HIV/AIDS & HEPATITIS C IN NYC – State of the Diseases and Barriers to Care

NYC DEPARTMENT OF HEALTH & MENTAL HYGIENE

VIRAL HEPATITIS PROGRAM

MAY 14, 2014

AGENDA

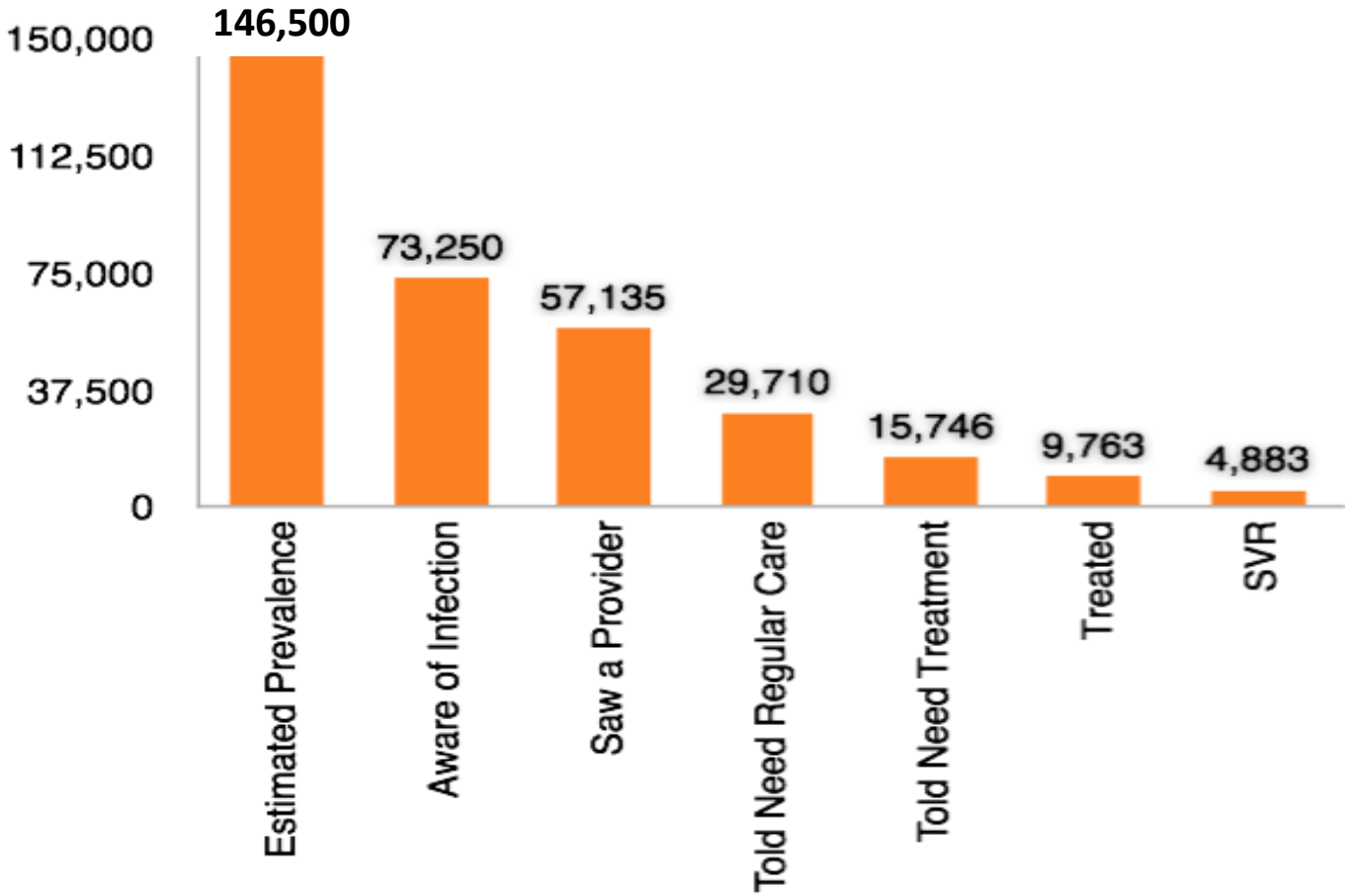
1. Epidemiology of HCV and HIV-Co-infection in NYC
2. Treatment update
3. Barriers to care
4. Costs
5. Payer update

