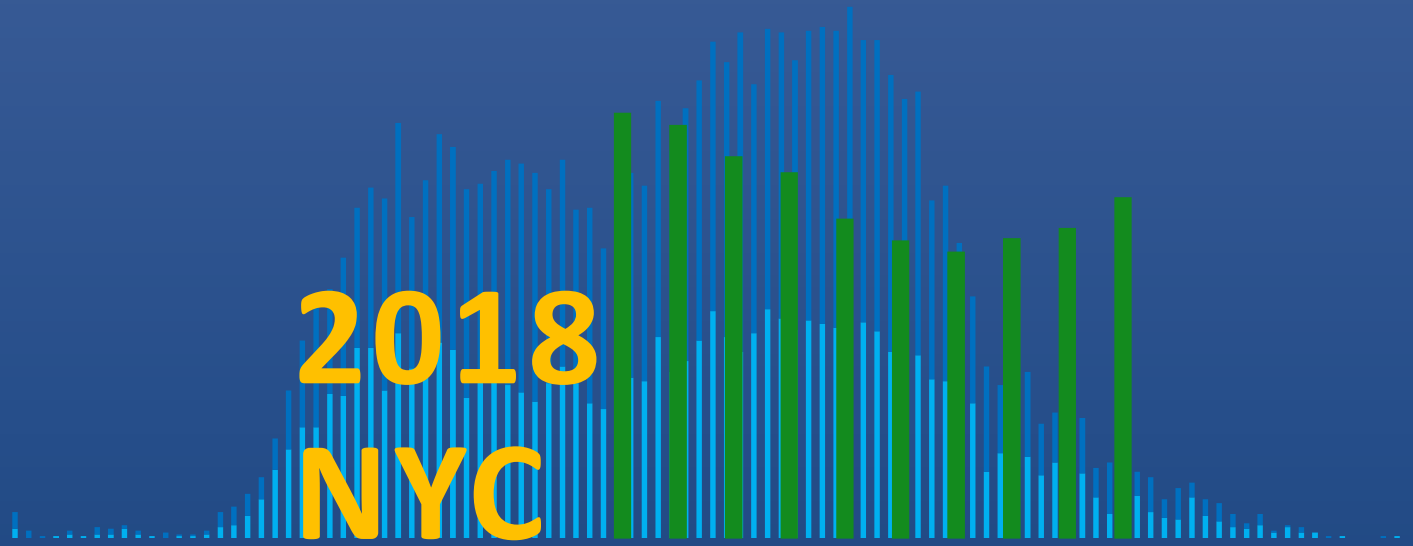


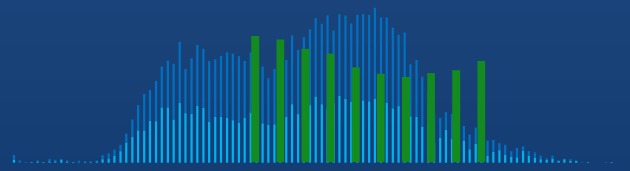
Viral Hepatitis Research Symposium

Project Inspire at Montefiore

Ginger Wey, MD

Montefiore Hospital

Bronx, NY

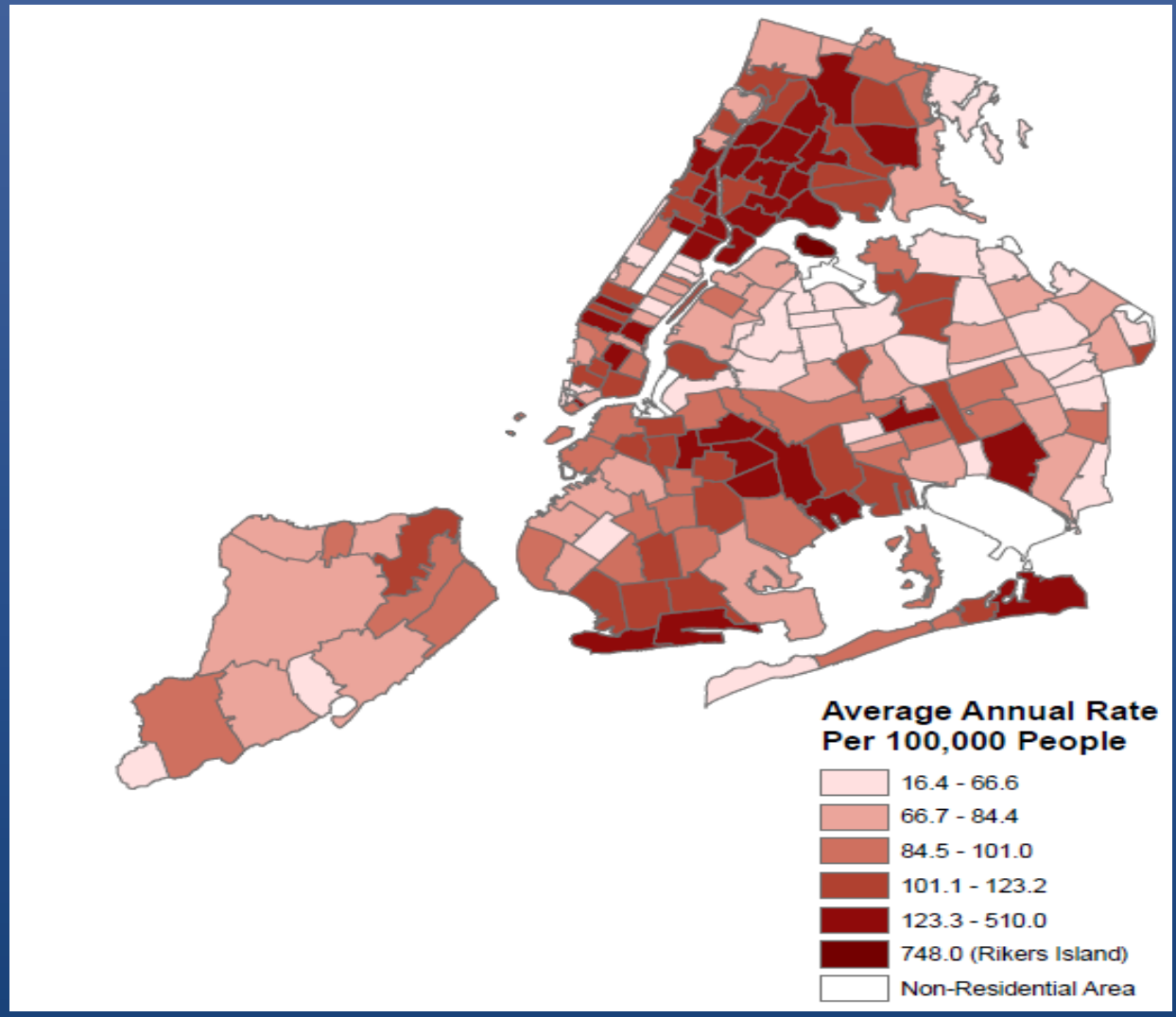


Disclosure

None

Hepatitis C geographic distribution from NYC DOH 2016 Annual Report

People newly reported with chronic hepatitis C in New York City by ZIP code, 2015-2016



Project INSPIRE

- **INSPIRE** - **I**nnovate & **N**etwork to **S**top HCV & **P**revent complications via **I**ntegrating care, **R**esponding to needs and **E**ngaging patients & providers
- **Program Period:** September 1st, 2014 – August 31st, 2017
- **Geographic Reach:** Bronx and upper Manhattan

Project INSPIRE – Goals & Activities

- **Primary Aim:** To demonstrate a model of service delivery and payment that can reduce morbidity and death from chronic illnesses and reduce costs associated with its complications using chronic HCV infection as a case study.
  1. **Better care**
     - Increasing hepatitis C cure rates
     - Increasing screening for depression and alcohol abuse
  2. **Lower costs**
     - Reducing expenses from hospitalizations and emergency department visits
     - Fewer complications related to hepatitis C infection

