBV infection.

#### Aim

To evaluate the change in patients' HBV attitudes and knowledge after reading "The Test," an educational comic book created to raise awareness about HBV screening.

#### Methods

We administered pre- and post- surveys in Chinese and English among 100 adult patients randomly selected in the waiting rooms of the Health Center.

The 23-questionnaire survey assessed (1) the patient's demographics, (2) familiarity with HBV (based on Likert scale of extremely familiar to not at all familiar), (3) attitudes (based on 5 point Likert scale -extremely likely = 5 to extremely unlikely= 1), and (4) knowledge using true and false questions assigning one point for every correct answer allowing a perfect score of 14.

Pre-and post- knowledge and attitudes were analyzed and mean scores were compared using a paired t-test. Knowledge gained and attitudes changed were further compared by patient's language preference (English vs. Chinese). Independent t-test was used to determine significance (p<0.05) between the two language subgroups.













Confused knowledge

#### Results

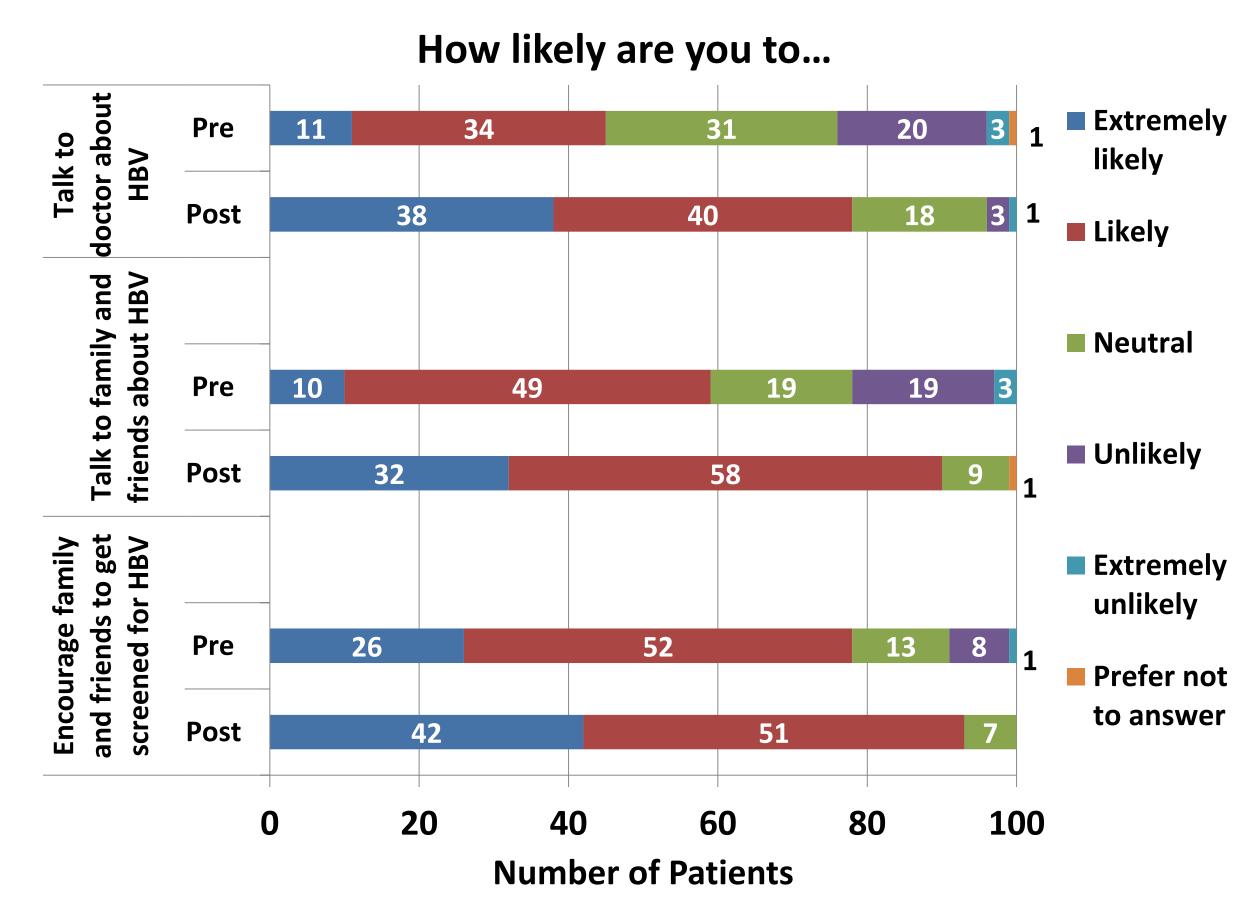
Gained

#### **Study Participant Characteristics**

Among the 100 adult patients surveyed, 51% were male, 78% ethnic Chinese, and 57% were limited English proficient with Chinese as their preferred language. A total of 85 participants reported their age and the mean age was 37.5 ± 13.1 years old (range 20 to 67 years). Of the 100 patients, 40% completed a high school degree or lower, 18% completed a two-year degree or some college, 39% had a Bachelor's degree or higher, and 3% preferred not to answer. Overall, 60% of the study participants were somewhat or slightly familiar with HBV.

#### Figure 1. Attitudes before and after reading "The Test"

Patients were significantly more likely to encourage and talk about HBV screening with family and friends as well as doctors after reading the comic book than before (p<0.01).



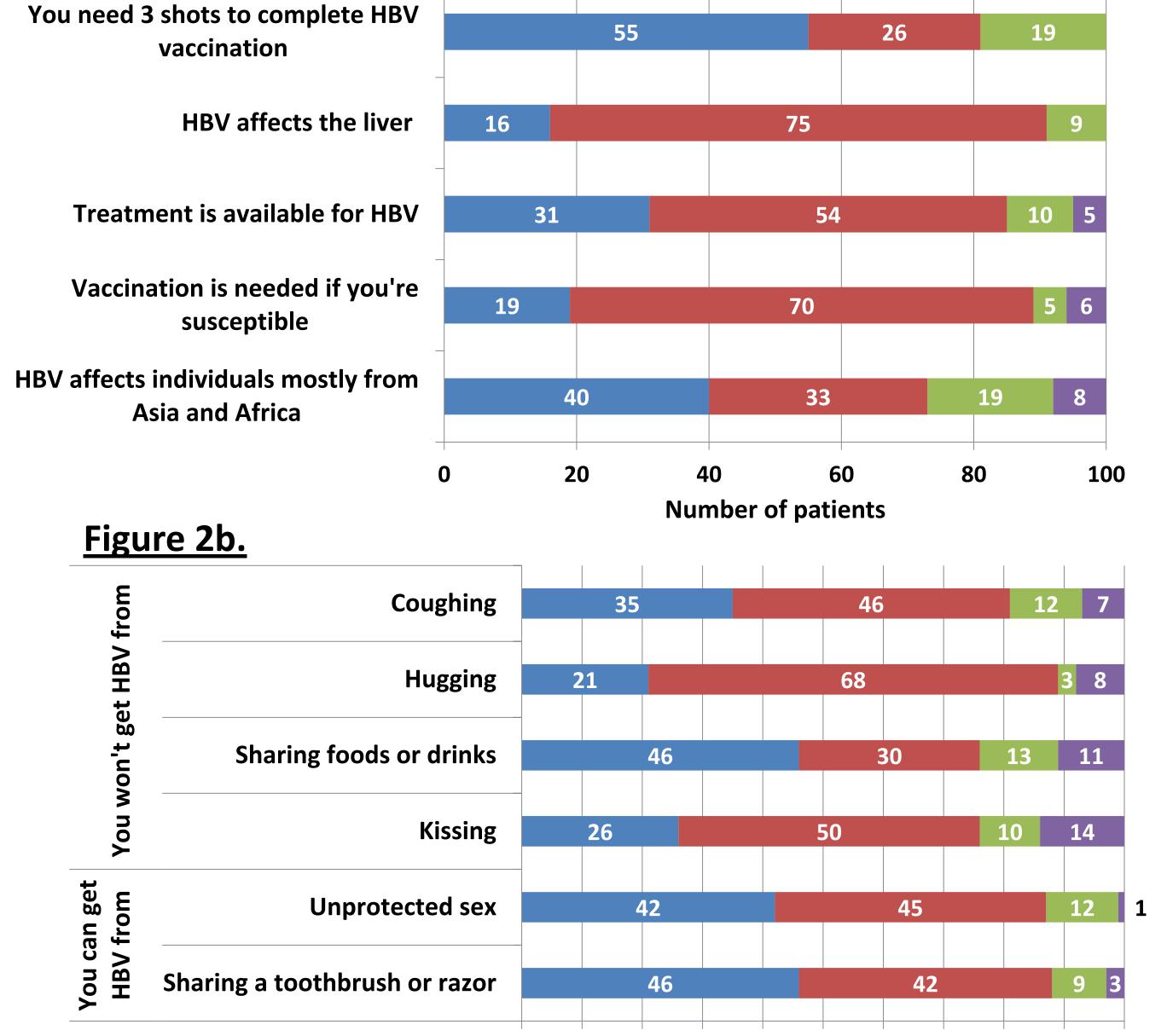
#### **Knowledge before and after reading "The Test"**

Compared with before reading the comic book, patients' mean scale scores for HBV knowledge significantly improved after reading the comic book (9.25 vs. 12.09, p<0.01).

Did not learn\*

#### Figure 2a. The Myths vs. Facts

Already knew



\* Continued to answer "don't know" or incorrectly in pre and post-survey

Number of patients

**‡** Answered correctly in pre-survey but "don't know" or incorrectly in post survey

#### Results (continued)

#### Chinese vs. English-speaking Participants

Among the Chinese-speaking group, 65% (37/57) had a high school degree or less, whereas 74% (32/43) of the English-speaking group had a Bachelor's degree or higher. Compared to those who preferred English, fewer participants who preferred Chinese were extremely or moderately familiar with HBV (16% vs. 42%).

There were no significant differences in knowledge gained (p=0.64) or likelihood of talking to a doctor (p=0.99) or family and friends (p=0.87) about HBV between the Chinese and English-speakers. However, English-speakers were significantly more likely to encourage family and friends to get screened for HBV compared to Chinese-speakers (0.56 vs. 0.30 increase in likelihood, p=0.03).

#### Conclusion/ Discussion

Despite HBV disproportionately affecting the Asian Americans and Pacific Islanders, the lack of familiarity with HBV among limited English proficient Chinese participants highlights the need to provide more targeted outreach and education with culturally appropriate resources to those with linguistic and cultural barriers.

The comic book is an effective tool in both language groups to raise awareness about HBV and encourage and educate patients with varying levels of education on HBV screening, prevention, and management.

Further studies and translations are needed to study the effect of the educational comic book in other high risk populations.

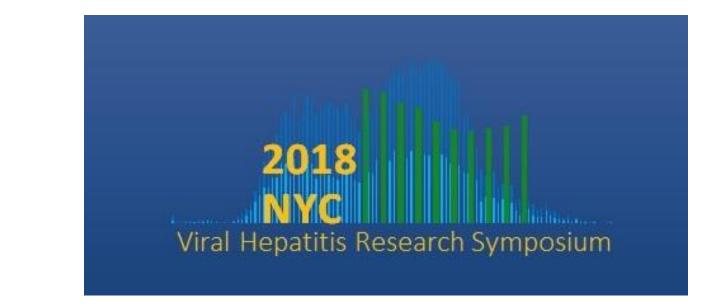
#### **Acknowledgements/ Disclosures**

We would like to thank the comic book writer, Amy Chu, and illustrator, Louie Chin, for partnering with the Health Center to create, "The Test," and Miranda Wong Tang for funding the comic book.

The authors have no conflicts of interest to disclose.



# Assessing trends in hepatitis B virus infection and immunity at a community health center with universal screening practices



Amy S. Tang, MD; Janice Lyu, MS; Qingqing He, MPH Charles B. Wang Community Health Center, New York, NY

IV. Results

#### I. Background

Universal childhood vaccination programs since the 1980s have sharply reduced new hepatitis B virus (HBV) infections in endemic countries while increasing immunity from vaccination.

Despite global efforts to implement childhood HBV vaccine programs, one-third of the world's population has been infected and there are currently 257 million individuals living with chronic HBV infection and most do not know their status.

Because of recent reports of HBV reactivation in patients undergoing immune therapy, chemotherapy, or treatment for hepatitis C, persons at risk should receive complete HBV serology testing and be counseled on their HBV reactivation risk.

Charles B. Wang Community Health Center is a Federally Qualified Health Center in New York City that serves a primarily low income Asian population with a high burden of HBV infection.

#### II. Aims

To assess trends in HBV infection and immunity at a health center with universal screening practices

#### III. Methods

#### Study design

We performed a retrospective chart review of adults age 18 years and older screened from 1997 to 2017 with

- HBV surface antigen (HBsAg)
- HBV surface antibody (anti-HBs)
- HBV total core antibody (anti-HBc)

Only patients who completed all 3 HBV serology tests were included in this study.

Screening results were categorized by infection and immunity states, then further analyzed by patients' sex, birth year, place of origin, and participation in the local health department's HBV household contacts program.

#### Data analysis

Chi square analysis and univariate and multivariate logistic regression were used to determine significance and odds ratios between subgroups.

#### Table 1. HBV status by category

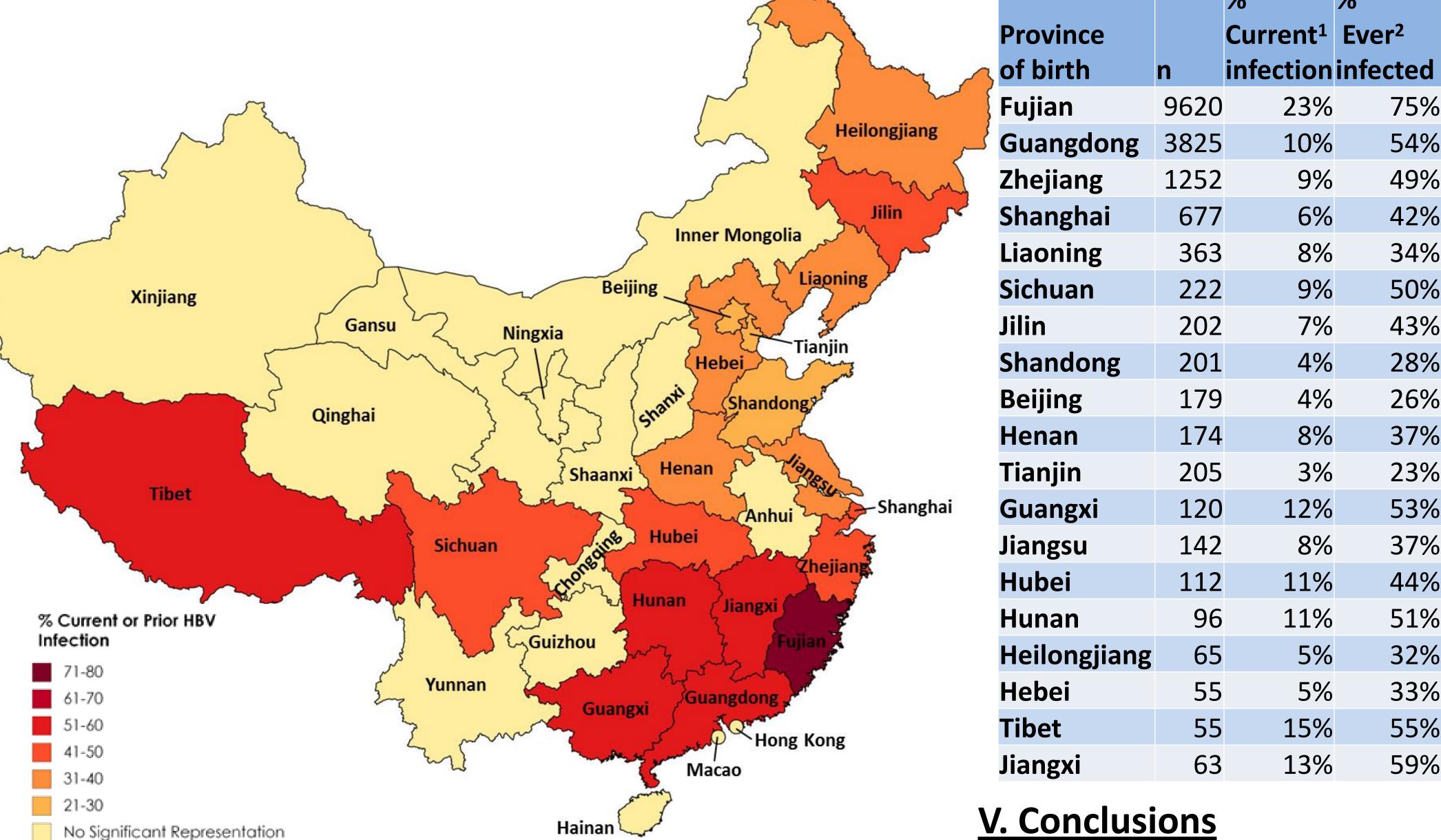
- Of 25,565 patients screened for HBV, 13% were currently infection, 52% were infected at some point, 33% were immune from vaccination and 15% were susceptible.
- Current HBV infection was highest among those with a family history of HBV (48%) or those living with HBV infected individual (22%).
- Significant predictors (p<0.001) of ever infected included birth before 1980</li> (OR 2.24; 95% CI 2.12-2.38), male sex (OR 1.39; 95% CI 1.31-1.47), and China-born (OR 12.96; 95% CI 10.99-15.28; U.S. born reference group)

Category	Subcategory	N	% Current infection <sup>1</sup>	% Ever infected <sup>2</sup>	% Immune by vaccine <sup>3</sup>	% Susceptible <sup>4</sup>
	ral screening opulation	25565	13%	52%	33%	15%
	Household contacts	773	22%	70%	18%	11%
	FHx of HBV	431	48%	76%	19%	6%
Year of	Before or in 1980	16424	13%	60%	26%	15%
birth	<b>After 1980</b>	9141	14%	39%	47%	14%
Sex	Female	14421	11%	48%	37%	14%
	Male	11144	16%	57%	29%	15%
	U.S.	1875	1%	9%	60%	31%
	China	18664	16%	61%	29%	9%
Country	Hong Kong	993	6%	30%	43%	21%
Country of birth	Taiwan	438	11%	49%	35%	15%
OI BII CII	Malaysia	892	4%	25%	50%	25%
	Vietnam	229	10%	53%	37%	10%
	Indonesia	273	4%	28%	39%	33%

<sup>1</sup>All HBsAg(+) <sup>2</sup>All anti-HBc(+) <sup>3</sup>HBsAg(-), anti-HBc(-), anti-HBs(+) <sup>4</sup>HBsAg(-), anti-HBc(-), anti-HBs(-)

#### Figure 1. Percentage of HBV infection by Chinese province/municipality

Fujian province had more than double the HBV burden compared to surrounding provinces



#### V. Conclusions

Data from our community health center demonstrate a high burden of current HBV infection (13%) and ever HBV infection (52%) most commonly among males born before 1980 who were born in China.

Our trend analysis is reflective of effective implementation of hepatitis B vaccination, however, the decline in anti-HBs among U.S. born persons born after 1985 is concerning. This may be due to waning anti-HBs titers, a possible decrease in vaccination, or because U.S. born persons were screened after risk assessment and may not represent a general population of this age group.

#### VI. Recommendations

Our results demonstrate the importance of complete HBV testing with HBsAg, anti-HBc, and anti-HBs to identify and counsel patients with current HBV infection or at risk for HBV reactivation, and assess effectiveness of public health interventions.

#### Acknowledgements/Disclosures

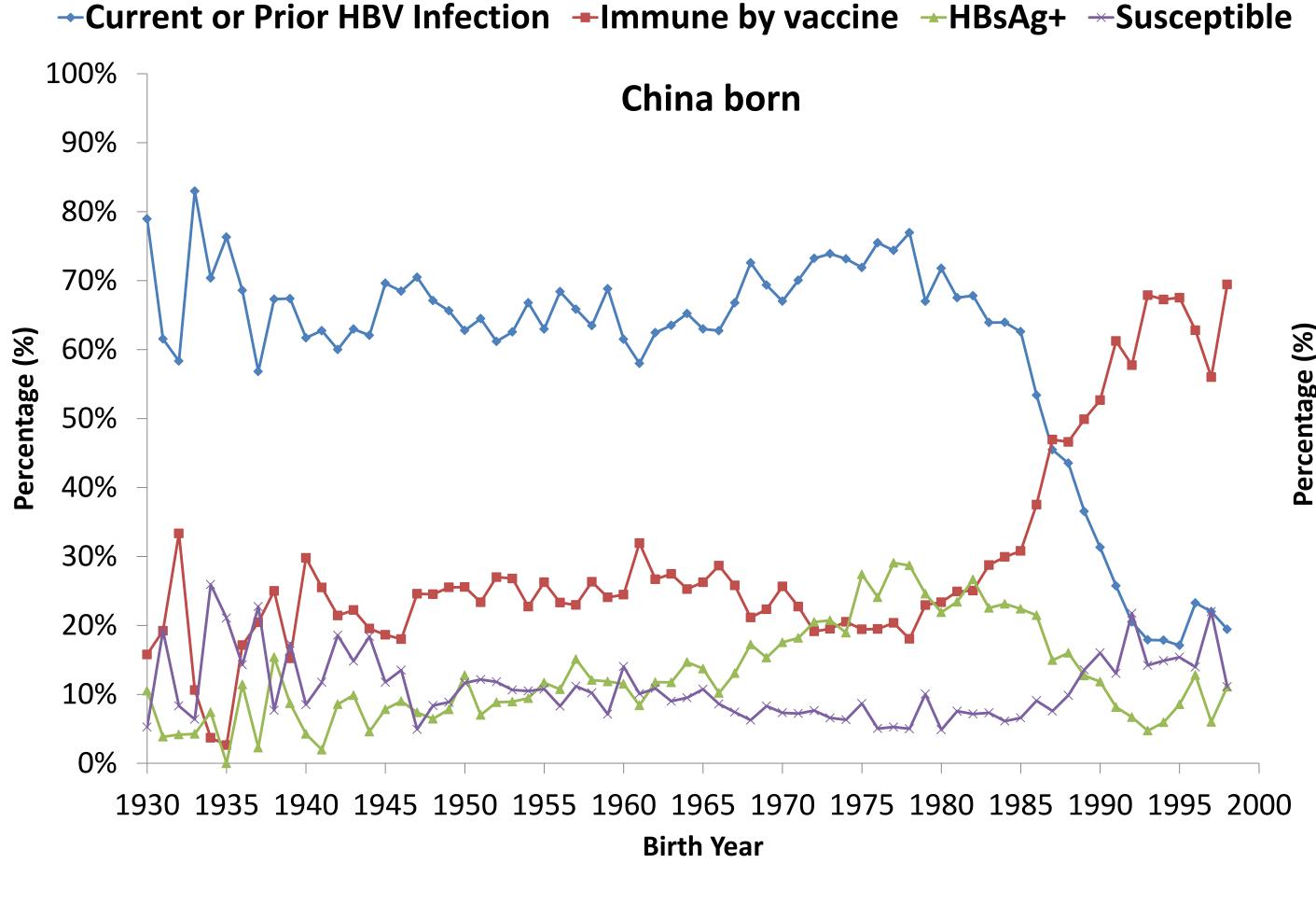
We would like to thank Drs. Su Wang (St. Barnabas Center for Asian Health) and Aaron Harris (Centers for Disease Control and Prevention) for consultation on this research, Kevin Lin (Brown University) for help with data analysis, and Miranda Wong Tang for funding this study.

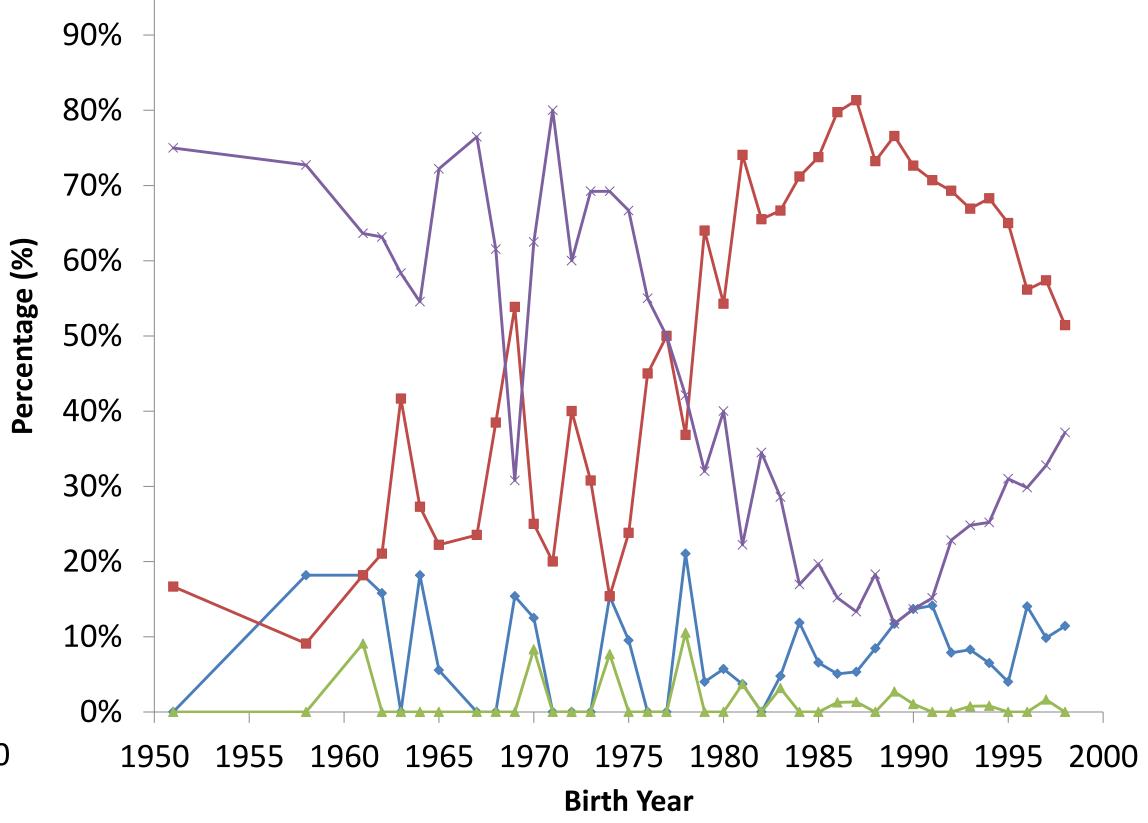
The authors have no conflicts of interest to disclose.

