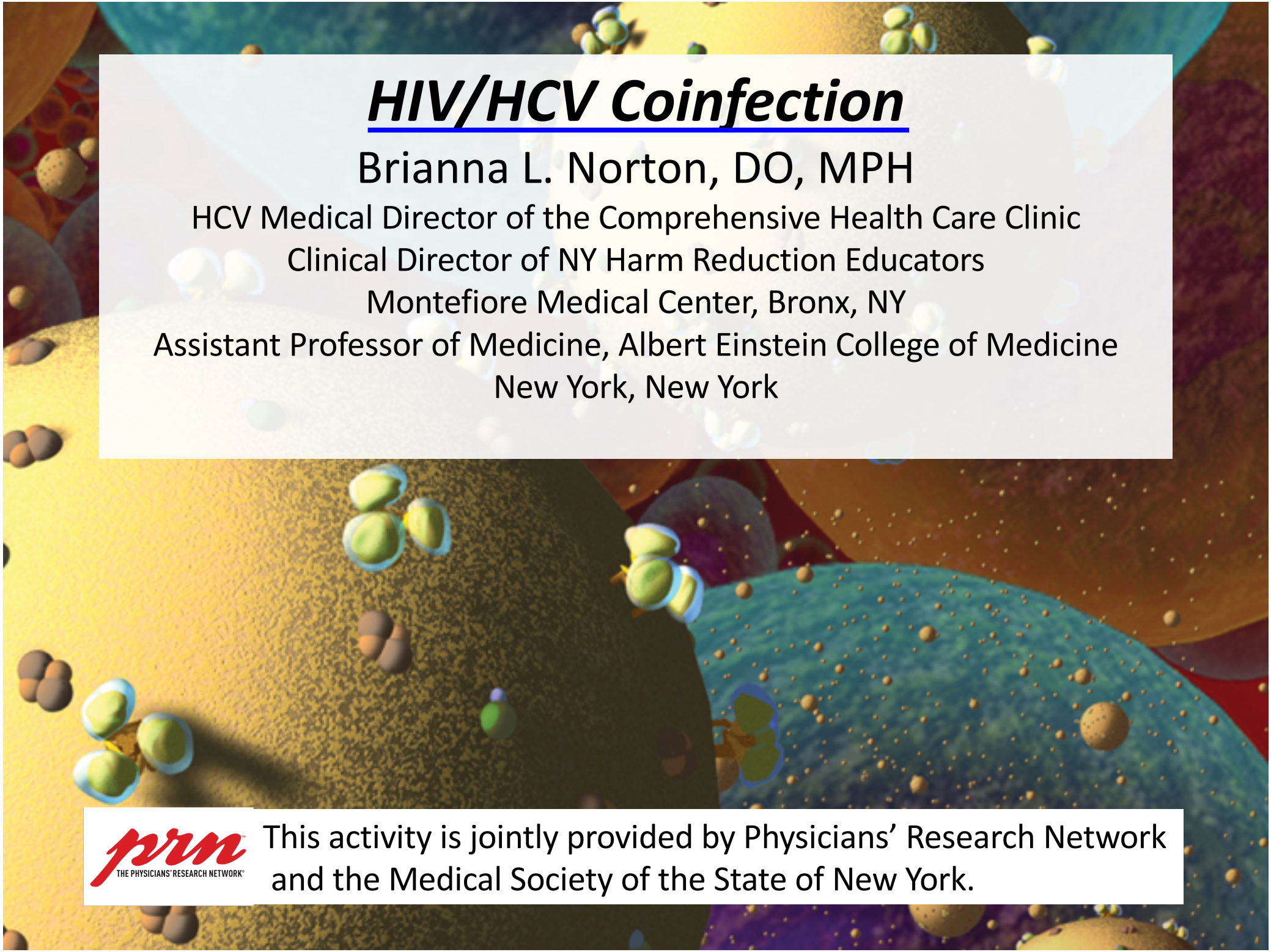


HIV/HCV Coinfection

Brianna L. Norton, DO, MPH

HCV Medical Director of the Comprehensive Health Care Clinic

Clinical Director of NY Harm Reduction Educators

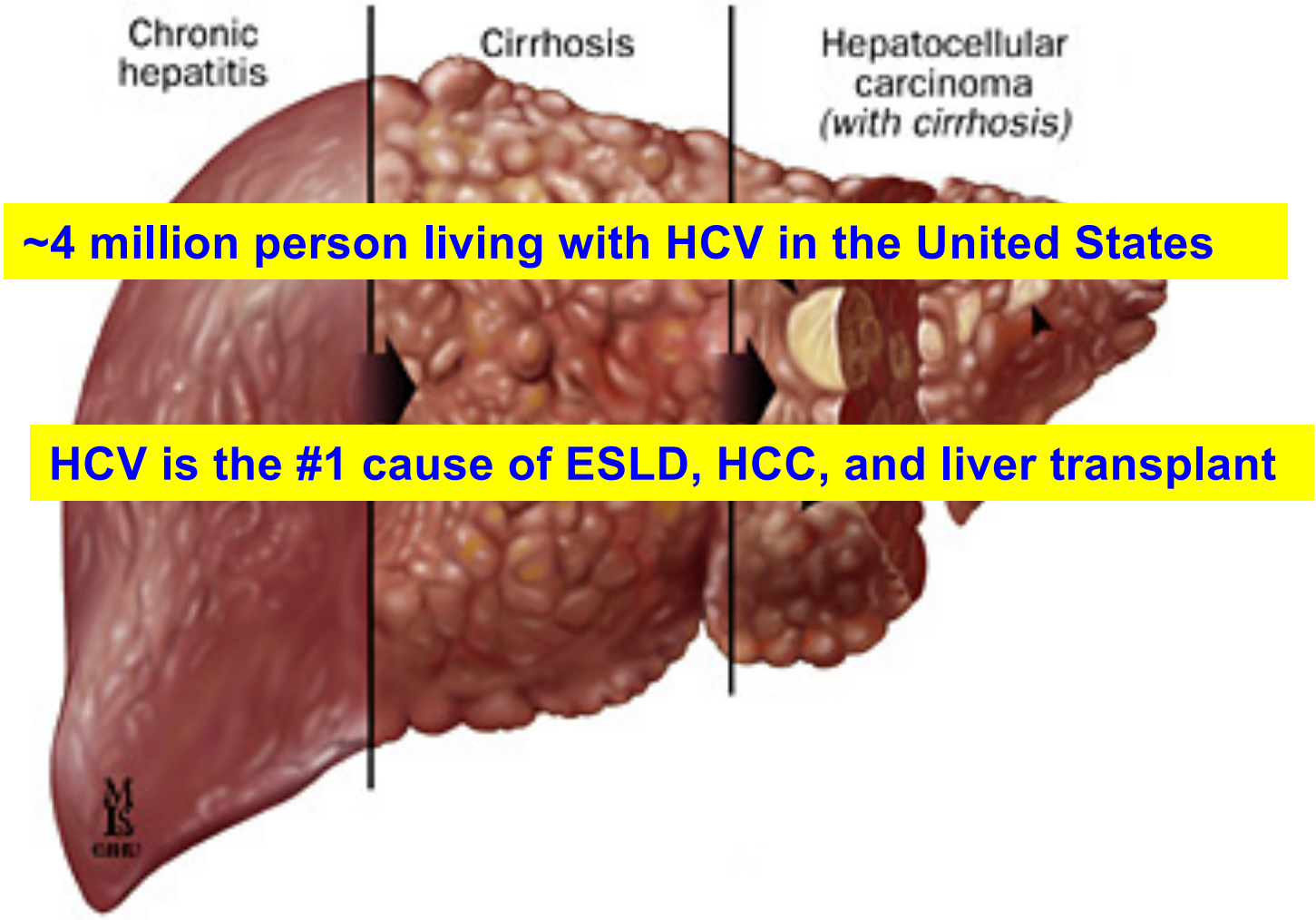
Montefiore Medical Center, Bronx, NY

Assistant Professor of Medicine, Albert Einstein College of Medicine

New York, New York

This activity is jointly provided by Physicians' Research Network and the Medical Society of the State of New York.

The Epidemic of HCV

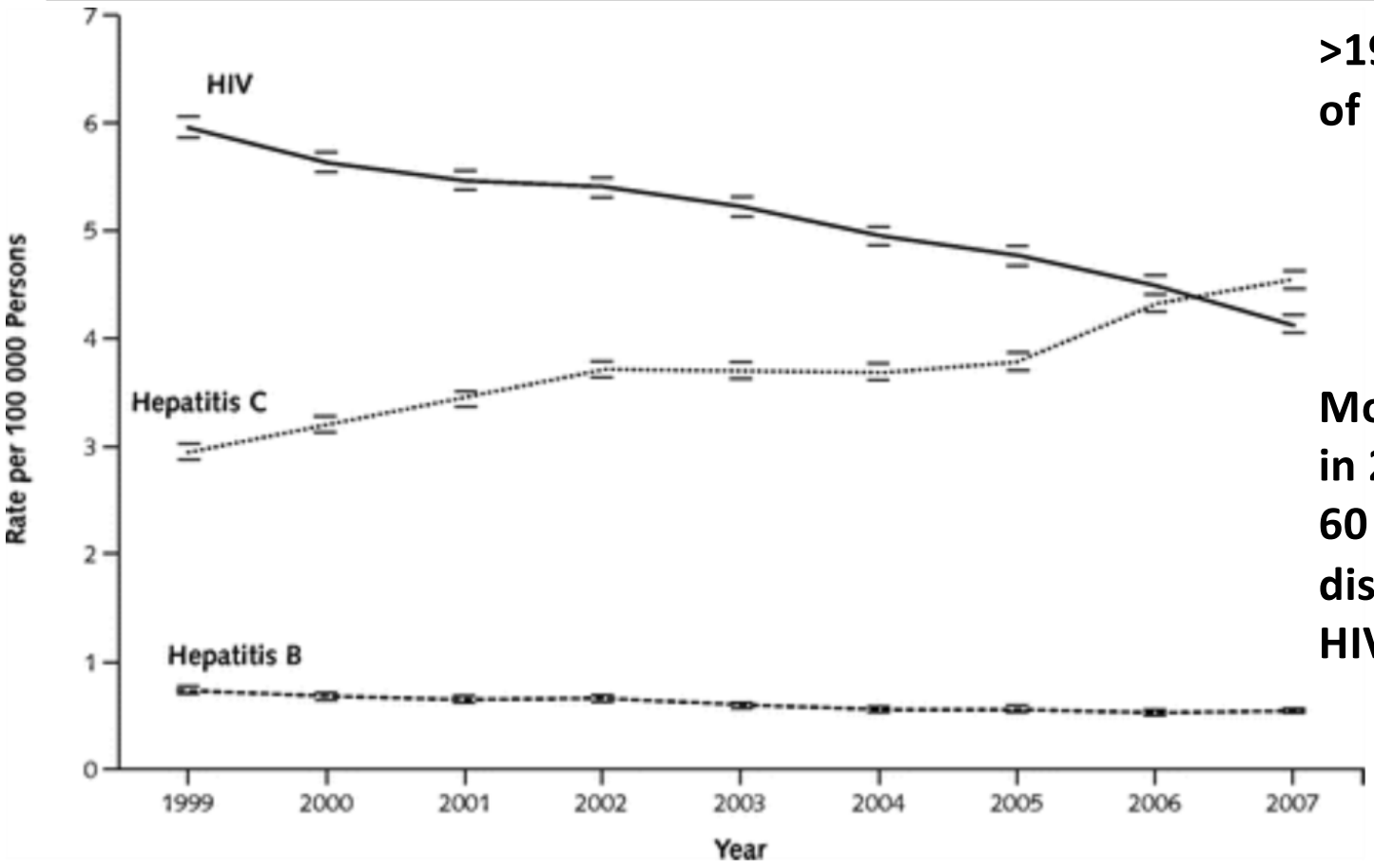


~4 million person living with HCV in the United States

HCV is the #1 cause of ESLD, HCC, and liver transplant

Annals of Internal Medicine
Established in 1927 by the American College of Physicians

The Increasing Burden of Mortality From Viral Hepatitis in the United States Between 1999 and 2007

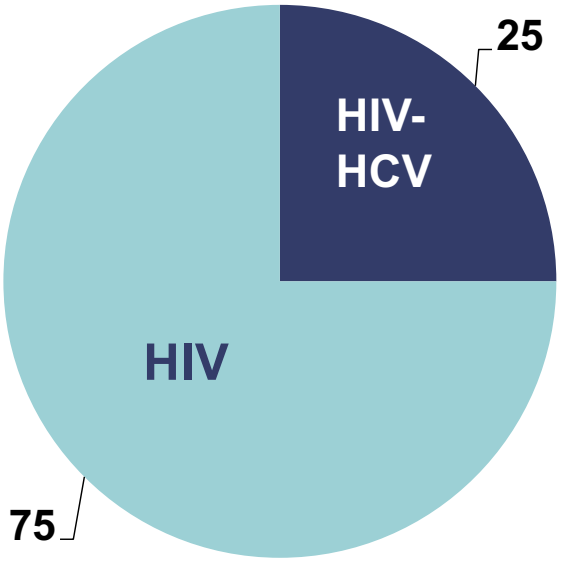


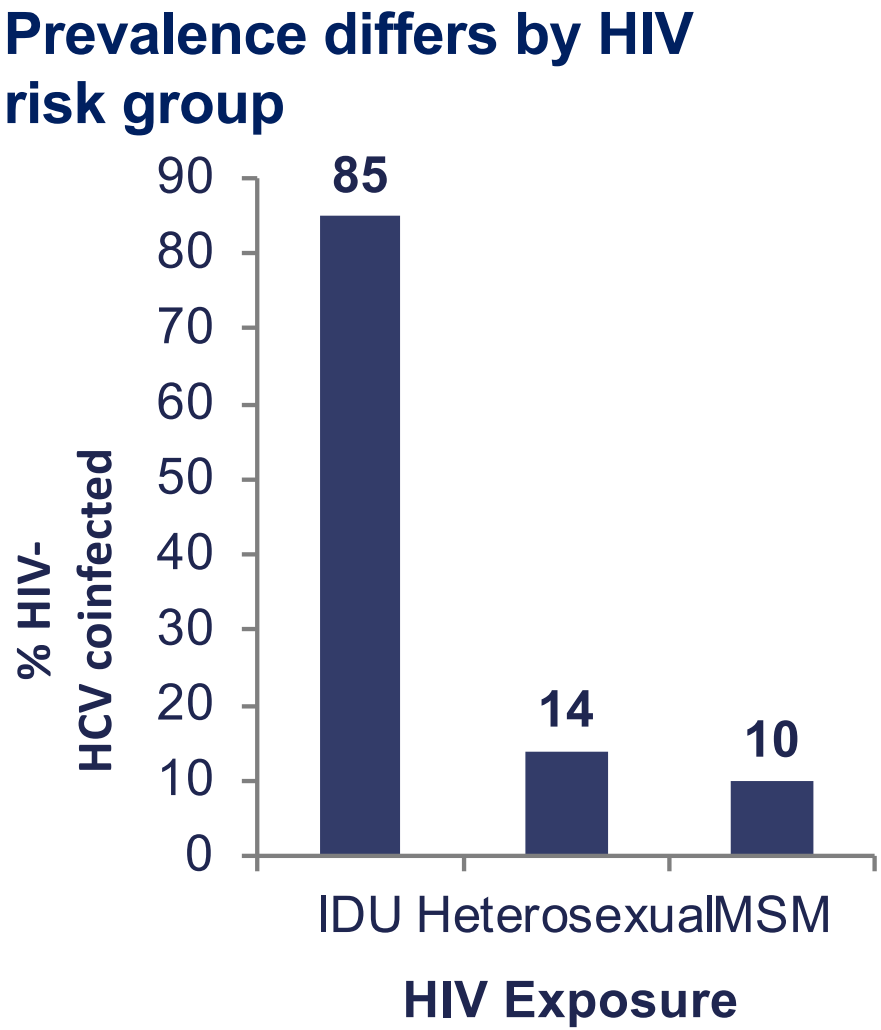
>19, 000 people died of HCV in the US in 2014

More people died of HCV in 2013 than from the top 60 other infectious diseases including HIV, TB, pneumonia.

Who has HIV/HCV Co-infection?

Prevalence of HCV infection among HIV infected individuals

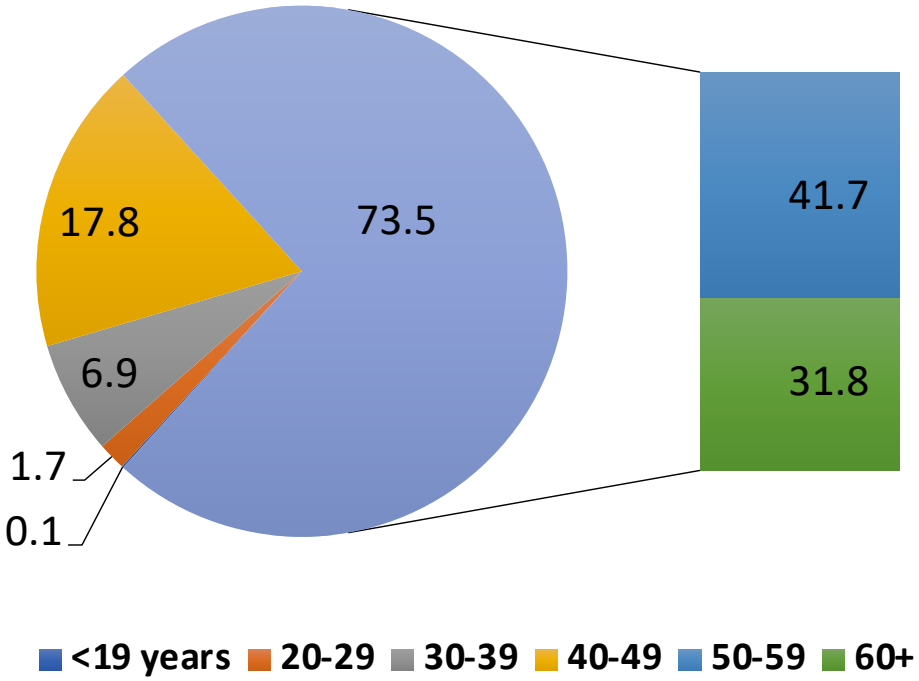




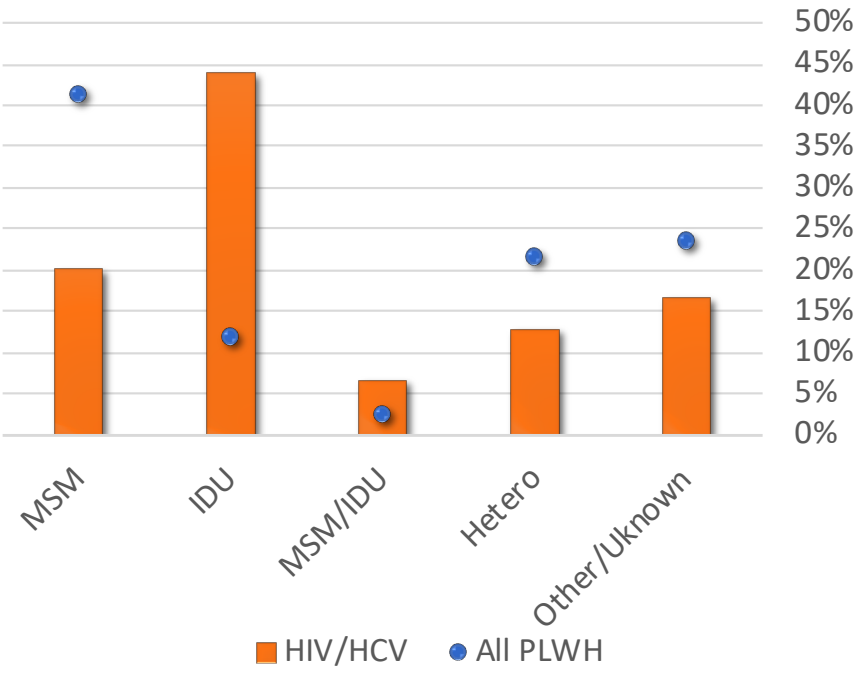
HIV/HCV Co-infected Demographics, NYC 2015