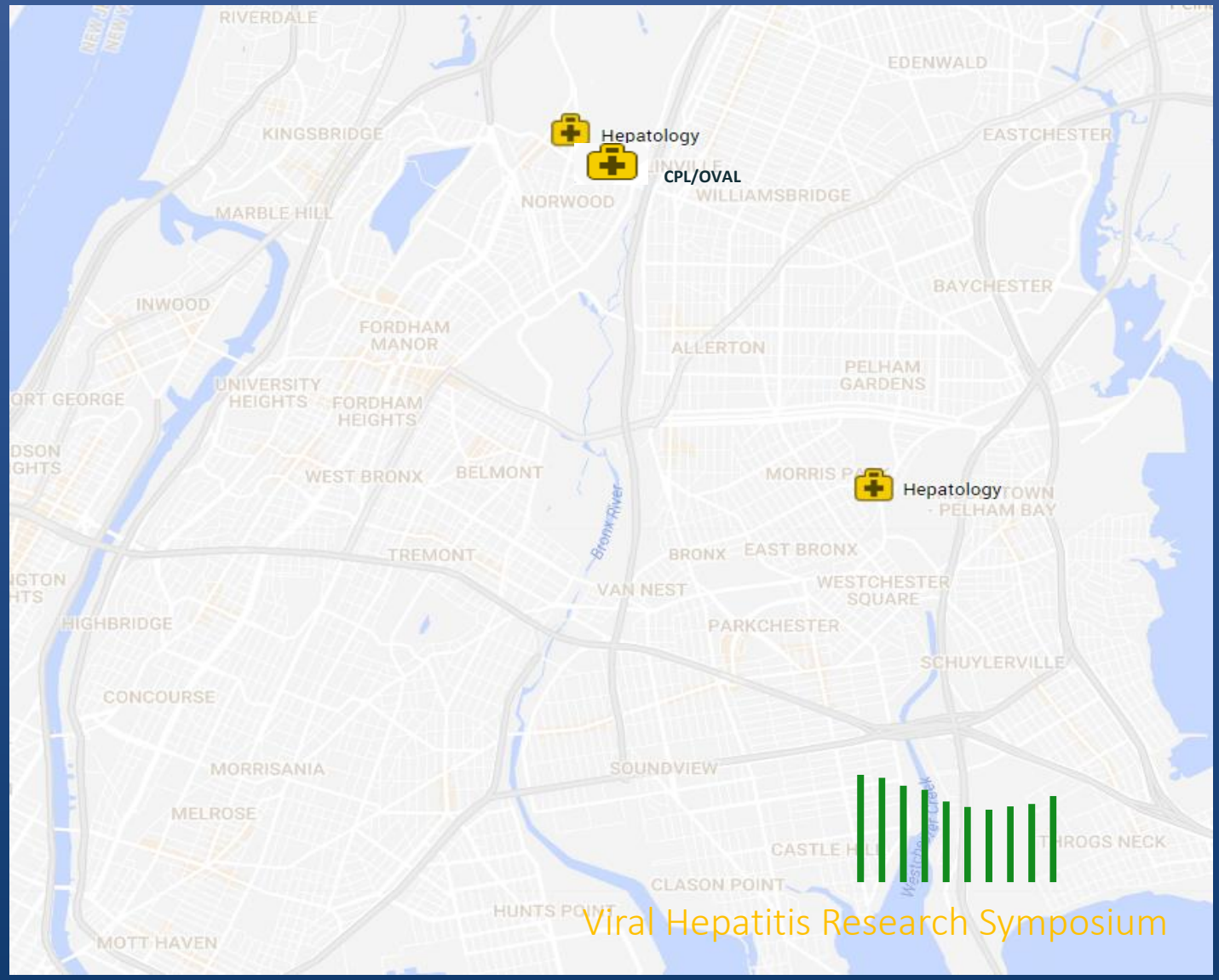
Interdisciplinary Team

- Primary care
- Infectious disease
- Hepatology
- Addiction medicine
- Psychology
- Care coordination