#### Figure 2. Trends in HBV infection vs. immunity by birth year

• HBV infection sharply decreased in China-born individuals born after 1980 with a corresponding increase in immunity from vaccination, whereas among U.S.-born individuals born after 1985, immunity from vaccination appeared to decrease with an increase in susceptibility

100%





U.S.-born

Preliminary screening results outside the 1945-1965 birth cohort: A forgotten population for HCV?

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Division of Infectious Diseases, Columbia University Medical Center-New York Presbyterian Hospital



## BACKGROUND

2018

Viral Hepatitis Research Symposium

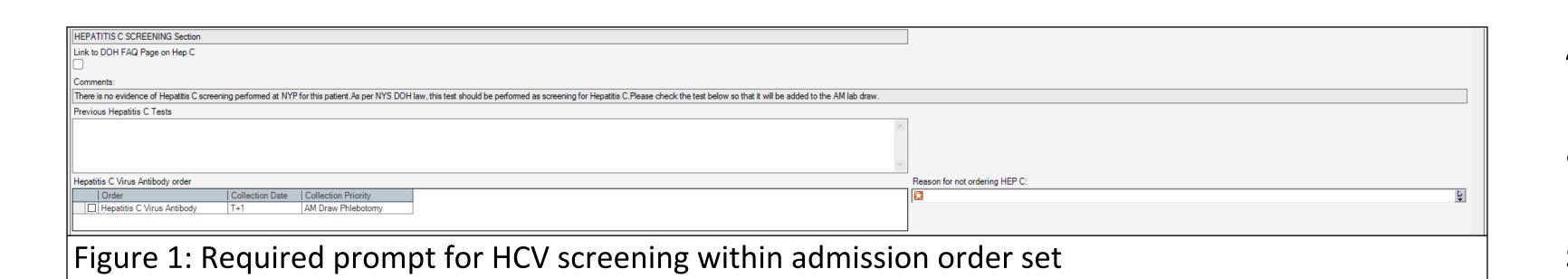
NYC

Until recently, hepatitis C virus (HCV) infection was most prevalent among those born between 1945 and 1965. As a result of this epidemiologic trend, the Centers for Disease Control and Prevention (CDC) recommend screening for HCV only among this birth cohort or in patients with known risk factors for HCV infection, such as injection drug use or hemodialysis [1]. Recent data shows increasing HCV incidence among younger patients, likely reflecting the ongoing epidemic of opioid use disorder (OUD) [2]. However patients with OUD and other people who inject drugs (PWID) face significant stigma at many levels of society, including among health care institutions [3]. As a result, some younger patients may be reluctant to disclose their injection behavior, resulting in missed opportunities for targeted HCV screening by health care providers. Universal screening may therefore facilitate earlier recognition among infected individuals.

#### **METHODS**

At our center, the admission order set previously included a required prompt to order HCV screening for patients born between 1945 and 1965, with a hard stop (see Figure 1). In December 2017, we expanded the default order to include all patients above the age of 18. We compared rates of HCV screening and positivity during the first three months of this policy to similar months in the preceding year.

We also reviewed the charts of HCV-positive patients to identify documented risk factors and forms of social vulnerability, including: age; status of housing, immigration, insurance and employment; criminal justice involvement; history of transactional sex; self-identification as a transgender woman or man who has sex with men (MSM); PWID status and other mental health comorbidities. Charts were also reviewed to determine the admission diagnosis and whether the diagnosis of HCV was previously known at the time of admission. Individuals were then categorized as those born either before or after the birth cohort. Chi-square and Fisher's exact tests were performed to assess differences between groups.



#### RESULTS

From December 2017 to February 2018, a total of 11,118 patients were screened with 389 (3.5%) positive results, compared with 8,423 patients and 361 (4.3%) positives during the same months in 2016-2017. Outside the birth cohorts, 179 (1.1%) patients were HCV-positive (3.7% and 1.9% among those born before 1945 and after 1965, respectively) in 2017-2018 compared with 117 (2.3%) in 2016-2017 (6.1% and 1.9%, born before and after the birth cohort, respectively).

Thirty-five HCV-positive inpatients were born outside the birth cohort. Twenty-one (60%) had no documented risk factors. Among the cohort born after 1965, only three out of 17 (17.6%) patients had no known risk factors, compared with all 18 (100%) patients born before 1945. Documented factors associated with social vulnerability were highly prevalent among HCV-positive individuals born after 1965, but uncommon in those born before 1945. Specifically, compared with those born before the birth cohort, individuals born after 1965 were significantly more likely to have known HCV risk factors (i.e. PWID or hemodialysis), mental health comorbidities and a history of homelessness, unemployment, transactional sex, or criminal justice involvement (see Table 1). Younger HCV-positive individuals were also more likely to identify as MSM or transgender women and were more likely to have a known diagnosis of HCV at the time the HCV antibody test was ordered.

Table 1: HCV risk factors and forms of social vulnerability among those testing positive and born before and after the 1945-1965 birth cohort						
	Born before 1945	Born after 1965	P-value			
	N = 18	N = 17				
PWID or hemodialysis (HD)			p < 0.01			
PWID	0 (0%)	13 (76.5%)				
HD	0 (0%)	1 (5.8%)				
Housing status			p < 0.01			
Housed	17 (94.4%)	8 (47.1%)				
Unstably housed/homeless	1 (5.6%)	8 (47.1%)				
Unknown	0 (0%)	1 (5.9%)				
Employment status			p < 0.01			
Employed	2 (11.1%)	2 (11.8%)				
Retired	14 (77.8%)	0 (0%)				
Disability	0 (0%)	8 (47.1%)				
Unemployed	0 (0%)	6 (35.3%)				
Unknown	2 (11.1%)	1 (5.8%)				
Mental health comorbidities	3 (16.7%)	12 (70.6%)	p < 0.01			
Transactional sex	0 (0%)	2 (11.8%)	p < 0.01			
MSM	0 (0%)	2 (11.8%)	p < 0.01			
Criminal justice involvement	1 (5.6%)	8 (47.1%)	p < 0.01			
Previously known diagnosis	9 (50%)	12 (70.6%)	p < 0.01			

Admission diagnoses directly related to substance use disorders and mental health comorbidities were also relatively common among individuals born after 1965, including severe bacterial infections (n = 4), suspected overdose (n = 2) and depression/suicidality (n = 3). No such admission diagnoses were found among individuals born before 1945.

#### CONCLUSION

Expanding hospital admission-based HCV screening to include universal testing for adults detected a similar overall prevalence of HCV-infection compared with previous years. However, two substantially different populations were discovered. Documented substance use disorders and social vulnerability were highly prevalent in HCV-positive patients born after 1965 and rare in those born before 1945.

# LIMITATIONS

These data represent a small, observational sample, which excludes patients visiting the ED not meeting criteria for admission. Our analysis also depended on retrospective chart review, so risk factors and forms of social vulnerability may not have been uniformly elicited from patients testing positive for HCV by their inpatient health care providers and social workers.

#### REFERENCES

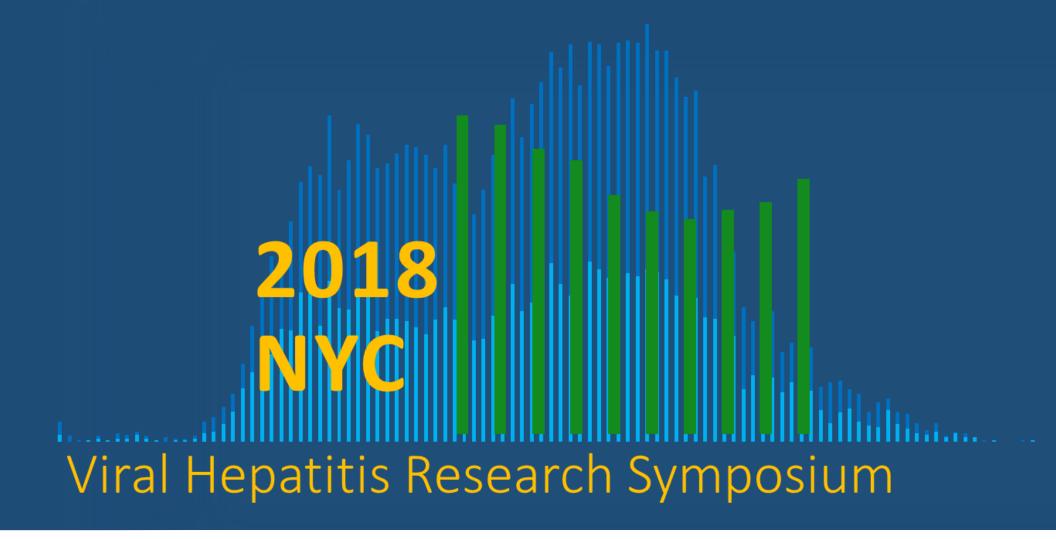
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https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm.

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# DISCLOSURES

Supported by funding from Gilead Sciences Inc. through a grant from the FOCUS program.



# HIV & HCV in Family Medicine:

# Laying the Data Groundwork for Meaningful Intervention Vanessa Pizarro, LMSW Institute for Family Health

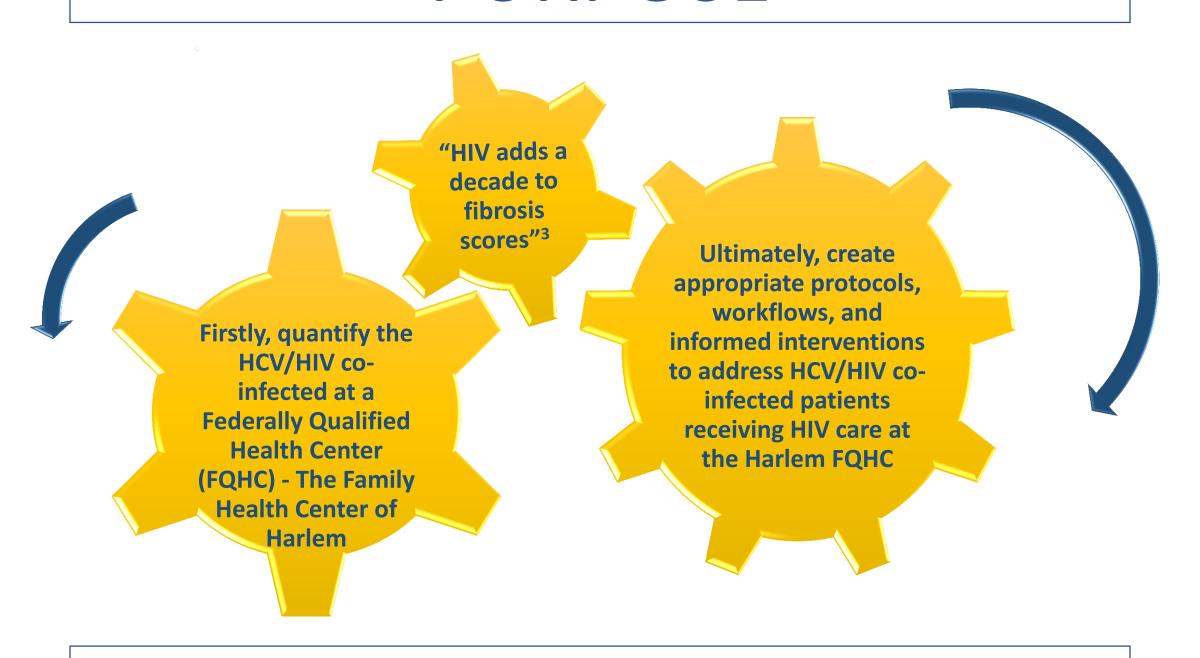


#### BACKGROUND

New York City Department of Health and Mental Hygiene (NYC DOHMH) initiative to address people living with both Hepatitis C (HCV) and HIV infections resulted in Project SUCCEED¹. This initiative highlights disproportionate morbidity/mortality rates among the HCV/HIV co-infected population. Research (2018) confirms that a significant number of persons who are HCV/HIV co-infected are regularly engaged in Primary Care settings.

Therefore, HCV/HIV co-infected patients are routinely diagnosed and/or treated by Primary Care providers. Despite advancements in simplified treatments<sup>2</sup>, many of these patients remain untreated and uncured in this setting. Of the Institute's approx. 1100 HIV+ patients, it remains unclear the precise number of HCV/HIV co-infected, those eligible for treatment, and those successfully treated. Upon obtaining accurate population data, we intend set the foundation for clear test/treatment protocols and, bio-psychosocial supports to improve cure rates of the HCV/HIV co-infected at the Institute.

# **PURPOSE**



#### **METHODS**

Patient level data was gathered from various sources –

- 1. Electronic medical record, EMR (Epic)
- 2. Data analytics software (Business Objects)
- 3. Commercial Laboratory Reports (Bio-Reference)

Reports were created to obtain preliminary numbers of HCV/HIV co-infected across the Institute. Once obtained, reports were analyzed to refine co-infected data by site, by listed diagnosis, and listed PCP.

Primarily, reports utilized were those specific to tracking and managing the Institute's HIV population.

# METHODS

Clinical discussions were conducted with the Institute's primary care providers, collecting information on current testing, treatment, and medical management practices. Specific HCV diagnosis codes were pooled to isolate existing patient population, and cross referenced with existing clinic HIV population data. Literature reviews were conducted to gather relevant models of intervention for HCV treatment in primary care. These will be used to inform the development of best practice guidelines for treatment of HCV/HIV co-infected at the Family Health Center of Harlem.







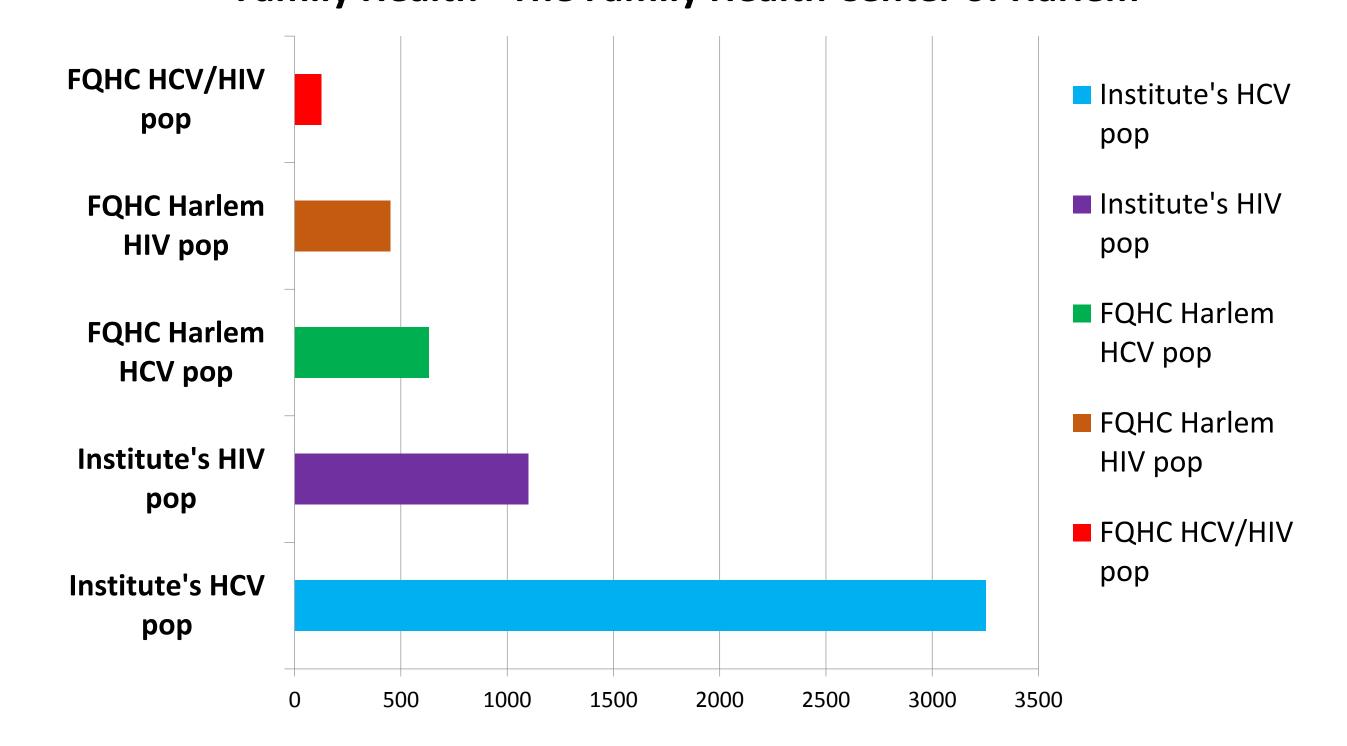
#### RESULTS

Preliminary data indicated 3,251 patients across 31 Institute clinics have had an HCV diagnosis attributed to them by an Institute medical provider. Of those preliminary patients, an estimated 632 were attributed to the FQHC Family Health Center of Harlem. Further review indicated that of the 632 patients, approx. 20% were identified as HCV/HIV co-infected. Further analysis is necessary via chart reviews to confirm more precise population figures, as several data reporting systems were used to obtain these initial results.

Initial chart reviews of Harlem's HCV/HIV co-infected overwhelmingly demonstrated –

- 1. unknown/unconfirmed HCV diagnosis status
- 2. inconsistent HCV diagnosis used by providers
- 3. unknown/unconfirmed HCV treatment status
- 4. outstanding/indeterminate-status of GI consult referrals

# 2017 Preliminary Data - HCV/HIV at The Institute for Family Health\* The Family Health Center of Harlem



\*Total Institute patient census: Approx. 117,000 patients in 2017

#### CONCLUSION



With Harlem HCV/HIV data, individual chart reviews will be conducted to determine –

- 1. Precise HCV Diagnosis in chart
- 2. HCV Antibody result, with date
- 3. HCV RNA result, with date
- 4. HCV Genosure result, with date
- 5. HCV Fibrosure result, with date
- 6. HCV SVR 12 result, with date

This project has created critical momentum and interest within the organization. An Institute HCV Workgroup has been formed in response to this project, including staff of diverse skills and disciplines. The group's focus will be on the development of appropriate protocols, workflows, and informed interventions (medical and social) to improve HCV outcomes for all patients, starting first with HCV/HIV coinfected patients at the Harlem FQHC.

## LIMITATIONS

Limitations arose during data collection and chart review process. Despite the Institute's incredible advancements with EMR use, this inadvertently caused challenges in collecting and tracking data.

The Institute offers several hundred HCV diagnosis types in Epic for providers to chose from when documenting in charts. HCV diagnoses chosen vary widely by provider. Inconsistent and poor documentation of treatment details was overwhelmingly present in charts, highlighting gap in clear and concise documentation of HCV treatment status.

# **ACKNOWLEDGEMENTS**

Natana Cruickshank, MPH Robert Murayama, MD, MPH Michelle Osterman, RN, MPH Rebecca Green, LMSW

# DISCLOSURES

No conflicts to disclose

<sup>1</sup>Project SUCCEED: Curing Hep C In People with HIV in NYC, <a href="https://hepfree.nyc/projectsucceed/">https://hepfree.nyc/projectsucceed/</a>

<sup>2</sup>Diagnosis and Management of Hepatitis C Infection in Primary Care Settings Debra Guss, MS, APRN, ANP-C1, Jagannath Sherigar, MD1, Paul Rosen, MD2, and Smruti R. Mohanty, MD, MS FACP1 1 Division of Gastroenterology and Hepatobiliary Diseases, New York

State HCV Provider Webinar Series (2018), Epidemiology of HCV and HCV/HIV Co-Infection, file:///C:/Users/vpizarro/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/K3OXJXQ6/06 NYSHCVCurriculum HCV-HIV.pdf

The Added Benefit of Patient Navigation Services Increasing Health Promoting Behaviors of Patients in Methadone Maintenance Programs During Treatment of Hepatitis C

Joseph Constantino, DO; Michael Ma, MD; Christine Cervini, DNP, ANP-BC; E. Caroline Snell, MPA; llan Weisberg, MD, MSc

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# BACKGROUND

- Providing adequate medical care for high risk individuals such as injection drug users continues to be a difficult endeavor.
- There has been growing evidence towards the efficacy of care coordination in the treatment of HCV and Hepatitis vaccinations in methadone maintenance programs.<sup>2</sup>
- The ability of care coordination services to provide additional resources and referrals for both the medical and psychological needs of these patients is important, yet unmeasured to this point.

# **OBJECTIVE**

• In this study, we aim to highlight the additional benefits of care coordination services during the treatment of HCV-seropositive patients recruited from methadone maintenance programs.

# METHODS

- Retrospective chart review.
- Single metropolitan urban center.
- Recruited subjects who are enrolled in methadone maintenance treatment undergoing HCV treatment with the support of patient navigator.
- Review of EMR for subject's adherence in treatment of HCV and health maintenance.

Table 4. Average Reimbursement rate for select Procedures					
Procedure	Average Reimbursement Rate (\$)*				
Colon Cancer Screening (Colonoscopy)	354				
Variceal Screening (EGD)	287				
Lung Cancer Screening (LDCT)	181				
AAA Screening (Abdominal U/S)	105				
TTE	269				
Carotid U/S	228				
*based on Medicare reimbursement rates found on www.cms.gov					

#### RESULTS

Table 1. Patient Chara	racteristics (n = 58)	Table 2. Treatment Disposition			
Age (mean) 52	2	Disposition	Completed Treatment	25 (43%)	
Gender 44	4 Men		Pretreatment Evaluation	14 (24%)	
	4 Women		On Treatment	13 (22%)	
	lispanic 43% (n = 25) aucasian 38% (n= 22)		Lost to Follow up	4 ( 7%)	
	AA 17% (n = 10)		Died	1 (2%)	
O <sup>-</sup>	Other 2% (n = 1)		Treated Elsewhere	1 (2%)	
Genotype 1a	a 66% (n = 38)	Approved	Elbasvir/Grazoprevir	19 (49%)	
	1b 10% (n = 6)	Regimen	Glecaprevir/Pibrentasvir	9 (23%)	
2 3			Sofosbuvir/Velpatasvir	6 (15%)	
	19% (n = 11)		Ledipasvir/Sofosbvuvir	4 (10%)	
Advanced Fibrosis 32	,		Sof/Vel/Voxilaprevir	1 (3%)	
(F3/4)		SVR	100%		

# Table 3. Services Provided by PCP/Subspecialists Since Inception of Patient Navigation Services for the Treatment of HCV at MMTP (5/2017)

	Number
Patients Enrolled in HCV Treatment	58
Patients with PCP Appointments	20
Patients with Subspecialty appointments	5
Referrals to subspecialists	41
Colon Cancer Screening (Colonoscopy)	4
Variceal Screening (EGD)	8
Lung Cancer Screening (LDCT)	2
AAA Screening (Abdominal U/S)	1
HTN Screening/Treatment	21
DM Screening/Treatment	20
HLD Screening/Treatment	16
Asthma/COPD Treatment	5
Smoking Cessation Counseling	18
HIV Screening/Treatment	8
STD Screening	5
Screening for Tb	1
Depression Screening	14
Influenza Vaccine	5
TDaP	4
PPSV23/PCV13	2
MMR/VZV Vaccination	1
EKG	3
TTE	3
Carotid U/S	1

#### DISCUSSION

- The preliminary data reviewed in this study is quite promising; suggesting that the patient navigator services offered at methadone maintenance programs for the treatment of HCV has additional benefits of encouraging health promoting behaviors.
- With the assistance of patient navigation services, topics of healthcare maintenance such as ageappropriate cancer screening, vaccinations, and treatment of chronic conditions are being reintroduced to this high risk, hard to reach subgroup of the population.
- Up to 50% of patients reintroduced to HCV treatment had advance fibrosis of the liver.
- This subset of population places a large economic burden that can be offset by a patient navigator with estimate over \$5000 on reimbursement of procedures alone.
- We were unable to obtain the data regarding the number of patients utilizing the patient navigator to reconnect with psychiatrists or other mental health specialist.

# CONCLUSION

 Care coordination services provide high risk, hard to reach subgroups with focused medical care specific to those patients, but also provide a gateway for further medical and psychological care and healthcare maintenance in specialized high risk populations.

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# Electronically-monitored adherence to a once-daily single-tablet regimen in inner-city patients with chronic hepatitis C infection treated in a primary care setting



Jeffrey J. Weiss<sup>1</sup>, Kyle Prochno<sup>1</sup>, Jason Rogers<sup>2</sup>, Tiffany Dawson<sup>3</sup>, Sudipto Srivastava<sup>3</sup>, Ashish Atreja<sup>2</sup>, Sue Preziotti<sup>1</sup>, Korin Parrella<sup>1</sup>, Amanda Davidson<sup>1</sup>, Brooke Wyatt<sup>4</sup>, Trang Vu<sup>1</sup>, Ponni V. Perumalswami<sup>4</sup>

Table 1 - Baseline Characteristics

Age, years, mean ± SD

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# 2018 NYC Viral Hepatitis Research Symposium

#### INTRODUCTION

- There are limited data on adherence to oncedaily single-tablet regimens for chronic hepatitis C virus (HCV) infection in real-world patient populations.
- Medication adherence is crucial to achieving sustained virologic response (SVR), yet there is no consensus on the minimum adherence level required.