Current age

Nearly 73.5% of HIV/HCV co-infected individuals are 50+, compared to only 50% of all PLWH



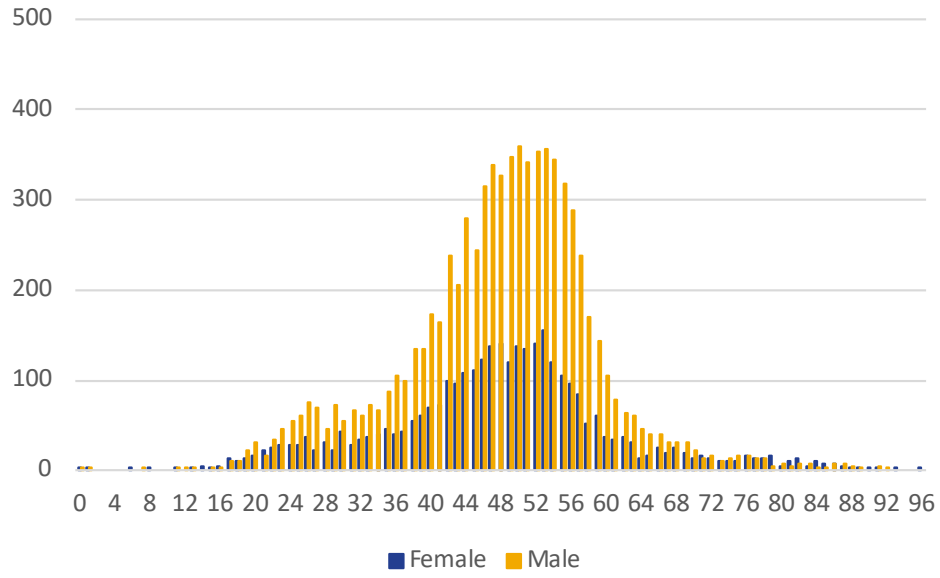
Exposure Category



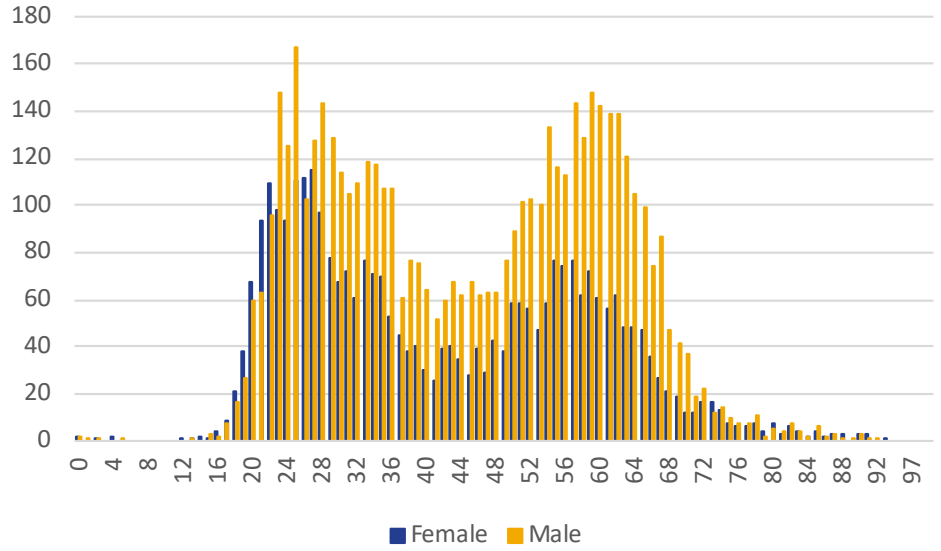
Over half of those with HIV/HCV report a history of injection drug use, compared to just under 15% of all PLWH

Total Hepatitis C by Age, Sex and Year, NYS (Excluding NYC)

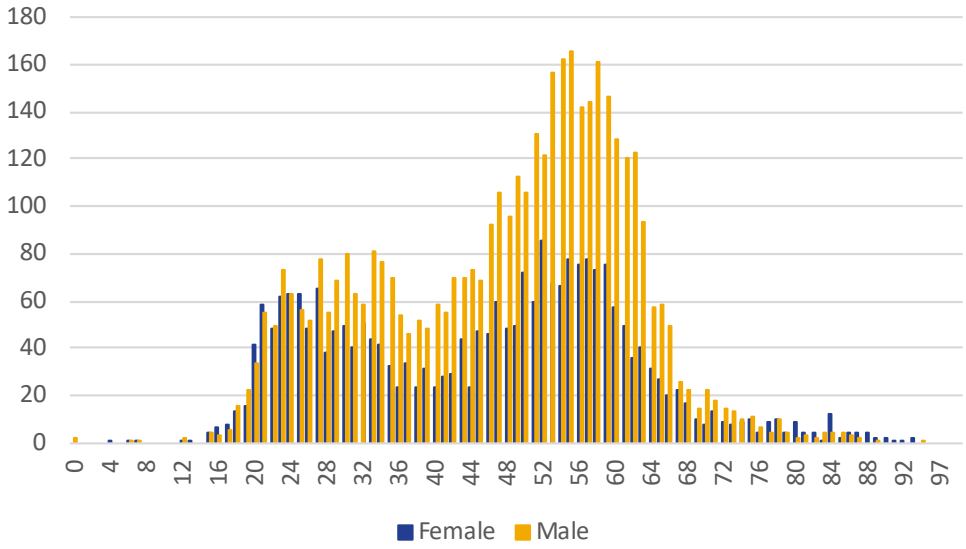
2006



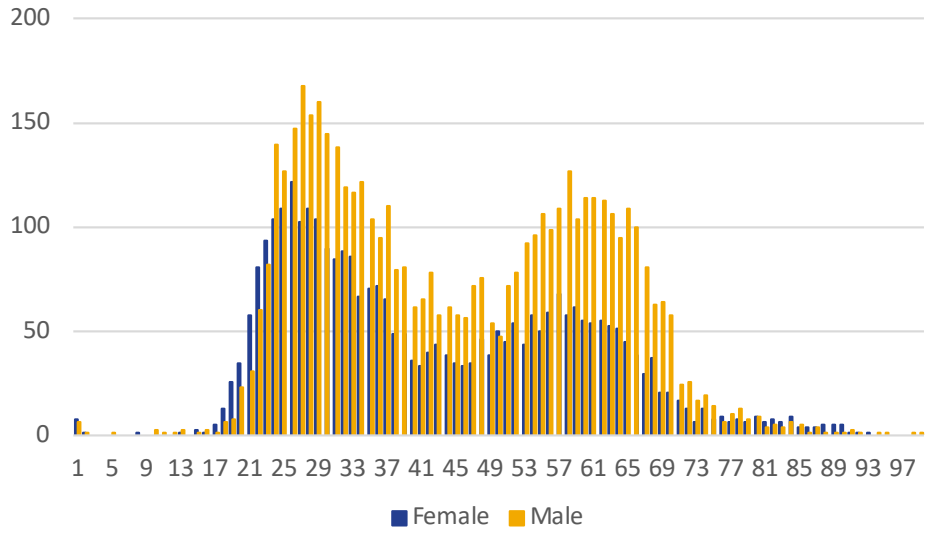
2015



2012



2016

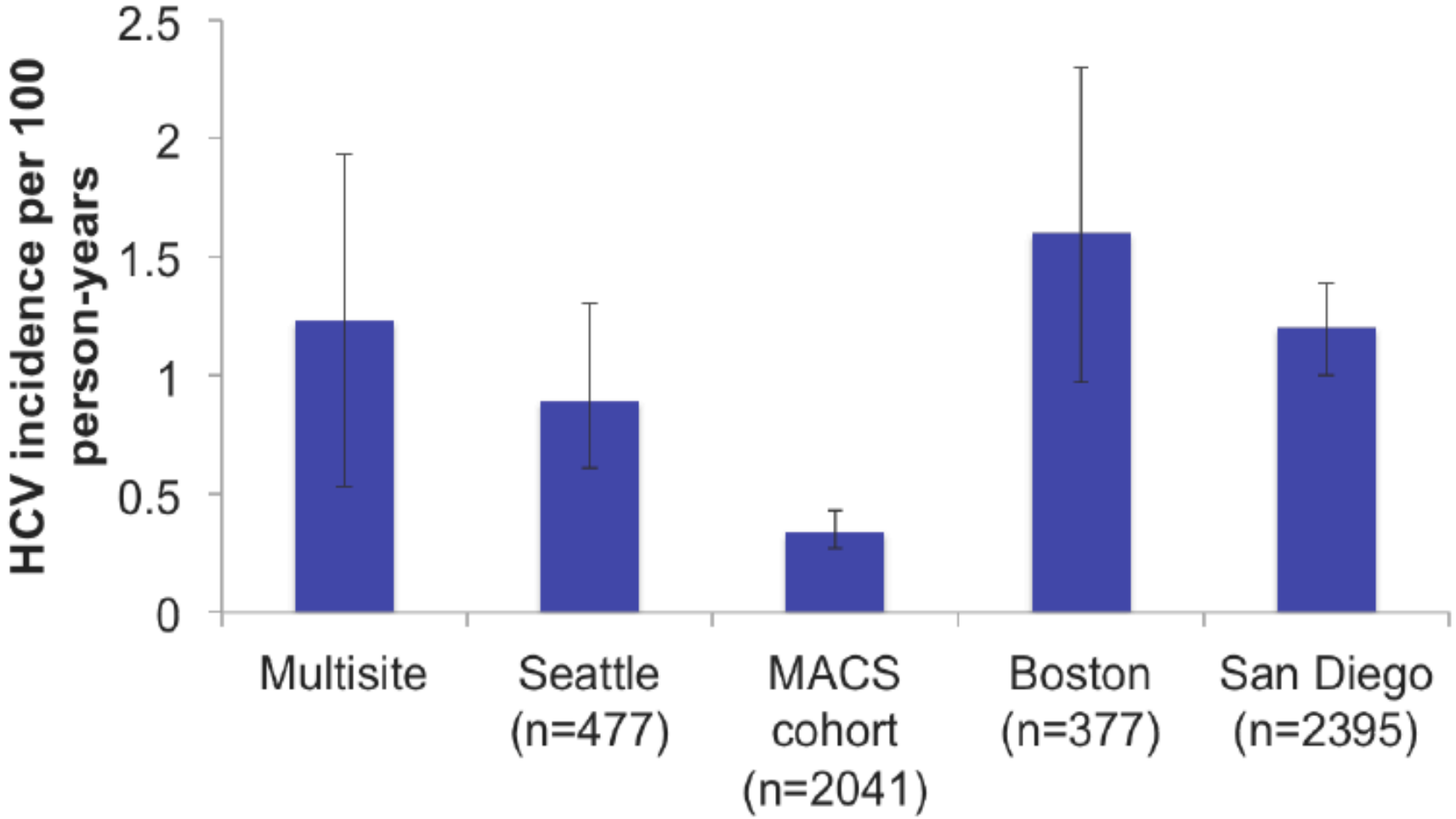


Acute HCV – an emerging infection

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 60 / No. 28
July 22, 2011

Sexual Transmission of Hepatitis C Virus Among HIV-Infected Men Who Have Sex with Men — New York City, 2005–2010

HCV primary incidence among HIV+ MSM in US cohorts



INCIDENCE OF HEPATITIS C AMONG HIV-INFECTED MEN WHO HAVE SEX WITH MEN IN SAN DIEGO, 2000–2015

Antoine Chaillon, Xiaoying Sun, Edward R Cachay, David Wyles
Christy M Anderson, Thomas CS Martin, Richard S Garfein,
Sonia Jain, Sanjay R Mehta, David Looney, Davey M Smith,
Susan J Little, Natasha K Martin

University of BRISTOL

UC San Diego SCHOOL OF MEDICINE

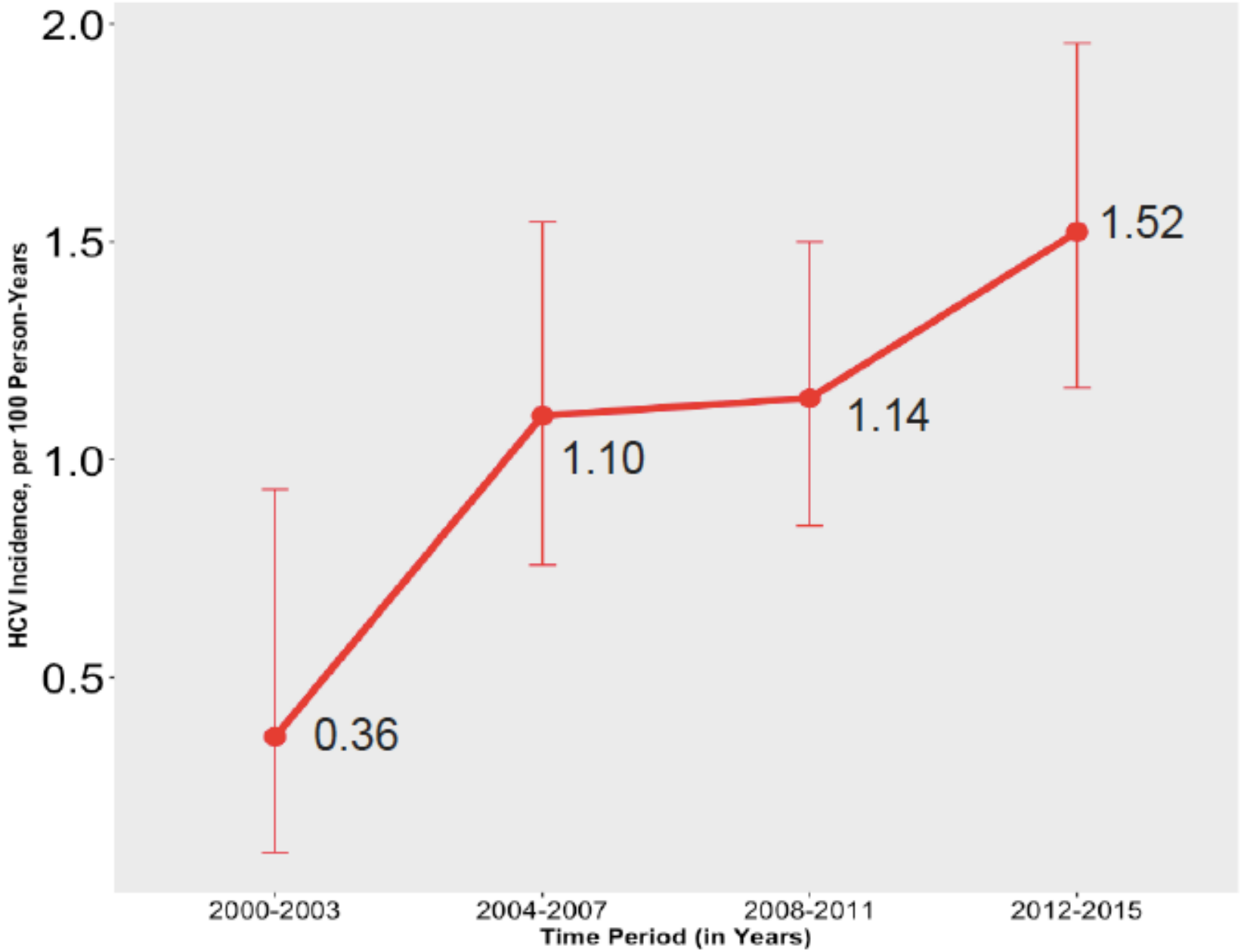
Baseline characteristics

	Total Population, N (%)
N	2,395
Age (median, IQR)	38 (31-45)
Race:	
-White	1,593 (68%)
-Black	234 (10%)
-Other	512 (22%)
Hispanic:	
-Yes	622 (26%)
-No	1,773 (74%)
IDU/Methamphetamine use (ever):	
-None	770 (32.2%)
-Meth only	1,012 (42.3%)
-IDU only	7 (0.3%)
-Meth+IDU	127 (5.3%)
-Unknown	479 (20%)

Incident HCV infection by baseline demographics

	N of event	Person Years	Incidence/100PY	CI.lower	CI.upper	IRR	p value
Overall	149	12573	1.185	1.002	1.391	-	-
Age							
≤30	37	2796	1.323	0.932	1.824	1	-
31-40	57	4755	1.199	0.908	1.553	0.906 (0.589-1.409)	p=0.642
41-50	46	3826	1.202	0.88	1.604	0.909 (0.577-1.441)	p=0.666
>50	9	1196	0.753	0.344	1.429	0.569 (0.241-1.2)	p=0.126
Race							
White	105	8202	1.28	1.047	1.55	1	-
Black	15	1254	1.197	0.67	1.974	0.934 (0.505-1.613)	p=0.807
Other	28	2918	0.96	0.638	1.387	0.75 (0.475-1.146)	p=0.176
Hispanic							
No	110	8978	1.225	1.007	1.477	1	-
Yes	39	3595	1.085	0.771	1.483	0.885 (0.598-1.287)	p=0.516
Meth/IDU use (ever)							
None	21	4424	0.475	0.294	0.726	1	-
Meth only	86	5991	1.436	1.148	1.773	**3.024 (1.860-5.132)**	**p<0.001**
IDU only	2	32	6.296	0.762	22.743	**13.167 (1.497-53.965)**	**p<0.001**
Meth+IDU	17	739	2.301	1.341	3.684	**4.896 (2.401-9.644)**	**p<0.001**