Patient Care Model

Montefiore pre-Inspire HCV Treatment Sites

HCV Treatment Sites
Infectious Disease clinic (CPL/Oval)
Hepatology clinic



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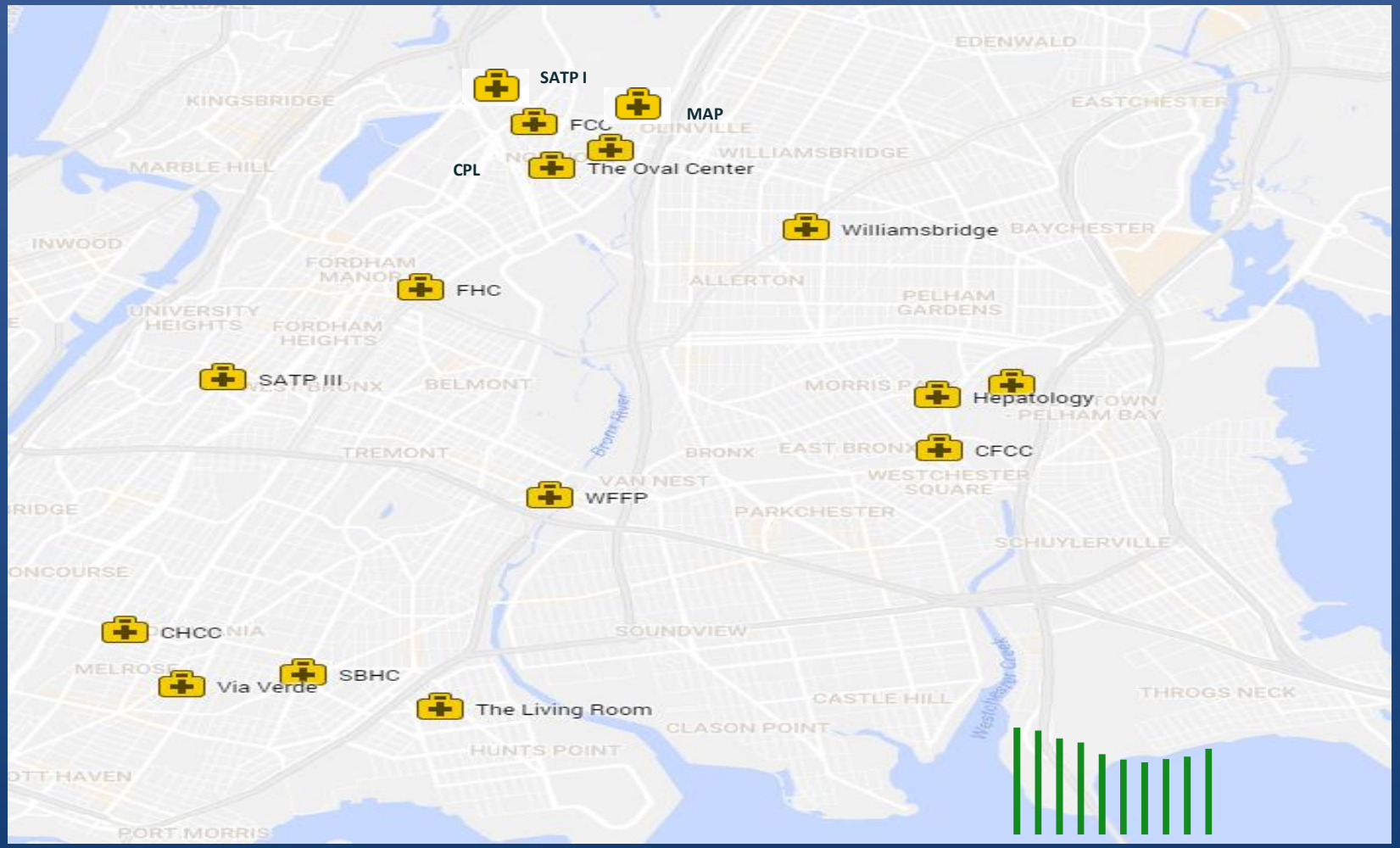
Montefiore Project Inspire Treatment Sites

HCV Treatment Sites

Hepatology
Infectious disease
Primary care
Methadone clinic



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Onsite Hepatitis C Treatment

- Increased access
  - Primary care locations
  - Methadone clinics
  - Hepatology clinic
  - Infectious disease clinic
- Care coordination