BACKGROUND

- **HCV infection is a progressive disease, and 60% – 70% will go on to develop chronic liver disease, 5% – 20% develop cirrhosis over 20 - 30 years**
  - Accelerated by factors such as alcohol use and HIV co-infection

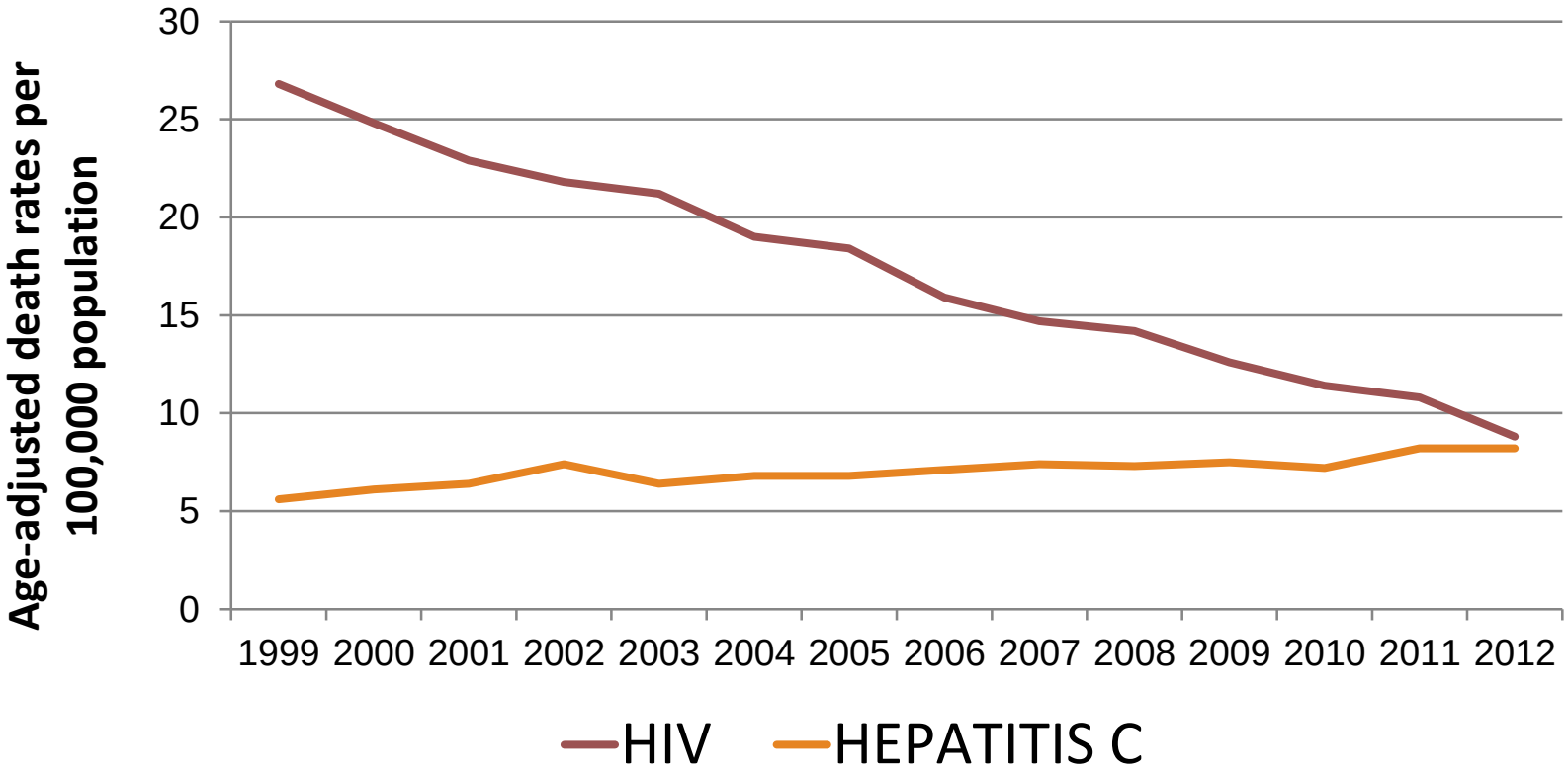
- **In the US, chronic HCV is the leading cause of liver transplantation**
- **Approx. 1 – 5% will die from chronic HCV due to liver cancer or cirrhosis**