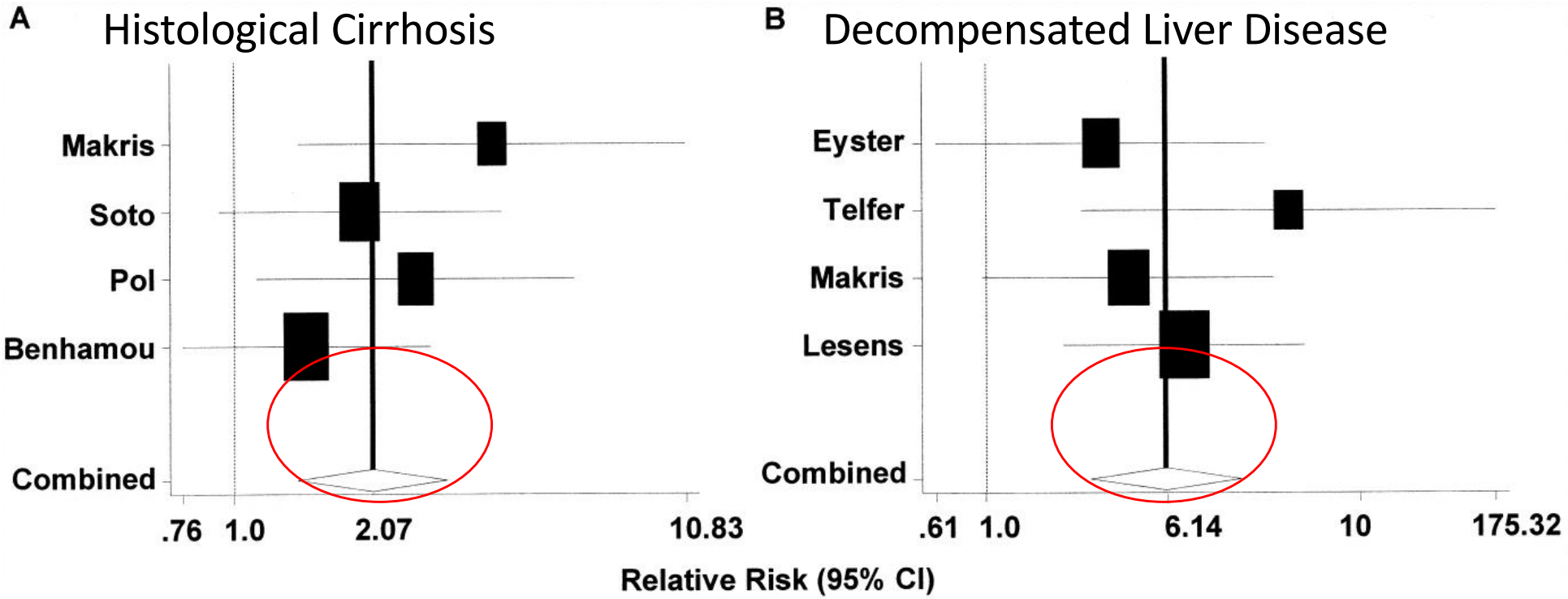
Increasing HCV primary incidence among HIV+ MSM in San Diego



test for trend
p=0.003

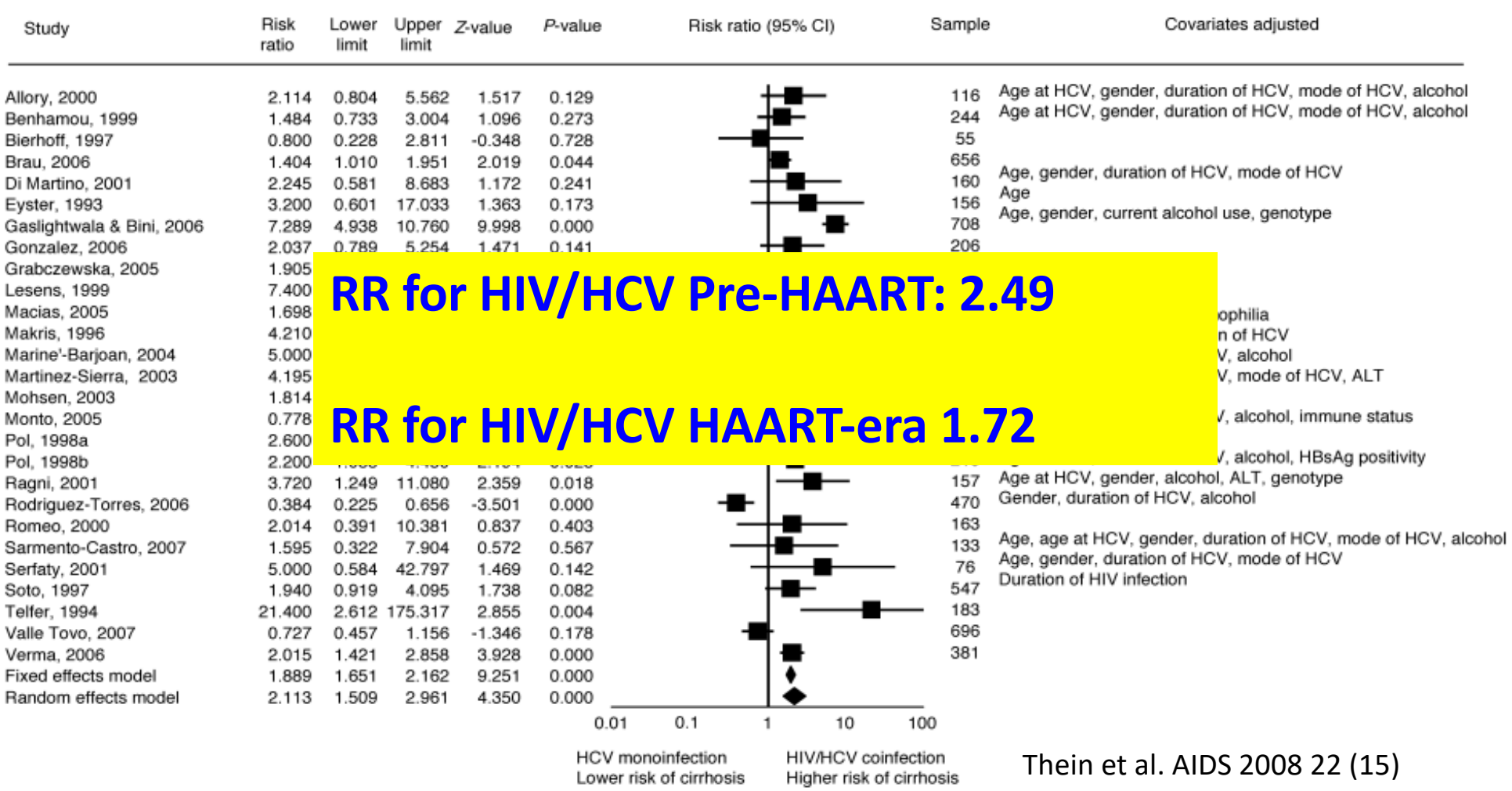
Why should we specifically care about HIV/HCV Co-infection?

Liver Disease is Worse in HIV/HCV



Risk of Cirrhosis in HIV/HCV Coinfected Patients

AIDS 2008, Vol 22 No 15

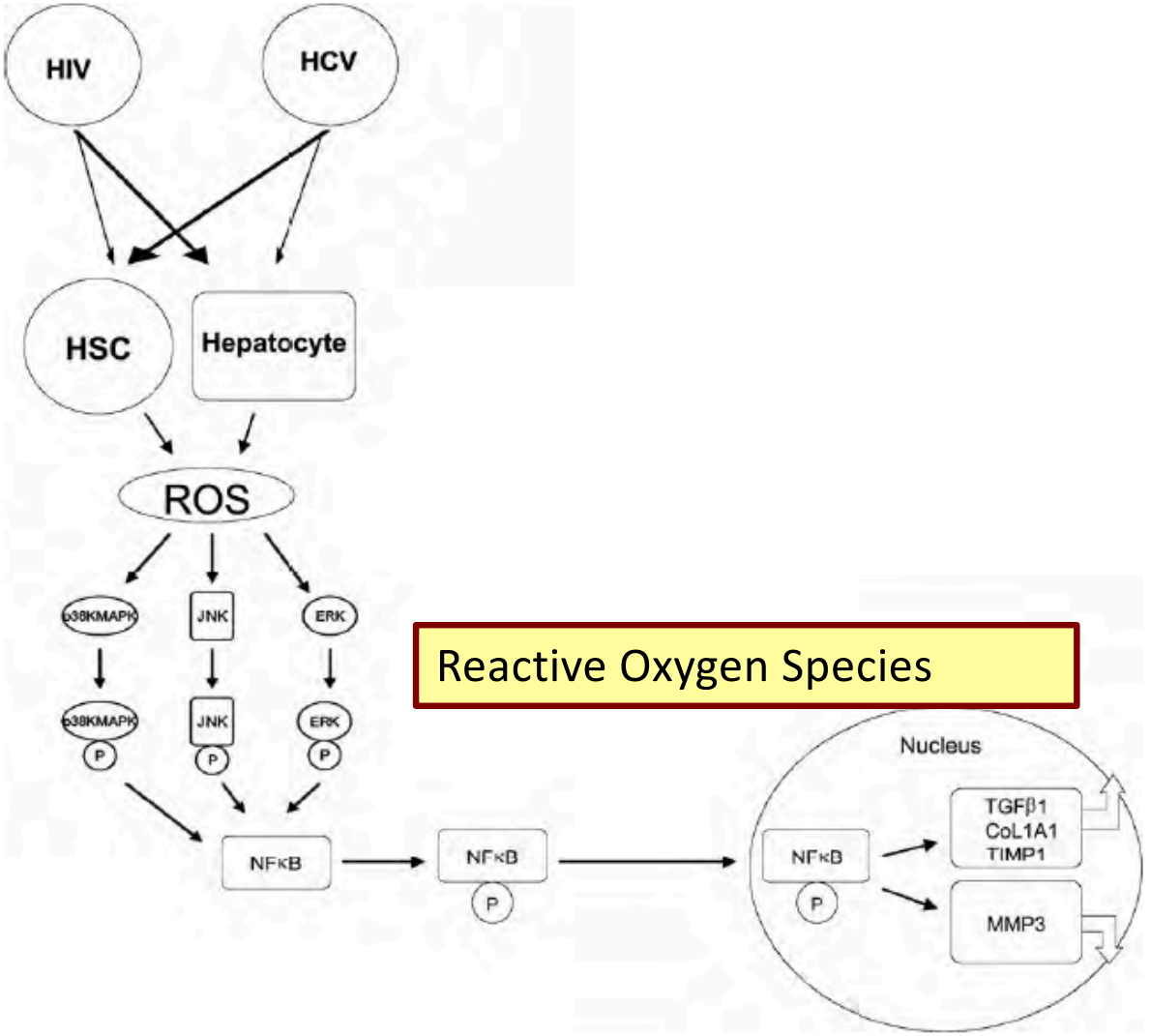


RR for HIV/HCV Pre-HAART: 2.49

RR for HIV/HCV HAART-era 1.72

Thein et al. AIDS 2008 22 (15)

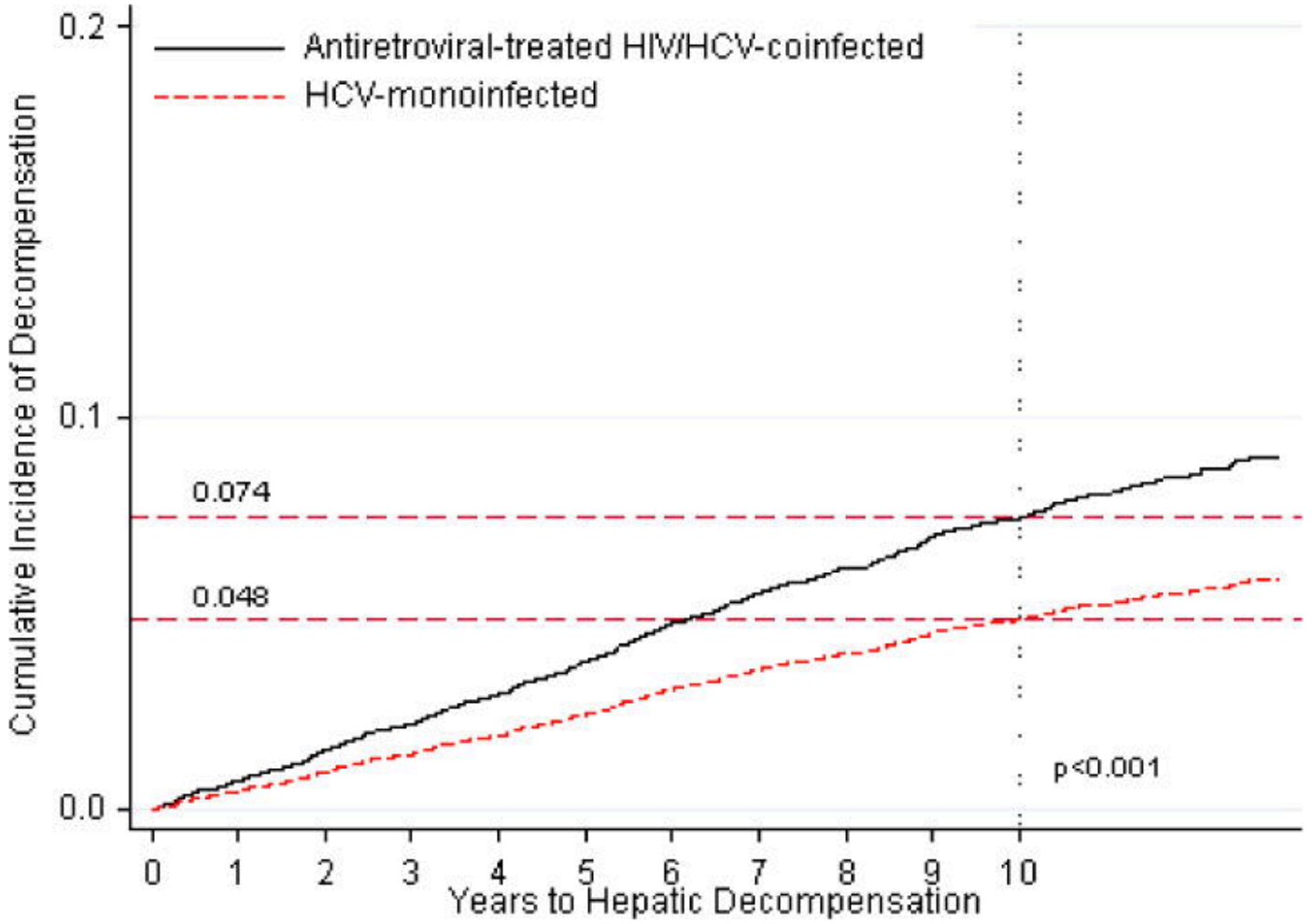
Pathogenesis of HIV/HCV Fibrosis



Reactive Oxygen Species

Expression of pro-fibrogenic genes

Higher Rates of Hepatic Decompensation for HIV/HCV: 1997-2010



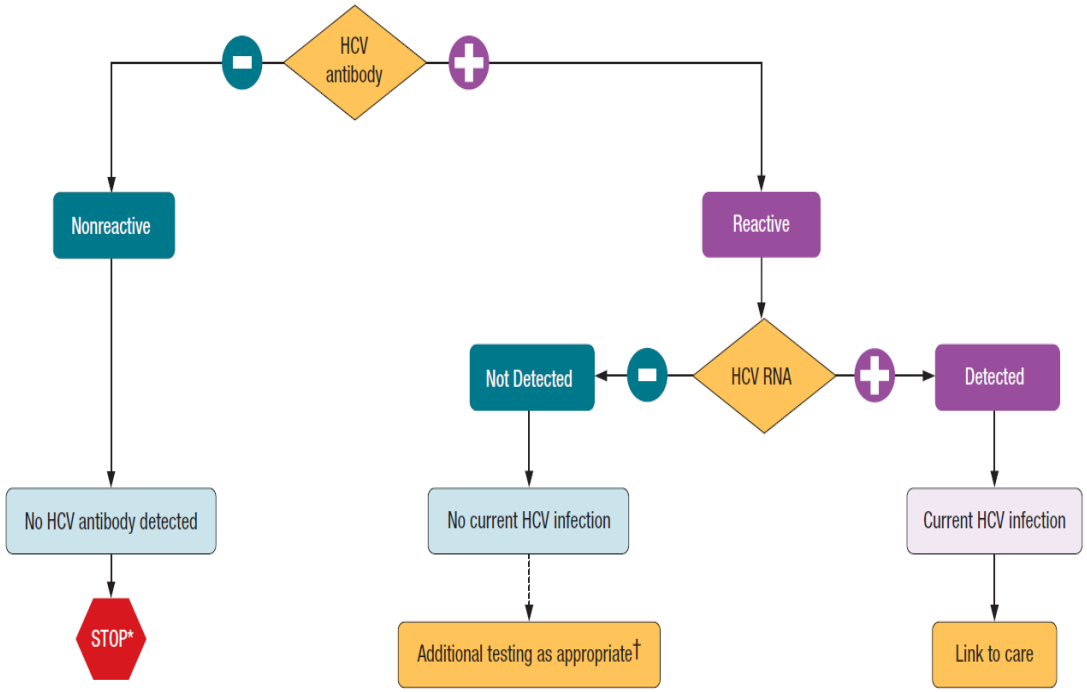
)

OK, so what's the work-up for HIV/HCV coinfected?

Test ALL HIV+ Person!
HCV Testing Algorithm

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Lab Tests to Obtain

- HCV VL
- HCV Genotype
- Fibrosure
- CBC
- LFTs
- BMP

Biomarkers for Staging (No More Biopsies!)

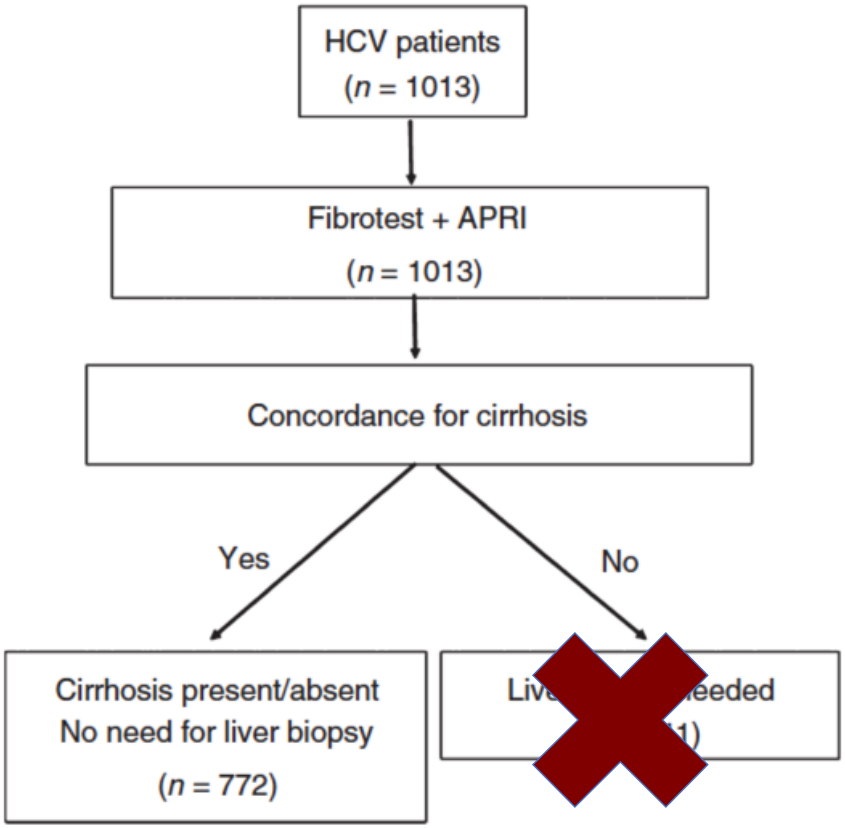
- APRI
  - (AST/normal AST)/PLT x 100

- Fibrosure/Fibrotest
  - Biomarker that uses six blood tests to generate a score that is correlated with the degree of liver Fibrosis

Fibrotest <0.75 and APRI <1
NPV for NO CIRRHOSIS of 95.6%

Fibrotest >0.75 and APRI >2
PPV for CIRRHOSIS of 73.4%

No More Biopsies!



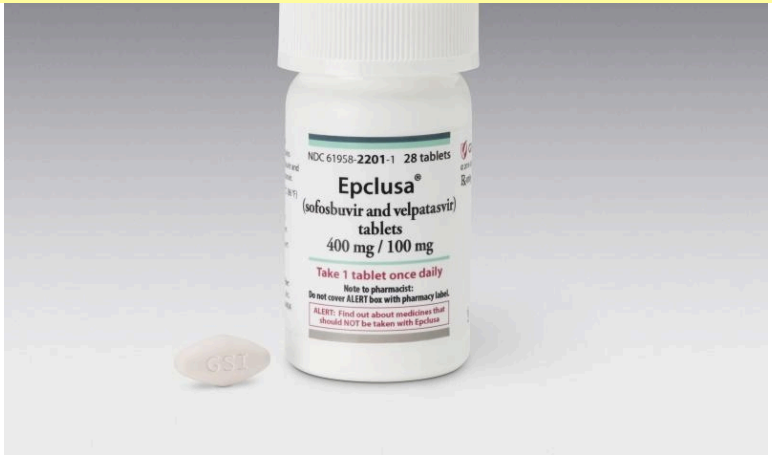
OK, so can we successfully treat HCV in HIV/HCV Co-infected patients?