#### **AIM**

To electronically assess adherence to direct-acting antiviral (DAA) HCV treatment in patients treated in a real-world clinical setting.



# MATERIAL & METHODS

- Thirty-three patients initiating single-tablet DAA treatment for at least 12 weeks were recruited from two primary care practices from January to December 2016.
- Patients used AdhereTech smart wireless pill bottles during the course of treatment, which provided real-time data on patient opening of the bottles using cellular technology.
- Adherence was examined over the 84 days immediately following treatment initiation in terms of:
  - Dosing adherence—percentage of days that bottle was opened at least once and
  - Timing adherence—percentage of days that bottle was opened ±4 and ±1 hours from patient's unique scheduled dose time

#### Thirty-two patients had usable adherence data; one patient broke the AdhereTech bottle excluded from all analyses.

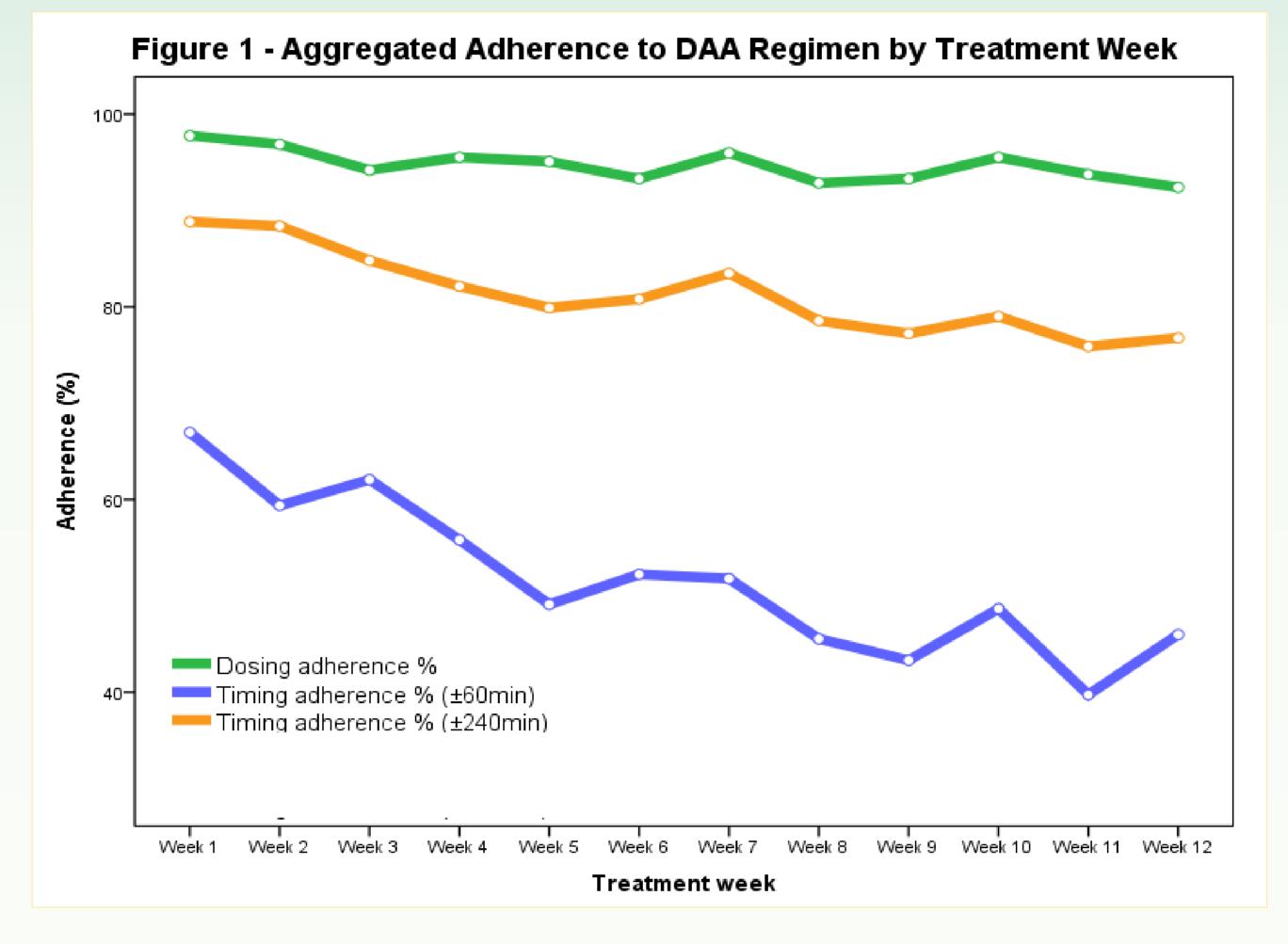
Age, years, mean ± 30	JO.4 ± J.4
Male, n (%)	20 (62.5)
Race/ethnicity, n (%)	
White	8 (25.0)
Black	15 (46.9)
Hispanic	8 (25.0)
American Indian	1 (3.1)
Monthly income, USD, mean ± SD	1317 ± 772
Education, years, mean ± SD	12.4 ± 2.3
Health insurance, n (%)	
Medicaid	18 (56.3)
Medicare	8 (25.0)
Private	2 (6.3)
Medicare and Medicaid	4 (12.5)
HCV prescription, n (%)	
Sofosbuvir/Ledipasvir	24 (75.0)
Sofosbuvir/Ledipasvir + Ribavirin	1 (3.1)
Sofosbuvir/Velpatasvir	7 (21.9)
HCV treatment length, n (%)	
12 weeks	30 (93.8)
24 weeks	2 (6.2)
HCV genotype, n (%)	
<b>1</b> a	18 (56.3)
1b	9 (28.1)
<b>2</b> b	2 (6.3)
3	2 (6.3)
4	1 (3.1)
Treatment naïve, n (%)	28 (87.5)
HIV-co-infected, n (%)	2 (6.2)

Table 2 – Aggregated Adherence	(n=32)
Adherence, mean % ± SD	
Dosing	94.7 ± 6.4
Range [min, max]	[70.2, 100.0]
Timing (± 4 hours)	81.3 ± 26.8
Range [min, max]	[9.5, 100.0]
Timing (± 1 hour)	51.7 ± 31.3
Range [min, max]	[1.2, 97.6]

#### RESULTS

(n=32)

 $58.4 \pm 9.4$ 



- Dosing adherence did not significantly change over the 12-week course of treatment.
- Timing adherence significantly decreased
  - **±** ±4 hours: [F(5.2,161.5)=2.3; p=0.042]

**±** ±1 hour: [F(5.6,172.8)=5.2; p<0.001]

Table 3 – SVR12 Status	(n=32)
SVR12 status, n (%)	
Achieved	25 (78.1)
Virologic relapse	2 (6.3)
Unknown – lost to follow-up	5 (15.6)

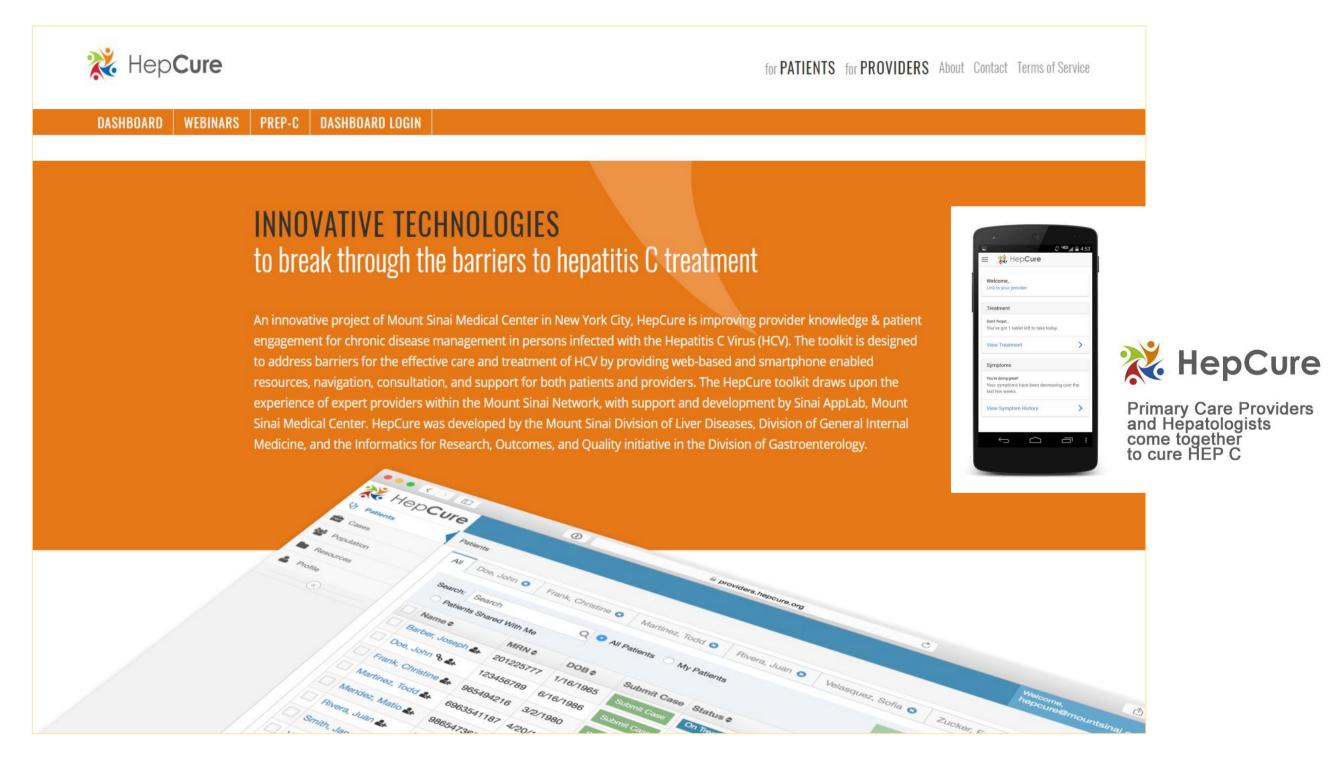
- In this small sample, there were no significant differences in dosing or timing adherence among patients of differing SVR 12 statuses.
- The two patients with virologic relapse were naïve, GT 1b, treatment sofosbuvir/ledipasvir for 12 weeks, relapsed at approximately post-treatment week 4, and had dosing adherences of 90.5% and 97.6%.

# **ACKNOWLEDGEMENTS**

Funding for this Investigator-Initiated Study is provided by Gilead Sciences, Inc.

#### CONCLUSIONS

- Overall, we found high dosing adherence in this sample of patients treated in a primary care setting utilizing an Internet of Things (IoT) device to objectively measure HCV medication adherence. Timing adherence did significantly decrease over the 12-week treatment course. Data in larger samples are needed to examine the relationship between adherence metrics and achievement of SVR.
- The second phase of this study is currently underway, in which 66 patients are randomized to one of two conditions:
  - HepCure toolkit (mobile application/ provider web dashboard) + AdhereTech monitoring, OR
  - HepCure toolkit + AdhereTech monitoring and medication reminders



- The second phase of this study is investigating interventions whether these improve adherence as compared to the patients reported on here for whom adherence was measured in clinical care without any additional adherence intervention.
- adherence-SVR **₩** We examine will the relationship in the total sample of 99 subjects.

Learn more at HepCure.org

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**Contact information** 



#### Sofosbuvir-Based Regimens in the Treatment of Chronic Hepatitis C Genotype 1 Infection in African-American Patients: A Community-Based Retrospective Cohort Study



Gayam, Vijay<sup>1</sup>; Khalid, Mazin<sup>1</sup>; Mukhtar, Osama<sup>1</sup>; Mandal, Amrendra Kumar<sup>1</sup>; Benjamin, Tiongson<sup>1</sup>; Gill, Arshpal<sup>1</sup>; Garlapati, Pavani<sup>1</sup>; Mansour, Mohammed<sup>1</sup>

#### > BACKGROUND

- Direct-acting antiviral (DAA) drugs have been highly effective in the treatment of chronic hepatitis C (HCV) infection.
- Limited data exists comparing the safety, tolerability, and efficacy of direct-acting antivirals (DAAs) in African-American (AA) patients with chronic hepatitis C genotype 1 (HCV GT-1) in the community practice setting.
- We aim to evaluate treatment response of DAAs in these patients.

#### > METHODS

- All the HCV GT-1 patients treated with DAAs between January 2014 and December 2017 in a community clinic setting were retrospectively analyzed.
- Pretreatment baseline patient characteristics, treatment efficacy with sustained virologic response at 12 weeks post treatment (SVR12), and adverse reactions were assessed.

#### > RESULTS

- Two-hundred seventy-eight patients of AA descent were included in the study.
- One hundred sixty two were treated with Ledipasvir/Sofosbuvir (Harvoni) ± Ribavirin, thirty-eight were treated with Simeprevir/Sofosbuvir (Sim/Sof) ± Ribavirin, and seventy-eight patients were treated with Sofosbuvir/Velpatasvir (Epclusa).
- Overall, SVR at 12 weeks was achieved in 94.6% in patients who received one of the three DAA regimens (93.8% in Harvoni group, 92.1 % in Sim/Sof group and 97.4% in Epclusa group).
- Prior treatment experience, HCV RNA levels and HIV status had no statistical significance on overall SVR achievement (p value = 0.905, p value = 0.680 and p value = 0.425 respectively).

#### > RESULTS

- Compensated cirrhosis in each of the treatment groups did not influence overall SVR 12. The most common adverse effect was fatigue (27%).
- None of the patients discontinued the treatment due to adverse events.

#### > DISCUSSION

• In the real-world setting, DAAs are safe, effective and well tolerated in African American patients with chronic HCV GT-1 infection with a high overall SVR rate of 94.6%.

#### Demographic and Clinical Characteristics of Patients at Baseline by Treatment Response

	All potionto	Treatment	Response	Univeriete	Multivariate
Characteristics	All patients	SVR	No SVR	Univariate	Multivariate
	(N = 278)	(n =263)	(n =15)	p value	p-value
Age (years)	61.4 (28-94)	61.5 (28-87)	59.0 (33-94)	0.363	NA
Sex					
Male	170 (57.0)	158 (60.1)	12 (80.0)	0.124	NA
Female	108 (38.8)	105 (39.9)	3 (20.0)		
BMI (Kg/m²)					
< 30	174 (62.9)	164 (62.4)	10 (66.7)	0.737	NA
≥ 30	104 (37.4)	99 (37.6)	5 (33.3)		
Genotybe subset					
GT1a	205 (73.7)	193 (73.4)	12 (80.0)	0.571	NA
GT1b	73 (26.3)	70 (26.6)	3 (20.0)		
HCV RNA (IU/mL)					
< 800,000	81 (29.1)	80 (30.4)	1 (6.7)	0.049	0.680
≥ 800,000	197 (70.9)	183 (69.6)	14 (93.3)		
Prior treatment					
Naïve	219 (78.8)	207 (78.7)	12 (80.0)	0.905	NA
Experienced	59 (21.2)	56 (21.3)	3 (20.0)		
HIV status					
positive	60 (21.6)	58 (22.1)	2 (13.3)	0.425	NA
Negative	218 (78.4)	205 (77.9)	13 (86.7)		
APRI score					
< 1	188 (67.6)	182 (69.2)	6 (0.4)	0.019	0.137
≥ 1	90 (32.4)	81 (30.8)	9 (0.6)		
MELD score					
< 10	197 (70.1)	188 (71.5)	9 (0.6)	0.341	NA
≥ 10	81 (29.1)	75 (28.5)	6 (0.4)		
Child-Pugh score					
Class A	241 (86.7)	231 (87.8)	10 (66.7)	0.019	0.548
Class B	37 (13.3)	32 (12.2)	5 (33.3)		

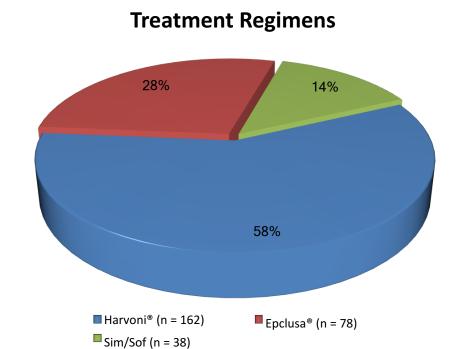


Figure 1. Treatment Groups with Different Regimens

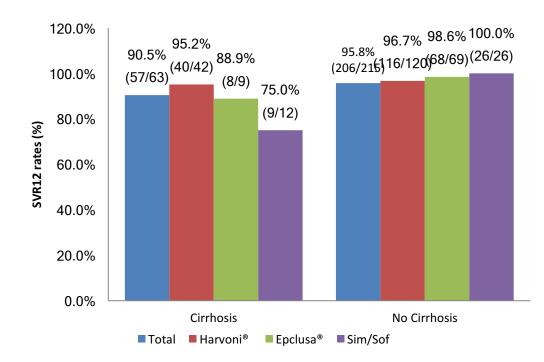


Figure 2. Treatment Response based on Compensated Cirrhosis Status.

# Empowering and Engaging Older Gay/BI Latino men to develop awareness and seek treatment/care for Hepatitis C

Carlos Maldonado, Luis Mares, LMSW, Axel Monroig, MPH, Latino Commission on AIDS

# BACKGROUND

Viral Hepatitis Research Symposium

A recent study of older Latinos living with HIV has highlighted the obstacles faced in achieving optimal health and well-being, including fear and mistrust of medical institutions, management of competing comorbidities, social isolation due to stigma, and health care maintenance and access challenges.. Peer-led empowerment and education models have been found to effectively bridge these gaps for vulnerable populations.

#### **PURPOSE**

In response to the unmet needs described above, the Maduros y Sabrosos (MyS) program was developed to provide participants with the knowledge, skills and self-efficacy to engage in health-seeking behavior.

# **METHODS**

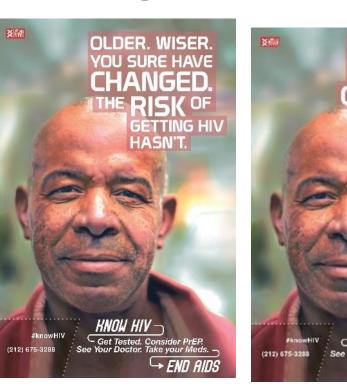
The health education foundation of MyS is guided by Freire's tenets of balancing the relationship "learner" and "sharer" of knowledge Learners are empowered to become active creators of the program, outlining themes, topics and activities at the beginning of each cycle and directors of their health seeking behaviors.

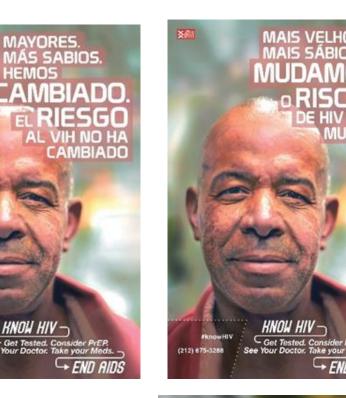
# EVALUATION METHOD

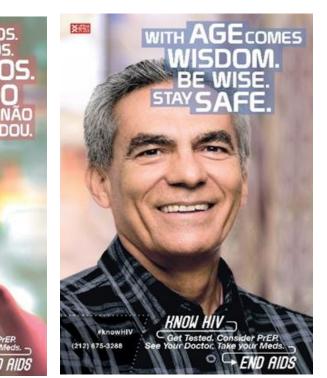
The evaluation tools for the intervention include a mixed-methods approach, whereby surveys are administered to capture qualitative and quantitative information on attitudes/perceptions, reported behaviors, and knowledge. Focus groups and key informant interviews are also employed to further contextualize and explore participants' experiences and outcomes.

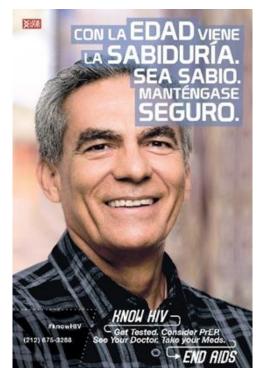
#### RESULTS

Hepatitis Social Messaging Campaign: Messaging in English and Spanish at minimum, as well as Portuguese



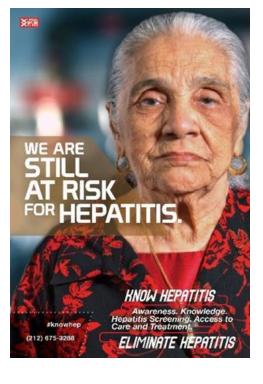
















**412 participants** in the past 2 years, age range 36-74, average age 59.

85% predominantly Spanish-speaking and mono-lingual, 15% proficient in English, 100% immigrants, with an average of 15 years residence in the U.S.

353 tests locally 2017-2018; 18 positive results; 100% connected to services and treatment.

Development of **24 health educational models** targeted to older adults, six of them on viral hepatitis, hepatitis C, liver care.

70% of participants living with HIV, 100% have had Hep C screening after receiving information.

65% o participants show depressive signs and suffer social isolation, almost all absence of family or other close support systems.

#### CONCLUSION

Preliminary evaluation results indicate that the MyS program is a cost-effective and feasible program for engaging vulnerable groups in health education messaging, empowering strategies, and socialization activities that reduce isolation. Results indicate that participants feel less isolated, more willing to discuss health concerns and behaviors, and more knowledgeable of sexual health topics as members of the program based on self-report.

## LIMITATIONS

Funding for Gay/Bi Men mostly targeted to a younger age group.

Integrating hepatitis as part of LGBT Health and Human Service Care.

Integrating hepatitis into HIV services that have limited capacity for people over 40.

# ACKNOWLEDGEMENTS

Thanks to the Members of Maduros y Sabrosos





# DISCLOSURES



# Stigmatization at the doctor's office: Deterrent to care for people who inject drugs?

Aponte-Meléndez, Y.ª Mateu-Gelabert P.,ª Fong, C.,ª Eckhardt, B., Marks, K., Kapadia, S, Davis, L., Goodbody, E., Edlin, BR. a. National Development and Research Institutes, b. NYU School of Medicine, c. Weill Cornell Medicine, d. Centers for Disease Control and Prevention





#### Background

Viral Hepatitis Research Symposium

2018

NYC

• An estimated 3.5 million people are living with HCV in the United States (CDC). Injection drug use is a leading cause behind HCV incidence. Despite high HCV prevalence among people who inject drugs (PWID), they are hesitant about accessing HCV treatment. Drug userelated stigma plays an important role on PWID access to HCV care.