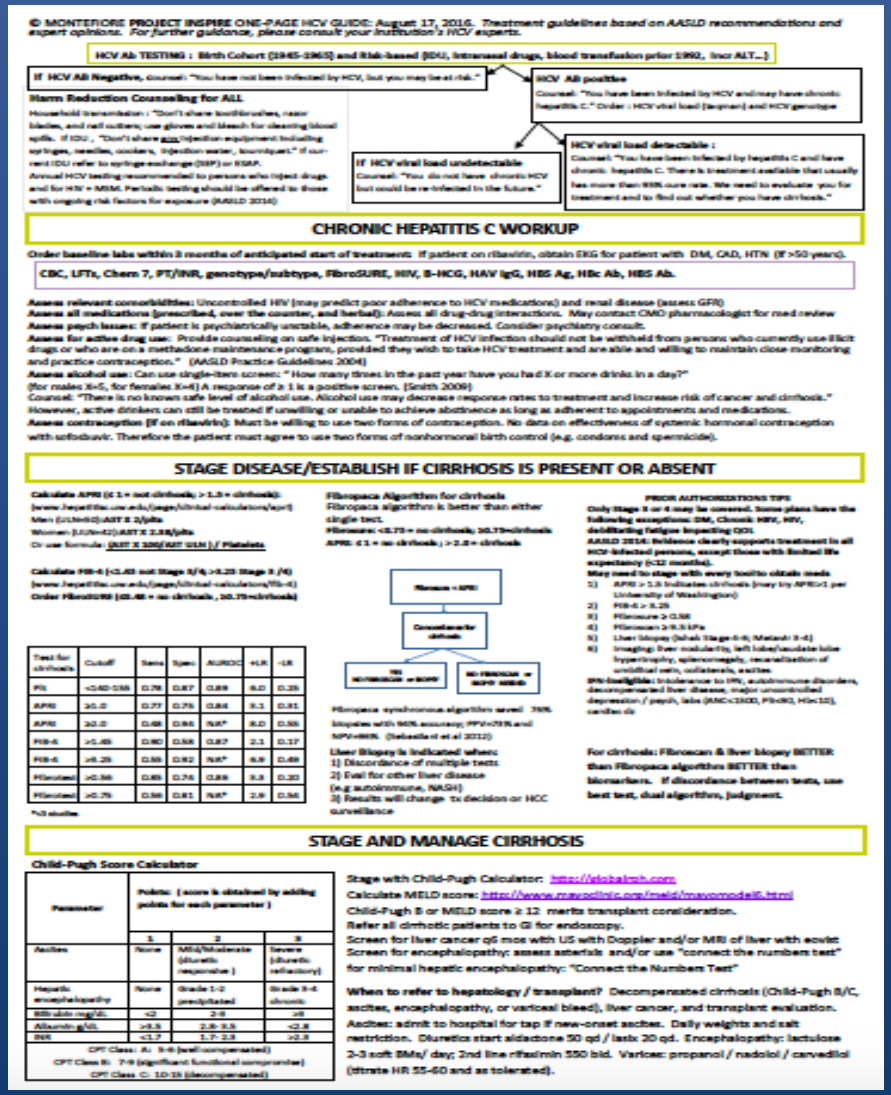
Care Coordination

- Prior authorization
- Specialty pharmacy access
- Medication adherence monitoring
- Scheduling & managing appointments
- Health promotion
- Comprehensive intake assessment
- Social services
- Support treatment – peer navigator

Telementoring

- Weekly online meeting with interdisciplinary team
- Didactics
- Case presentations
- CME credit

Provider Resources



© MONTEFIORE PROJECT INSPIRE ONE-PAGE HCV GUIDE: August 17, 2016. *Treatment guidelines based on AASLD recommendations and expert opinions. For further guidance, please consult your institution's HCV experts.*

HCV Ab TESTING : Birth Cohort (1945-1965) and Risk-based (IDU, intranasal drugs, blood transfusion prior 1992, liver ALT…)

If HCV Ab Negative, counsel: "You have not been infected by HCV, but you may be at risk."