Good News: We Have Great Medications!

Sofosbuvir/Ledipasvir

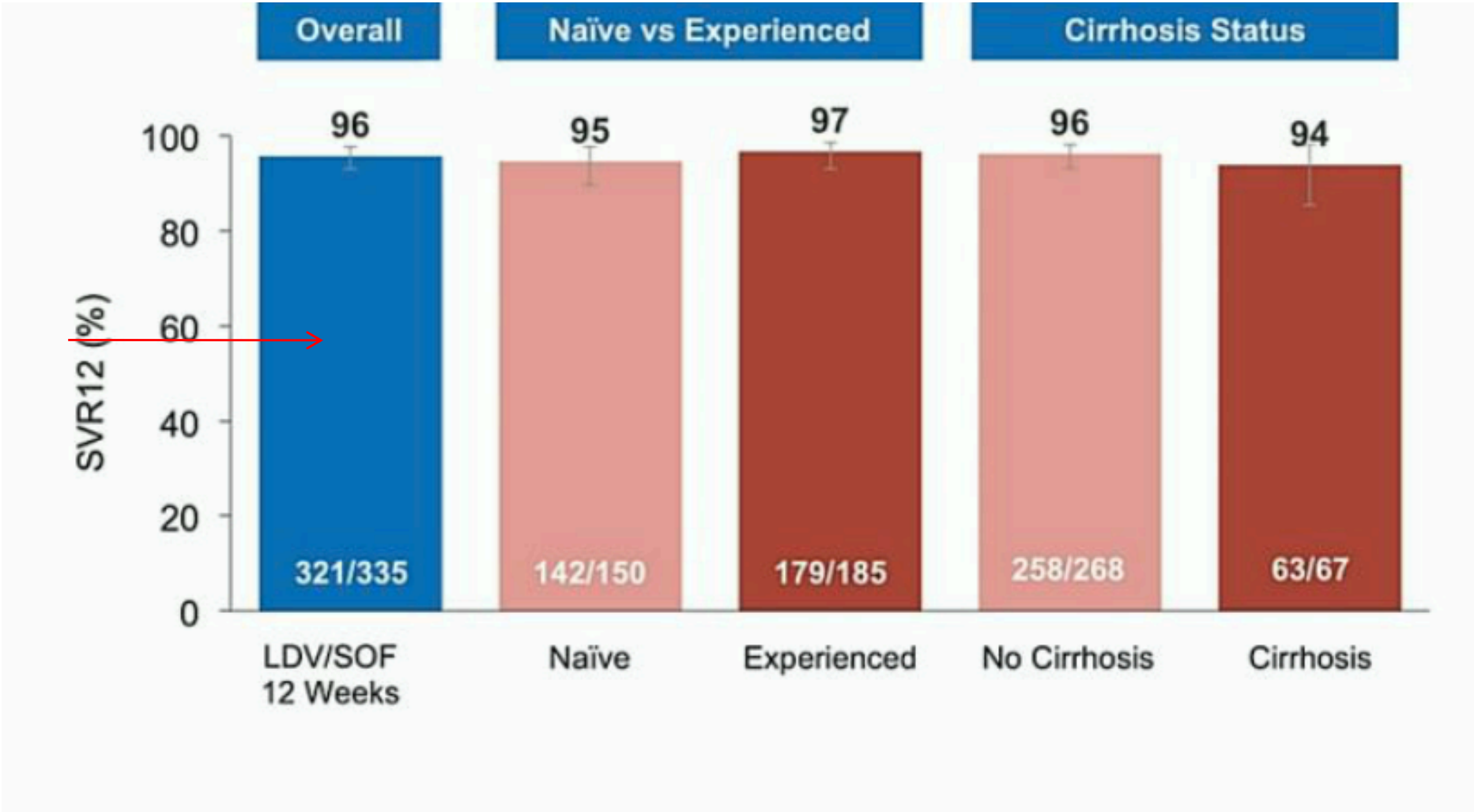
Elbasvir/Grazoprevir

Sofosbuvir/Velpatasvir



Glecaprevir/Pibrentasvir

Cure Rates for 335 HIV/HCV patients on 12 weeks of Harvoni



Side Effects

	Patients, n (%)	LDV/SOF 12 Weeks N=335
Overall safety	AEs	257 (77)
	Grade 3–4 AE	14 (4)
	Serious AE	8 (2)*
	Treatment D/C due to AE	0
	Death	1 (<1)†
	Grade 3–4 laboratory abnormality	36 (11)

- Stable CD4 counts through treatment and follow-up phase
- No patient had confirmed HIV virologic rebound

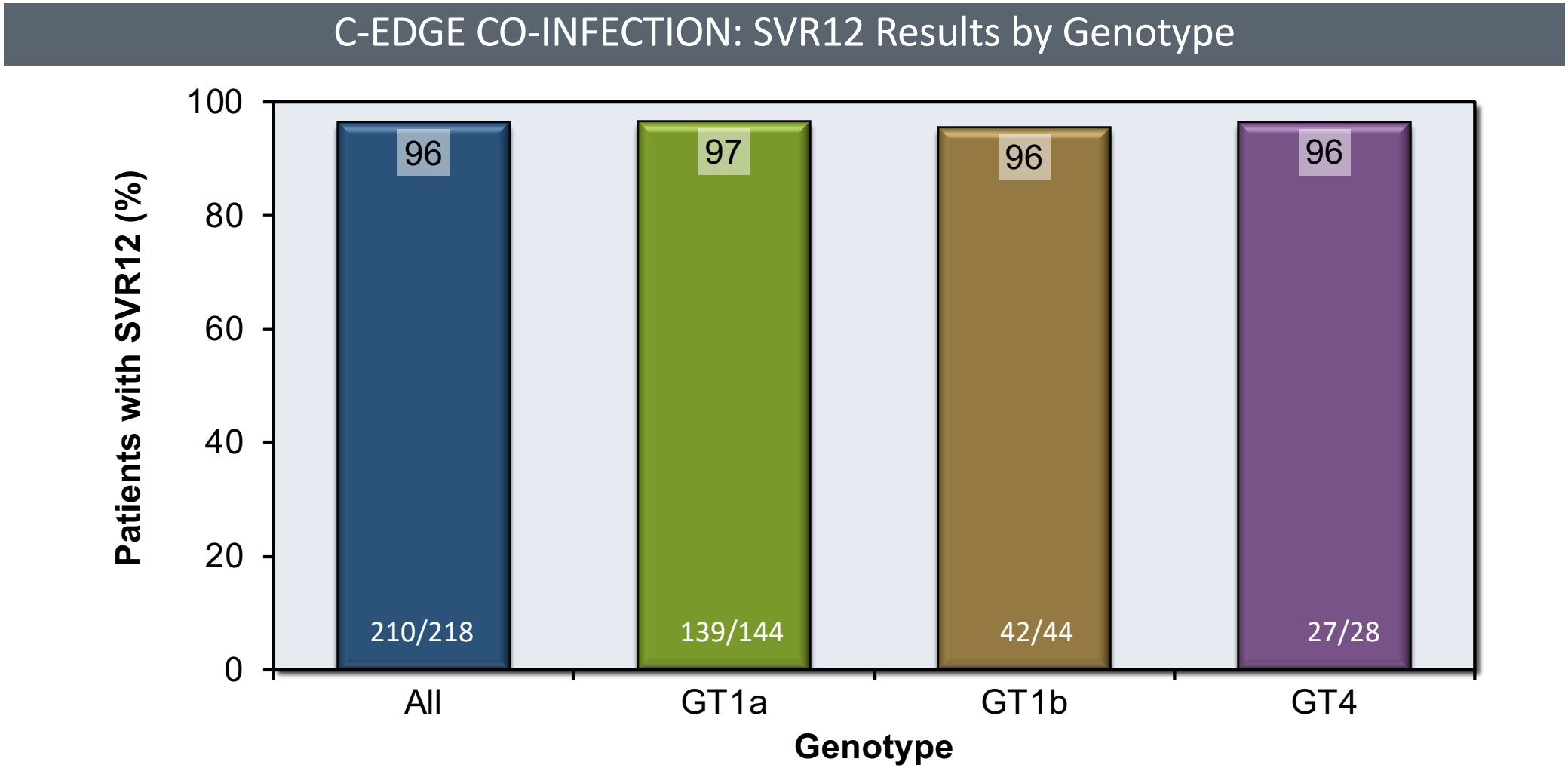
*Serious AEs in >1 patient were hepatocellular carcinoma (n=2) and portal vein thrombosis (n=2) in patients with cirrhosis.
†Confirmed IV drug user developed *Staphylococcus aureus* sepsis, endocarditis with associated embolic brain abscesses, and multi-organ system failure.

Side Effects in >5% of people

<u>Harvoni's Claim to Fame</u>:
First one pill a day for Geno 1 with nearly 100% cure rates!

<u>Problem:</u>
-Cant Use in renal Disease (GFR>30)
-Expensive! $94,000 per course

Zepatier: Cure Rates in 218 HIV/HCV Patients on 12 week regimen



Side Effects

Adverse Event (AE), n (%)	**Elbasvir-Grazoprevir** (N=218)	
Discontinuation due to AE	0	
Serious AEs	2 (1%)	
Deaths	0	
Any AE in >5% of patients		
Fatigue	29 (13%)	
Headache	27 (12%)	
Nausea	20 (9%)	
Upper respiratory tract infection	18 (8%)	
Diarrhea	16 (7%)	
Insomnia	15 (7%)	
Grade 3 or 4 laboratory abnormality	Grade 3	Grade 4
Total bilirubin	1 (<1%)	0
ALT elevation	3 (1%)	2 (1%)
AST elevation	0	1 (<1%)
Hemoglobin	0	0

Side effects of HCV Drug vs. Placebo

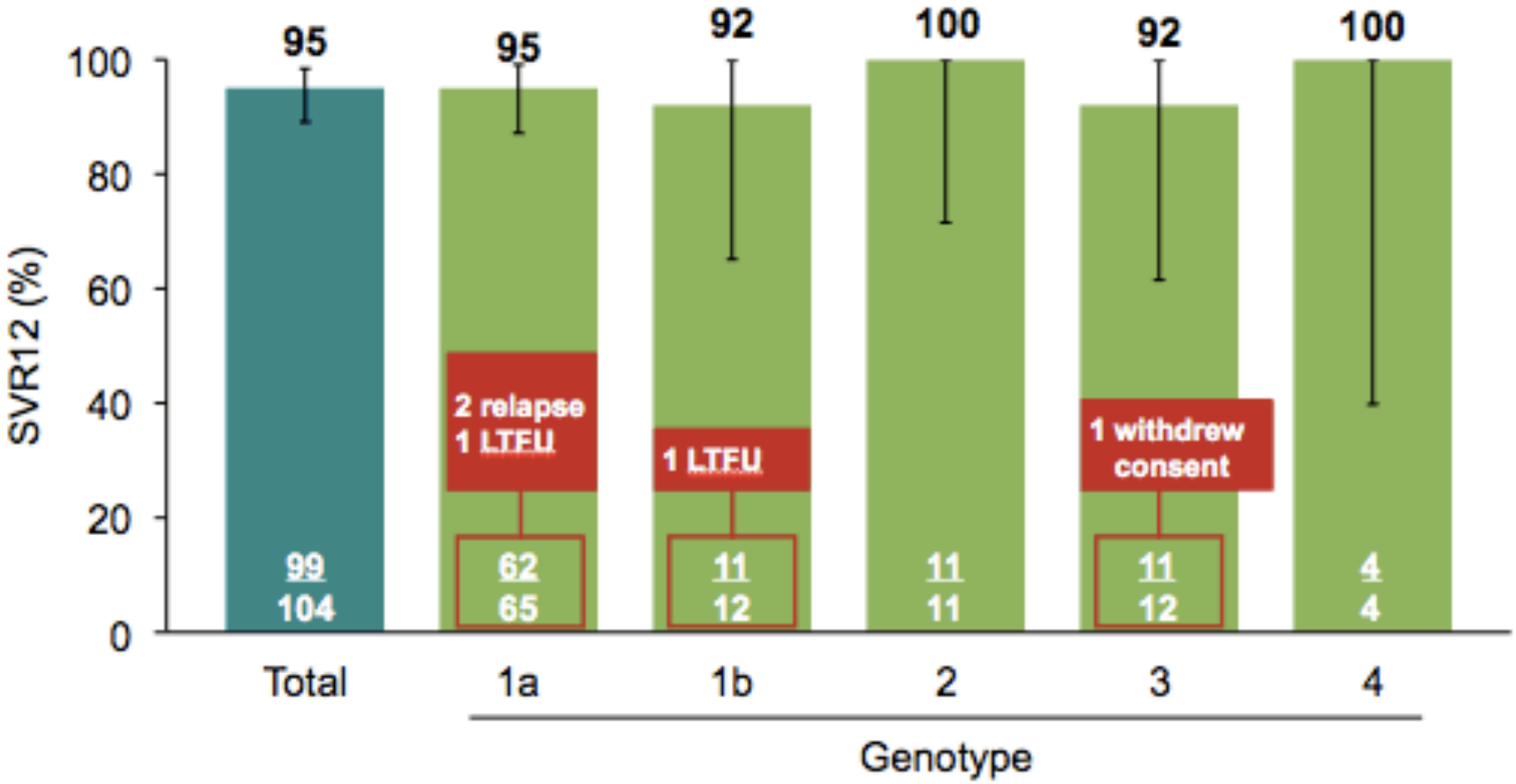
	Grazoprevir and elbasvir immediate treatment group (n=111)	PLACEBO elbasvir deferred treatment group (n=113)
Any adverse event*†	84 (75·7%)	95 (84·1%)
Headache		
Nausea		
Fatigue		
Insomnia		
Dizziness		
Diarrhoea		
Drug-related adverse		
Serious adverse ever		
Drug-related serious		
Discontinuation due to an adverse event	0	5‡ (4·4%)
Deaths	1 (0·8%)	3 (2·7%)

Zepatier's Claim to Fame:

1. **First Drug studied in PWID**
2. **Can be used in Renal Disease**
3. **Cheaper! (54,000 versus 94,000)**

Problem: Must check for baseline resistance in patients with Geno 1a= if resistance then ADD ribavirin

Epclusa: Cure Rates for 104 HIV/HCV Patients on 12 week regimen



Side Effects

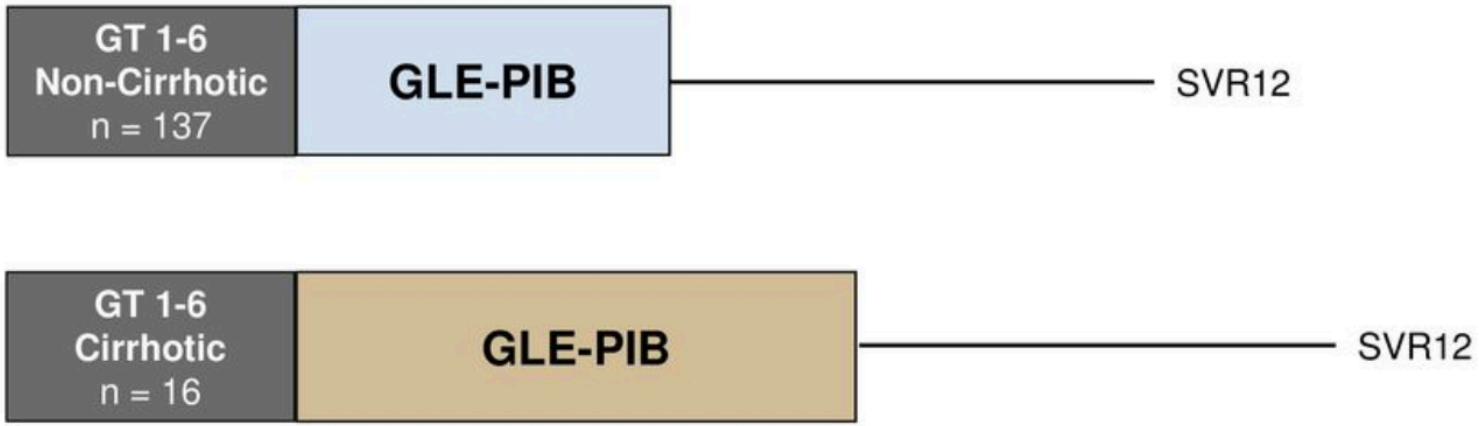
<u>Epclusa's Claim to Fame</u>:

1. **Pangenotypic**
2. **Better for Geno 3!**
3. **Cost: $74,000**

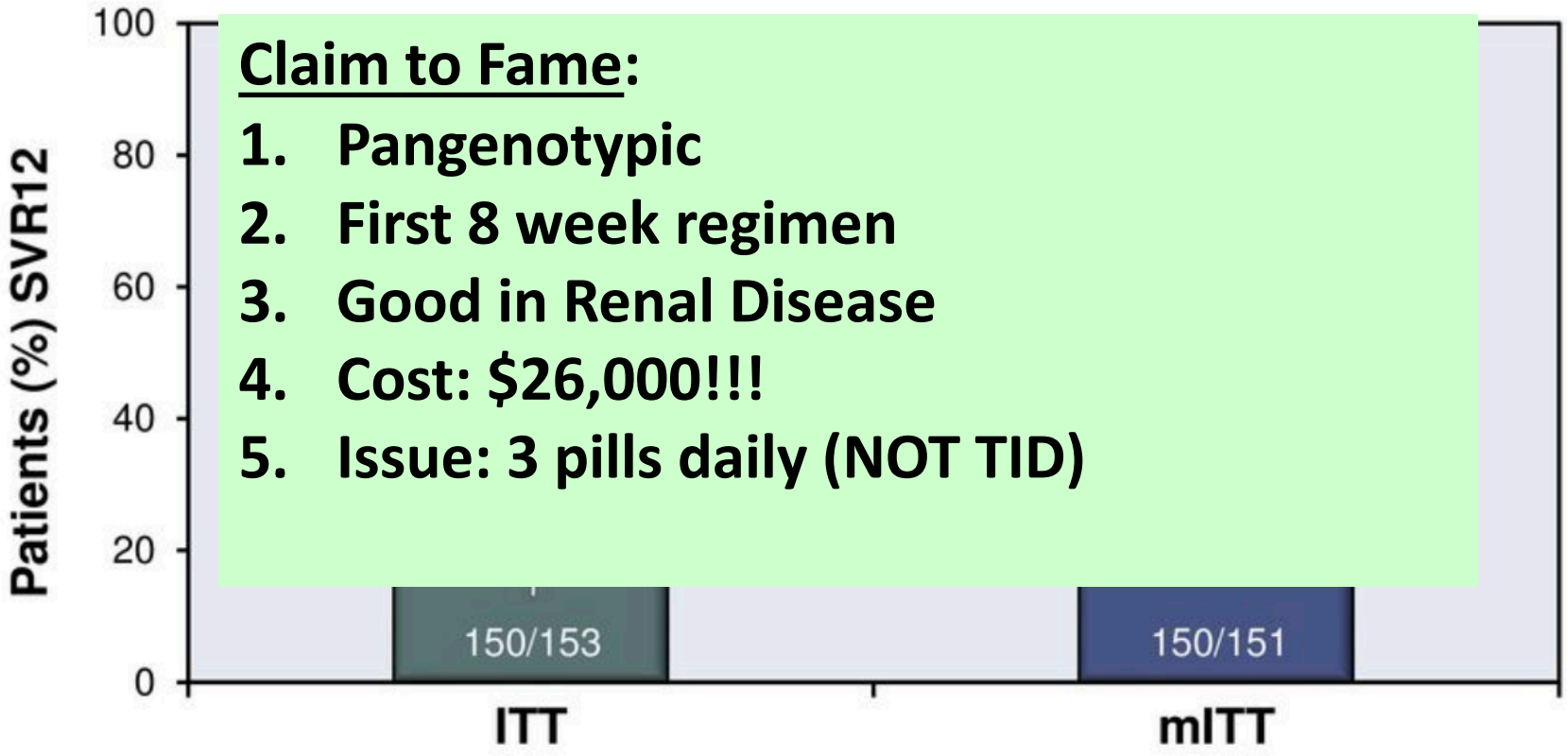
Insomnia	7 (7)
Nausea	7 (7)