#### Purpose

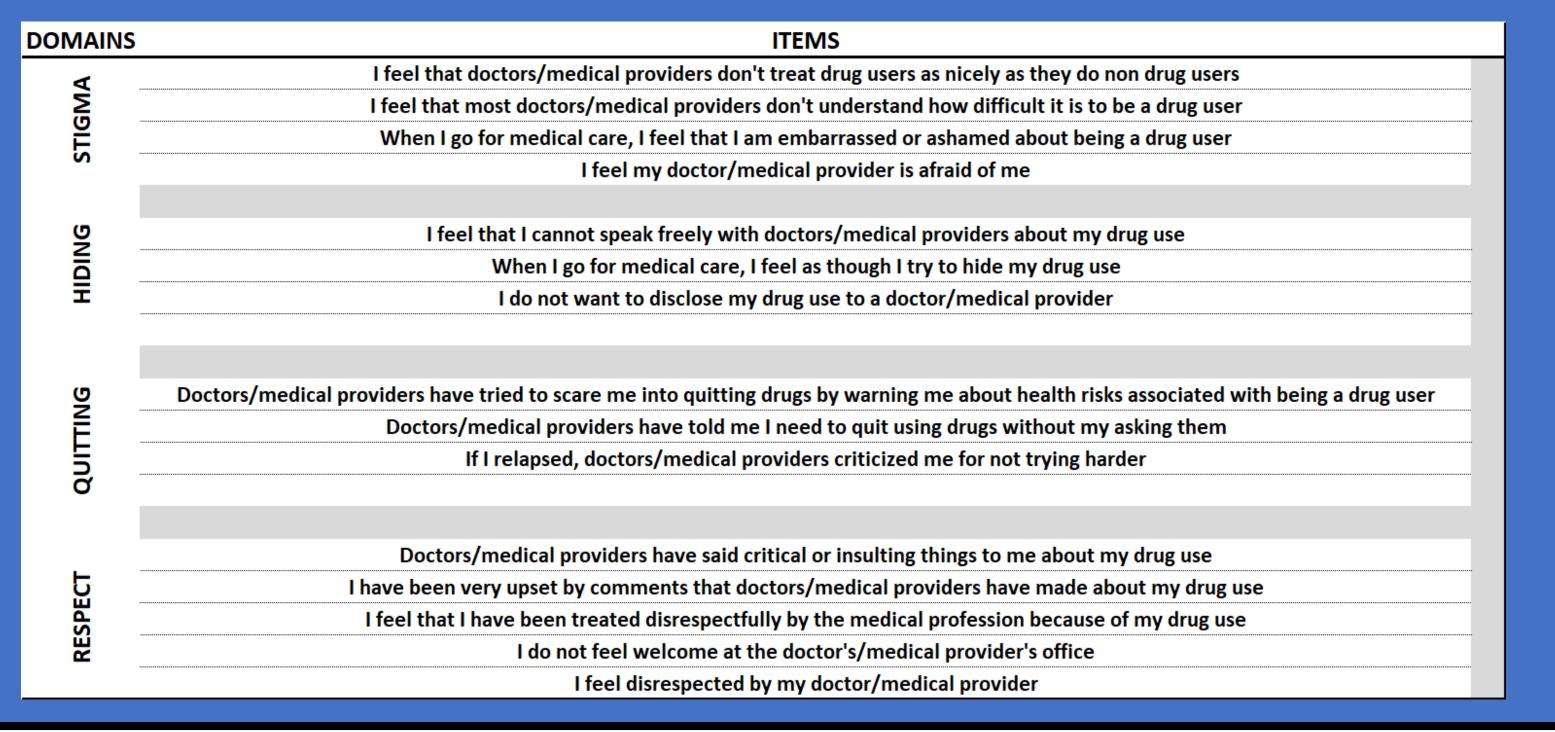
• This analysis presents stigma experienced by PWID when interacting with health care providers

#### Methods

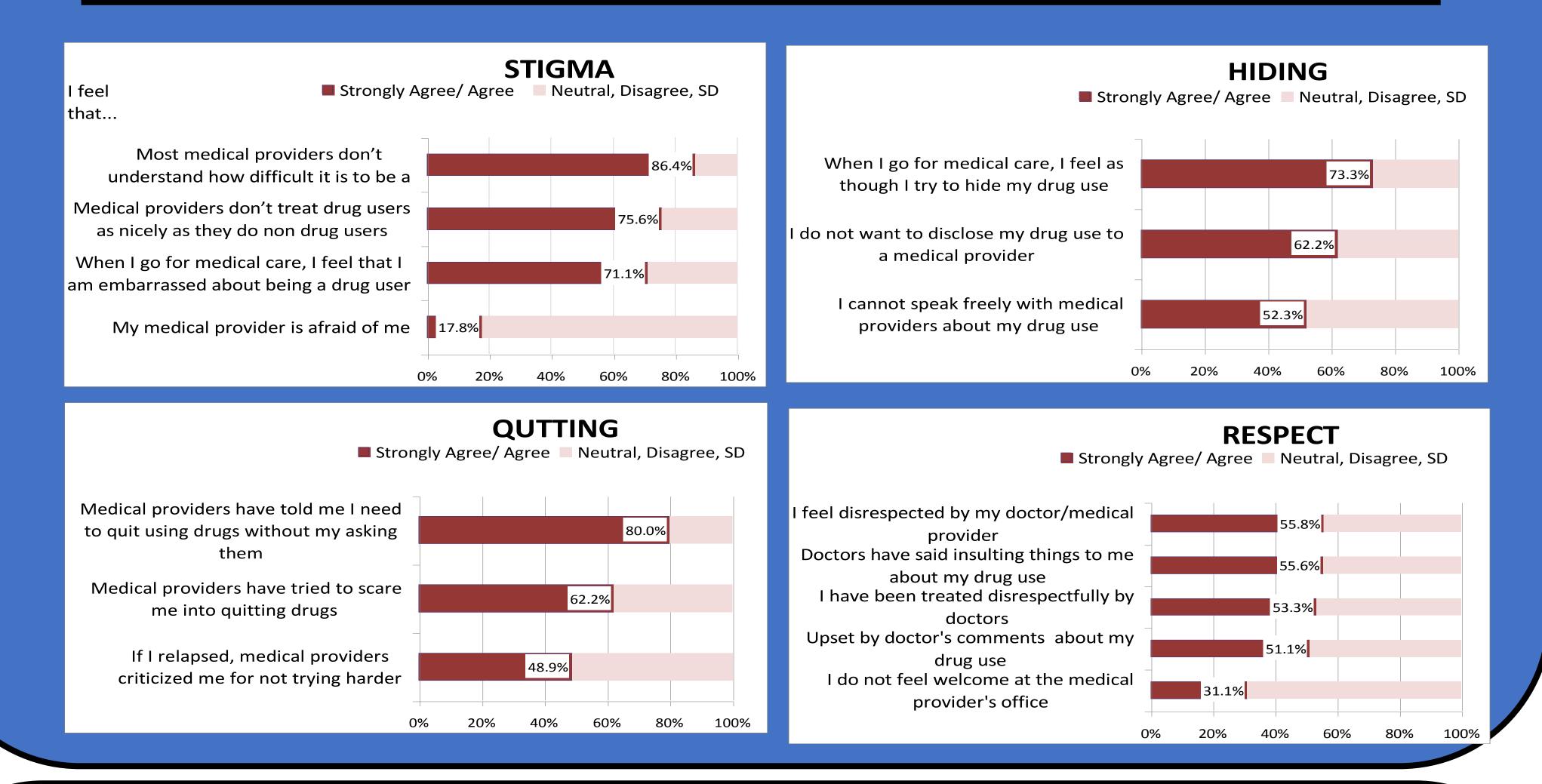
In an on-going study to examine HCV care for PWID delivered at needle exchange programs, we present data on the first 46 participants recruited. •Eligibility criteria includes positive HCV RNA and reported recent injection. Participants completed baseline structured interviews on health care experiences, HCV treatment, and drug use. Fifteen items were developed to assess PWID experiences with medical providers with four different domains: stigmatization, hiding drug use, requests to quit drugs, and feeling respected. We assessed the statistical correlations between medical services utilization

and these fifteen items.

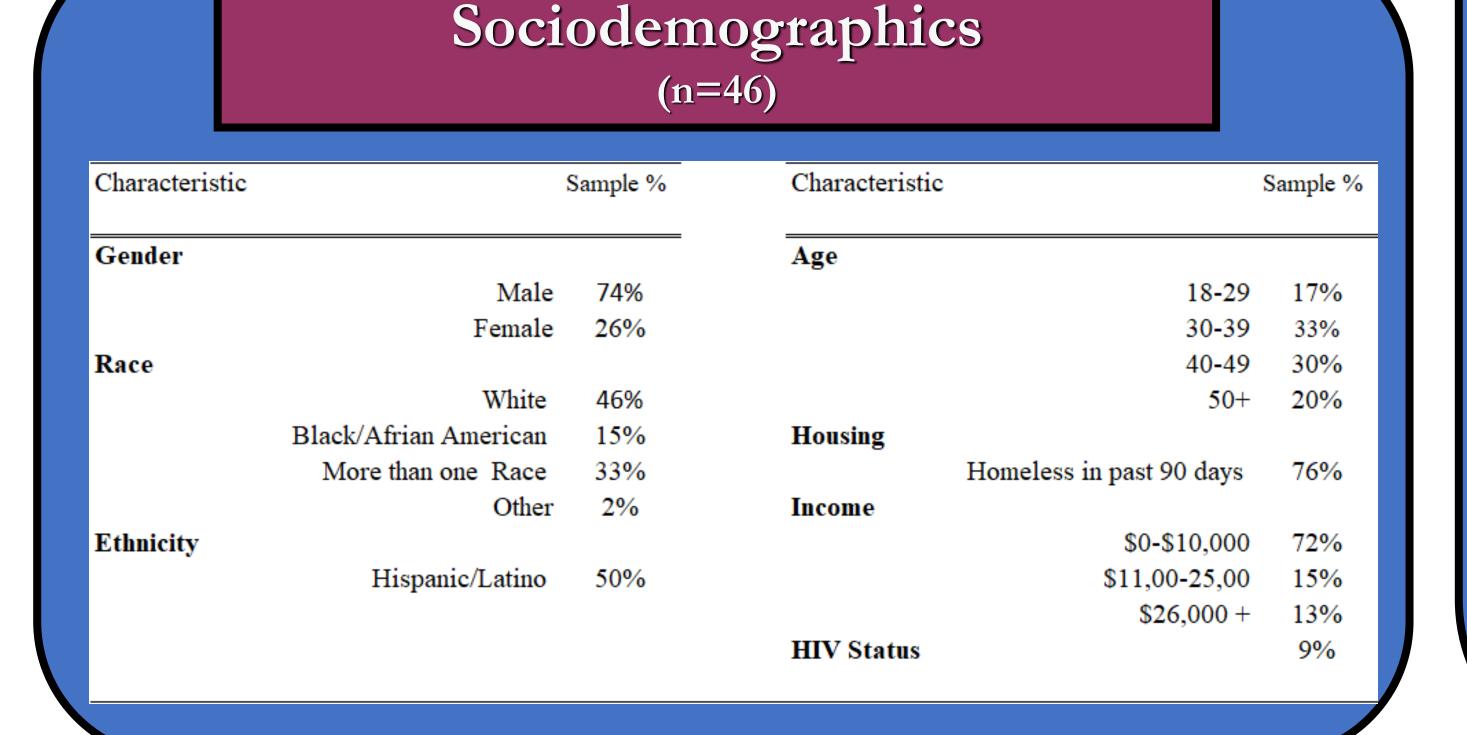
# Domains items of PWID's experiences with Doctors/Medical Providers

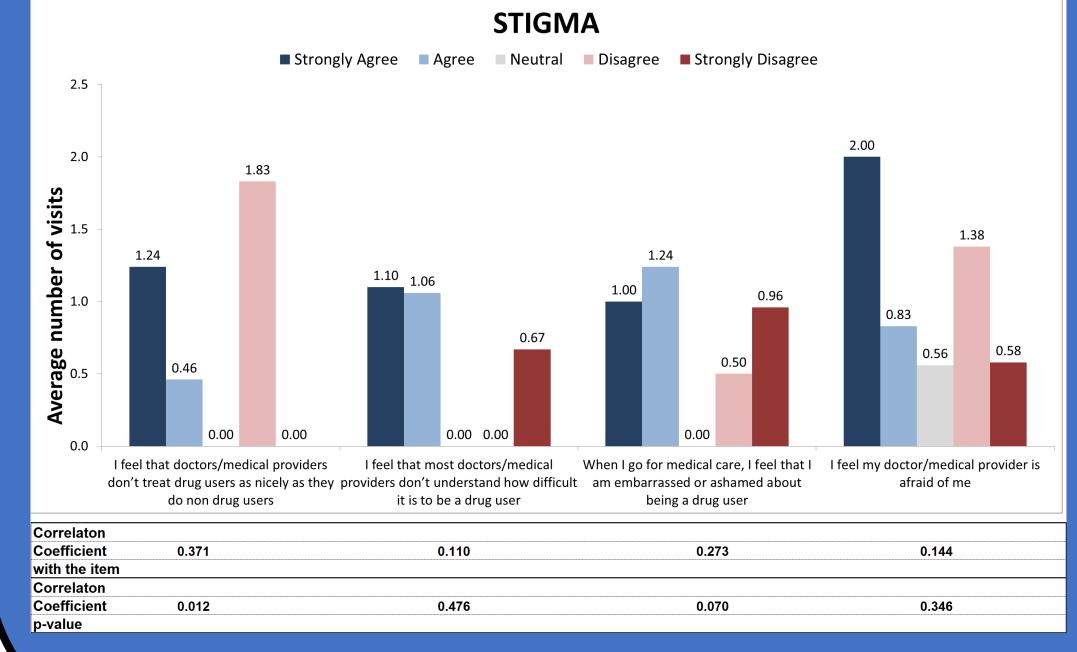


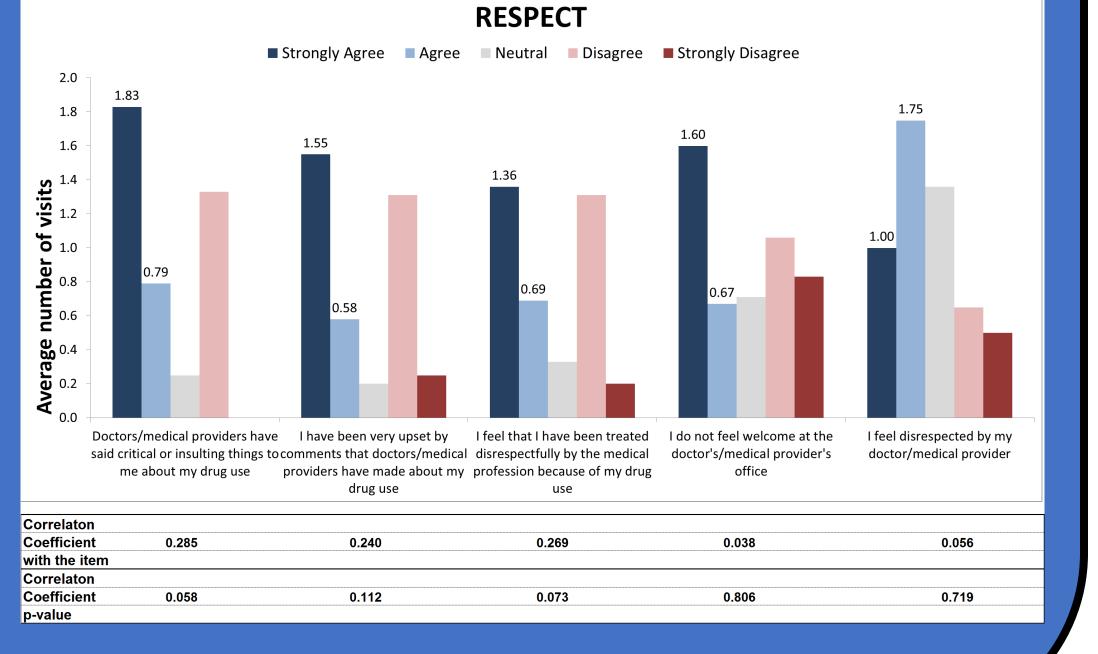
# PWID's Experiences with Doctors/Medical-Providers by Domains sorted by descending percentage



Domains having correlated or trending PWID's Experiences with Doctors/Medical -Providers visit in the past 90 days







#### Results

•The median age was 39.5, most were men (74%), 46% White, 59% homeless, and 9% HIV+. Before the study, 91% of participants knew their HCV+ status and 74% had not sought HCV treatment. Twelve of the fifteen items reported more 50% negative experiences with medical providers. A majority of participants report being stigmatized at the doctor's office (>50% in 3 of the 4 'stigma' items); over 50% report feeling the need to hide their drug use in all three 'hiding' items. Also, in 2 of 3 items >60% report being told to 'quit drugs' by their doctors, with 45% reporting this experience in the 3<sup>rd</sup> item. Regarding 'respect,' >51% of participants report experience of being disrespected in 4 of 5 items, with 31% reporting this experience in the 5<sup>th</sup> item. Finally, there are statistically significant or trending correlations between 'medical service utilization' and two 'stigma' item (feeling that doctors do not treat equally drug users and non drug users and feeling embarrassed and ashamed being a drug user) and two 'respect' item (providers make insulting comments about drug use and being treated disrespectfully because of my drug use).

#### Conclusion

A majority of PWID report feeling stigmatized and needing to hide their drug use when interacting with medical providers. Stigma increases with frequency of engagement in medical care. These experiences could negatively influence HCV care. Medical providers should be trained in providing judgment-free care for PWID. Reducing stigma in medical settings may help increase PWID engagement in HCV care.

#### Limitations

There are a number of limitations in this analysis. First, results are not final, for recruitment is still ongoing. Second, for the small sample size, findings are not representative of the PWID population. Third, data is based on self-reports.

**Disclosures:** Dr. Eckhardt and Dr. Kapadia have received research grants from Gilead Sciences Inc. Dr. Marks has received research grants from Gilead Sciences Inc, Merck, and Bristol-Meyers Squibb. No pharmaceutical grants were received in the development of this study.

**Acknowledgments**: This study is supported by National Institute of Drug Abuse grant # R01DA041298-02. The authors acknowledge the continuous support of the Lower East Side Harm Reduction Center.

# HCV Care-Coordination Experiences and Perspectives: Findings from Project INSPIRE Stakeholder Focus Groups

<sup>2</sup> BLS Research & Consulting LLC, New York, NY

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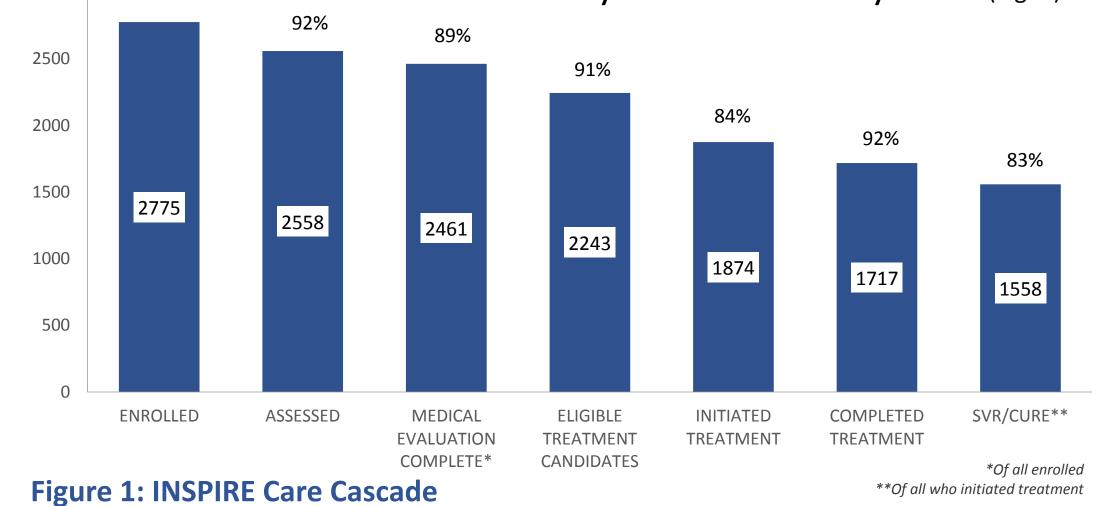
Viral Hepatitis Research Symposium

**2018** 

NYO

### BACKGROUND

- Currently an estimated 146,500 persons (2.4% of the population) are infected with chronic hepatitis C (HCV) in New York City (NYC)<sup>1</sup>.
- Project INSPIRE was a three-year program designed to deliver comprehensive HCV service model that combined care coordination, health promotion, medication adherence support, and HCV infection-centered care to patients, while additionally providing telementoring to HCV providers.
- INSPIRE was implemented at and in collaboration with Montefiore Medical Center and Mount Sinai Hospital System.
- 2,775 NYC residents, infected with HCV, who were 18 years or older and beneficiaries of Medicare and/or Medicaid were enrolled between January 2015 – February 2017 (Fig. 1).



# **PURPOSE**

Focus groups were conducted in order to get a more in-depth understanding on the perceptions, insights and experiences of the INSPIRE patients and clinical care teams.

# **PARTICIPANTS**



The following inclusion criteria was used to select participants for the focus groups:

- Patients needed to have participated in INSPIRE for > 6 months, and have enrolled prior to starting HCV treatment
- Providers needed to be MDs, and have provided clinical care to least 10 INSPIRE patients
- Care coordinators and Peer navigators needed to be currently residing in NYC and

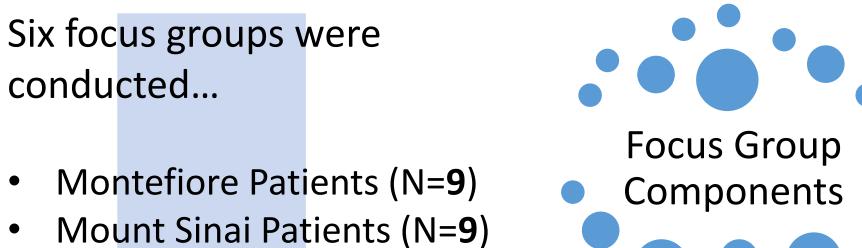


- Eligible individuals were contacted by recruiters by phone or email.
- completed over the phone to confirm eligibility and enroll individuals into the focus groups.
- Each group was overrecruited in order to account for possible noshows.
- reachable during recruitment.

A screening survey was

give us a script..."

# METHODS



Spanish-speaking Patients

Medical Providers (N=8)

Care Coordinators (N=8)

...with a total of 46 INSPIRE

†All groups were at-capacity,

agreed to participate, only 1

appointments, not as

much."

Pare Coordinator

and of all individuals who

ultimately did not attend.

Peer Navigators (N=4)

(N=8)

stakeholders

- In December 2017, focus groups were conducted with INSPIRE patients and three groups of care team members: medical providers, care coordinators, and peer navigators.
- Discussions lasted approximately 90 minutes, and were recorded and transcribed.

Qualitative data analysis

- Transcripts were analyzed using iterative qualitative methods to identify key discussion themes.
- Meanings and interpretations of various themes were used to construct an overall narrative of findings and implications from the data.

# **OVERARCHING THEMES**

From the perspectives of both patients and providers, Project INSPIRE was a highly successful program.

From an outcomes perspective, the only shortcoming of INSPIRE is that the extent to which it encouraged selfsufficiency among patients is debatable.

Providers and care coordinators perceived certain program requirements as burdens and even obstacles to successful care - in particular, requirements around data entry and health promotion modules were seen as taking away valuable time with patients.

Patient co-morbidities often needed to be addressed before discussing HCV care, and the time it took to do so was substantially more than care coordinators had expected, and seemed to be more than the program had budgeted.

Peer Navigators provided critical support to Care Coordinators and should be leveraged more in future program iterations.

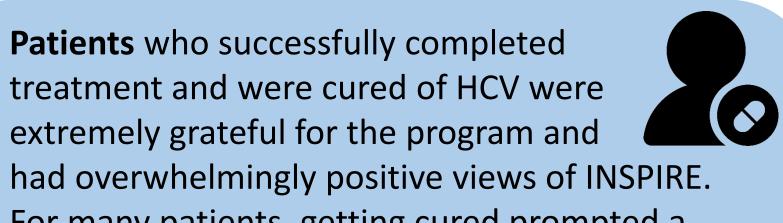
CONSIDERATIONS FOR

FUTURE IMPLEMENTATION

# RESULTS

"The attempts [at creating selfsufficiency] were there big time, but in to on their own. terms of changing my patient's habits to necessarily occur. make their own

- To **providers**, INSPIRE was a success in that they were able to successfully treat many more HCV patients than they would have been able
- Providers noted that patient self-sufficiency didn't
- Many appreciated working in a coordinated team setting and reported benefitting especially from the telementoring sessions.



had overwhelmingly positive views of INSPIRE. For many patients, getting cured prompted a transformation of mindset and encouraged them to focus on other aspects of their health in addition to HCV.

Patients report positive interactions with the INSPIRE care team, which helped increase their overall trust of healthcare providers.

"What was most helpful for me was the affection and support, the way they talk to you. The way they treated me. I had never felt like they judged me... They make you feel like a person. Like a human."



Restructure or condense the data collection system to make it more user-friendly and efficient.

Consider adding flexibility to the health promotion

requirements so that care coordinators can take

care of other patient needs when necessary.

Ensure proper staffing, with clearly defined roles and support structures, potentially including staff dedicated to prior authorizations.

#### REFERENCE

1. Balter, S., J. H. Stark, J. Kennedy, K. Bornschlegel, and K. Konty. 2013. "Estimating the prevalence of hepatitis C infection in New York City using surveillance data." Epidemiology and Infection 142(2): 262-69.

#### **FUNDING STATEMENT**

The project described is supported by Grant Number 1C1CMS331330 from the Department of Health and Human Services, Centers for Medicare & Medicaid Services. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the U.S. Department of Health and Human Services or any of its agencies. The research presented was conducted by the awardee. Preliminary findings may or may not be consistent with or confirmed by the findings of the independent evaluation contractor.

#### **CONTACT INFORMATION**

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"What I thought would be most helpful and also give us more time and flexibility to engage our patients is don't

Care coordinators felt that INSPIRE was a success in terms of the number of patients cured; however, they felt they had to go far beyond their contractual responsibilities to meet those goals.

- Sources of time burdens included health promotion sessions, data entry, and the intensive prior authorization process required by insurers to get patients approved for HCV treatment.
- Peer Navigators see themselves as educators and could be better leveraged in future programs to help care coordinators meet educational responsibilities

# Quality Improvement Initiatives for Hepatitis C Management in Hospital-Based Practices in New York City



2018

Nadine Kela-Murphy, MPH; Emily Harrison, MD; Ryan Duerme, MPH; Marie P. Bresnahan, MPH; Ann Winters, MD. NYC Department of Health and Mental Hygiene.