HCV Ab positive
Counsel: "You have been infected by HCV and may have chronic hepatitis C." Order : HCV viral load (aegnan) and HCV genotype

HCV viral load detectable :
Counsel: "You have been infected by hepatitis C and have chronic hepatitis C. There is treatment available that usually has more than 95% cure rate. We need to evaluate you for treatment and to find out whether you have cirrhosis."

IF HCV viral load undetectable
Counsel: "You do not have chronic HCV but could be re-infected in the future."

Harm Reduction Counseling for ALL

Household transmission : "Don't share toothbrushes, razor blades, and nail cutters; use gloves and bleach for cleaning blood spills. If IDU , "Don't share any injection equipment including syringes, needles, cookers, injection water, tourniquet." If current IDU refer to syringe exchange (SEP) or RIAP.
Annual HCV testing recommended to persons who inject drugs and for HIV + MSM. Periodic testing should be offered to those with ongoing risk factors for exposure (AASLD 2014)

CHRONIC HEPATITIS C WORKUP

Order baseline labs within 3 months of anticipated start of treatment: If patient on ribavirin, obtain EKG for patient with DM, CAD, HTN (if >50 years).

CBC, LFTs, Chem 7, PT/INR, genotype/subtype, FibroSURE, HIV, B-HCG, HAV IgG, HBS Ag, HBc Ab, HBS Ab.

Assess relevant comorbidities: Uncontrolled HIV (may predict poor adherence to HCV medications) and renal disease (assess GFR)
Assess all medications (prescribed, over the counter, and herbal): Assess all drug-drug interactions. May contact CMO pharmacologist for med review
Assess psych issues: If patient is psychiatrically unstable, adherence may be decreased. Consider psychiatry consult.
Assess for active drug use: Provide counseling on safe injection. "Treatment of HCV infection should not be withheld from persons who currently use illicit drugs or who are on a methadone maintenance program, provided they wish to take HCV treatment and are able and willing to maintain close monitoring and practice contraception." (AAGLD Practice Guidelines 2004)
Assess alcohol use: Can use single-item screen: " How many times in the past year have you had X or more drinks in a day?"
(for males X=5, for females X=4) A response of ≥ 1 is a positive screen. (Smith 2008)
Counsel: "There is no known safe level of alcohol use. Alcohol use may decrease response rates to treatment and increase risk of cancer and cirrhosis." However, active drinkers can still be treated if unwilling or unable to achieve abstinence as long as adherent to appointments and medications.
Assess contraception (if on ribavirin): Must be willing to use two forms of contraception. No data on effectiveness of systemic hormonal contraception with sofosbuvir. Therefore the patient must agree to use two forms of nonhormonal birth control (e.g. condoms and spermicide).

STAGE DISEASE/ESTABLISH IF CIRRHOSIS IS PRESENT OR ABSENT

Calculate APRI (≤ 1 = not cirrhosis; > 1.5 = cirrhosis):
(www.hepatitis.uw.edu/page/clinical-calculators/apri)
Men (ULN=50):AST ÷ 2/plts
Women (ULN=32):AST ÷ 2.5/plts
Or use formula: (AST X 100/AST ULN) / Platelets

Calculate FIB-4 (<1.45 not Stage 3/4; >3.25 Stage 3 /4)
(www.hepatitis.uw.edu/page/clinical-calculators/fib-4)
Order FibroSURE (≤0.48 = no cirrhosis , ≥0.75=cirrhosis)

Test for cirrhosis	Cutoff	Sens	Spec	AUROC	+LR	-LR
Fib	<1.45-3.25	0.78	0.87	0.89	6.0	0.25
APRI	≥1.0	0.77	0.75	0.84	3.1	0.31
APRI	≥2.0	0.68	0.96	NA*	8.0	0.33
FIB-4	>1.45	0.90	0.68	0.87	2.1	0.17
FIB-4	>3.25	0.55	0.92	NA*	6.9	0.49
Fibrotest	≥0.59	0.85	0.74	0.84	3.3	0.20
Fibrotest	≥0.75	0.66	0.81	NA*	2.9	0.54