- The majority of AEs were mild in severity (Grade 1 and 2)

Gleceprevir/Pibrentasvir
HIV/HCV co-infection



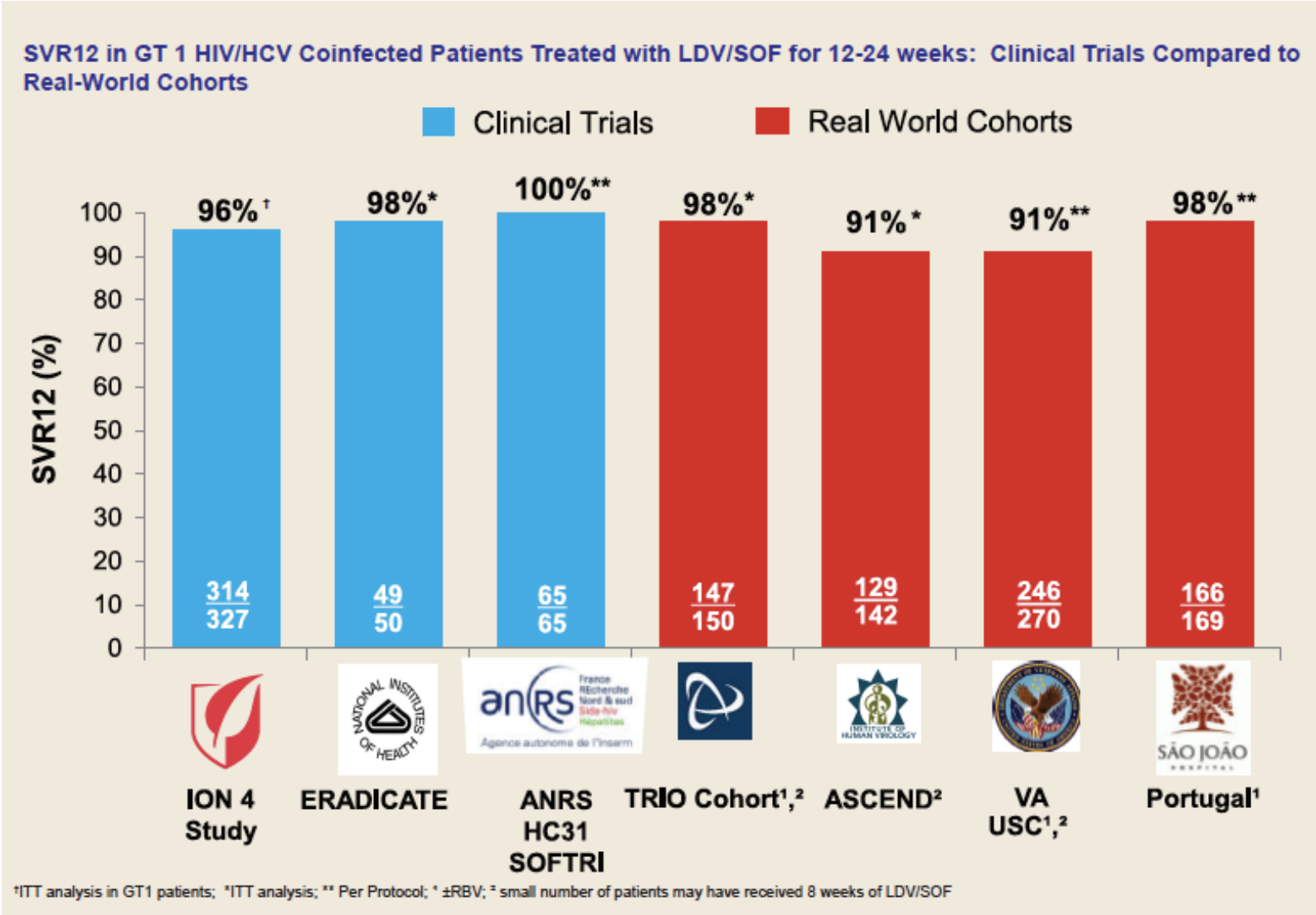
Gleceprevir/Pibrentasvir: Results



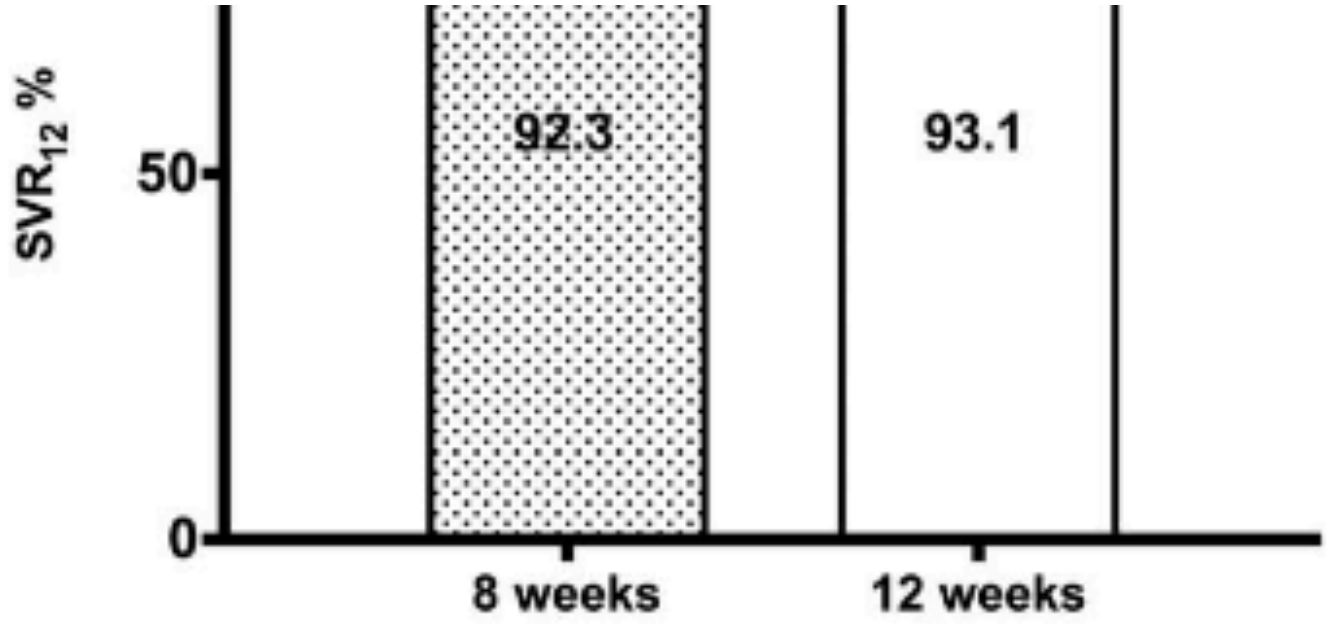
Claim to Fame:

1. **Pangenotypic**
2. **First 8 week regimen**
3. **Good in Renal Disease**
4. **Cost: $26,000!!!**
5. **Issue: 3 pills daily (NOT TID)**

Real World Data



Real World Data: 8 weeks vs 12 weeks for sofosbuvir/ledipasvir



No.	104	204	*P*
SVR ITT	96 (92.3)	190 (93.1)	0.79
SVR ITT (95% CI)	(85.4 - 96.6)	(88.8 - 96.2)	-
Relapse	6 (5.8)	8 (3.9)	0.46
Breakthrough	0	0	-

Yes, but what about all the drug-drug interactions?

Drug Interactions: ART and DAAs

	DCV	EBR-GRZ	LDV-SOF	SOF-VEL	PrOD	SMV	Ribavirin
AZT	OK	OK	OK	OK	OK	OK	Avoid: Risk of severe anemia
TDF	OK	OK	*Caution if r/PI or cobi; CrCl <60-80	*Caution if r/PI or cobi; CrCl <60-80	OK	OK	OK
TAF/FTC	OK	OK	OK	OK	OK	OK	OK
ATV/r	Decrease DCV to 30 mg	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	DC ritonavir & take ATV 300 mg with PrOD	Avoid	OK
DRV/r	OK	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	Avoid: ↓DRV levels	Avoid	OK
LPV/r	OK	Avoid	No data	OK (*caution w/ TDF)	Avoid: ↑GI effects	Avoid	OK
EFV	Increase DCV dose to 90 mg	Avoid	↓LDV	Avoid	Avoid – may ↓PrOD	Avoid	OK
RPV	OK	OK	OK	OK	Avoid - ↑rilpivirine	OK	OK
ETR	Increase DCV to 90 mg	Avoid; may ↓EBR-GRZ	Avoid; may ↓LDV	No data - Avoid	Avoid: may ↓PrOD	Avoid	OK
RAL	OK	OK	OK	OK	OK	OK	OK
DTG	OK	OK	OK	OK	Prob OK	OK	OK
cobi-EVG	No data - Decrease DCV to 30 mg	No data – May ↑EBR-GRZ	↑LDV, ↑TDF *Caution w/ TDF, TAF OK	OK (caution w/ TDF)	No data	No data	OK

Drug Interactions: ART and DAAs

	DCV	EBR-GRZ	LDV-SOF	SOF-VEL	PrOD	SMV	Ribavirin
AZT	OK	OK	OK	OK	OK	OK	Avoid: Risk of severe anemia
TDF	OK	OK	*Caution if r/PI or cobi; CrCl <60-80	*Caution if r/PI or cobi; CrCl <60-80	OK	OK	OK
TAF/FTC	OK	OK	OK	OK	OK	OK	OK
ATV/r	Decrease DCV to 30 mg	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	DC ritonavir & take ATV 300 mg with PrOD	Avoid	OK
DRV/r	OK	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	Avoid: ↓DRV levels	Avoid	OK
LPV/r	OK	Avoid	No data	OK (*caution w/ TDF)	Avoid: ↑GI effects	Avoid	OK
EFV	Increase DCV dose to 90 mg	Avoid	↓LDV	Avoid	Avoid – may ↓PrOD	Avoid	OK
RPV	OK	OK	OK	OK	Avoid - ↑rilpivirine	OK	OK
ETR	Increase DCV to 90 mg	Avoid; may ↓EBR-GRZ	Avoid; may ↓LDV	No data - Avoid	Avoid: may ↓PrOD	Avoid	OK
RAL	OK	OK	OK	OK	OK	OK	OK
DTG	OK	OK	OK	OK	Prob OK	OK	OK
cobi-EVG	No data - Decrease DCV to 30 mg	No data – May ↑EBR-GRZ	↑LDV, ↑TDF *Caution w/ TDF, TAF OK	OK (caution w/ TDF)	No data	No data	OK

Drug Interactions: ART and DAAs

	DCV	EBR-GRZ	LDV-SOF	SOF-VEL	PrOD	SMV	Ribavirin
AZT	OK	OK	OK	OK	OK	OK	Avoid: Risk of severe anemia
TDF	OK	OK	*Caution if r/PI or cobi; CrCl <60-80	*Caution if r/PI or cobi; CrCl <60-80	OK	OK	OK
TAF/FTC	OK	OK	OK	OK	OK	OK	OK
ATV/r	Decrease DCV to 30 mg	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	DC ritonavir & take ATV 300 mg with PrOD	Avoid	OK
DRV/r	OK	Avoid	OK (*caution w/ TDF)	OK (*caution w/ TDF)	Avoid: ↓DRV levels	Avoid	OK
LPV/r	OK	Avoid	No data	OK (*caution w/ TDF)	Avoid: ↑GI effects	Avoid	OK
EFV	Increase DCV dose to 90 mg	Avoid	↓LDV	Avoid	Avoid – may ↓PrOD	Avoid	OK
RPV	OK	OK	OK	OK	Avoid - ↑rilpivirine	OK	OK
ETR	Increase DCV to 90 mg	Avoid; may ↓EBR-GRZ	Avoid; may ↓LDV	No data - Avoid	Avoid: may ↓PrOD	Avoid	OK
RAL	OK	OK	OK	OK	OK	OK	OK
DTG	OK	OK	OK	OK	Prob OK	OK	OK
cobi-EVG	No data - Decrease DCV to 30 mg	No data – May ↑EBR-GRZ	↑LDV, ↑TDF *Caution w/ TDF, TAF OK	OK (caution w/ TDF)	No data	No data	OK

Drug-Drug Interactions
They are Manageable

- Harvoni:
  - No Etravirine
  - Boosted PI's with TDF and Stribild= only if CrCl>60 and must monitor renal function
- **INTEGRASE INHIBITORS and NRTI's OK!**
  - No Efavirenz (Atripla)
- Epclusa:
  - Same as Harvoni
  - But ALSO no EVF (Atripla)

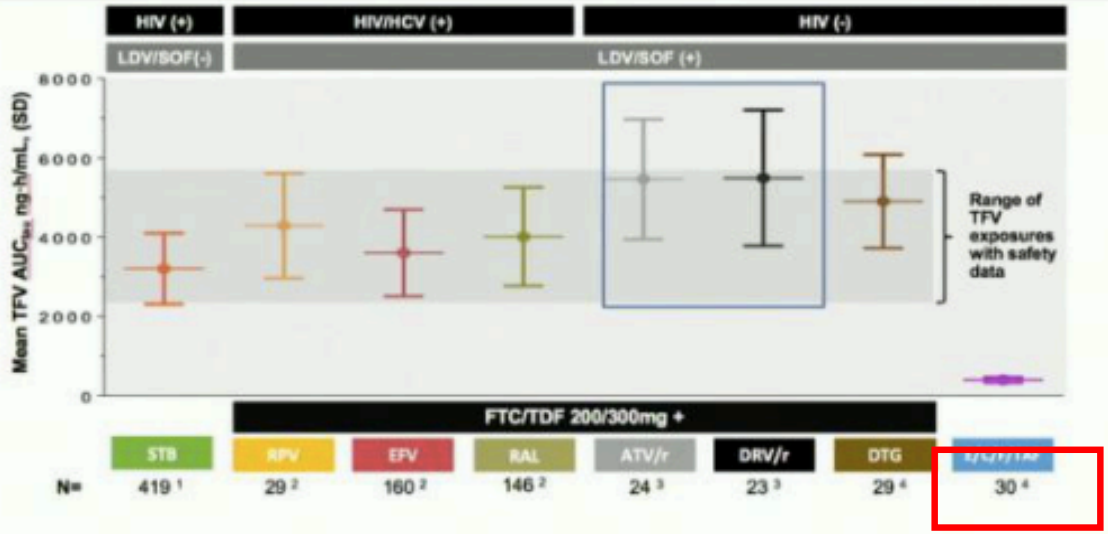
What about Mavyret?

- NO PI's
- NO Efavirenz

- OK:
  - Integrase Inhibitors
  - Complera
  - Stribild (Must monitor hepatic function)

TENOFOVIR LEVELS:
SOF/LDV and HIV Regimens

Impact of ARV regimens on TFV levels: SOF/LDV

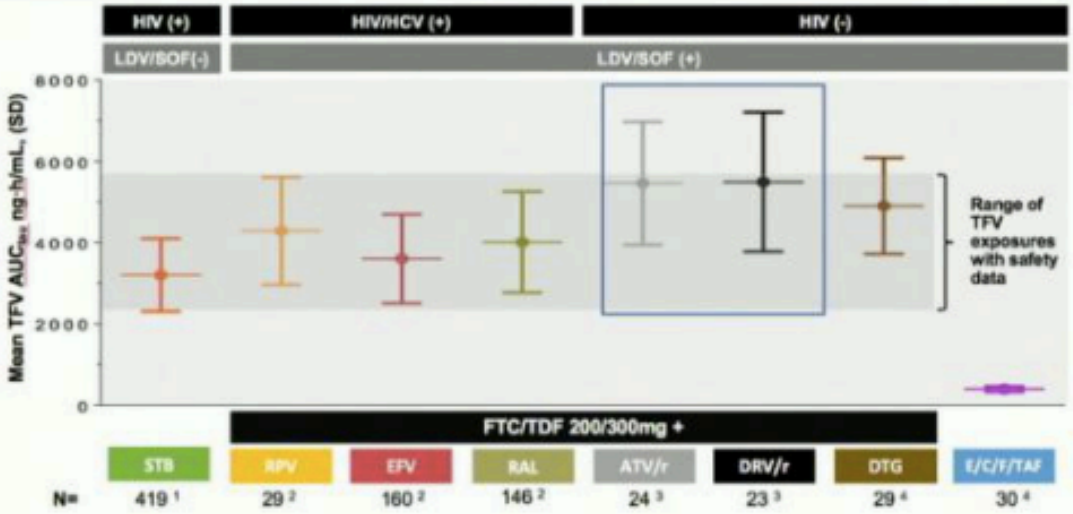


- Co-administration of SOF/LED with TDF-containing ARVs increased TFV trough ~40-60%
- TFV levels from TAF are low compared to other regimens

1. Ramanathan S, et al. IWCPHHT 2013. Washington, D.C. Poster #372. 2. Data on file. Gilead Sciences, Inc. March 2015. GS-US-337-0115 (ION 4) 3. German P, et al. CROI 2015. Seattle, WA. Oral #82 4. Garrison K, et al. IWCPHHT 2015. Washington, D.C. Poster #71 5. Luetkemeyer A et al AIDS 2016. Select information on this slide is courtesy Gilead Sciences, 2017

TENOFOVIR LEVELS: SOF/VEL and HIV Regimens

Impact of ARV regimens on TFV levels: SOF/LDV



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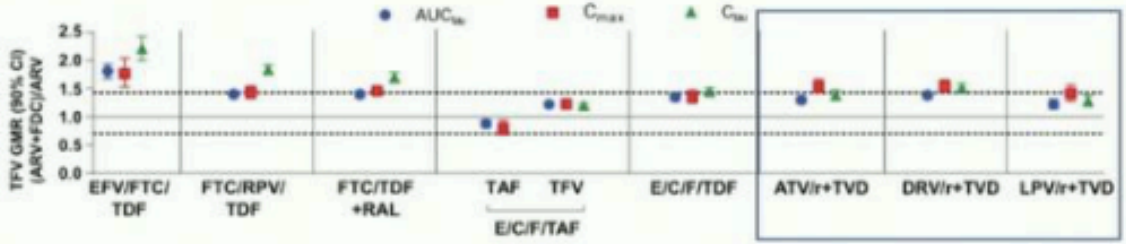
Impact of ARV regimens on TFV levels: SOF/VEL



*Dotted lines depict no-PK-alteration boundary.