Figure 1: People Newly Reported with Chronic Hepatitis C in New York City by Zip Code, 2015-2016<sup>1</sup>

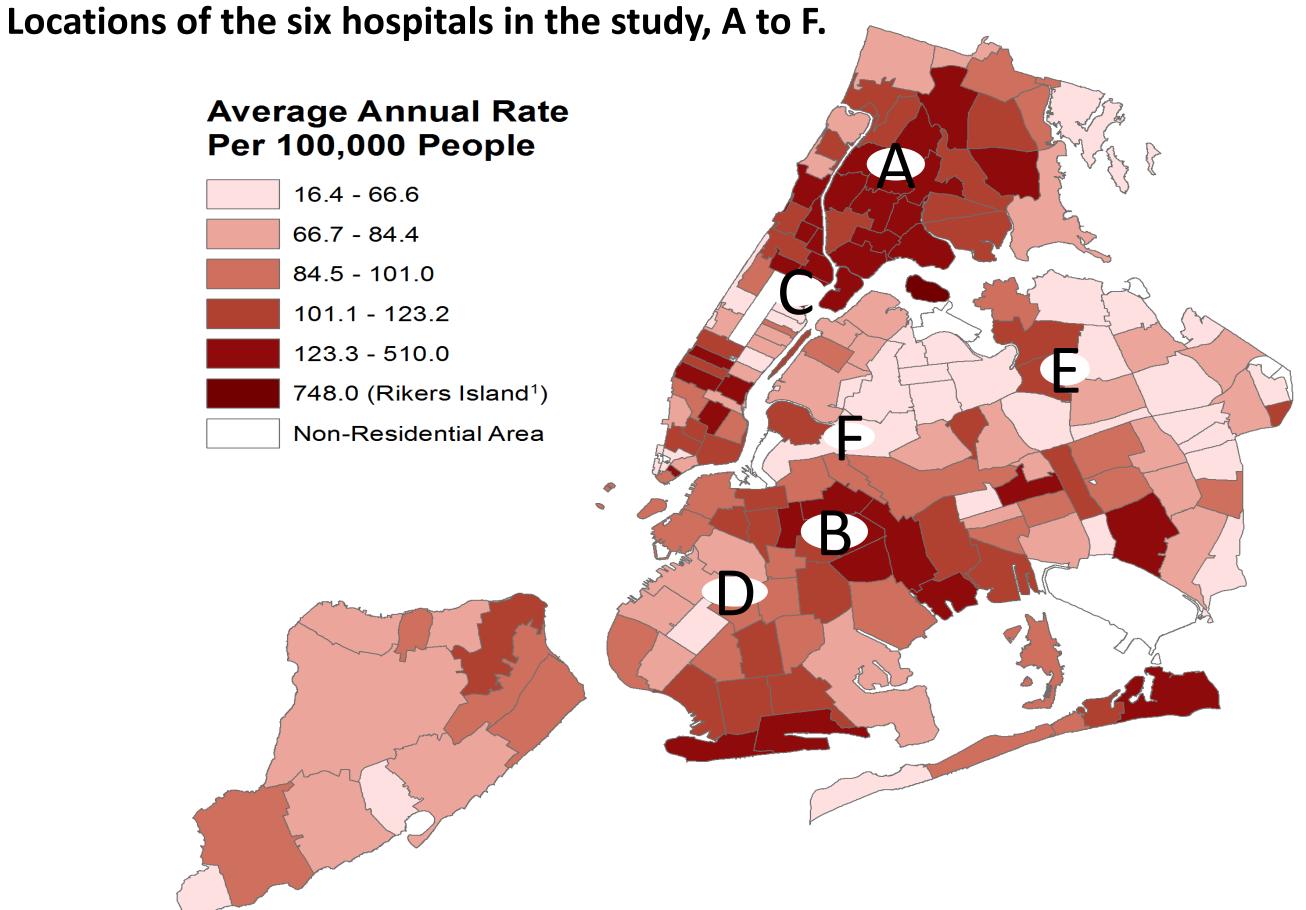


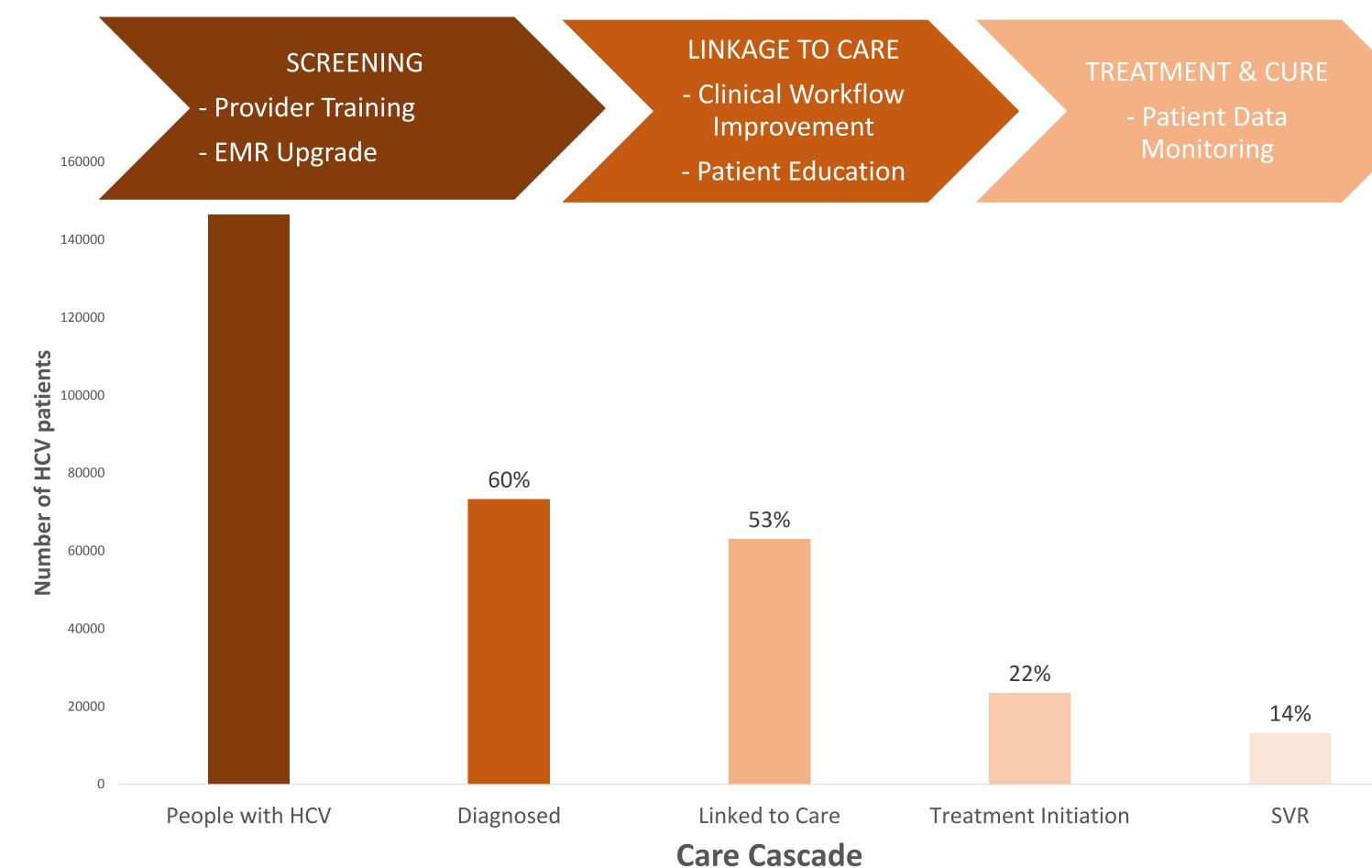
Figure 2: Baseline Hospital Capacity, 2016
Hospital-reported HCV providers and HCV tests at baseline.

Hospital	Number of HCV Providers	Number of HCV antibody screening tests performed	Number of positive HCV antibody tests (% of tests performed)	Number of HCV RNA tests performed*	Number of HCV RNA Positive tests (% of RNA tests performed)
Α	6	3,477	844 (24%)	171	82 (48%)
В	2	5,153	203 (4%)	211	109 (52%)
С	1	2,524	206 (8%)	206	110 (53%)
D	4	1,609	69 (4%)	N/A <sup>†</sup>	N/A <sup>†</sup>
E	6	2,041	35 (2%)	43	12 (28%)
F	9	8,601	382 (4%)	284	131 (46%)

<sup>\*</sup> Not a percentage of HCV positive antibody because some patients only had HCV RNA test performed.

# Figure 3: Quality Improvement Initiatives and HCV Care Cascade<sup>2</sup>

Initiatives in relation to care cascade.



#### REFERENCES

- 1. New York City Department of Health and Mental Hygiene. Hepatitis B and C in New York City 2016 Annual Report
- Balter S, Stark JH, Kennedy J, Bornschlegel K, Konty K. Estimating the prevalence of hepatitis C infection in New York City using surveillance data. Epidemiol Infect. 2014

#### CONTACT

For more information contact Nadine Kela-Murphy, MPH, nkelamurphy@health.nyc.gov

#### **DESCRIPTION**

- The public health burden of hepatitis C (HCV) in New York City (NYC) is substantial with an estimated 146,500 adults infected with the virus.
- In 2016, there were 11,847 people newly reported with chronic HCV in NYC.
- The National Strategy for the Elimination of Hep B and Hep C highlights the importance of partnerships between local governments and provider organizations.
- The New York City Department of Health and Mental Hygiene oversees the Hepatitis C Clinical Exchange Network (HepCX) a peer-to-peer learning collaborative of 59 HCV clinical providers champions at 38 hospitals.
- In 2017, the NYC Health Department funded two-year quality improvement projects at six HepCX hospitals to increase screening, linkage to care and cure for patients with HCV. (Figure 1)

#### AIM

Evaluate the progress of HCV-related quality improvement initiatives at six NYC hospitals

#### **ACTIONS TAKEN**

- Participating hospitals responded to qualitative and quantitative surveys about quality improvement initiatives at baseline in March and again in September 2017.
- Initiatives were classified in five categories: provider training, clinical workflow improvement, systematic patient data monitoring, electronic medical record (EMR) upgrade, and patient education.
- Successes and challenges in implementing these initiatives were analyzed.

#### **RESULTS**

- Hospitals reported baseline (2016) number of HCV-treating providers and screening rates. (Figure 2)
- Table 1 displays qualitative survey results on the progress of implementation of quality initiatives by category. Figure 3 shows the initiatives' categories as aligned with the HCV care cascade.

Initiative Category	Successes	Challenges
Provider Training	Enhanced provider training through the delivery of lectures and mentorships as well as the development of educational materials	Limited time in provider schedules for training
EMR Upgrade	Established collaborations with Information Technology representatives to plan and review EMR projects	Cumbersome alert development process and requirements for hospital system-wide upgrade
Clinical Workflow Improvement	Implemented automatic RNA testing on all positive HCV antibody test (reflex testing) and allocated staff to patient navigation activities	Lack of support from leadership
Patient Education	Established partnerships with community organizations to organize outreach activities and events	Lack of resources for patient outreach
Patient Data Monitoring	Created HCV monitoring system that includes indicators to track screening and treatment initiation	Absence of relevant HCV performance indicators

#### CONCLUSION

These preliminary results will be used to guide the next phase of this quality improvement study. As we learn from these successes and challenges, we aim to further expand the projects at other HepCX hospitals with the goal of overcoming barriers to screening, linkage to care and expanded treatment capacity and achieving HCV elimination in NYC.

<sup>†</sup> N/A = not available. This data point was not shared by the participating hospital.

#### Using Surveillance Data to Understand Hepatitis C Testing Practices at New York City Hospitals

Perminder Khosa, MPH, Angelica Bocour, MPH, Ryan Duerme, MPH, Nadine Kela-Murphy, MPH, Eric Peterson, MPH Ann Winters, MD

Viral Hepatitis Program, New York City Department of Health and Mental Hygiene

# BACKGROUND

Viral Hepatitis Research Symposium

2018

NYC

Patients with a positive hepatitis C virus (HCV) antibody test result require a confirmatory HCV RNA test to establish current infection status. Confirmatory RNA testing can be ordered at a follow-up provider visit, or done as reflex testing (automatically performed on same specimen as positive antibody test). Although, RNA confirmation rates for antibody positive patients in NYC have improved in recent years, in 2017, 20% of patients newly reported to the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) with a positive antibody test did not have a RNA test within three months. Using reportable surveillance data from patients of the Hepatitis C Clinical Exchange Network (HepCX), a DOHMH-facilitated provider-to-provider learning collaborative comprised of 38 NYC hospitals, DOHMH created HCV testing dashboards. Through HepCX's connections with infectious disease specialists, gastroenterologists and hepatologists at the HepCX facilities, DOHMH is able to share dashboards directly with those providing care to the hepatitis C patients at the hospitals.

# PURPOSE

In NYC, most hospitals do not have the capacity to routinely analyze HCV testing practices at their facilities or to compare their rates to other hospitals. Developing DOHMH surveillance-based dashboards can help hospitals make data-driven decisions to improve their testing and care practices.

# METHODS

DOHMH receives electronic reporting by laboratories in near-real time of positive HCV antibody and positive and negative HCV RNA results for NYC residents, which were used to assess rates of confirmatory RNA testing. Test results were assigned to a standardized facility by evaluating health care facility data for matches to key values of name, address and phone number of HepCX facilities using SAS 9.4 software. Dashboards displaying percentage of patients with a positive antibody test in 2017 who received a RNA confirmatory test ordered by the same hospital within 3 months were created.

# RESULTS

In 2017, 16,279 patients tested antibody positive at one of the HepCX hospitals and 76% (12,352) had RNA test within 3 months of their antibody test. The median hospital RNA confirmatory testing rate was 90% (interquartile range 40.4%). Hospitals that implemented HCV reflex testing showed higher confirmatory RNA rates. Dashboards are emailed to each HepCX hospital biannually, and high volume hospitals will be displayed on the DOHMH website.

Figure 1: Hospital-Specific HCV RNA Confirmation Rates, Dashboard Data - 2017

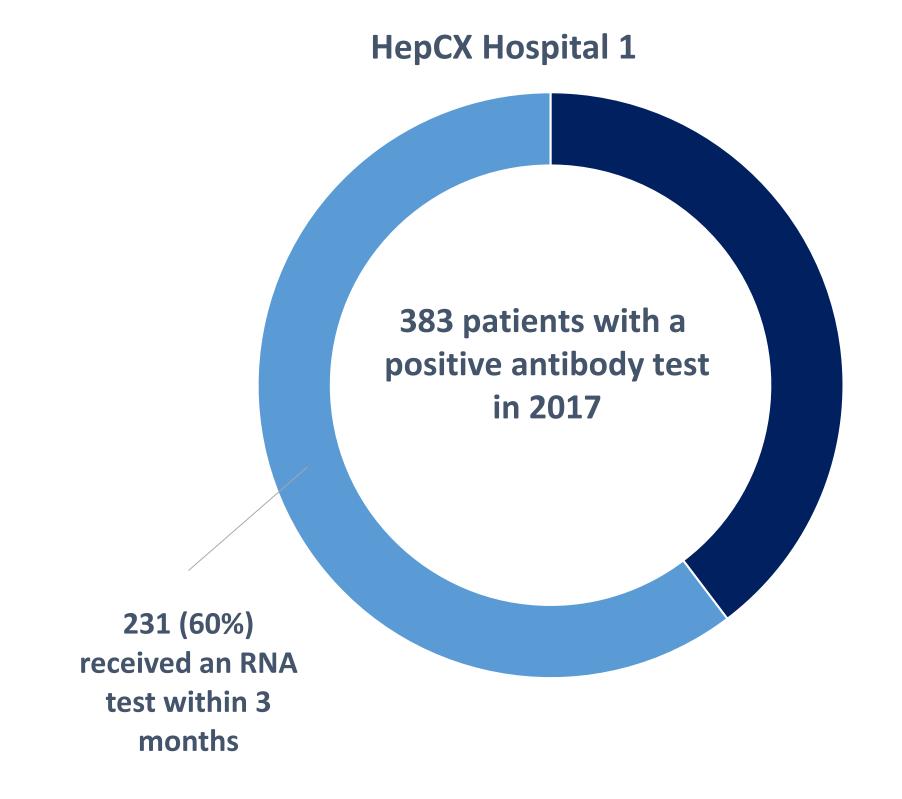


Figure 2. Average RNA Confirmation Rates At HepCX Hospitals By Reflex Testing Status - 2017

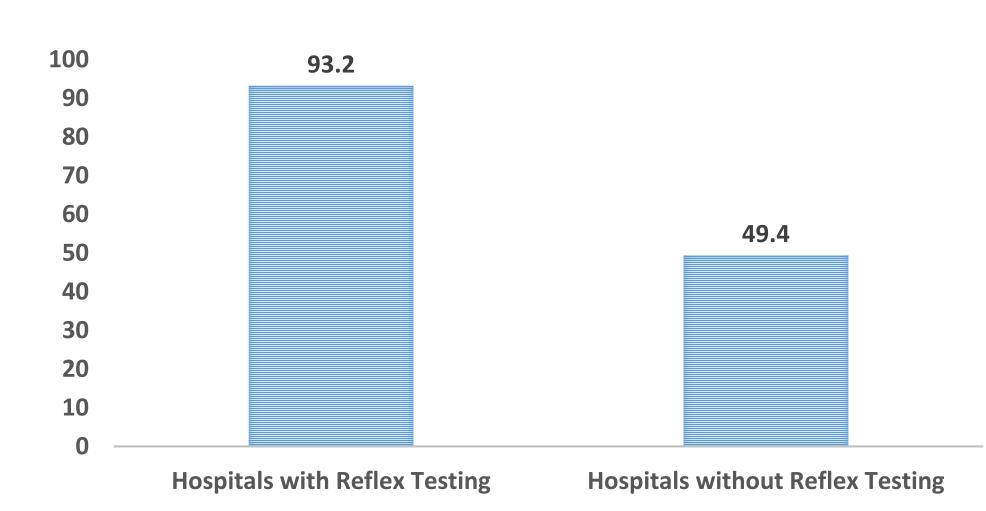
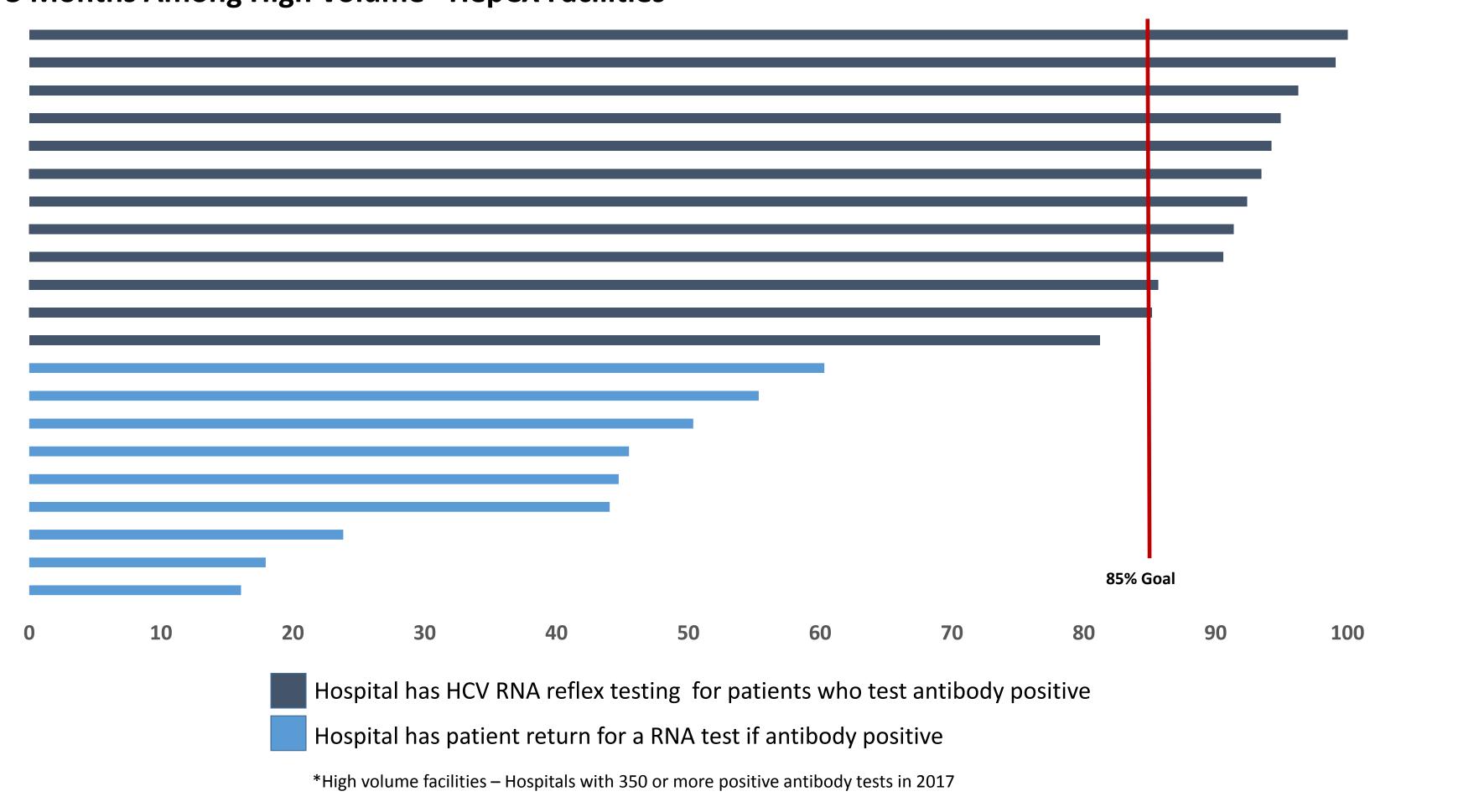


Figure 3. Percentage of Patients With Positive Antibody Test Result in 2017 Who Received an RNA Test Within 3 Months Among High Volume\* HepCX Facilities



# CONCLUSION

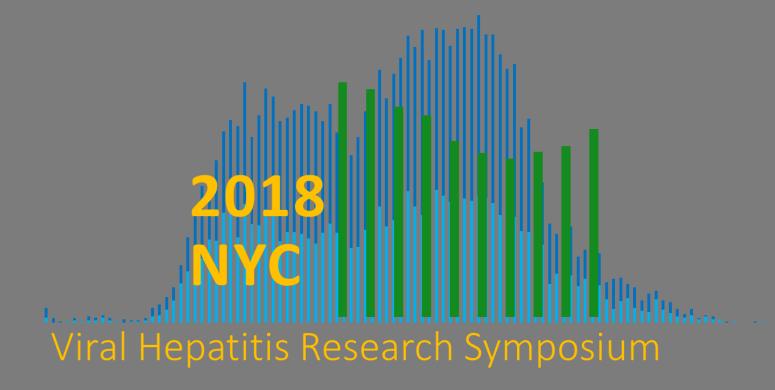
Monitoring the capacity of NYC hospitals to diagnose and treat HCV is a public health priority. Our findings indicate challenges in HCV testing at NYC hospitals. Although, several of the HepCX hospitals provide reflex RNA confirmatory testing, confirmatory rates are still low for some. HCV facility dashboards can be used to illustrate differences in HCV testing practices among facilities. By sharing dashboards with the hospitals, DOHMH highlights the gap in confirmatory testing and aims support the hospitals to use the data to drive change at their facility and improve RNA rates. These findings illustrate the benefit reflex RNA testing has for complete diagnostic testing.

# LIMITATIONS

- Variability of data used to standardize health care facility was a limitation of this analysis which could underestimate confirmatory testing rates for these hospitals.
- Positive HCV rapid test results are not reportable to DOHMH, and thus are excluded in the analysis

# NEXT STEPS

- Future dashboards will include surveillance-based HCV treatment initiation and cure rates to assess linkage to care and treatment.
- Dashboards will be created for facilities outside the HepCX program, such as NYC's Community Health Centers (CHC) which see many patients in the community and provide a large array of primary care services including HCV screening and treatment. Including CHCs in the HepCX network will expand the number of providers who exchange best practices and include primary care physicians.
- In September 2017, the NYC Board of Health amended Health Code §13.03(b)(3) to require all laboratories to automatically perform a confirmatory HCV RNA test (reflex test) when there is a positive antibody test. This change will further the DOHMH's efforts to ensure all New Yorkers with HCV get complete testing.



# PERSONS WITHOUT DURABLE HIV VIRAL SUPPRESSION ARE LESS LIKELY TO INITIATE TREATMENT FOR HEPATITIS C

Health

Katherine Penrose<sup>1</sup>, Miranda Moore<sup>2</sup>, Kizzi Belfon<sup>1</sup>, Amber Casey<sup>1</sup>, Nirah Johnson<sup>2</sup>, Jessie Schwartz<sup>2</sup>, and Angelica Bocour<sup>2</sup> New York City Department of Health and Mental Hygiene, New York, NY, <sup>1</sup>HIV Care and Treatment Program and <sup>2</sup>Viral Hepatitis Program



#### PURPOSE

Individuals co-infected with HCV and HIV experience accelerated liver disease progression and higher mortality than HCV mono-infected individuals.

Current guidelines recommend that HIV/HCV coinfected individuals be prioritized for HCV treatment. However, many co-infected individuals have not yet been treated for HCV.

We examined factors associated with not initiating HCV treatment in 2016 among coinfected individuals in New York City (NYC).

#### METHODS

A deterministic cross-match of the NYC HIV and HCV surveillance registries was conducted to identify individuals who:

- were diagnosed with both viruses by the end of 2015
- were alive and living in NYC at the end of 2016
- had ≥1 positive HCV RNA test prior to 2016

#### **Definitions**

- Co-infection an HIV diagnosis and a positive HCV RNA test reported by December 31, 2015
- HCV treatment initiation first negative RNA result in 2016 preceded by a high positive RNA result (≥1,000 IU/mL)
- Durable HIV viral suppression ≥2 HIV viral loads (VL) that were ≥3 months apart, and no VLs >200 copies/mL in 2016

Multivariable Poisson regression with robust error variance was used to identify factors associated with non-initiation of HCV treatment. Adjusted risk ratios (aRR) were reported.

#### RESULTS

- Of 5,568 co-infected individuals without a negative HCV RNA result reported prior to 2016:
  - 26% initiated HCV treatment and
  - 46% achieved durable HIV viral suppression in 2016
- Compared to those with durable HIV viral suppression, individuals without durable HIV viral suppression were 66% less likely to initiate
   HCV treatment in 2016 (aRR: 1.35; 95% CI: 1.30 1.39).
- Among co-infected individuals without durable HIV viral suppression who had not initiated HCV treatment in 2016, 53% had ≥1 suppressed HIV VL in 2016.