*>3 studies

Fibropaca Algorithm for cirrhosis
Fibropaca algorithm is better than either single test.
Fibrosure: <0.73 = no cirrhosis; ≥0.73=cirrhosis
APRI: ≤1 = no cirrhosis ; >2.0 = cirrhosis

Fibropaca synchronous algorithm saved 76% biopsies with 96% accuracy; PPV=75% and NPV=98%. (Sebastiani et al 2012))

Liver Biopsy is indicated when:
1) Discordance of multiple tests
2) Eval for other liver disease (e.g autoimmune, NASH)
3) Results will change tx decision or HCC surveillance

PRIOR AUTHORIZATIONS TIPS
Only Stage 3 or 4 may be covered. Some plans have the following exceptions: DM, Chronic HBV, HIV, debilitating fatigue impacting QOL
AASLD 2014: Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (<12 months).
May need to stage with every tool to obtain meds
1) APRI > 1.5 indicates cirrhosis (may try APRI>1 per University of Washington)
2) FIB-4 > 3.25
3) Fibrosure ≥ 0.58
4) Fibroscan ≥ 9.5 kPa
5) Liver biopsy (Ishak Stage 5-6; Metavir 3-4)
6) Imaging: liver nodularity, left lobe/caudate lobe hypertrophy, splenomegaly, recanalization of umbilical vein, collaterals, ascites

Ineligible: Intolerance to IFN, autoimmune disorders, decompensated liver disease, major uncontrolled depression / psych, labs (ANC<1500, Plt<80, Hb<10), cardiac dz

For cirrhosis: Fibroscan & liver biopsy BETTER than Fibropaca algorithm BETTER than biomarkers. If discordance between tests, use best test, dual algorithm, judgment.

STAGE AND MANAGE CIRRHOSIS

Child-Pugh Score Calculator

Parameter	Points: (score is obtained by adding points for each parameter)		
	1	2	3
Ascites	None	Mild/Moderate (diuretic responsive)	Severe (diuretic refractory)
Hepatic encephalopathy	None	Grade 1-2 precipitated	Grade 3-4 chronic
Bilirubin mg/dL	<2	2-3	>3
Albumin g/dL	>3.5	2.8-3.5	<2.8
INR	<1.7	1.7- 2.3	>2.3
CPT Class A: 5-6 (well compensated)			
CPT Class B: 7-9 (significant functional compromise)			
CPT Class C: 10-15 (decompensated)			

Stage with Child-Pugh Calculator: http://globalmh.com
Calculate MELD score: http://www.mayoclinic.org/meld/mayomodel6.html
Child-Pugh B or MELD score ≥ 12 merits transplant consideration.
Refer all cirrhotic patients to GI for endoscopy.
Screen for liver cancer q6 mos with US with Doppler and/or MRI of liver with eovist
Screen for encephalopathy: assess asterixis and/or use "connect the numbers test" for minimal hepatic encephalopathy: "Connect the Numbers Test"

When to refer to hepatology / transplant? Decompensated cirrhosis (Child-Pugh B/C, ascites, encephalopathy, or variceal bleed), liver cancer, and transplant evaluation.
Ascites: admit to hospital for tap if new-onset ascites. Daily weights and salt restriction. Diuretics start aldactone 50 qd / lasix 20 qd. Encephalopathy: lactulose 2-3 soft BMs/ day; 2nd line rifaximin 550 bid. Varices: propanol / nadolol / carvedilol (titrate HR 55-60 and as tolerated).

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Project Inspire Outcomes

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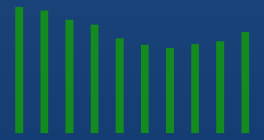