NYC HCV Estimated Treatment Cascade



Prevalence estimates among persons ≥20 years: Balter et al, Epidemiol Inf 2013
NHANES 2001-2008: Denniston, et al, Hepatology 2012

Trends of Age-adjusted Death Rates per 100,000 Multiple Cause Mention of HIV and Hepatitis C NYC* 1999 to 2012



*All events occurring within NYC

Source: Contributing causes of death were obtained from the NCHS Multiple Cause files for NYC except for 2012 which use the OVS statistical file

Revised 7/7/14

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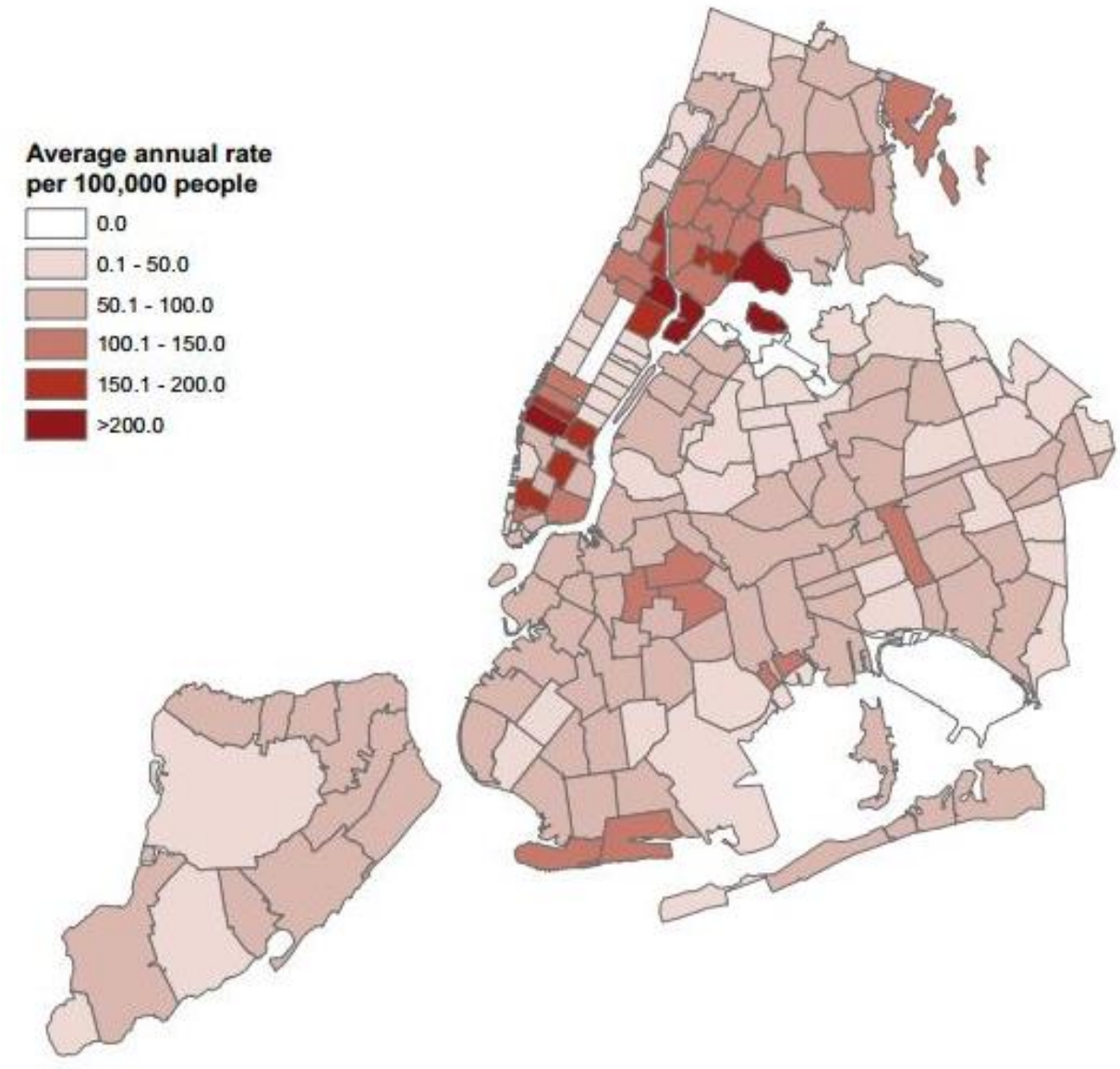
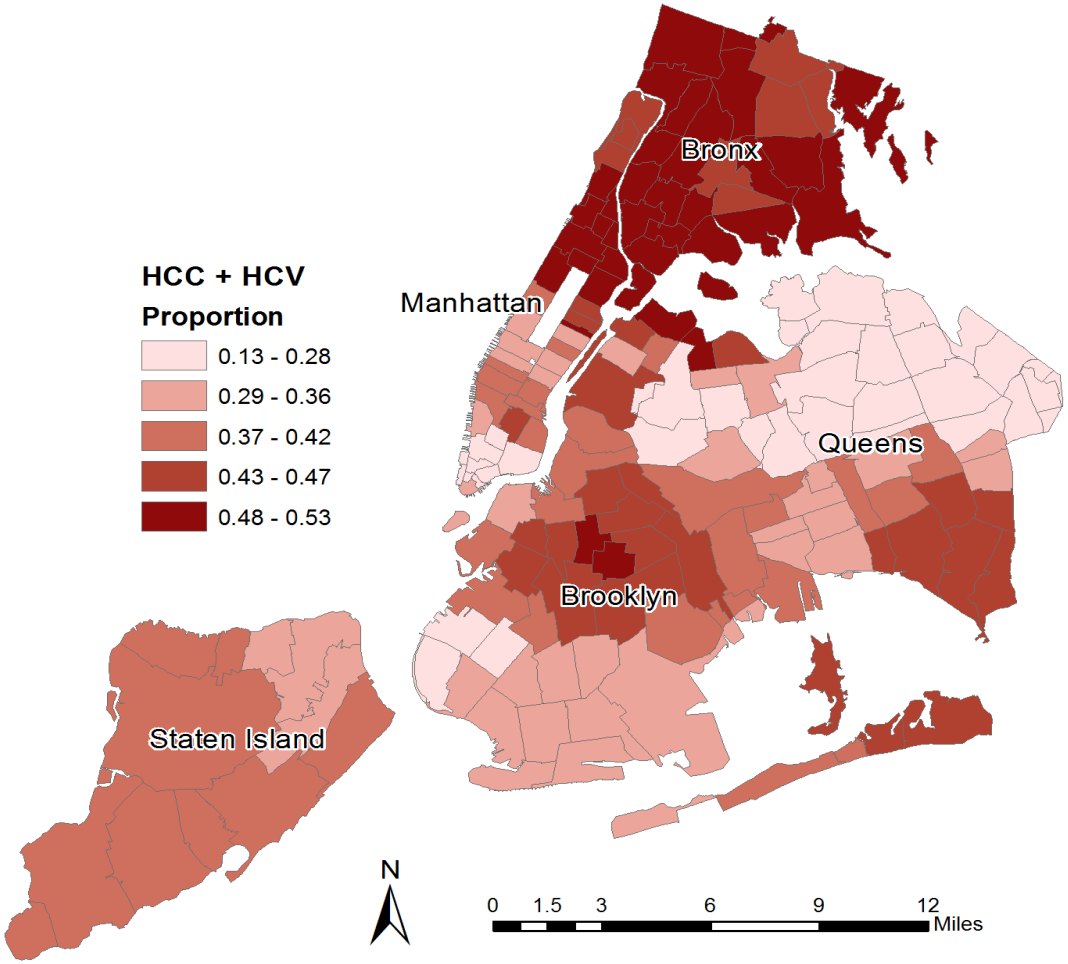
HCV Rates by Zip Code, 2012-2013