**Table 1**. Characteristics<sup>1</sup> of individuals living and reported with HIV and HCV by December 31, 2015 in NYC, by HCV treatment (Tx) initiation in 2016

**INITIATED HCV TX** 

ARR (95% CI)

NO HCV TX

	INTIALED HEV IX	He Het IX	Attit (3370 Cl)
All (N=5,568)	1,450 (26.0%)	4,118 (74.0%)	
<b>Durable HIV Viral Suppression (2016)</b>			
No	480 (15.8%)	2550 (84.2%)	1.35 (1.30 – 1.39)
Yes	970 (38.2%)	1568 (61.8%)	Ref
Race/Ethnicity		,	
Black	590 (24.3%)	1826 (75.6%)	1.03 (0.98 – 1.08)
Latino/a	634 (27.6%)	1661 (72.4%)	0.97 (0.93 – 1.02)
White	204 (26.2%)	575 (73.8%)	Ref
Other/Unknown <sup>2</sup>	22 (28.2%)	56 (71.8%)	1.01 (0.88 – 1.16)
Gender			
Male	1061 (25.9%)	3031 (74.1%)	Ref
Female	374 (26.5%)	1037 (73.5%)	1.00 (0.96 – 1.03)
Transgender	15 (23.1%)	50 (76.9%)	1.01 (0.88 - 1.15)
Birth cohort			
<1945	37 (25.9%)	106 (74.1%)	1.06 (0.96 – 1.17)
1945-1965	1075 (27.7%)	2807 (72.3%)	Ref
>1965	338 (21.9%)	1205 (78.1%)	1.04 (1.01 - 1.08)
Area-based Poverty Level (2016) <sup>3</sup>			
<10% below FPL	118 (30.6%)	267 (69.4%)	Ref
10 to <20% below FPL	364 (26.1%)	1031 (73.9%)	1.04 (0.97 – 1.12)
20 to <30% below FPL	347 (29.3%)	837 (70.7%)	1.00 (0.93 – 1.08)
≥30% below FPL	614 (25.4%)	1799 (74.6%)	1.06 (0.98 – 1.13)
Unknown	7 (3.7%)	184 (96.3%)	1.34 (1.25 – 1.44)
Incarceration History <sup>4</sup>			
No	1034 (27.6%)	2715 (72.4%)	Ref
Yes	416 (22.9%)	1403 (77.1%)	1.02 (0.99 – 1.06)
Years since HCV Diagnosis			
1-5 years	213 (26.1%)	602 (73.9%)	Ref
6-10 years	436 (24.1%)	1371 (75.9%)	1.03 (0.98 – 1.08)
>10 years	801 (27.2%)	2145 (72.8%)	1.01 (0.96 – 1.06)

<sup>1</sup>Demographic characteristics were obtained from the NYC HIV Surveillance registry.

<sup>2</sup>Other race/ethnicity includes Asian/Pacific Islander, Native American and multiracial categories.

<sup>3</sup>Area-based poverty is based on NYC ZIP code of residence and is defined as the percent of the population in a ZIP code whose household income is below the Federal Poverty Level (FPL.). This measure is not available for people missing ZIP code or living outside of NYC.

<sup>4</sup>Incarceration history was defined as having ≥1 HIV lab reported from a correctional facility prior to the end of 2016.

#### CONCLUSIONS

- People who did not achieve durable HIV viral suppression in 2016 were less likely to have initiated HCV treatment.
- Lower HCV treatment initiation among those without durable HIV viral suppression could be a holdover from the previous New York State Medicaid HCV treatment requirement of controlled HIV viral load.
- Half of individuals without durable HIV viral suppression achieved at least one suppressed HIV VL, indicating that short-term treatment adherence was manageable for many of those who had not achieved durable HIV viral suppression.
- As HCV treatment is of short duration, our findings suggest that individuals without durable HIV viral suppression could adhere to HCV treatment with appropriate support.

# LIMITATIONS

 Our durable HIV viral suppression definition may be restrictive, as it does not include individuals who are monitored less frequently due to well-controlled HIV, though 83% of individuals without durable viral suppression had at least one unsuppressed HIV VL or no HIV labs in 2016.

# ACKNOWLEDGEMENTS

We would like to thank Ann Winters of the Viral Hepatitis Program, Sarah Braunstein and Sonny Ly of the HIV Epidemiology and Field Services Program, and Mary Irvine and Graham Harriman of the HIV Care and Treatment program for their input. This work was supported through a grant from the Health Resources and Service Administration (U90HA30517).



# Leveraging Off-The-Shelf Tools to Drive Real-Time Care Management for HCV Positive Patients

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Comprehensive Health Program, Columbia University Medical Center-New York Presbyterian Hospital

NewYork-Presbyterian

Analytics

#### BACKGROUND

Linking newly diagnosed HCV positive patients to care is challenging in large, multi-campus institutions with complex third-party vendor relationships.

Every day, New York Presbyterian sees almost 7,000 patients and processes an average of 49,000 labs. Acquiring dedicated resources to translate these volumes of data into actionable, real-time information for population-based programs is a significant hurdle.

By leveraging data from New York Presbyterian's clinical data warehouse (CDW) the Comprehensive Health Program (CHP) has developed an in-house alert mechanism using out-of-the-box software that significantly enhances linkage rates for HCV-positive patients.

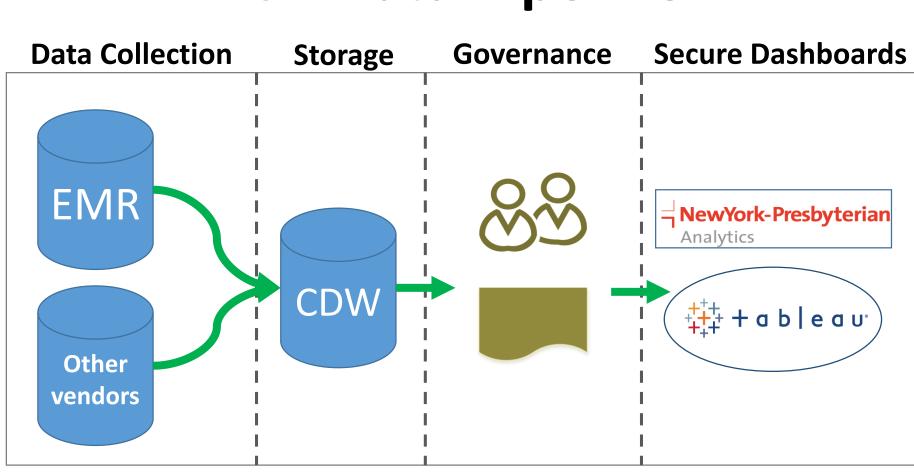
#### PURPOSE

Provide care management teams tools that enhance the ability to rapidly identify and outreach newly-diagnosed HCV patients across NYP's hospital campuses.

## **METHODS**

- Aggregate clinical data from across the healthcare enterprise into a clinical data warehouse (CDW)
- Work with internal IT security and analytics to obtain appropriate access to CDW
- Identify and assemble local subject matter experts in data processing and clinical etiology
- Establish robust data governance policies that ensure extract-transform-load (ETL) procedures into the analytics platform accurately reflect the clinical environment
- Democratize findings by publishing analytics dashboards to an internal, secure site whose access is governed by hospital IT best practices

#### **HCV Data Pipeline**



## RESULTS

We found that up to 70% of newly diagnosed HCV infections since 12/1/2016 are from inpatient visits. Rapid outreach to positive patients is of paramount importance while they are in the hospital. Pairing enhanced outreach services with the implementation of the CHP HCV Tracking Dashboard has more than doubled the overall linkage to care rate for qualifying, newly-infected patients (27% to 63%). This translates to 205 linked-to-care patients as of 5/14/2018.

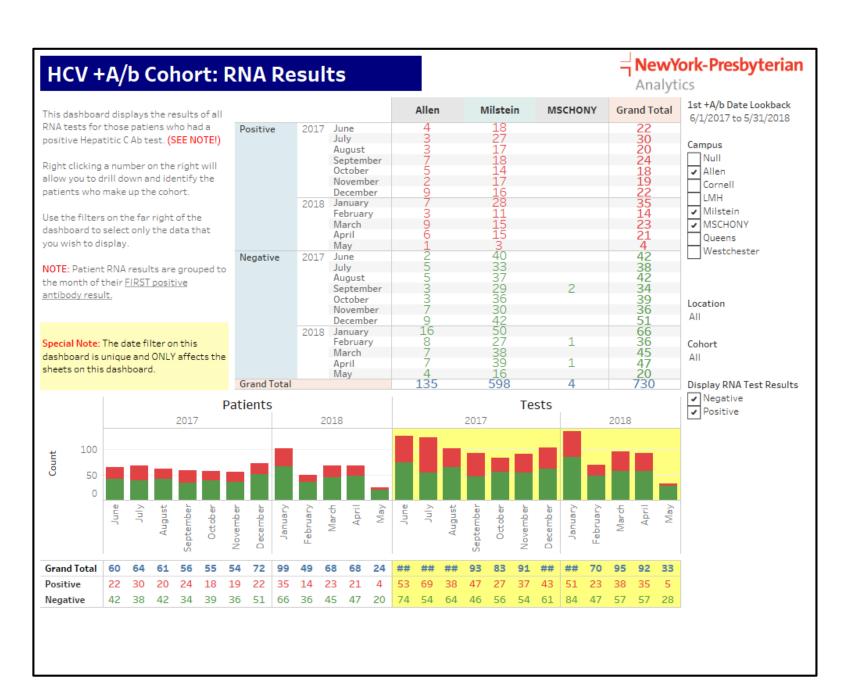
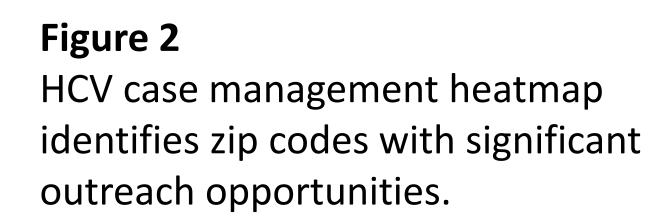
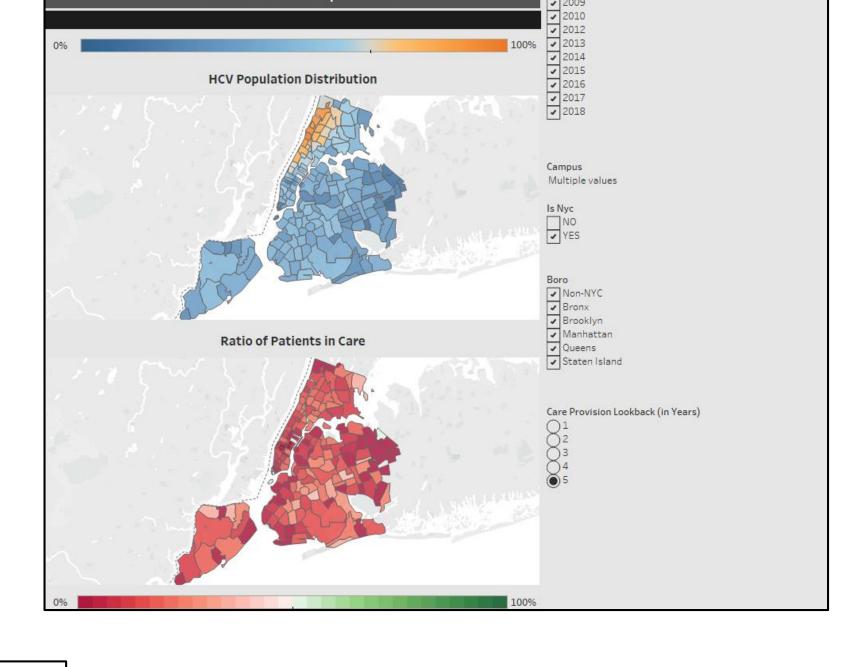


Figure 1

HCV seropositivity tracking by month. Dashboard allows drill downs to monthly patient cohorts for additional data.





# 

Figure 3

Outreach alert dashboard is updated twice per day(AM/PM). Individuals may subscribe to the dashboard to receive screenshots directly to their email. Inpatient unit locations are displayed for immediate outreach.

#### CONCLUSION

No matter the resilience of project champions, even a carefully curated and adhered-to outreach workflow can suffer from missed linkage opportunities for HCV patients. By capturing subject-matter expertise in a Tableau dashboard, CHP has more than doubled its linkage for qualifying HCV positive patients.

Robust HCV care in large-complex institutions requires an understanding of how data is collected and stored, as well as democratized, secure access to data streams.

Enhanced care for HCV-positive patients is possible by strengthening the relationship between hospital's EMR provider, internal Information Technology support services, subject matter experts, and patient-facing clinical staff.

### LIMITATIONS

**Data Latency:** HCV labs typically have a 48hr processing turnaround with an additional 6hr lag between the labs live in the EMR vs in the CDW. This shortens the time horizon for successful outreach to HCV+ inpatients.

**Data Pipeline:** EMR takes priority with all hospital IT resources and service bandwidth. Data integration into the CDW is contract dependent. Current dashboard is specific to uptown NYP campus only.

Operating Environment: Clinical testing environments can change, which affects the code underlying the ETL into the analytics platform. Unless periodic auditing is performed there is significant risk of errors over time.

#### ACKNOWLEDGEMENTS

Significant data infrastructure support/quality control and subject matter expertise from:

Ilir Decka, Director IT Business Solutions
Nebojsa Mirkovic, Analytics Infrastructure Team
Dr. Peter Gordon, CHP HCV Subject Matter Expert
Dr. Jason Zucker, CHP HCV Subject Matter Expert
Dr. Matthew Scherer, CHP HCV Subject Matter Expert

#### DISCLOSURES

Supported by funding from Gilead Sciences Inc. through a grant from the FOCUS program.

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#### BACKGROUND

Despite having New York State laws mandating screening for hepatitis C virus (HCV) and human immunodeficiency virus (HIV), screening rates for these viruses remains low. New York-Presbyterian/Queens (NYPQ) launched the Viral Testing Initiative project (VTI) to increase detection among the adult patient population infected with HCV, HBV and HIV in the community and link them to care.

# PURPOSE

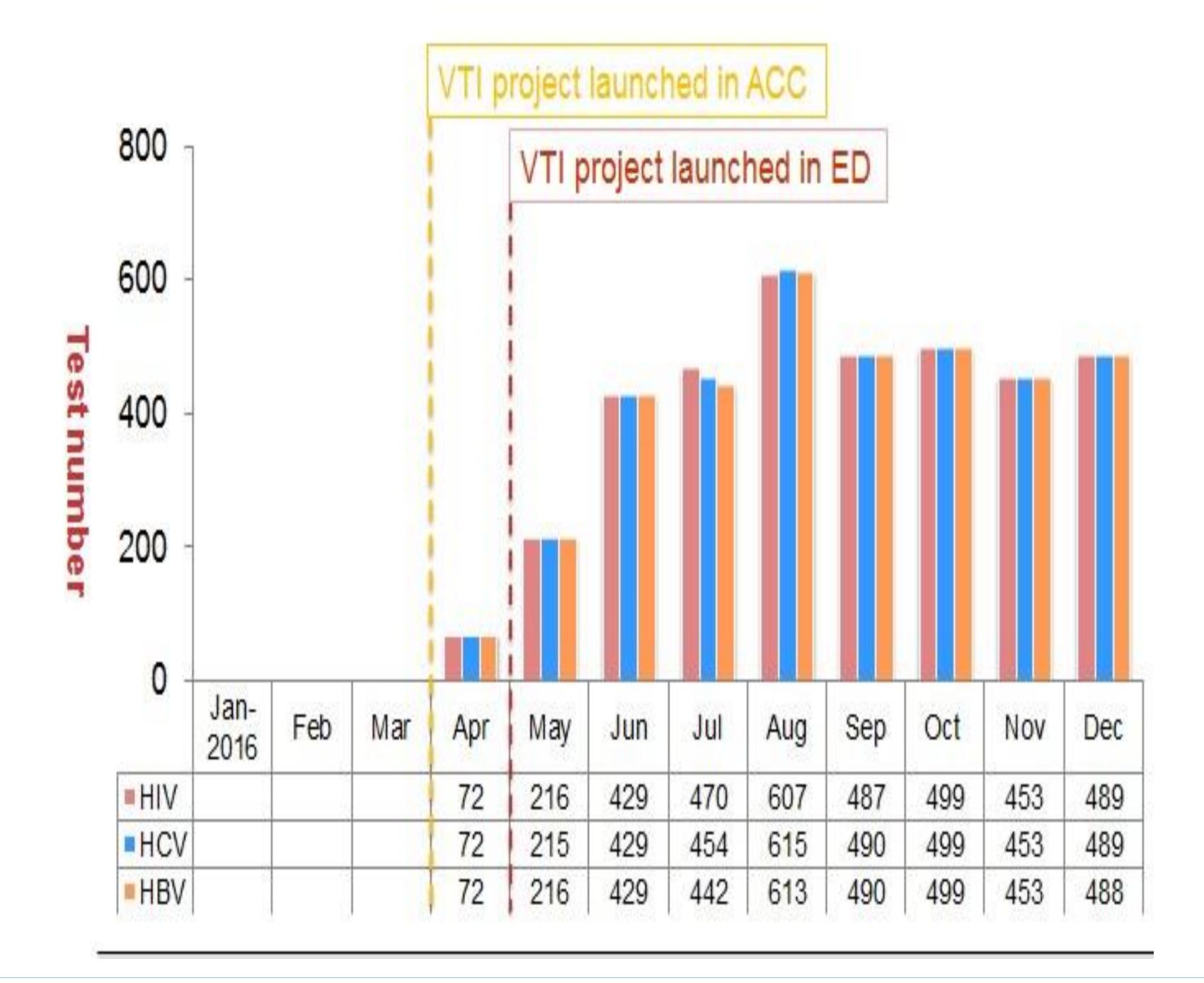
To offer routine screening of HCV, HBV and HIV in our emergency department and ambulatory clinic to assess disease burden of the community.

# METHODS

A prospective cohort study was initiated by routine HCV, HBV and HIV tests in the ACC and the ED in April/May 2016. If a patient consented, an order generated for HCV, HBV and HIV test while continuing to receive standard care. A patient navigator contacted all patients with positive test results and linked them to care.

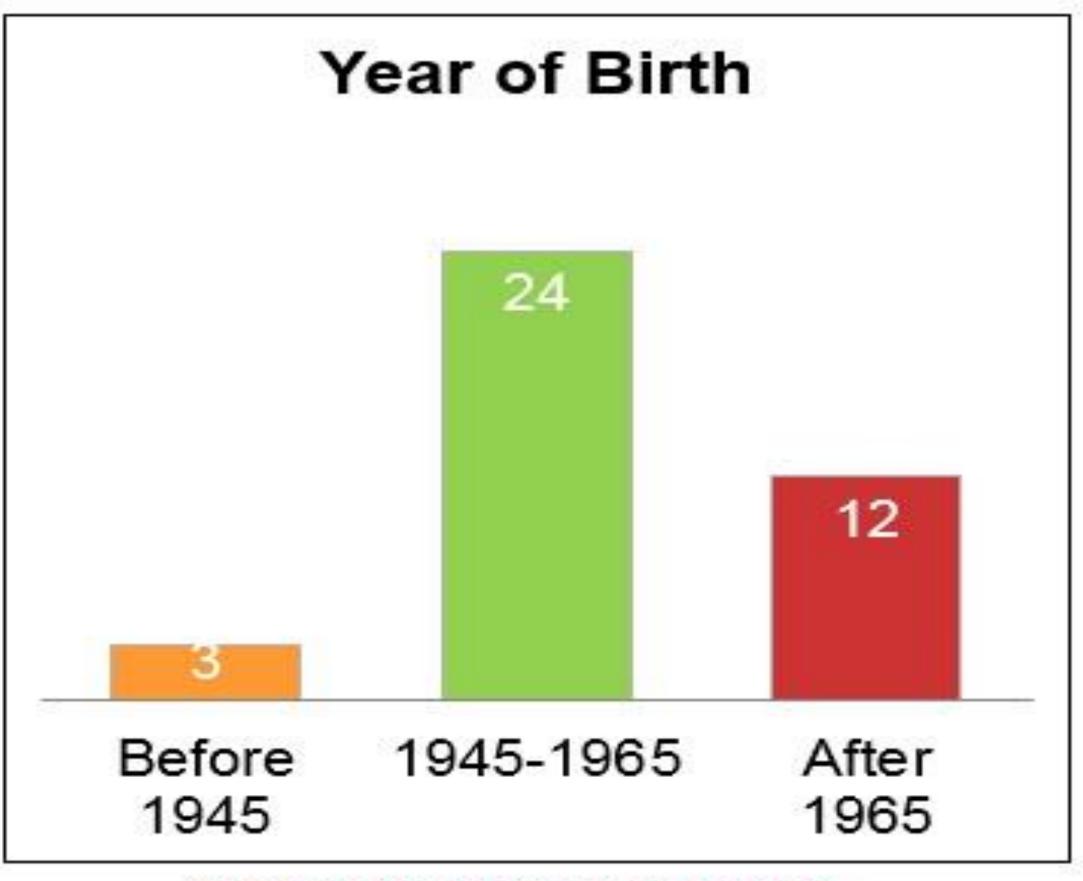
#### RESULTS

A total of 57,213 patients were eligible, of which 3,641 patients consented. 64.3% of tested patients were female, and 35.7% male. 32.2% (1,185) were born between 1945 and 1965. 3,676 HCV antibody tests were offered and 1.03% (38) were positive of which 20% (7) had detectable viral loads. 71.4% (5) were linked to care. 30.8% (12) of patients positive for HCV antibody were younger than baby boomers. 3,677 HBV surface antigen (HBsAg) tests and 3,676 HBV surface antibody (HBsAb) tests were offered, 1.33% (49) were positive for HBsAg, of which 46 (93.9%) were linked to care and 93.9% of them were born in the area which has a HBV prevalence greater than 2%. Over 60% of individuals did not have detectable HBsAb and 26% of them are female under the age of 40. For HIV, 3,670 HIV tests were offered and 0.25% (9) tested positive, of which 7 (77.8%) were linked to care.



#### RESULTS cont.

#### **HCV** Antibody Positive



30.8% are younger than baby boomers

#### CONCLUSION

The VTI has dramatically increased screening for HCV, HBV, and HIV at NYPQ. Not only did we increase detection of disease prevalence in patients who only use ED to receive their medical care but also in the ACC setting which allowed for earlier intervention. Patients who tested positive were referred to an appropriate specialist for further management. Similar projects at other hospitals around the country would significantly decrease the morbidity from these diseases.

#### ACKNOWLEDGEMENTS

New York Presbyterian Queens Ambulatory Care Center New York Presbyterian Queens Emergency Medicine Department

New York Presbyterian Queens Gastroenterology Department New York Presbyterian Queens Infectious Disease Department New York Presbyterian Queens Lang Research Department

# Successful Retreatment of Hepatitis C (HCV) Direct Acting Anti-Viral Therapy (DAA) Failures: Utilizing Currently Available Therapies to Achieve Success

David Bernstein MD, Susan Lee PharmD, Tai Ping Lee MD, Maly Tiev NP, Monique Demabildo RN David Bernstein MD, Susan Lee Pharmb, Tai Ping Lee MD, Maly Tiev MP, Monique Demabilido KN
Sandra Atlas Bass Center for Liver Diseases and Transplantation Division of Hepatology at Northwell Health **Zucker School of Medicine at Hofstra/Northwell** 



#### BACKGROUND

Viral Hepatitis Research Symposium

2018

NYC

**Current direct acting antivirals (DAA) therapies for** chronic hepatitis C achieve a sustained viral response rate of greater than 95%, regardless of genotype or fibrosis stage. Despite this high cure rate, there are still patients who fail to respond to these therapies. As of June 2017, there were no standard salvage therapies for DAA failures leading to provider and patient frustration. In 2016, we treated more than 500 patients with DAA therapies at our center. Eleven patients were identified as DAA failures.

#### PURPOSE

The purpose of this study is to report the characteristics of the patients and the outcome of those who were retreatment with another DAA(s).

#### METHODS

Retrospective observational study from October 2016-April 2017 at Northwell Health to assess the descriptive demographic and clinical characteristics of patients who have had virology failure with the new DAA regimens.

#### **Inclusion Criteria:**

- Age ≥ 18 years old
- Any patients undergoing Hepatitis C through Northwell health from October 1<sup>st</sup> 2016 to April 31<sup>st</sup> 2017
- Patients who have had treatment relapse or virologic breakthrough.

#### **Exclusion Criteria:**

Patients who have not completed their full duration of therapy

#### CONCLUSION

Salvage retreatment DAAs has shown significant success with a cure rate of 82% (9/11). Two out of ten patient failed the retreatment regimen and one patient passed away from renal failure. Both patient that failed the retreatment had resistance associated variants (RAVs). Patient 8 had RAVs Q30H and Y90H which was resistant to all commercially available NS5A inhibitor, velpatasvir was not tested. Patient 9 had RAVs Q30Q/Q and **Y93Y/C** which were resistance to all NS5A inhibitor except velpatasvir.