- Co-administration of SOF/VEL with TDF-containing ARVs increased TFV exposure ~20-81%
- No significant impact of SOF/VEL on TAF or TFV derived from TAF

1. Ramanathan S, et al. IWCPHHT 2013. Washington, D.C. Poster #372. 2. Data on file. Gilead Sciences, Inc. March 2015. GS-US-337-0115 (ION 4) 3. German P, et al. CROI 2015. Seattle, WA. Oral #82 4. Garrison K, et al. IWCPHHT 2015. Washington, D.C. Poster #71 5. Luetkemeyer A et al AIDS 2016. Select information on this slide is courtesy Gilead Sciences, 2017

Real Life Impact on Renal Function

Impact on renal function: SOF/LDV and TDF

Table 1: VAMC HIV/HCV National Cohort- Clinical Case Registry:SOF/LDV

	TDF+PI (n=100)	TDF and no PI (n=372)	No TDF (n=423)	p value
Delta Cr	0.17 mg/dL	0.18 mg/dL	0.15 mg/dL	0.30

L. Bhattacharya et al CID 2017 in press

Real Life Impact on Renal Function

Impact on renal function: SOF/LDV and TDF

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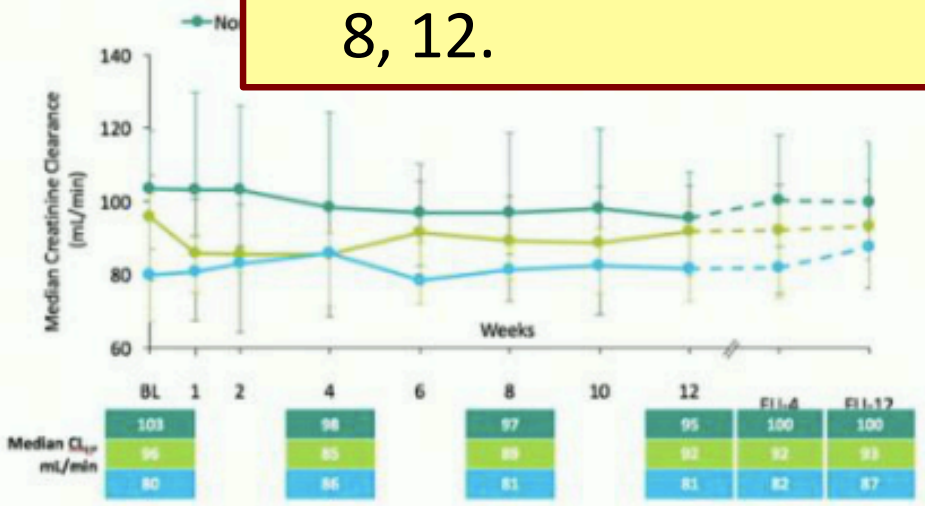
Delta Cr	0.17 mg/dL	0.18 mg/dL	0.15 mg/dL	0.30

- Do not use boosted PI with TDF if GFR <60
- Otherwise, can use but monitor GFR at week 2, 4, 8, 12.



	TDF-Containing Regimens (N = 35)	Boosted ining Regimens (N = 56)
AUC_{tau} (h•ng/mL)	3590 (23.2)	3740 (26.3)
C_{max} (ng/mL)	319 (26.4)	351 (30.8)
C_{tau} (ng/mL)	91.2 (37.9)	92.9 (41.4)

3 pts had Cr >0.4 mg/dL, 2 on pharm. boosted TDF reg, but had co-morbid conditions

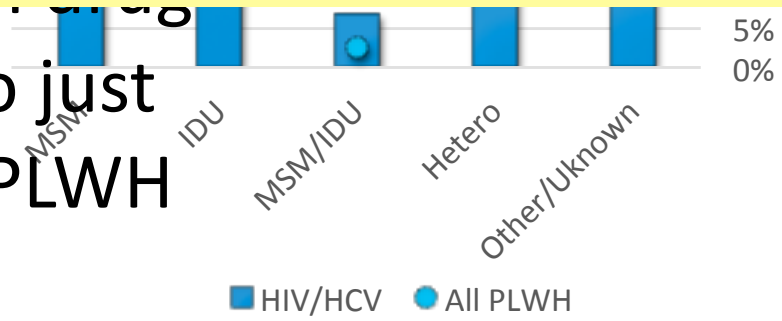
1. Bhattacharya et al CID 2017 in press, 2. Brau et al AIDS 2016 3. Wyles et al CID 2017 in press

What about hard-to-treat populations like PWID?

IDU is greater among HIV/HCV than HIV mono-infection

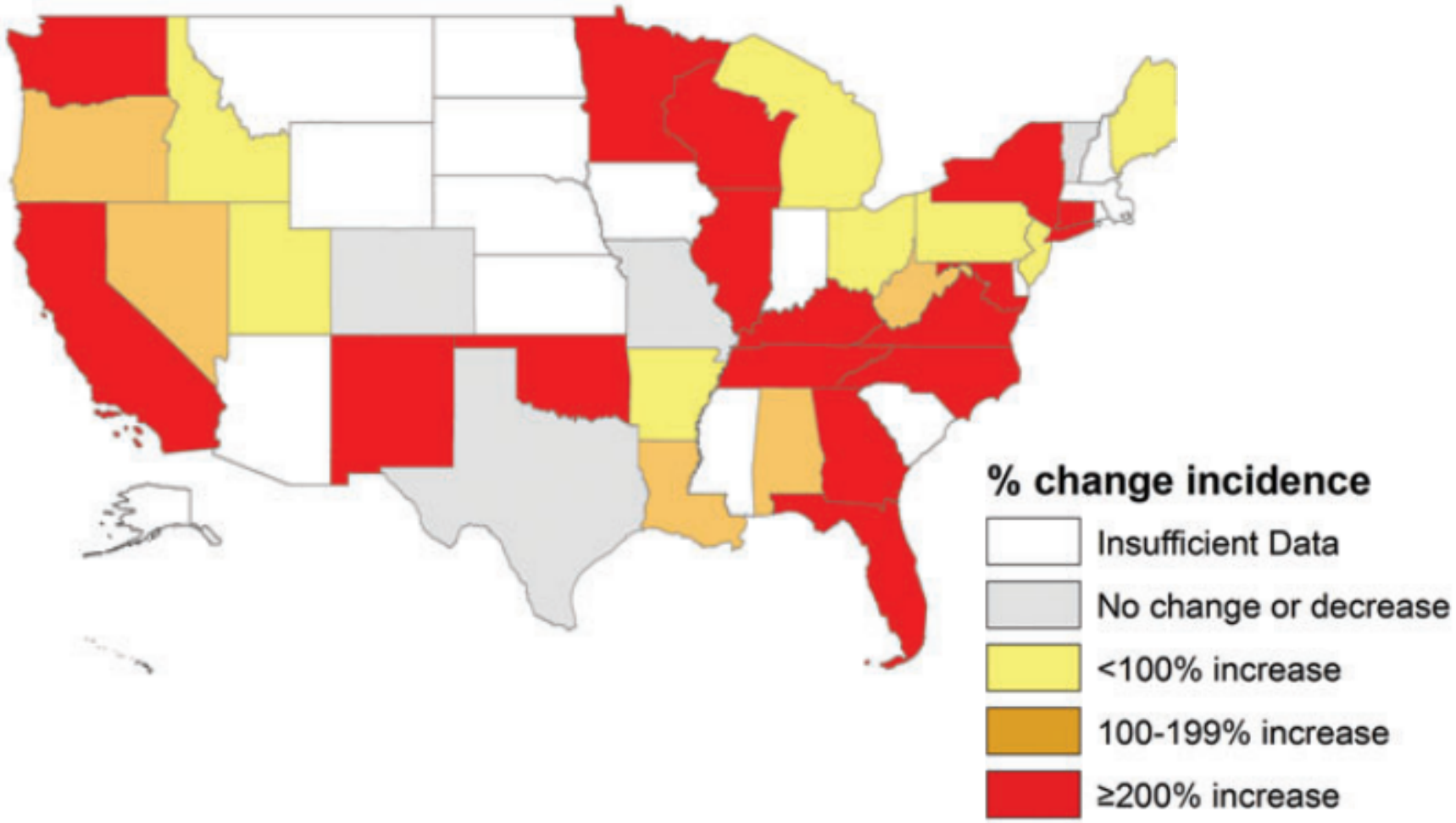
- **1 in 10 new HIV diagnoses are among people who inject drugs (PWID)**
- **About 80% of people with HIV who inject drugs also have hepatitis C virus (HCV)**

Over h
HIV
history of injection drug
use, compared to just
under 15% of all PLWH

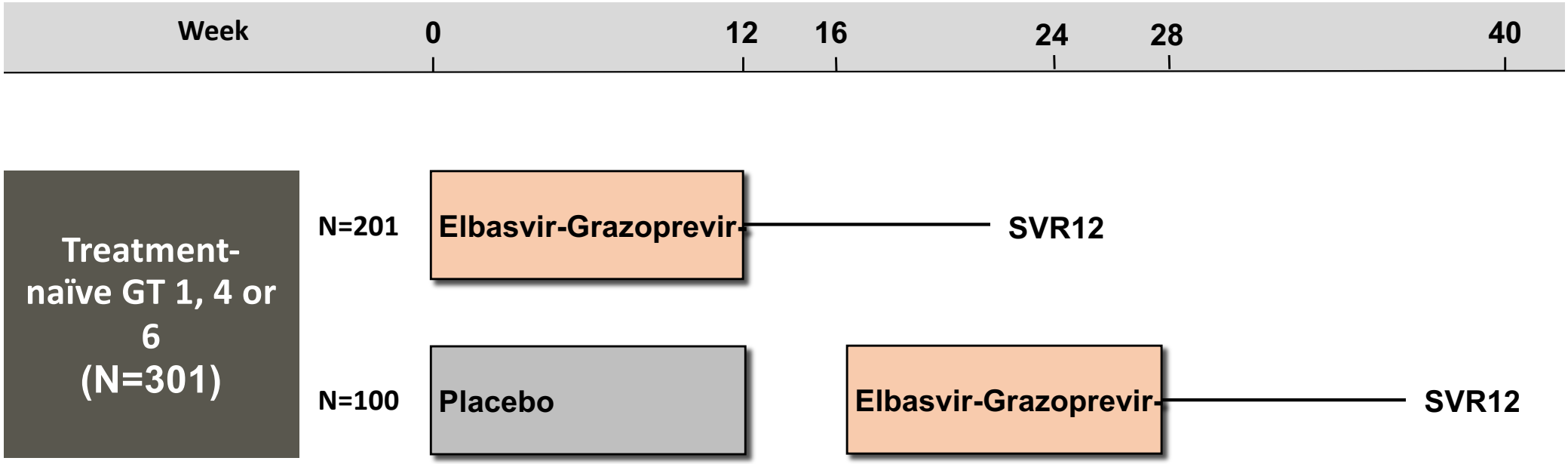


NYC DOH Data 2015

Continued Transmission of HCV 2007-2012



C-EDGE CO-STAR
Elbasvir-Grazoprevir in PWID on Opiate Agonist Therapy



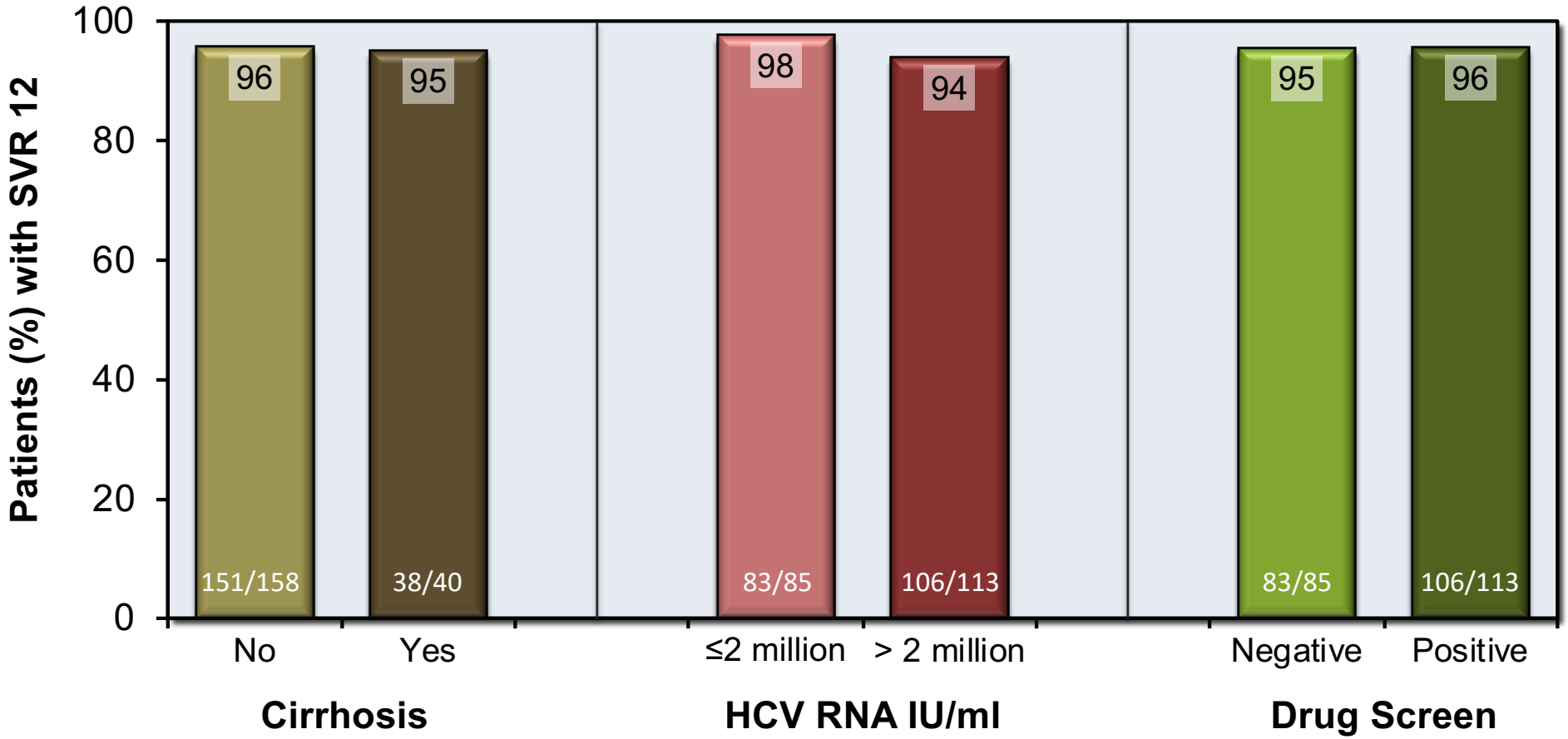
20% with cirrhosis

8% with HIV/HCV Coinfection

60% with positive baseline urine toxicology

Great Cure Results Despite Drug Use

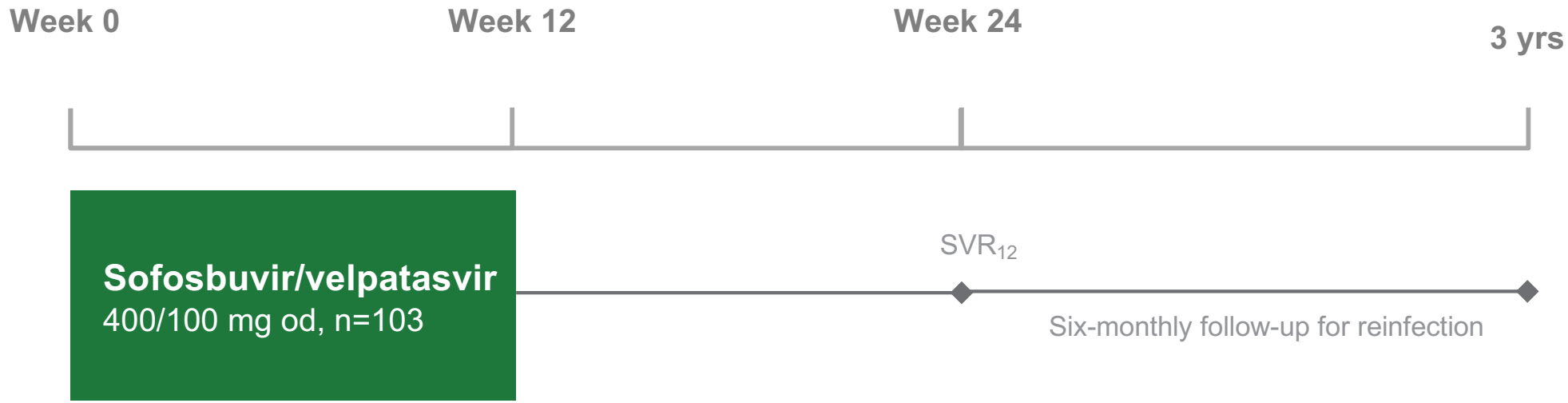
C-EDGE CO-STAR: SVR12 Results with Modified Full Analysis Set^



^Excludes patients who discontinued trial for non-treatment related reasons

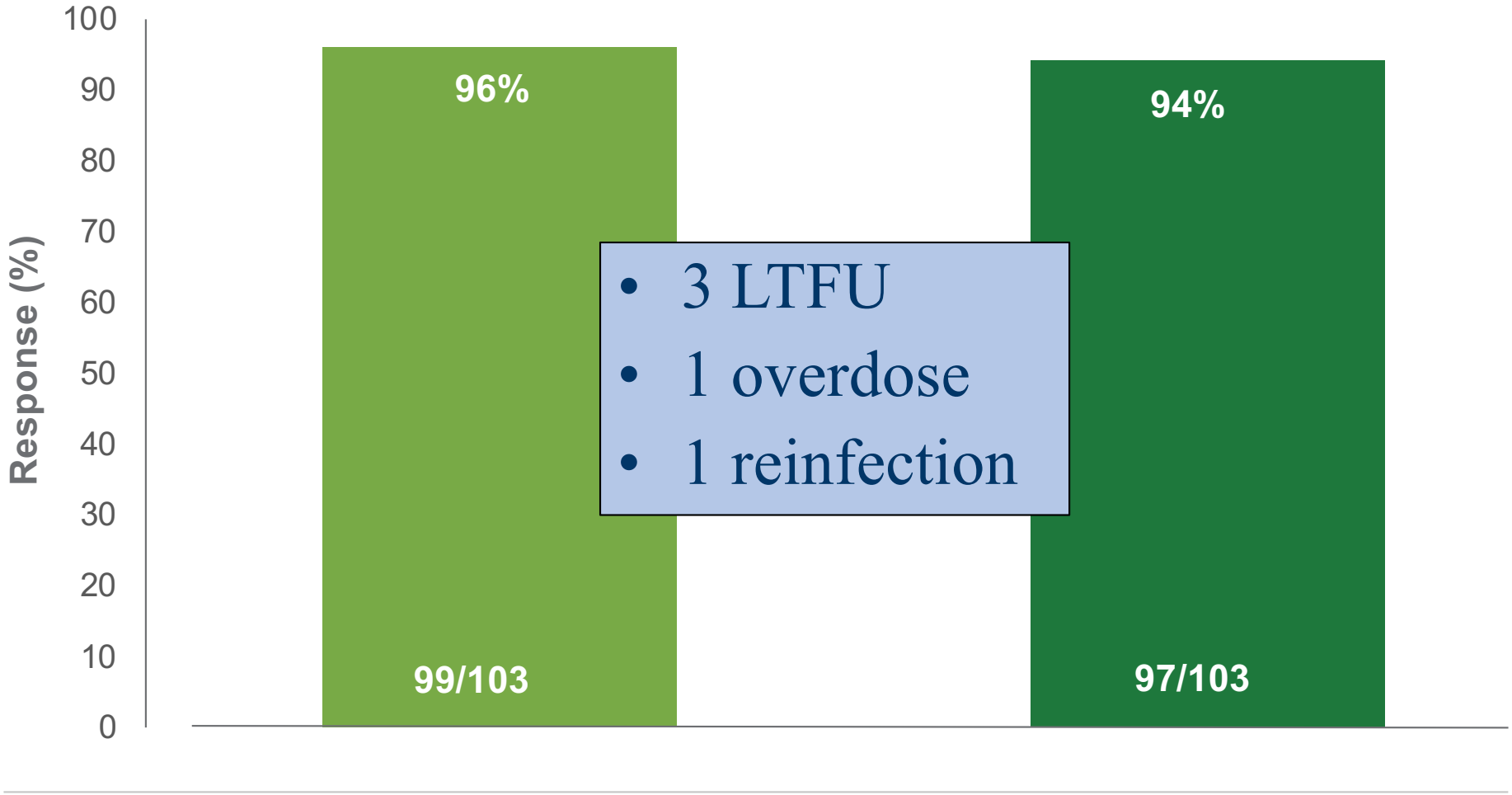
All Recent PWID – The SIMPLIFY Study

- Kirby/UNSW sponsored, international open-label trial
- DAA treatment-naïve patients with GT1-6 chronic HCV infection (F0-4)
- Electronic blister packs to monitor adherence
- 100% people with recent injecting drug use (past six months)
- 74% Injection use in last 1 month
- 57% on OST