Hepatocellular Carcinoma Cases Infected with HCV by Zip Code, 2001-2012



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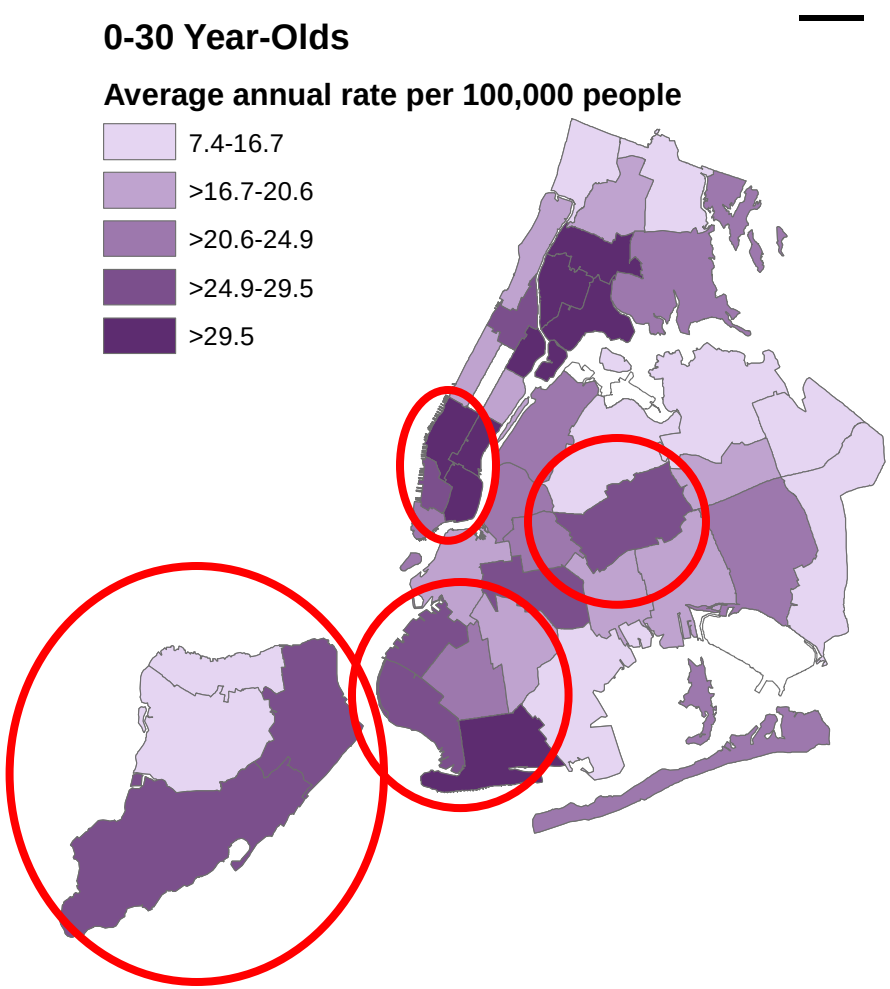
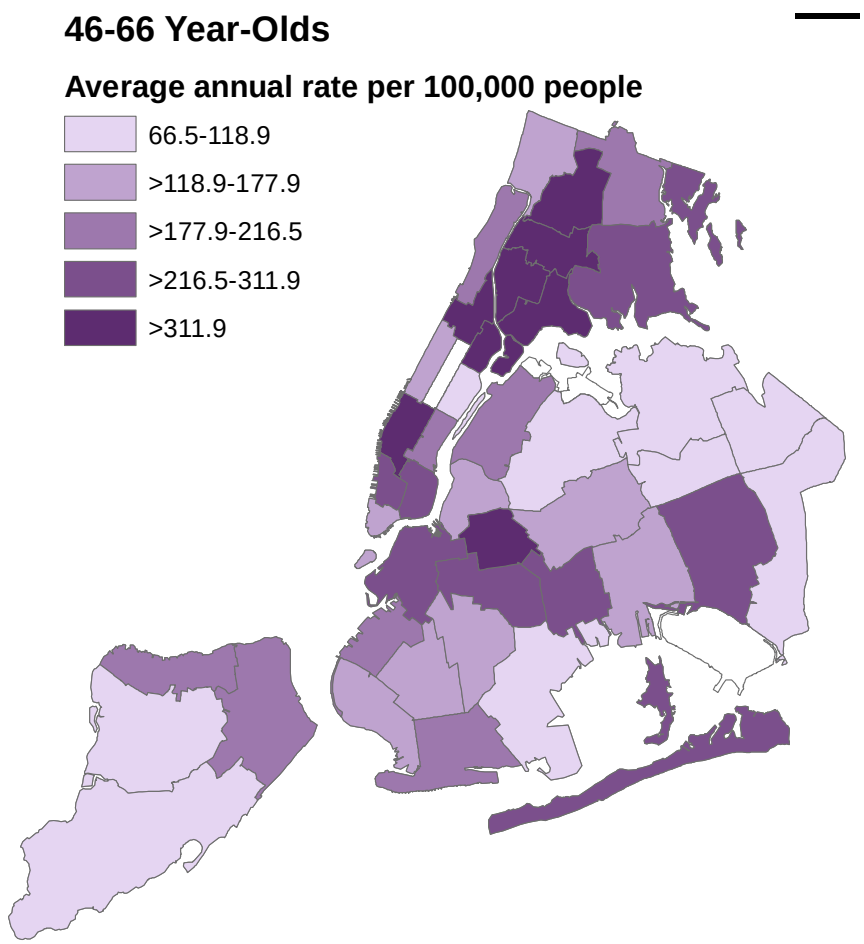
HCV Rates by United Hospital Fund Neighborhood, 2009-2013