#### DISCLOSURES

Nothing to disclose

#### RESULTS

Patient #	1	2	3	4	5	6	7	8	9	10	11
Age	67	71	69	62	61	56	65	55	65	67	72
Gender	F	M	M	F	F	M	M	F	M	M	M
Race	Caucasian	Caucasian	Caucasian	Caucasian	African-American	Caucasian	Caucasian	Caucasian	African-American	Caucasian	Caucasian
Initial DAA regimen that patient failed	S + D	V+RBV/ PEG INF +RBV+I /S+O	Н	Н	V+RBV/ PEG IFN +RBV + I	D + S/ PEG IFN +RBV	H / PEG IFN+RBV	H / PEG INF+RBV	Н	Z+RBV 16week	D+S/PEG INF+RBV
Retreatment Regimen	E +RBV	S+RBV+Z	E+RBV	E	S+RBV+Z	E+RBV	Z+RBV	Е	E+RBV	E+RBV	E+RBV
Duration of Treatment (In weeks)	12	12	12	12	12	12	16	12	12	12	12
Fibrosis Score	С	С	F4	F2	C	C	F2	F3	F1	F3	F4
BMI	24.44	31.87	N/A	19.08	30.54	30.85	27.02	38.3	21.96	27.26	33.3
HCV Genotype	3	<b>1</b> a	<b>1</b> a	1b	<b>1</b> a	<b>3</b> a	<b>1</b> a	<b>1</b> a	<b>1</b> a	<b>1</b> a	<b>3</b> a
Baseline Viral Load	1,009	75,336	348,000	1,480,796	41	270,565	286,114	1,174	2343820	1144	315,056
Resistance Associated Variant	Not detected	M28T	Q30E/R/G/Q	Not detected	M28L, Y93H	Not detected	L31M/V, H58P	Q30H, Y90H	Q30Q/R, Y93Y/C	Q30H, Y93H	N/A
PPI	No	No	No	No	No	No	No	No	No	No	No
<b>End of Treatment Response</b>	SVR	SVR	SVR	SVR	SVR	SVR	SVR	Relapse	Relapse	SVR	SVR
SVR 12	Yes	Yes	Yes	Yes	Yes	Yes	Yes	1065968	2164738	Yes	Yes
# of weeks post Treatment – Relapse	N/A	N/A	N/A	N/A	N/A	N/A	N/A	16	16	N/A	N/A

Z=Zepatier SVR: Sustained virological response N/A = Not Applicable or Appliable

PATIENT # 8: Viral load

**PATIENT # 9: Viral load** ON FROM THE POLA THE POLA STEP OF THE OFF THE STEP OF THE POLATION OF THE POLA

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# Access to Direct Acting Anti-viral (DAA) Therapies for HCV Infection: An Analysis of Various DAA Therapies and Copays by Select Insurance Carrier

Susan Lee PharmD, David Bernstein MD, Tai Ping Lee MD, Maly Tiev NP Sandra Atlas Bass Center for Liver Diseases and Transplantation Division of Hepatology at Northwell Health **Zucker School of Medicine at Hofstra/Northwell** 



#### BACKGROUND

The advent of new direct acting antivirals (DAAs) medications has transformed the landscape of Hepatitis C Virus (HCV) treatment in terms of ease of use, side effects and cure rates. However, the cost of the medications is a barrier to curing hepatitis C. The process of obtaining DAA therapy is onerous and often restrictive making it sometimes difficult for HCV patients to obtain curative therapy. As our office has a greater than 98% success rate in DAA approval, we analyzed the first month copayment stated by patient at the time of pharmacist counseling session.

#### PURPOSE

The purpose of this study is to quantify the real cost burden of the hepatitis C regimen the patients incur in our practice.

## METHODS

Retrospective chart review of patients approved for DAAs was analyzed by insurance carrier, prescription plan, copayment and type of insurance

#### **Inclusion Criteria:**

Age ≥ 18 years old

Any patients undergoing or currently receiving treatment for Hepatitis C through Northwell health from October 1st **2014 to September 30<sup>th</sup> 2016** 

Any patients with documented copayments of the first fill of DAA

Any patients with documented insurance carrier of the DAA approval

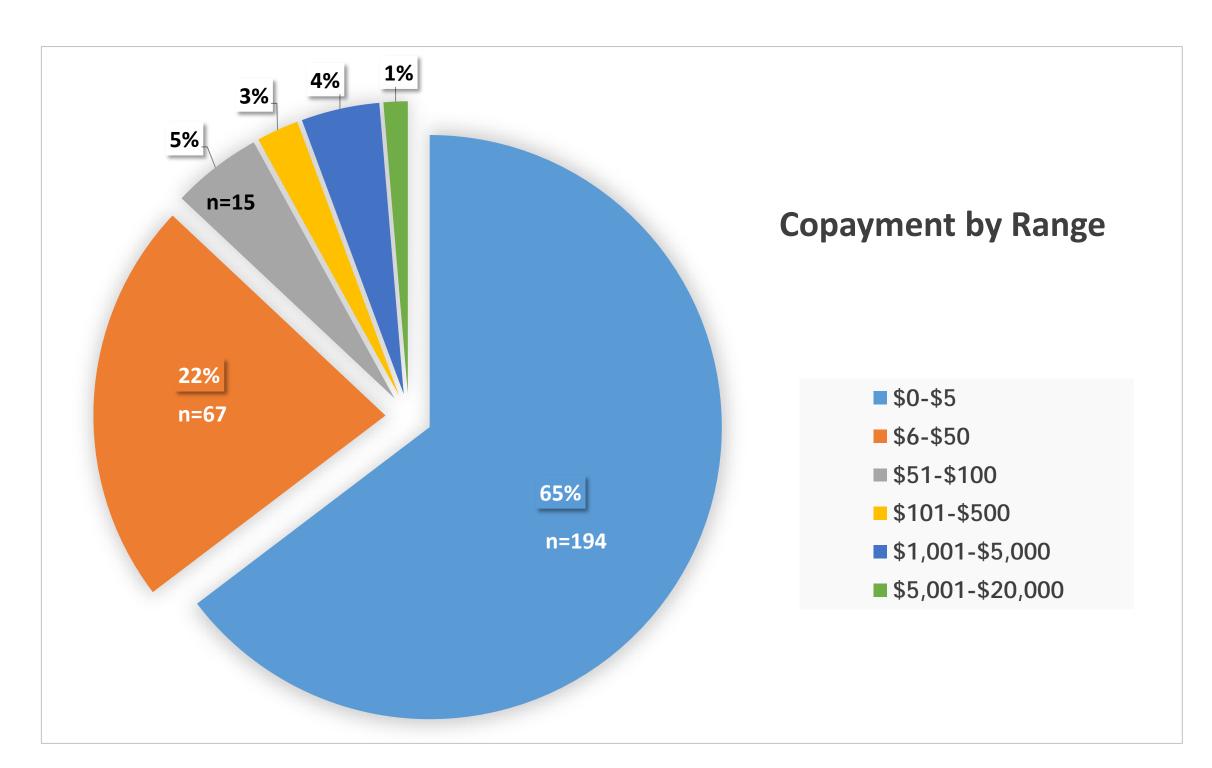
#### **Exclusion Criteria:**

Any patient who did not have documented DAA copayment or insurance carrier

#### RESULTS

Prescription Insurance	# of Patients	Average of Copayment	Min of Copayment	Max of Copayment
CVS Caremark	56	\$12.66	\$0.00	\$110.00
OptumRx	55	\$924.85	\$0.00	\$26,708.87
Emblem Health	45	\$190.14	\$0.00	\$4,470.00
Express Scripts	38	\$25.30	\$0.00	\$129.00
Aetna	15	\$280.42	\$0.00	\$4,039.38
Silverscript	13	\$1,871.94	\$0.00	\$16,536.93
Fidelis	12	\$4.17	\$0.00	\$23.00
Cigna	11	\$314.29	\$0.00	\$3,283.61
BlueCrossBlueShield	9	\$11.84	\$0.00	\$35.00
Empire BCBS	6	\$8.33	\$0.00	\$25.00
Anthem	4	\$30.00	\$5.00	\$60.00
Humana	4	\$3.70	\$0.00	\$7.40
Empire Plan	4	\$398.64	\$3.00	\$1,581.57
Careconnect	3	\$5.00	\$5.00	\$5.00
Envisionrx	3	\$3.33	\$0.00	\$5.00
Medco	3	\$36.67	\$5.00	\$100.00
GHI- Emblem	3	\$0.00	\$0.00	\$0.00
VA	2	\$0.00	\$0.00	\$0.00
Wellcare	2	\$0.00	\$0.00	\$0.00
The Empire Plan	1	\$45.00	\$45.00	\$45.00
Amidacare	1	\$0.00	\$0.00	\$0.00
Liberty Health Advantage	1	\$0.00	\$0.00	\$0.00
Magnacare	1	\$45.00	\$45.00	\$45.00
Healthplus	1	\$0.00	\$0.00	\$0.00
Maxor	1	\$20.00	\$20.00	\$20.00
The State Insurance Fund	1	\$0.00	\$0.00	\$0.00
Innoviant	1	\$10.00	\$10.00	\$10.00
Welldyne	1	\$70.00	\$70.00	\$70.00
Elderplan	1	\$0.00	\$0.00	\$0.00
Affinity	1	\$6.50	\$6.50	\$6.50
NYS Medicaid	1	\$0.00	\$0.00	\$0.00
Grand Total	300	\$320.38	\$0.00	\$26,708.87

Type of Insurance	# of Patients	Average of Copayment	Min of Copayment	Max of Copayment
Indeterminate	125	\$198.21	\$0.00	\$5,000.00
Medicare	75	\$317.01	\$0.00	\$16,536.93
Commercial	53	\$890.44	\$0.00	\$26,708.87
Medicaid	43	\$2.33	\$0.00	\$23.00
Medicare/Medicaid	2	\$0.00	\$0.00	\$0.00
Worker's comp	1	\$0.00	\$0.00	\$0.00
VA	2	\$20.00	\$20.00	\$20.00
<b>Grand Total</b>	300	\$320.38	\$0.00	\$26,708.87



#### CONCLUSION

Despite the high cost of HCV medication, the out of pocket cost is less than what was anticipated by patients. Of the 300 patients' copayments, the average copay was \$320.38 and the sum of all 300 patients' copayments was \$95,151.81. Majority of the patients, 65% had a copay of \$5.00 or less.

#### LIMITATIONS

125 patients' type of insurance was indeterminable.

#### DISCLOSURES

Nothing to disclose

Financial Assistance	Count of Financial Assistance	Average of Copayment	Sum of Copayment
None	224	\$428.18	\$94,626.81
Coupon	32	\$12.19	\$390.00
PAN	26	\$0.00	\$0.00
Supportpath	7	\$0.00	\$0.00
Indeterminant	5	\$15.00	\$75.00
PAF	<b>25</b> % 3	\$0.00	\$0.00
Proceed	1	\$0.00	\$0.00
Healthwell	1	\$0.00	\$0.00
BMS	1	\$60.00	\$60.00
<b>Grand Total</b>	300	\$320.38	\$95,151.81

# eHEPQUAL — A Web-Based Hepatitis C Quality of Care Application for Providers



Larissa Wilberschied, Colleen Flanigan NYS Department of Health AIDS Institute, Bureau of Hepatitis Health Care



Institute

# BACKGROUND

eHEPQUAL, a web-based application (eHEPQUAL.org) designed to capture data and generate reports, including a care cascade, enables health care providers to assess the quality of care provided to patients living with the hepatitis C virus (HCV). The eHEPQUAL system was developed by the New York State Department of Health AIDS Institute (AI). Thirteen quality of care indicators were developed by a group of 53 healthcare providers on the NYS AI, Quality of Care Advisory Committee, using the Delphi method, a process which started in 2015 and was finalized in 2016. A randomly selected sample of patients are reviewed on an annual basis and data are submitted during a three-month-long data entry window. Prior to final submission of review data, programs examine reports, summarize findings and identify actions planned in response to the findings.

# PURPOSE

This analysis summarizes the results of the second year of retrospective quality of care reviews among fifteen NYS Department of Health AI-funded hepatitis care and treatment programs located in community health centers and hospital-based clinics and drug treatment programs across the state.

# METHODS

- The cohort sample was based on eligibility criteria requiring that patients have a positive HCV antibody test conducted on an outpatient basis from 4/1/2016-12/31/2016 and that they not be on HCV medication at the time of the antibody test. Patients referred with documentation of a qualifying antibody test were also eligible.
- Programs with more than 25 eligible patients could either review all patients or a random sample. Programs with 25 or fewer eligible patients conducted reviews on all eligible patients.
- Data were collected on patient demographics, risk factors and thirteen quality indicators across the HCV care continuum including:
- HCV RNA testing;
- Among those with a positive HCV RNA test during the review period: HIV testing, linkage to care, alcohol assessment, alcohol counseling for alcohol users, substance use screening, pre-treatment assessment of barriers to adherence, fibrosis staging, treatment initiation;
- Among those initiating treatment during data collection period: genotype testing, quantitative assessment of treatment adherence during treatment;
- Among those completing treatment during the review period: assessment & achievement of 12-week post-treatment sustained virologic response (SVR)
- Data were collected on services provided during the 15-month data collection period from 4/1/2016 - 6/30/2017. Data on fibrosis staging, alcohol and substance use assessments prior to the data collection period were included if the assessment was completed within 12 months prior to the first positive RNA. HIV test results from any time in the past were also acceptable.
- Following completion of the review cycle, aggregate results from all 15 programs were shared and discussed with participating programs.

# RESULTS

#### **Patient Characteristics:**

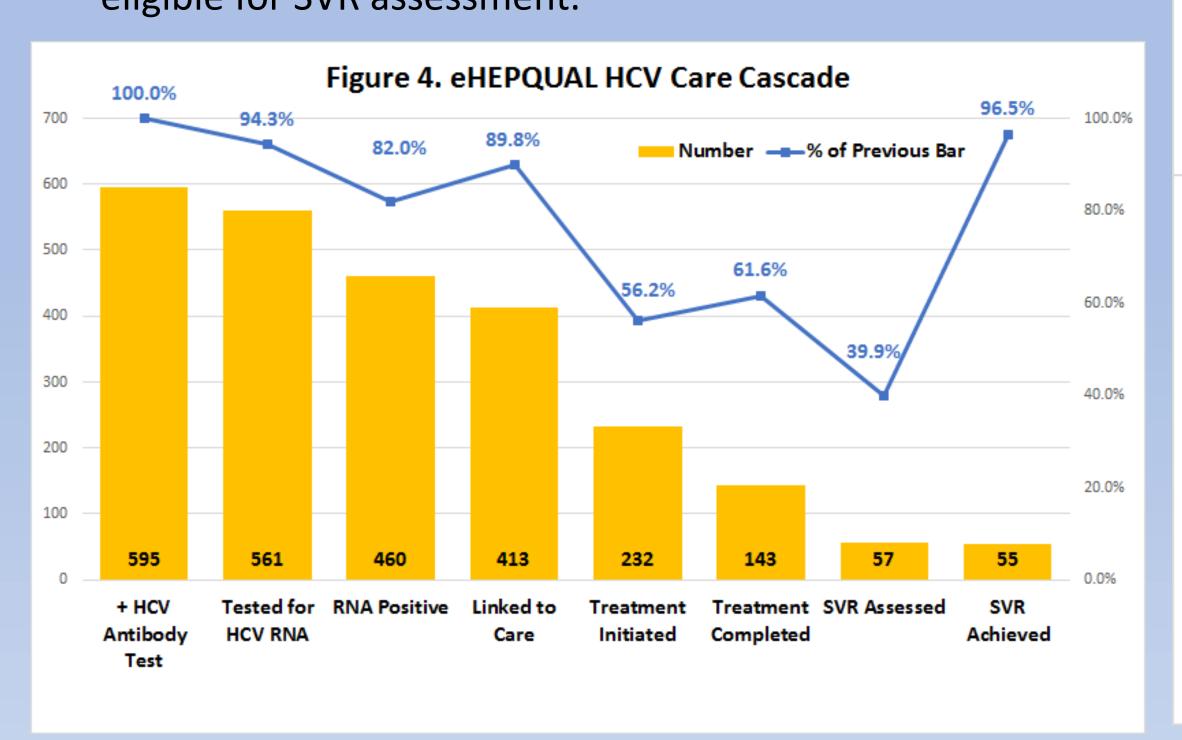
- A total of 595 patients were reviewed. Sample sizes ranged from 11 to 73 patients from each program.
- A majority (52%) of patients were aged 40-59, 67% were male. Approximately a third were white, non-Hispanic (36%) or Hispanic (34%), 26% were black non-Hispanic.
- 67% of patients were reported with a history of current or past injection drug use, 16% had a history of incarceration and 13% were co-infected with HIV. Multiple risk factors could be reported for a single patient.

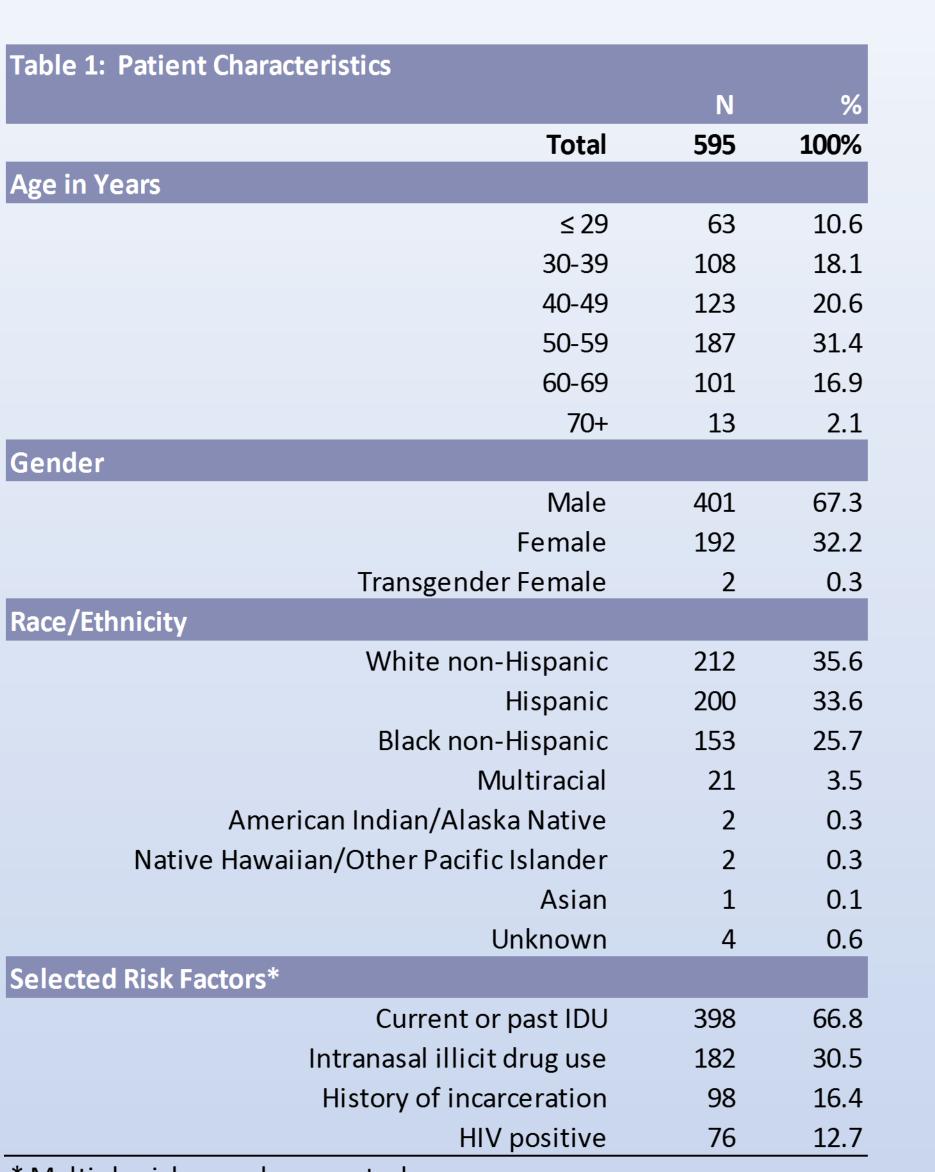
#### **Quality of Care Indicators:**

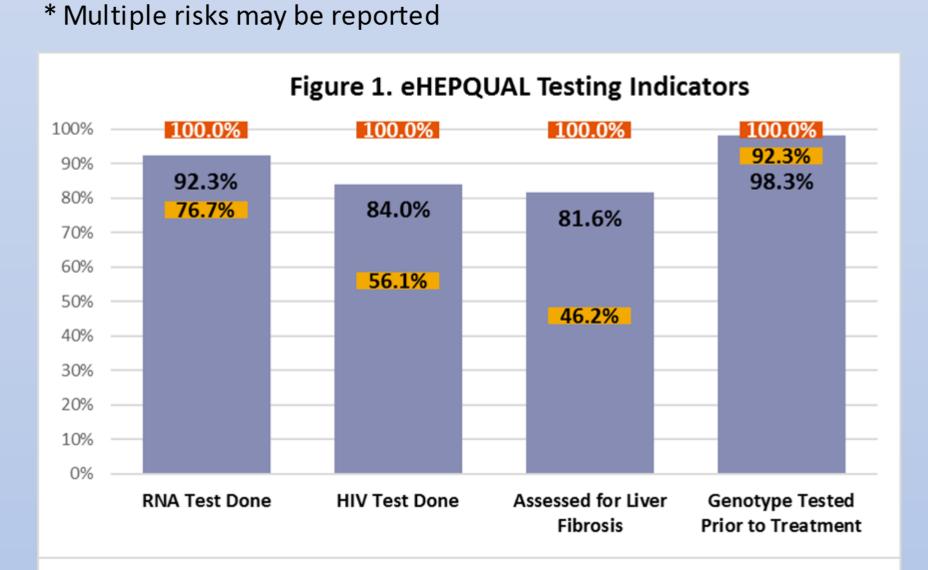
- Results for individual indicators varied by program. When taken in aggregate, treatment initiation and SVR assessment indicators were the biggest challenges for programs. However, some programs were able to achieve levels as high as 87% and 100% respectively.
- Among patients initiating treatment, the time from the date of the first positive RNA result to treatment initiation was as little as 2 weeks and as much as 53 weeks. Half of patients initiating treatment did so within 14 weeks, 75% initiated within 22 weeks and 90% initiated within 32 weeks.
- Among patients completing a 12-week post-treatment SVR assessment, some were assessed 12 weeks after treatment completion, 50% returned after 18 weeks, 75% returned after 28 weeks, and some took as long as 47 weeks.

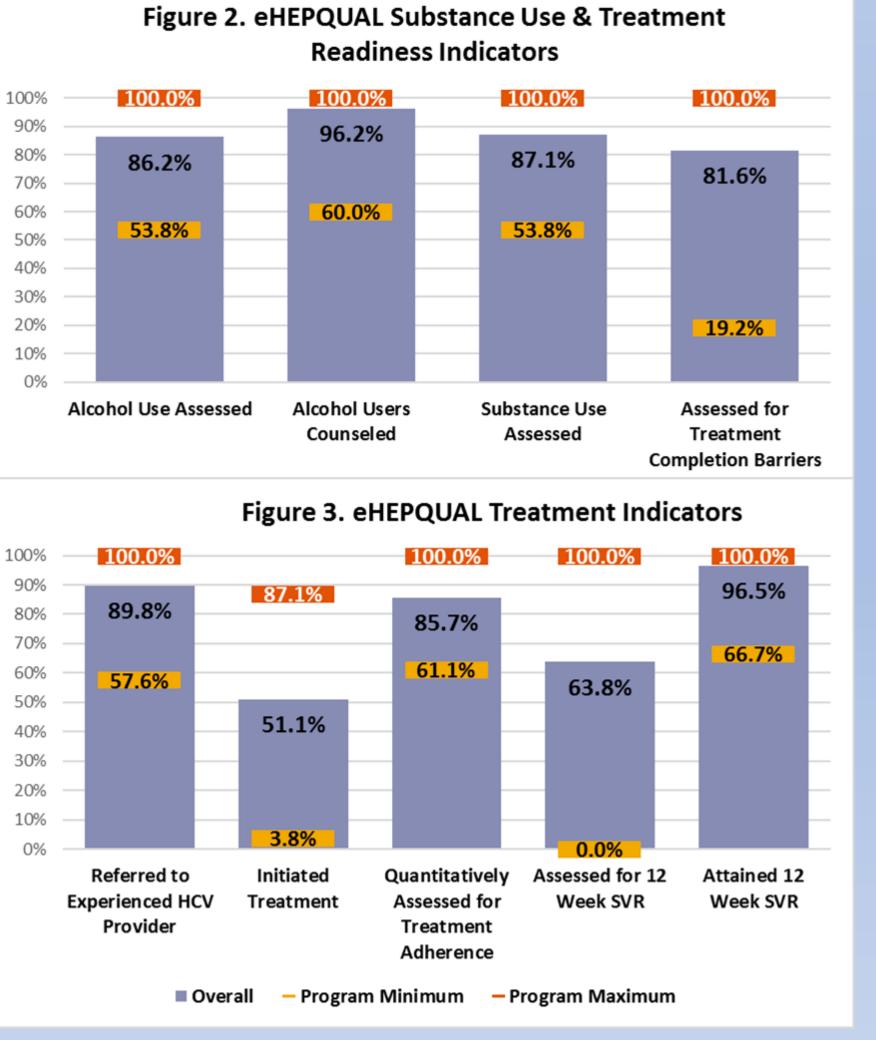
#### **Care Cascade:**

- Care cascades reflecting the flow of patients reaching each step of the care continuum during the data collection period can be created on demand.
- For the purposes of the care cascade, patients who did not complete treatment during the review period, but had at least 12 weeks of medication during the data collection period, were considered to have completed treatment.
- 50% of all RNA+ patients initiated treatment within the 15 month data collection period.
- 40% of patients who completed treatment at any time during the data collection period returned to be assessed for SVR. Patients completing treatment less than 12 weeks from the end of the data collection period were not yet eligible for SVR assessment.