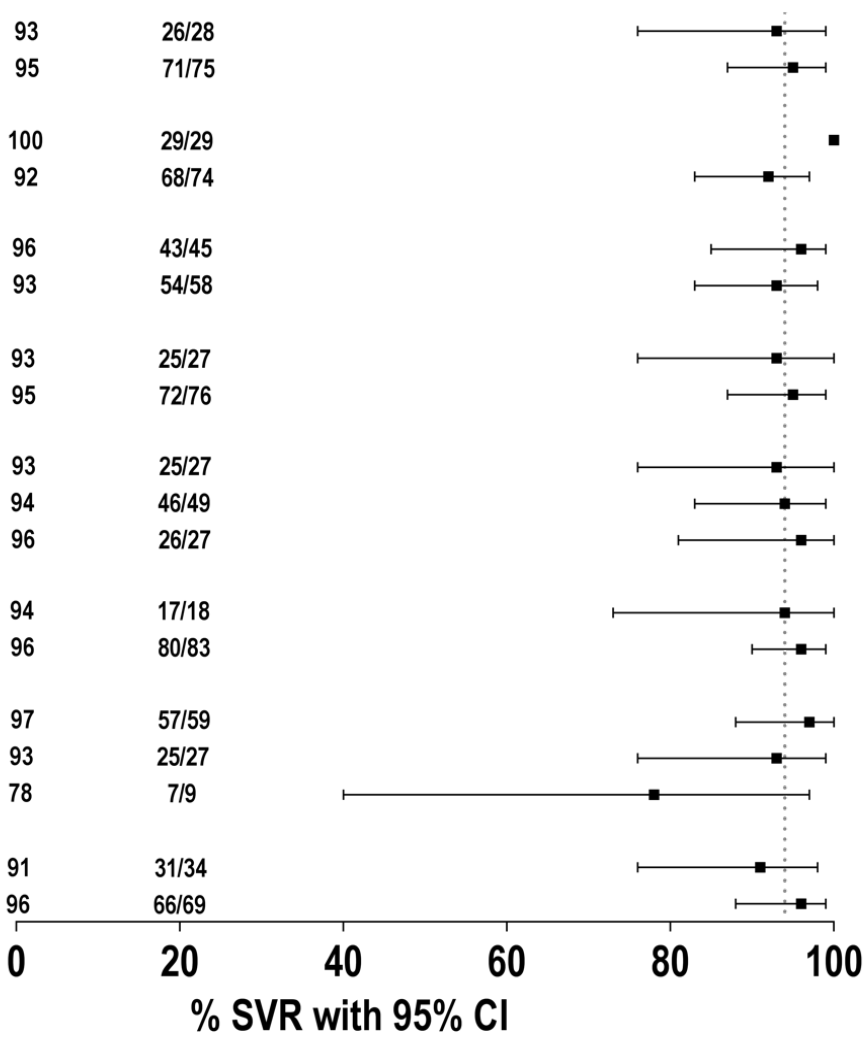
Recent PWID – The SIMPLIFY Study

- 74% injecting in past 30 days
- 35% G1a, 58% G1b, 9% cirrhosis, DAA-treatment naïve



Simplify: SVR, stratified by patient characteristics

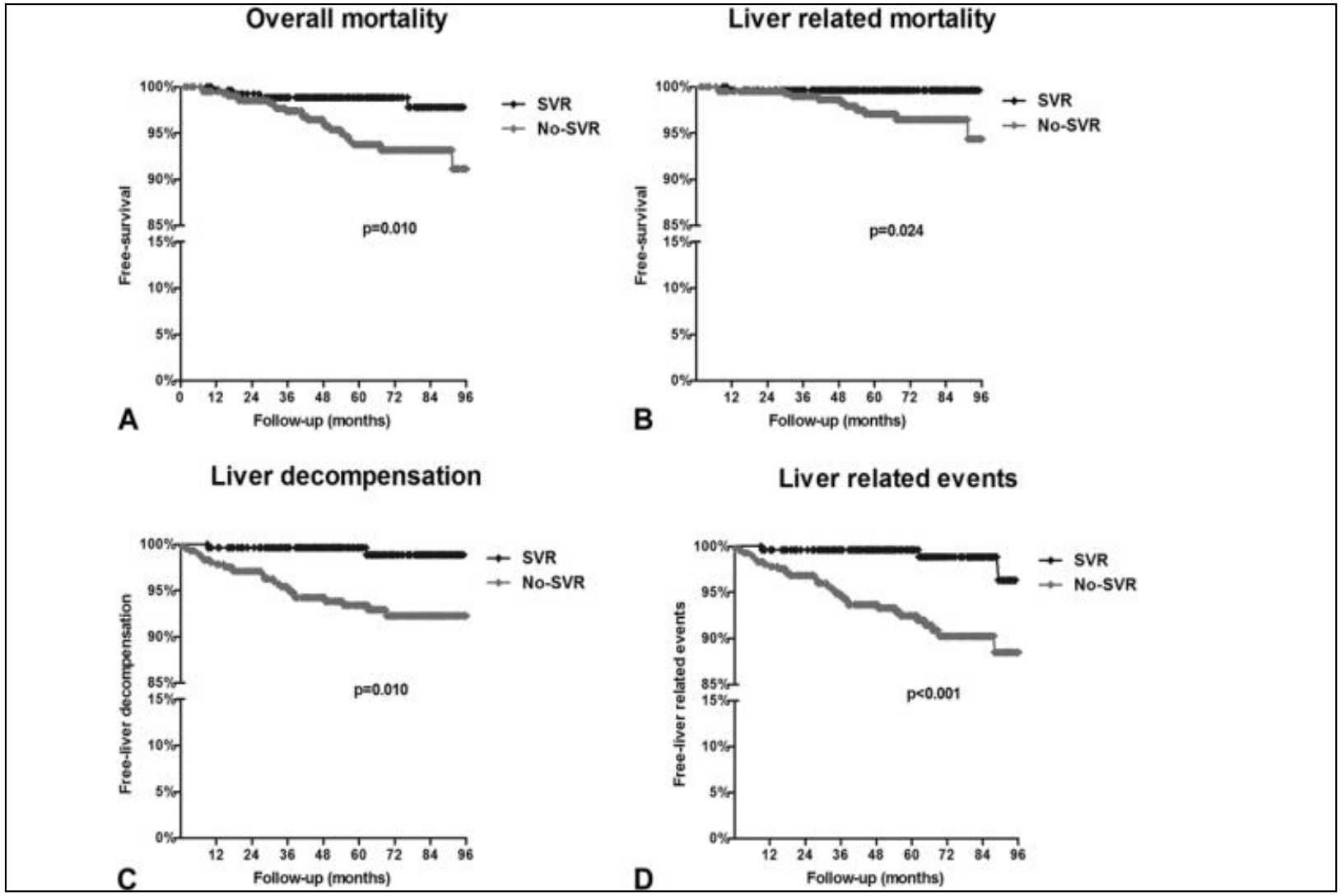
Variable	SVR12	Patients With SVR12/ Total Patients, n/N
Age		
<40 years	93	26/28
>40 years	95	71/75
Sex		
Female	100	29/29
Male	92	68/74
Current OST		
No	96	43/45
Yes	93	54/58
Recent injecting at baseline		
No	93	25/27
Yes	95	72/76
Frequency of injecting at baseline		
None	93	25/27
Less than daily	94	46/49
Daily or greater	96	26/27
Recent injecting during therapy		
No	94	17/18
Yes	96	80/83
Liver Fibrosis		
F0-1	97	57/59
F2-3	93	25/27
F4	78	7/9
Sofosbuvir and velpatasvir adherence		
≤90%	91	31/34
>90%	96	66/69



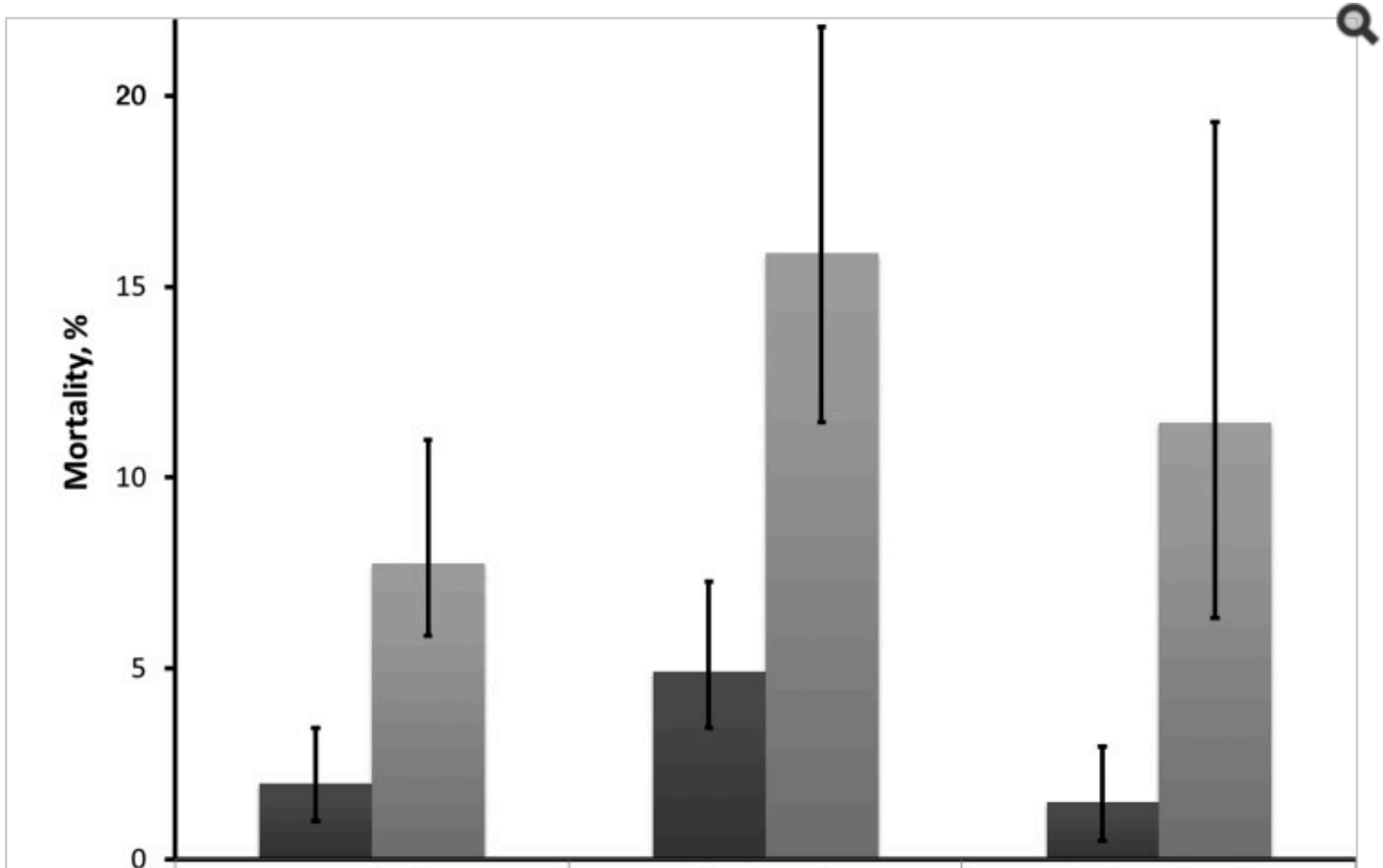
Yes, but what does SVR really mean?

Do we actually get better clinical outcomes?

Cure Actually Leads to Better Health!
695 HIV/HCV Cure vs. No Cure



Mortality: HCV Cure vs. No Cure



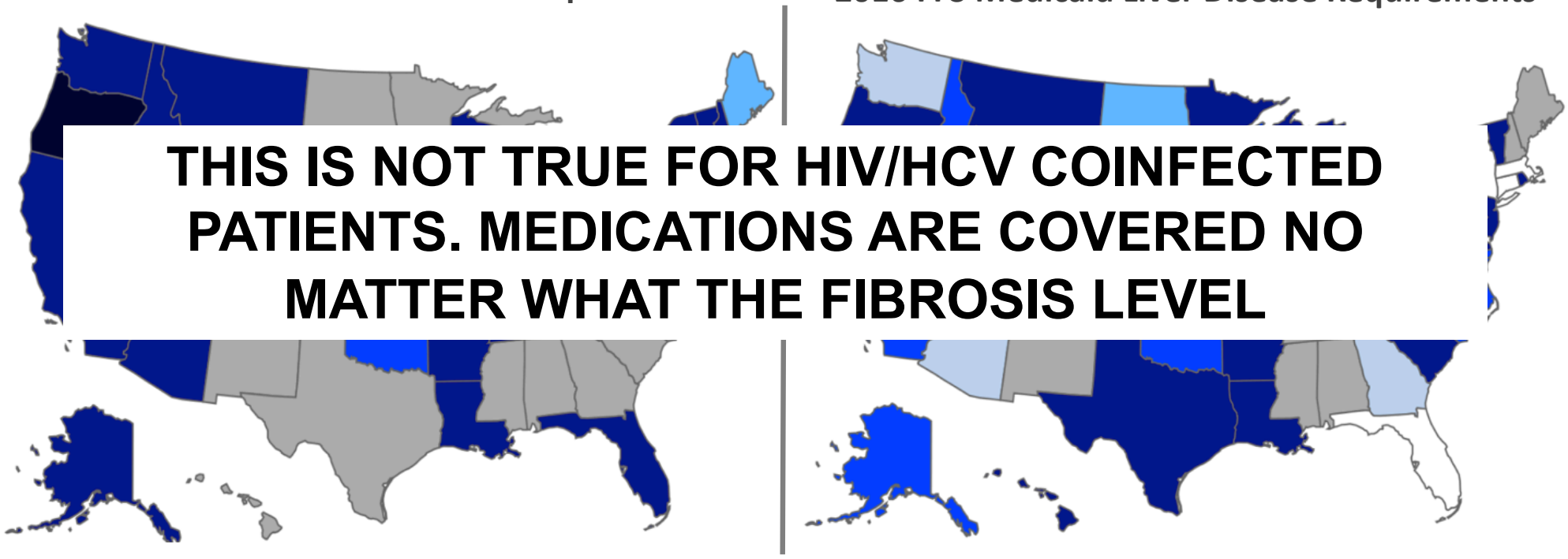
	General cohort	Cirrhotic cohort	Co-infected cohort
SVR	1.98 (1.00, 3.45)	4.90 (3.45, 7.28)	1.49 (0.50, 2.96)
non-SVR	7.75 (5.86, 10.98)	15.88 (11.44, 21.80)	11.44 (6.33, 19.31)

OK, but can you even get the meds?

Restrictions by Fibrosis Stage

2014 FFS Medicaid Liver Disease Requirements

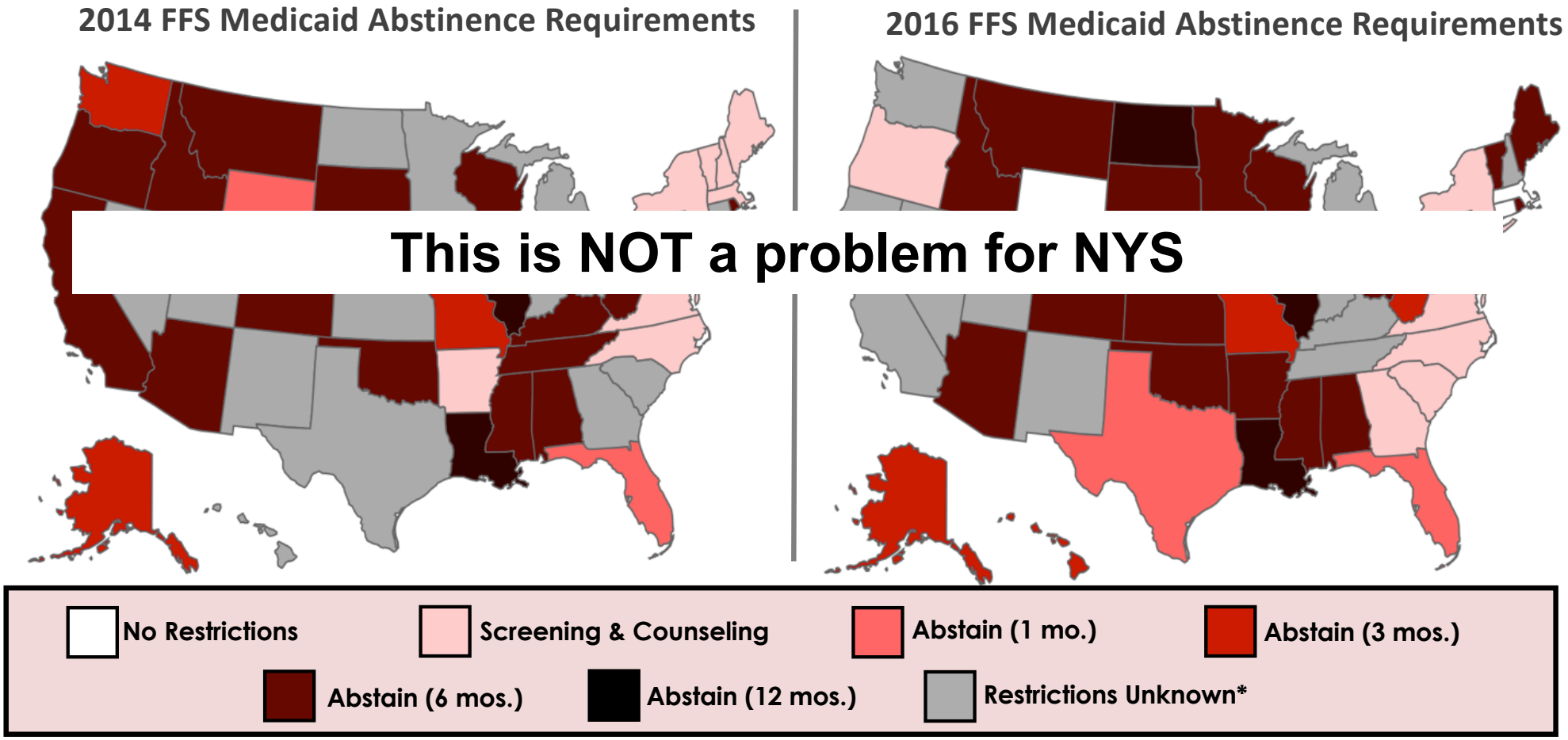
2016 FFS Medicaid Liver Disease Requirements