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MATCH OF HIV & HCV SURVEILLANCE DATA, 2000-2010 & HIV CARE AND TREATMENT DATA (2010 – 2013) -PCSI SYNDEMIC PROJECT

- **140,606 persons with HIV reported to DOHMH by 2010 and not known to be dead as of 2000**
- **16% HIV/HCV co-infected**
  - 71% Male
  - 39 yrs median age at HIV diagnosis
  - 43% Non-Hispanic Black, 42% Hispanic, 14% White, 0.5% Asian/Pacific Islander
  - 60% IDU for HIV transmission risk category
- **Between 2010 -2013, preliminary data show of 19,474 Ryan White Clients**
  - 24% had HCV (4673)
  - By service category
    - 21% of MHS Ryan White clients and 33% of HRR Ryan White clients receiving services had a prior HCV report

Sources: NYC DOHMH, Division of Disease Control, PCSI Syndemic Project, 2012
Prussing, et. al. *HIV and Viral Hepatitis Co-Infection in New York City 2000-2010*: Prevalence and Case Characteristics. Epidemiol. Infect. 2014.

CHRONIC HCV TREATMENT GOAL

- **The primary goal of HCV therapy is to cure the infection**
  - Reduce all-cause mortality and liver-related adverse health consequences by achieving virologic cure
- **Evidenced by sustained virologic response (SVR)**
  - Undetectable HCV RNA 12 weeks (SVR12) or 24 weeks (SVR24) after treatment completion

EASL Recommendations on Treatment of Hepatitis C:

http://www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf

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FDA-APPROVED PRODUCTS

Agents Approved for Treatment of Chronic Hepatitis C		
Drug (Trade Name)	**FDA Approval Date**	**Adult Dose**
PegIFN-α2a	2002	Once weekly subcutaneous injection
PegIFN-α2b	2001	Once weekly subcutaneous injection
Ribavirin	1998	2 capsules in the morning and 2 or 3 in the evening depending on body weight
Sofosbuvir (Sovaldi)	2013	One tablet once daily (morning)
Simeprevir (Olysio)	2013	One capsule once daily (morning)
Sofosbuvir/ledipasvir (Harvoni)	2014	One tablet once daily (morning)
Paritaprevir/ombitasvir/ Ritonavir (Viekira Pak)	2014	Two tablets once daily (morning)
Dasabuvir	2014	One tablet twice daily (morning and evening)

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INDICATIONS FOR TREATMENT IN 2015: WHO SHOULD BE TREATED AND WHEN?

Treatment priority	Patient group
Treatment is indicated	• All treatment-naïve and treatment-experienced patients with compensated and decompensated liver disease
Treatment should be prioritized	• Patients with significant fibrosis (F3) or cirrhosis (F4), including decompensated cirrhosis • **Patients with HIV coinfection** • Patients with HBV coinfection • Patients with an indication for liver transplantation • Patients with HCV recurrence after liver transplantation • Individuals at risk of transmitting HCV (**active injection drug users, men who have sex with men with high-risk sexual practices**, women of child-bearing age who wish to get pregnant, haemodialysis patients, incarcerated individuals)
Treatment is justified	• Patients with moderate fibrosis (F2)
Treatment can be deferred	• Patients with no or mild disease (F0-F1) and none of the above-mentioned extrahepatic manifestations
Treatment is not recommended	• Patients with limited life expectancy due to non-liver related comorbidities

http://www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf

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NEW RECOMMENDATIONS FOR HIV CO-INFECTION

- **Indications for HCV treatment in HCV/HIV coinfected persons are identical to those in patients with HCV monoinfection**
- **Notwithstanding the respective costs of these options, IFN-free regimens are the best options when available in HCV-monoinfected and in HIV-coinfected patients without cirrhosis or with compensated or decompensated cirrhosis, because of their virological efficacy, ease of use and tolerability**
- **The same IFN-free treatment regimens can be used in HIV-coinfected patients as in patients without HIV infection, as the virological results of therapy are identical**

http://www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf

SPECIAL CONSIDERATIONS

Doctors will decide which treatment to prescribe, and how long the treatment should be taken based on many factors:

- **Ribavirin-tolerant vs. intolerant**
- **Genotype (1 – 6)**
- **With cirrhosis (compensated) vs. without**
- **Treatment naïve vs. those who failed on treatment vs. re-infected**
- **Co-morbidities (renal impairment, diabetes, etc.)**

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CLINICAL CRITERIA IN NYS REQUIRED FOR PRIOR AUTHORIZATION BY MEDICAID

- **Patient has demonstrated treatment readiness and ability to adhere to drug regimen;**
  - To be evaluated by using scales or assessment tools to begin hepatitis C treatment

AND

- **Baseline HCV RNA must be submitted with a collection date within the past three months. Prescriber must submit lab documentation indicating HCV genotype and quantitative viral load;**

AND

- **Stage 3 or Stage 4 hepatic fibrosis:**

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DISEASE SEVERITY CONT.