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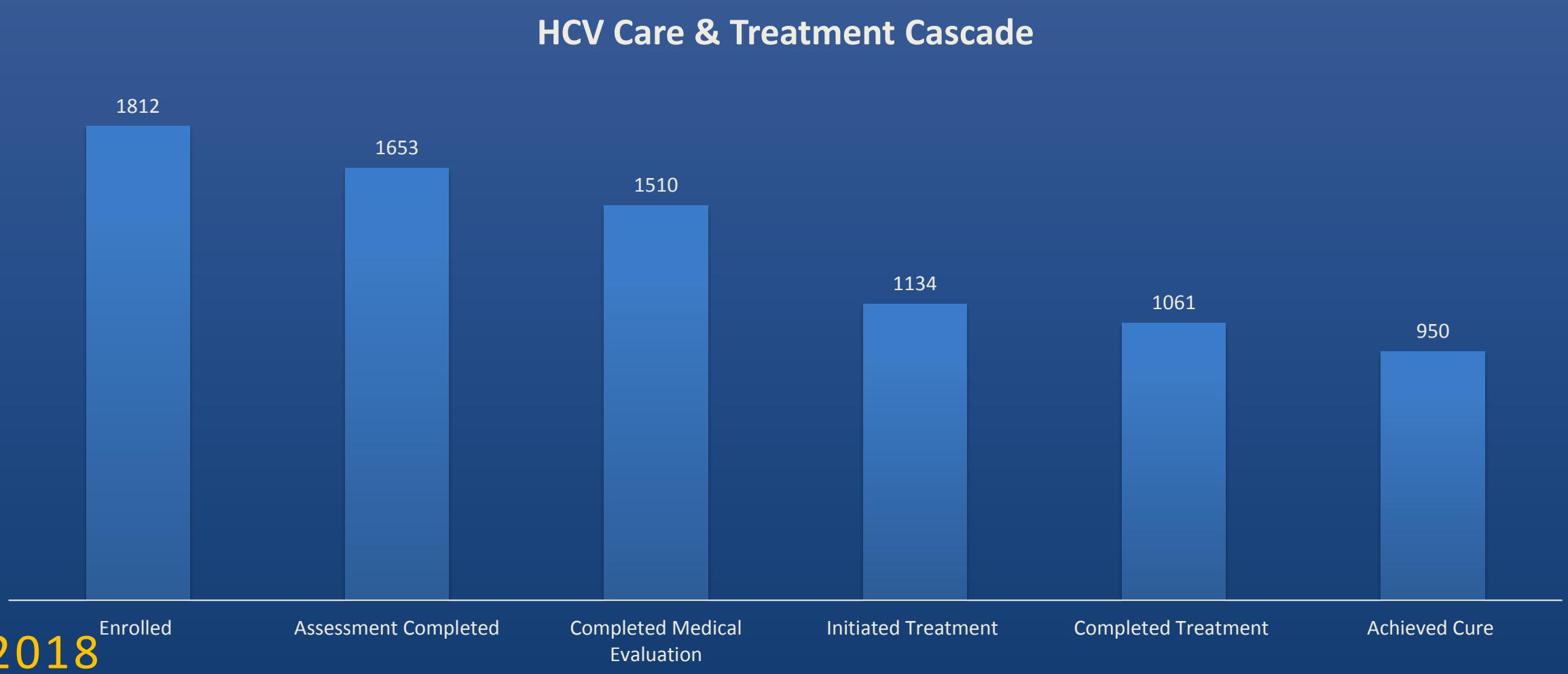
INSPIRE Outcomes



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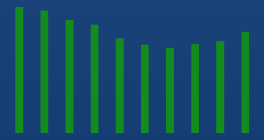
Patient Demographics

	N	%
Gender		
Male	1135	63%
Female	671	37%
Trans M-F	2	0.1%
Race/Ethnicity		
Hispanic/Latino	924	51%
Black, Non-Hispanic	602	34%
White, Non-Hispanic	147	8%
Other	48	3%
Unknown	78	4%
Age		
Baby Boomers (born 1945-65)	1291	71%

	N	%
HIV		
Yes	475	28%
No	1056	69%
Liver Stage Result		
F0-F2	657	48%
F3-F4 Cirrhosis	690	50%
Unknown	27	2%



Post-Inspire

- Project Inspire ended August 31, 2017
- Re-organized as HCV Treatment Network
  - Departmental support
  - 340B program
  - Care coordination

Conclusion

- Successful treatment of large patient cohort
- Expanded access treatment model
    - primary care champions
    - care coordinators
    - specialists
- Patient group
    - Advanced liver disease
    - Socioeconomic barriers

Acknowledgements

- A lot of people