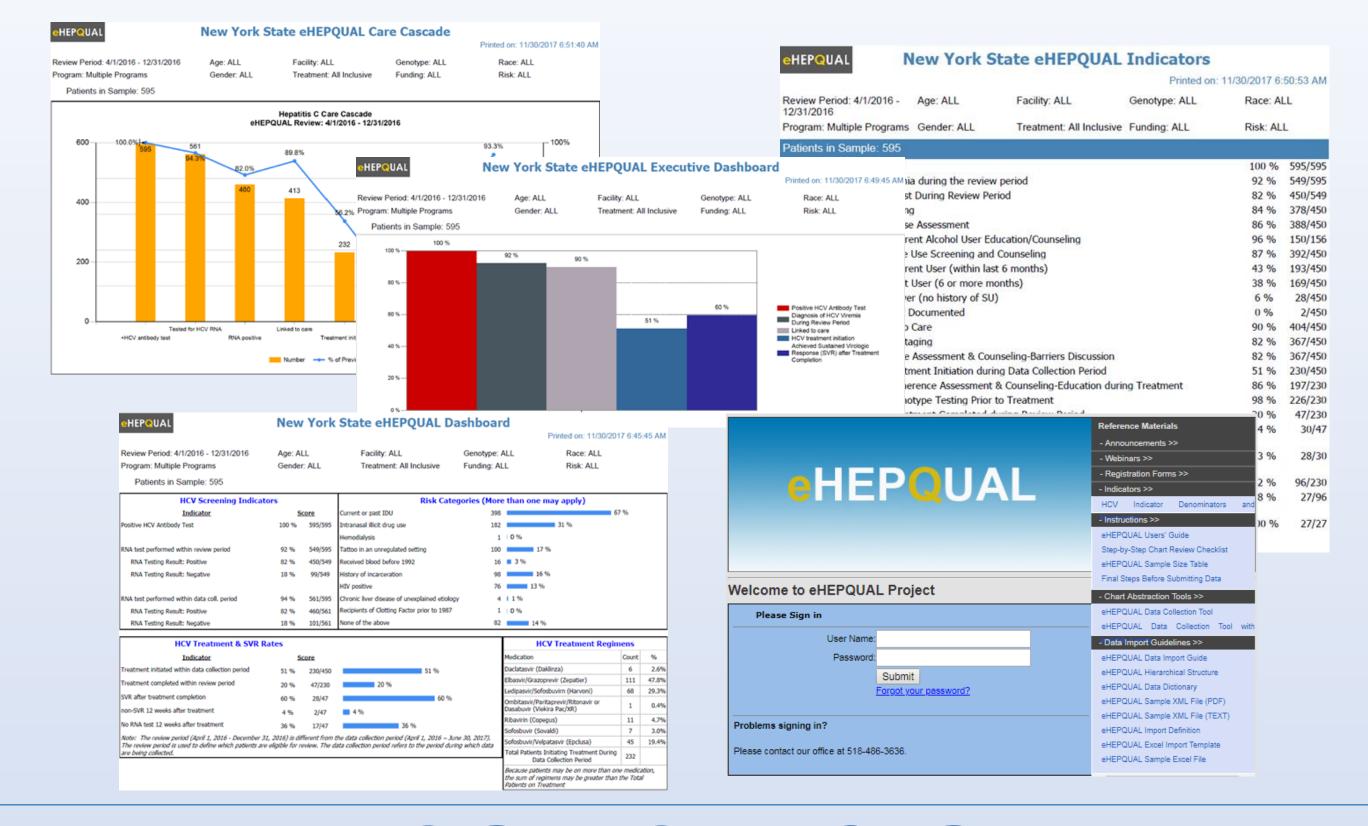








#### **eHEPQUAL Screenshots:**



# CONCLUSION

- eHEPQUAL is a free tool that can be used by outpatient healthcare providers in NYS to assess the quality of hepatitis C-related care on an annual basis.
- On-demand reports describe the patient population and help identify strengths and challenges in care and treatment procedures. Building on strengths and addressing challenges can improve the quality of care provided to patients with HCV and increase the number of patients who are cured of HCV.
- Aggregate data from all eHEPQUAL participants provide useful benchmarks for comparison.

- Data related to indicators that are not clearly recorded in a patient's medical chart or electronic medical record may not be captured in the eHEPQUAL review.
- Data for patients whose treatment process extended beyond the data collection period are not reflected in the review.

# ACKNOWLEDGEMENTS

The authors thank Stephanie McHugh and Meaghan Tartaglia, both of the NYS AI, Bureau of Hepatitis Health Care, who were contract managers for the participating programs during this review. The authors also gratefully acknowledge the dedication and hard work of staff at the following AI-funded programs: Albert Einstein College of Medicine, Anthony L. Jordan Health Center, Brightpoint Health, Erie County Medical Center, Evergreen Health Services, Hudson River HealthCare, Montefiore Medical Center, Mount Sinai Medical Center, New York and Presbyterian Hospital, PROMESA Inc., St. John's Riverside Hospital, St. Luke's-Roosevelt Hospital Center, SUNY Downstate Medical Center, Trillium Health, Whitney M. Young Jr. Health Center. The eHEPQUAL system was built and is maintained by Hugh Dai of LBJ Solutions LLC.

# DISCLOSURES

The authors have no financial disclosures to make.

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# The Cost-Effectiveness of Birth-Cohort Hepatitis C Screening During Pre-Admission Testing for Elective Procedures at an Urban Orthopedic Hospital

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<sup>1</sup>NYU School of Medicine, <sup>2</sup>NYU Langone Orthopedic Hospital



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#### **PROBLEM**

3.5 million Americans¹ and 200,000 New Yorkers² are infected with Hepatitis C virus (HCV). Though 75% of infected persons in the U.S. are unaware of their status², consequences of HCV are devastating. HCV-associated mortality is now greater than HIV-associated mortality³, and HCV is the leading indication for liver transplantation in the U.S. Management of chronic HCV is also costly, including screening and therapeutic endoscopies for variceal bleeding, diuresis, and treatment of hepatocellular carcinoma. In 2011, billed charges for liver transplant alone averaged \$577,100 (not including immunosuppressants or post-transplant care)⁴. Identification of these patients is also more critical now, given the recent commercial availability of all-oral direct-acting antiviral agents, with rates of sustained virological response approaching 100%⁵.

Since 81% of HCV-positive Americans were born between 1945-1965<sup>1</sup>, the CDC issued a recommendation in 2012 for birth-cohort screening<sup>3</sup>. New York State then signed this into Public Health Law, mandating that screening is offered to inpatients born between these years<sup>2</sup>. NYU Langone Orthopedic Hospital incorporated birth-cohort screening into its pre-admission testing (PAT) for elective procedures on February 3, 2015. Though this screening recommendation would theoretically result in the national testing and identification of 66.9 million and 1.1 million people, respectively<sup>6</sup>, how this would translate into long-term cost-effectiveness or future health benefits is still unclear.

#### **GOAL**

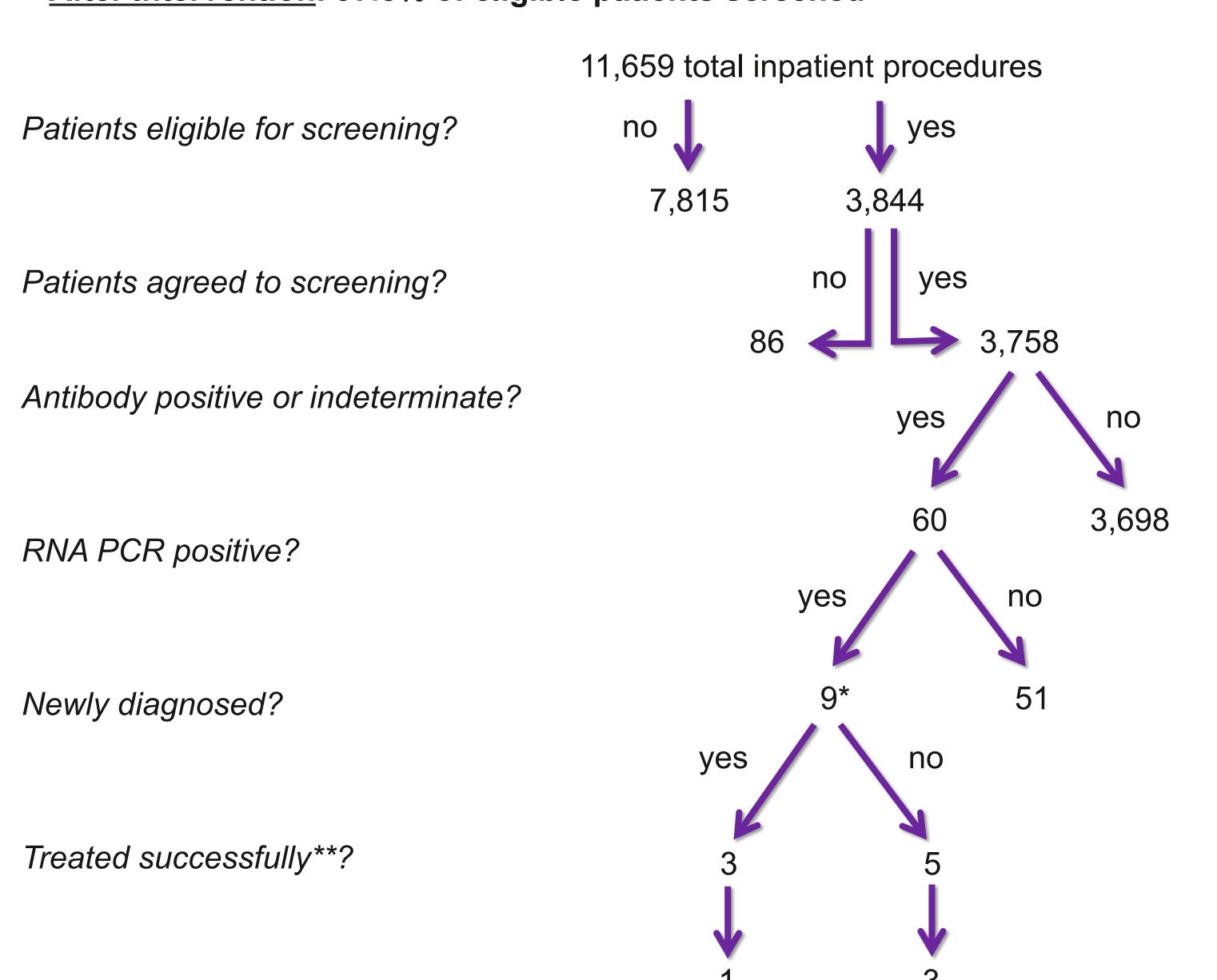
To report the results and costs of birth-cohort screening during PAT at NYU Langone Orthopedic Hospital from 2/3/15 to 1/27/17.

#### INTERVENTIONS

- Trained PAT RN and PAs to educate patients about HCV
- Coordinated with NYU Laboratory Services to use one sample for antibody titer and reflexive RNA PCR
- Created Epic requirement so eligible patients with unplanned admissions were still screened by inpatient nursing staff

#### **RESULTS**

Before Intervention: Zero patients routinely screened After Intervention: 97.8% of eligible patients screened



Costs (calculate using time-driven activity-based costing):

PA + RN's Time: \$18.80

(calculated using salary including fringe benefits, hours worked per week, weeks worked per year, and total 15 minutes involved in screening)

t

Antibody Titer: \$19.57

+

Quantitative RNA PCR: \$58.67

Cost per screen = \$38.37

Cost per screen after positive or indeterminate titer = \$97.13

Screening cost over this time period = \$147,720.06

Cost per *newly* diagnosed patient = \$49,240.02

Screening cost per successfully treated patient = \$36,930.03

#### CONCLUSIONS

Our 97.8% screening capture rate demonstrates that pre-admission testing for elective orthopedic procedures is a novel, yet effective and underutilized way, to engage the "baby boomer" generation in HCV screening. Our study *newly* identified three chronic HCV infections. Though two of these patients declined antiviral therapy, identification is still critical, allowing patients to receive other healthcare interventions that reduce future morbidity and mortality. Additionally, only one of the four *treated* patients was *newly* diagnosed, demonstrating that redundant birth-cohort screening is a unique opportunity for *re-linkage* to care. Finally, a cost of \$49,240.02 per newly diagnosed patient and a screening cost of \$36,930.03 per successfully treated patient is cost-effective when compared to costs of end-stage liver disease, hepatocellular carcinoma, and liver transplant (which cost \$577,100 in 2011, not including pre or post-transplant care<sup>4</sup>).

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<sup>\*</sup>Of the nine patients identified with chronic active HCV infection, one could not be reached for further follow-up.

<sup>\*\*</sup>Four patients declined treatment. The four treated patients all reached complete virologal response in follow-up.



# Adherence Impact for New Hepatitis C Treatment on Cost Effectiveness in a Managed Care Organization

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#### Description

- New direct-acting agents (DAA) have revolutionized the treatment of chronic hepatitis C virus (HCV) offering cure rates greater than 95%.
- These all-oral, interferon-free regimens require daily dosing for 8-24 weeks with cost per treatment at nearly \$100,000. A cost-per-cure analysis supports these treatments, but the ultimate value to public health depends on adherence rates and completion of the treatment.
- VNSNY CHOICE SelectHealth, a managed care organization (MCO) for HIV+ adults with Medicaid living in NYC, was conscious of the many challenges in treatment initiation, avoidable interruptions or non-completion of therapy. In result, the team strategically anticipated and overcame these challenges.

#### Aim

 MCO pharmacist interventions implemented to avoid disruption of HCV therapy and cost of re-treatment.

#### Actions Taken

- Weekly monitoring of HCV therapy by MCO pharmacist was implemented to reduce interruption and improve adherence.
- The pharmacy claim data from January 2014 to June 2016 for completed cases was examined.
- MCO pharmacist reviewed all approved Prior Authorization (PA) cases for appropriate duration and timely refills until end of therapy.

#### Changes Made

 The requirement for HCV virologic response at week 4 was removed as part of the Prior Authorization Criteria.

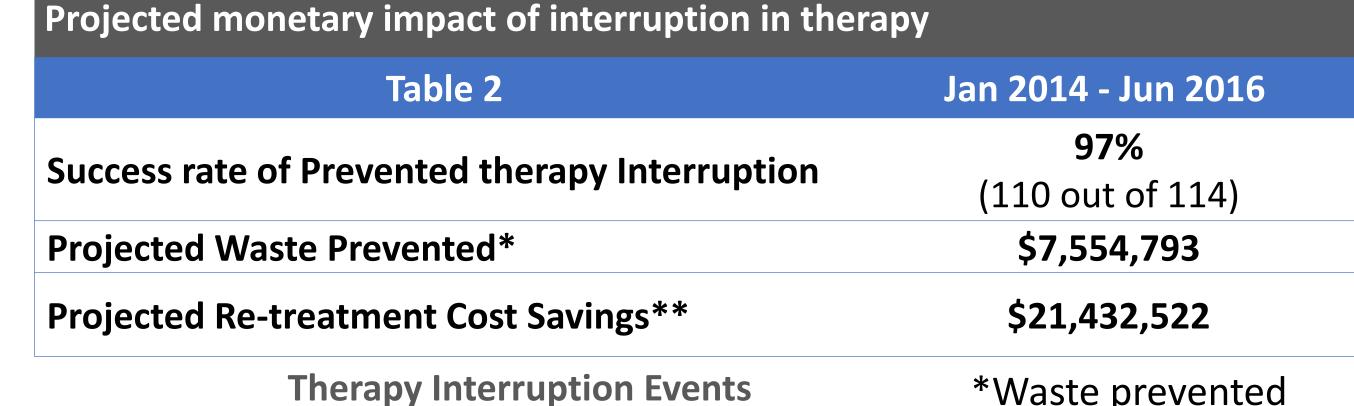
#### Multi-Disciplinary Team

- **Channel Outreach**  MCO Pharmacists Specialists
- Medical Directors
- Social Workers
- Care Managers

#### Results

- Table 1 demonstrates approved PA cases with at least 1 fill and the number of cases with potential therapy interruption.
- Table 2 demonstrates the success rate of prevented therapy interruption cases and projected monetary impact.
- The completion rate of HCV therapy for cohort was 99% (409 out of 413 cases).

Composition of Cohort Analyzed						
Table 1	Jan 2014 - Jun 2016					
Cases with at least 1 fill	432					
Excluded Cases	19					
Cases eligible for intervention	413					
Cases with potential therapy interruption	114					



■ Forgot Refill

■ Week 4 HCV VL

Processing Info

Omitted

Prevented Interruptions:

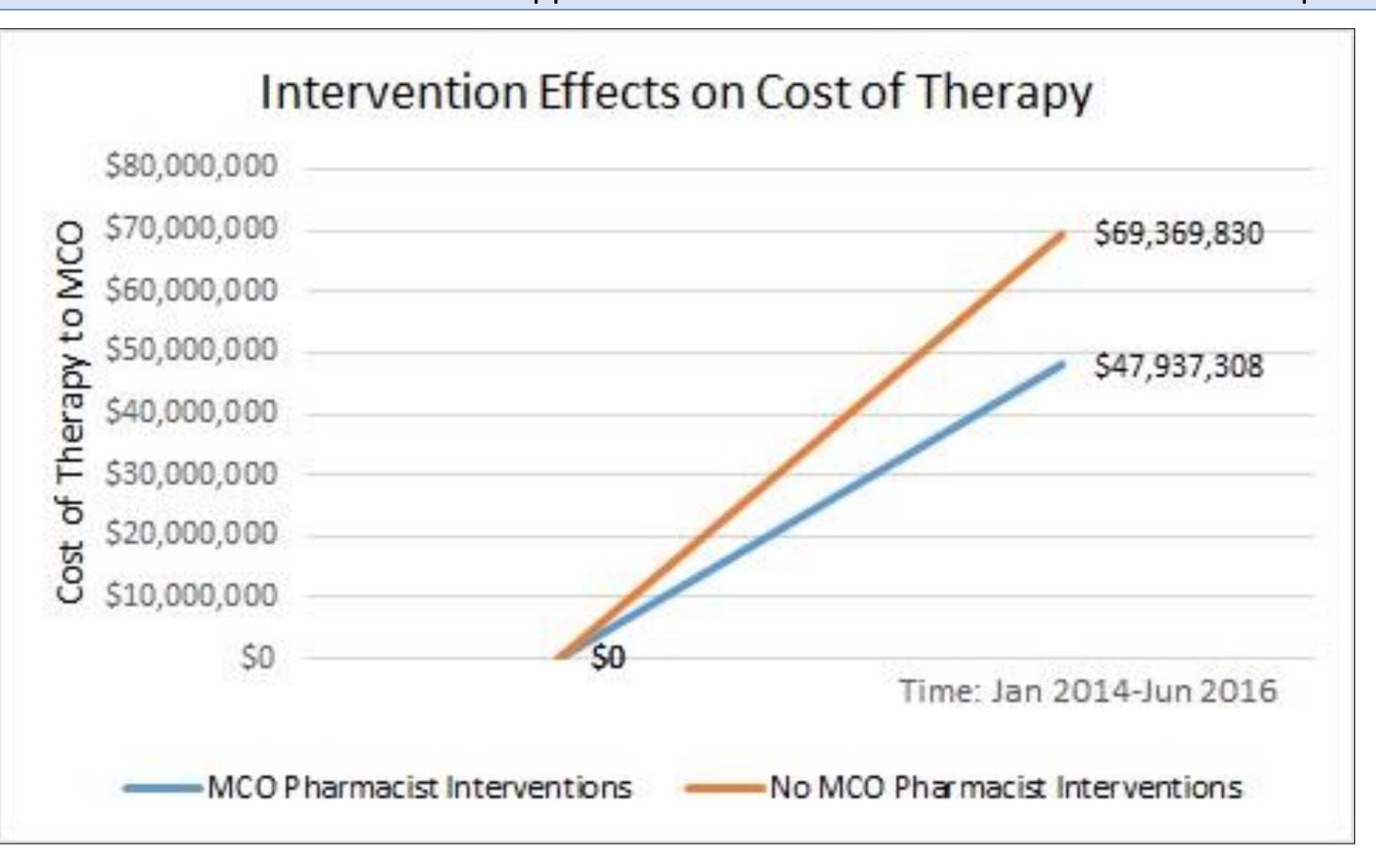
110 out of 114

■ PA extension



\*Waste prevented was calculated as the number of drug fills prior to the potential ■ Specialty at Retail interruption event. \*\*Cost savings was Pharmacy Restriction calculated as the total cost of retreatment with the same drug and duration.

#### Therapy Interruption Event Description Forgot Refill Member or prescriber forgot to request refill on time. Pharmacy forgot to process auto-refill. Prescriber did not write for sufficient refills to complete therapy. Requirement for HCV Viral Load at week 4 of therapy as part of the Prior Authorization criteria. Has since been removed as a Week 4 HCV VL requirement. Specialty at Retail Provision that enables members of MCO SNP Plans to obtain mail order specialty drugs at any retail network pharmacy. MCO allows their members to use any network pharmacy if that pharmacy agrees to accept a price comparable to the mail order specialty pharmacy price. Member is restricted to a specific pharmacy by State. Pharmacy Restriction **Processing Info Omitted** Member ID #, BIN# or PCN# were not available to the pharmacy at time of service, resulting in a denied claim. Prior Authorization expired prior to the completion of therapy due to late member start date. Or prescriber requested PA Extension extension to original PA timeframe due to new clinical information (ex: AASLD guideline recommendations) Lost to Follow Up Prescriber stated that member missed appointments and could not be located for follow up.



#### Conclusion and Lessons Learned

- This analysis demonstrates the dramatic potential impact that interrupted or noncompleted HCV treatment can have on the cost-effectiveness of this promising new treatment modality. As well as, highlighting the significant impact of interventions by a Managed Care Organization (MCO) to prevent waste of this valuable resource.
- The unique role of the MCO acts as an interface between members, prescribers, pharmacies and pharmacy benefits managers (PBMs) enabling the occurrence of these interventions, which the individual parties would unlikely be able to implement alone.
- While the traditional practice of MCOs and PBMs focus on cost control as a top priority, there is increasing recognition that inconsistent medication refill adherence may provide short term cost savings to a payer but at an unacceptable long-term cost in quality outcomes and overall expenses.

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#### Barriers to hepatitis C treatment access across the United States: perspectives of public health officials and advocates

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#### Background

#### Hepatitis C (HCV) affects 5 million Americans and is disproportionately concentrated in low-income populations including people who inject drugs

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- Curative medications for HCV have been available since 2014, but uptake has been limited by high drug prices · Anticipating the budget impact of the new drugs, state fee-for-service
- Medicaid programs implemented treatment restrictions to limit access to those with:
- · High disease severity · Abstinence from substance use

(PWID)

- A specialist medical prescriber
- State health agencies face the challenge of implementing treatment access in a restrictive, but dynamic, policy environment,

#### Objective

To understand barriers to and enablers of HCV treatment access across

different state political environments and patient populations

#### Research Methods

- . Key informant interviews with health officials and advocates in diverse states with expertise in HCV treatment access and policy
- Purposive and snowball sampling, aiming for diversity in:
- State characteristics (region, political environment, known HCV treatment)
- restrictions) · Professional roles (Viral hepatitis, HIV, and Infectious disease bureaus of
- public health agency; AIDS Drug Assistance Programs; non-governmental organizations)
- · Evolving sample until no new topics or viewpoints emerged
- · Final sample: 18 interviews across 6 states
- Main focus of interview guide related to HCV treatment access:
- · Contrasts between key subpopulations: HIV / HCV co-infected · Facilitators of treatment uptake

· Barriers to treatment uptake

- . The role of Medicaid restrictions **PWID** 
  - · Policy changes over time
- · Transcripts analyzed using content analysis to discover and report themes and concepts
- Preliminary coding guide developed based on iterative review of transcripts . Data analyzed in NVivo with constant comparative method, with subsequent
- interviews used to refine existing codes and identify new ones
- · All authors reviewed coded data for synthesis and insights Categories/themes developed during monthly phone meetings among authors

#### **Results: Barriers to HCV Treatment Access**

Cost motivated payers to enact restrictions

Medicaid managed care restrictions are diverse and challenging to regulate. compared to fee-for-service Medicaid

Lack of transparency on drug pricing limits informed decision making

Stigma surrounding substance use limits provider and patient willingness to undergo treatment

Fear of the side effects of older treatments limits uptake even as new regimens are more tolerable

A repeal of the ACA could limit access to affordable coverage

"Cost concerns were just so overwhelming...and state Medicaid programs... had not budgeted for these drugs and were just grappling with how they could make access a

reality."

"It's very clear in the law that Medicaid managed care plans cannot use criteria that are more restrictive than the fee for service standard. Now, that doesn't always mean that all states follow that law."

"There are a lot of providers out

there that don't want to screen for hep-C because they think they're going to bring in this flood of people who are drug users, and they don't want to take care of those individuals."

#### Results: HIV/HCV Coinfected Populations Have Better Access

AIDS Drug Assistance Programs directly support HCV treatment

ADAP-enrolled patients face less restrictive treatment eligibility requirements than they would on Medicaid

Health homes, care coordination, and housing support for people living with HIV enable engagement in care

"Over the past several years we've seen a more integrated approach related to the Ryan White Program, in that Ryan White Part B and other program parts have taken on the role of providing medical care related to individuals with hepatitis C..."

"The HIV epidemic was changing and needs were changing, but there was an incredible infrastructure here. Why don't we start using that for hepatitis?"

#### **Results: Some Barriers Have Nuanced Impact**

The impact of cost is not as severe as initially feared

Lack of transparency allows for 'behind-the-scenes' negotiations

"if everyone had presented for care simultaneously and we had paid full price for those drugs, it would have broken the bank for Medicaid and even strained the ability of our HIV drug assistance program to keep up...neither one of those was a reality."

#### Results: Regional Variation in Political Support and Provider Availability

Rural areas face a shortage of specialty providers

Statehouse political and financial support varies

providers—and there's an awful lot of rural [areas]--you're not going to be travelling...to the doctor unless you're almost dead." "It was an effective treatment, and therefore

"If you're not...where there're a lot of

we should cover it, and that's just how the leadership at Medicaid is...they made that decision early on and there was no muss or fuss about it."

#### Conclusions

- There are dynamic mechanisms by which cost affects treatment access at the paver and provider levels. Our findings demonstrate that the impact of cost is less severe than first feared, and this has
- allowed improvement in treatment restrictions
- Early literature on treatment restrictions focused on fee-for-service Medicaid, but our findings show that Medicaid managed care plans also have variations in treatment access which need further characterization
- · Urban-rural variation in specialty provider availability may be a significant disparity in this field, and warrants further study.

#### Limitations

- Due to purposive sampling, results are not representative of the average response
- Recruited individuals whose focus was on treatment access, not on resource allocation · State and federal policy landscape is shifting, our findings represent the policies in late
  - 2016-early 2017

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