OR

- **Evidence of extra-hepatic manifestation of hepatitis C; OR**
  - Organ transplant; OR
  - HIV-1 coinfection; OR
  - HVB coinfection; OR
  - Other coexistent liver disease; OR
  - Type 2 diabetes mellitus (insulin resistant); OR
  - Debilitating fatigue
- **For HIV-1 co-infected patients, patients must have the following:**
  - No detectable viral load for the past 6 months

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DRUG UTILIZATION REVIEW BOARD UPDATE

- **All new HCV drugs have been added to Medicaid formulary since the first set of Clinical Criteria has been written post-Sofosbuvir (Sovaldi) in 2013**
  - Apply to all new drugs, except for…

- **Viekira Pak is the latest drug to be added to the Medicaid formulary**
  - For Fee-For-Service Medicaid patients, providers must only prescribe Viekira Pak for their patients
  - All others are “non-preferred”

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COSTS

- **HCV-related healthcare utilization and costs increase significantly with age and disease severity**
- **Total long-term cost associated with chronic HCV infection is expected to rise from $6.5 billion in 2012 to and estimated $9.1 billion by 2024**
- **Successful treatment during the early stages of disease can reduce events associated with advanced liver disease and costs**
- **HCV patients experience higher risk of inpatient hospitalizations, ER visits, outpatient hospitalizations, and physician office visits compared to patients without HCV**
  - Increased with more advanced liver disease

D. R. Walker, S. R. Manthena, T. R. Juday. *Healthcare Costs by Stage of Liver Disease in Chronic Hepatitis C Patients in the United States. EASL 2015*

QUALIFIED HEALTH PLANS IN NYC

**PRICES DO NOT INCLUDE SUBSIDIES AVAILABLE FOR THOSE UNDER 400% FPL*

TIERS

- **Platinum – Monthly premiums for singles between: $443.24-$913.99**
  - covers 90% of the benefit costs of the plan
- **Gold – Monthly premiums for singles between: $395.76-$749.13**
  - covers 80% of the benefit costs of the plan
- **Silver – Monthly premiums for singles between: $359.26-$635.60**
  - covers 70% of the benefit costs of the plan
- **Bronze – Monthly premiums for singles between: $308.33-$548.66**
  - covers 60% of the benefit costs of the plan
- **Catastrophic coverage – only for 30 years old and under**
  - Monthly premiums for singles costs between: $183.53-$370.59

QUALIFIED HEALTH PLANS IN NYC

**PRICES DO NOT INCLUDE SUBSIDIES AVAILABLE FOR THOSE UNDER 400% FPL*

Plan	MMC Plan?	Bronze	Silver	Gold	Platinum
1. Affinity	✔	$378.58	$441.81	$509.54	$601.28
2. Empire		$406.46	$468.43	$552.95	$650.28
3. Fidelis	✔	$308.33	$390.15	$477.71	$577.18
4. Freelancers		$311.77	$394.58	$445.93	$523.23
5. HIP	✔	$334.28	$386.69	$462.24	$555.61
6. Healthfirst	✔	$384.19	$450.00	$526.02	$623.30
7. MetroPlus	✔	$334.44	$359.26	$395.76	$443.24
8. NSLIJ		$330.13	$419.62	$487.34	$568.13
9. Oscar		$361.64	$446.01	$517.55	$602.75
10. United	✔	$548.06	$635.60	$749.13	$913.99

PUBLIC COVERAGE OVERVIEW

Under 138% FPL

Medicaid, CHIP

139%-400% FPL

CHIP

"Financial Assistance" – *Sliding Scale Premium and Cost sharing Support;*

Easy to compare plans on the Marketplace

PATIENT ASSISTANCE PROGRAMS

All drug companies provide some patient assistance

- **All require intake form**
- **Will cover varying amount of expenses of medication**
  - Some cover co-pay
  - Some cover deductible
- **No reliable information on how much they cover or how many people receive assistance**
- **Eligibility criteria is not evident**

QUESTIONS

- **How many individuals in the Ryan White program would be eligible for the LPAP program?**
  - New PCSI/HIV data match done by Aug 2015
- **How many co-infected individuals are not known yet?**
  - Haven't been tested for HIV or HCV
  - Are undocumented
- **What will the cost of the new treatments be in 1 year? 2 years?**
- **Will the Medicaid restrictions be reversed?**
  - i.e. will more people be treated under Medicaid or SNPs?
- **How generous will the Patient Assistance programs be in the future?**
- **Can an LPAP negotiate directly with a drug company?**
- **?**