THIS IS NOT TRUE FOR HIV/HCV COINFECTED PATIENTS. MEDICATIONS ARE COVERED NO MATTER WHAT THE FIBROSIS LEVEL

75% of states still required ≥F2 for therapy

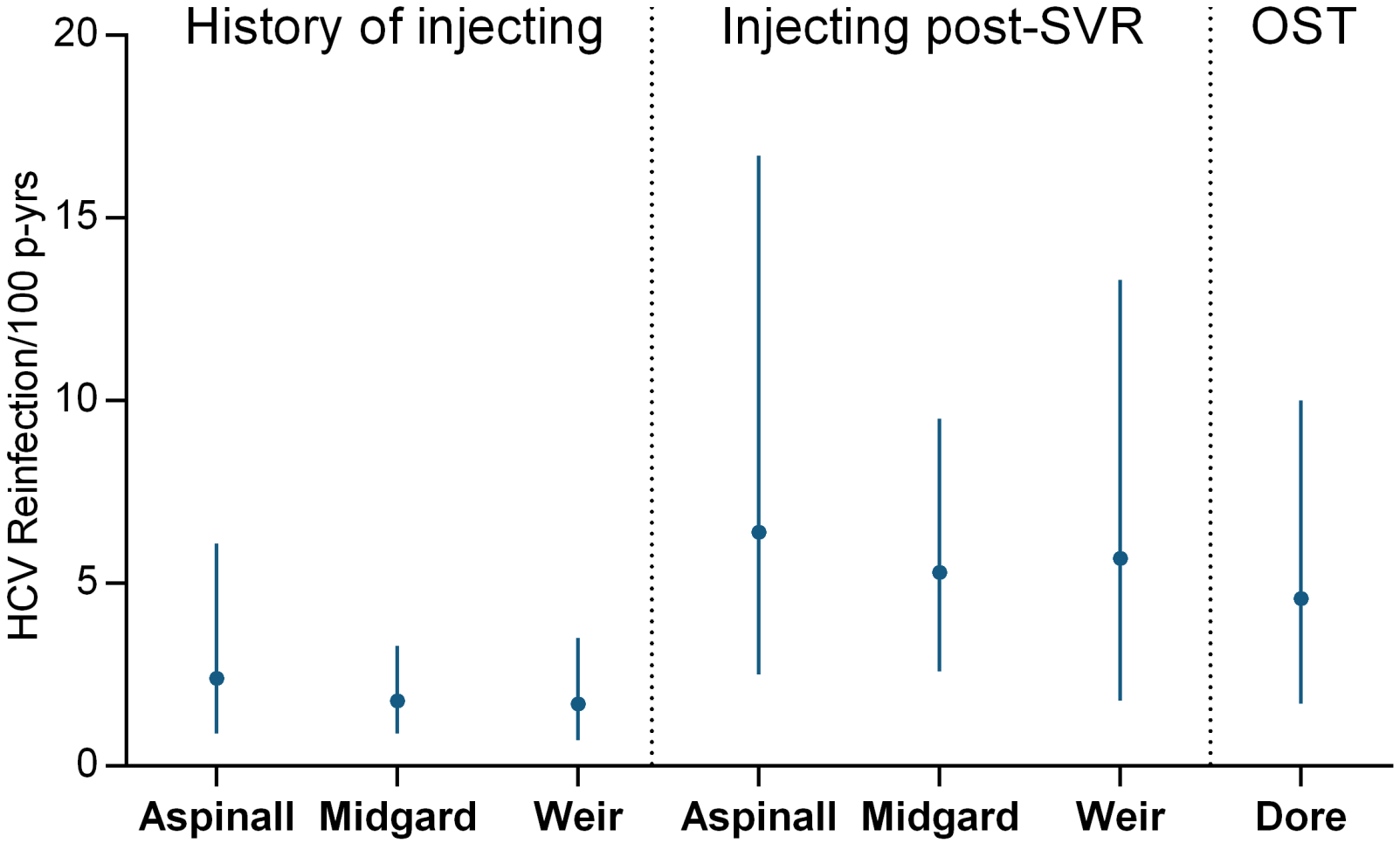
Restrictions by Drug Use



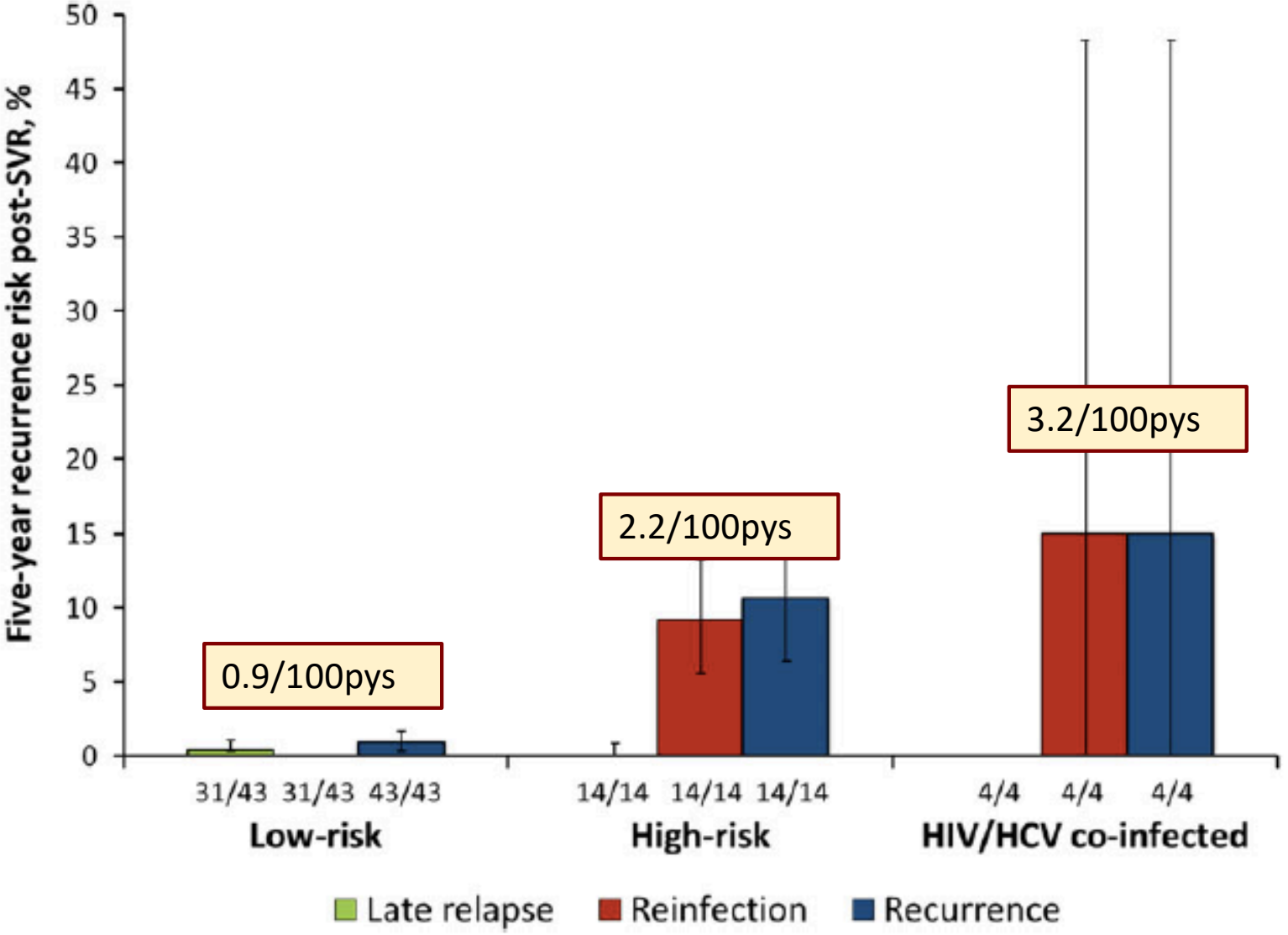
71% of states have restrictions related to drug use

Ok, but is this all for naught due to reinfection?

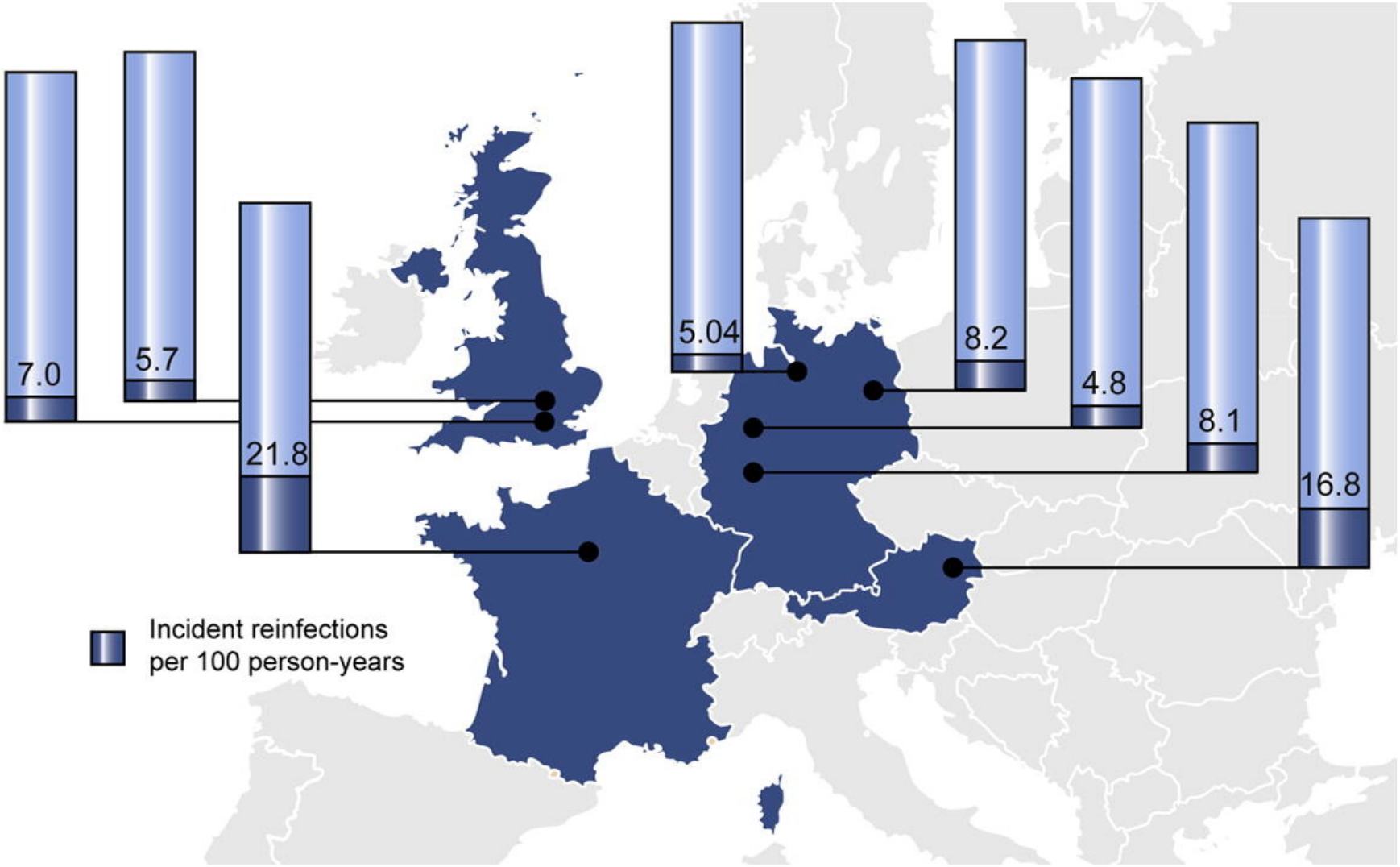
What about reinfection?



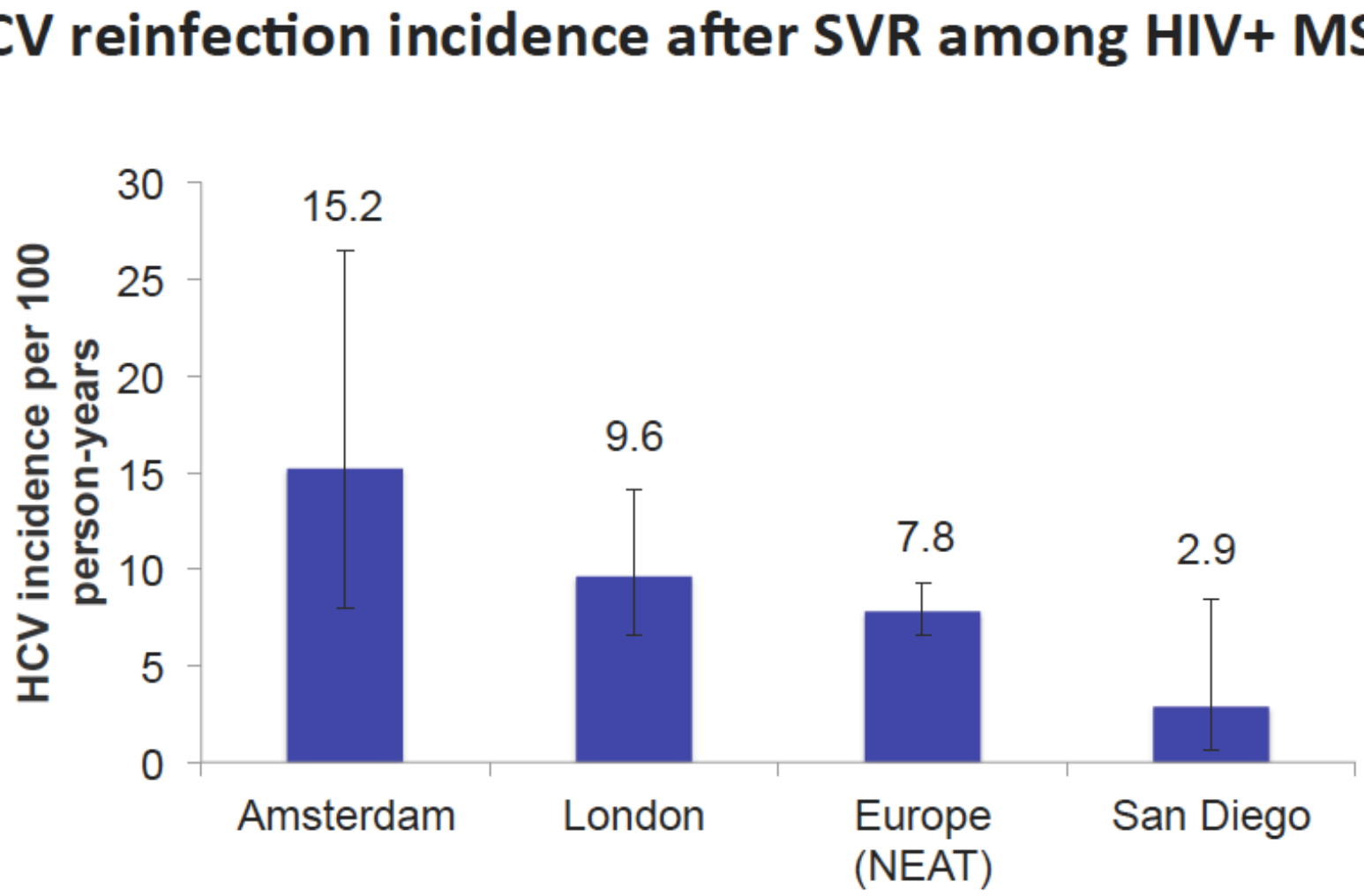
Meta-Analysis Reinfection Rates



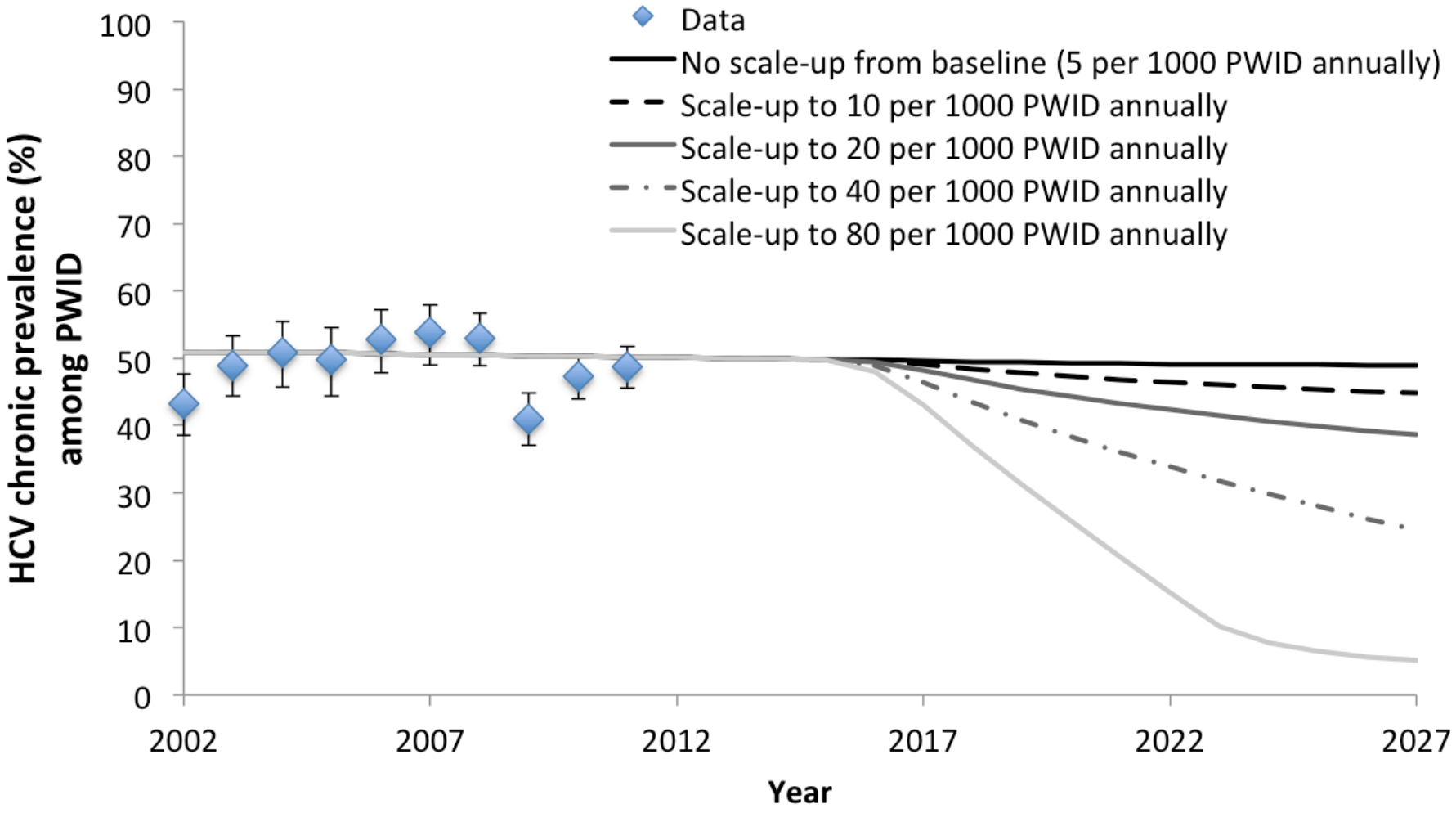
Reinfection among HIV+ MSM



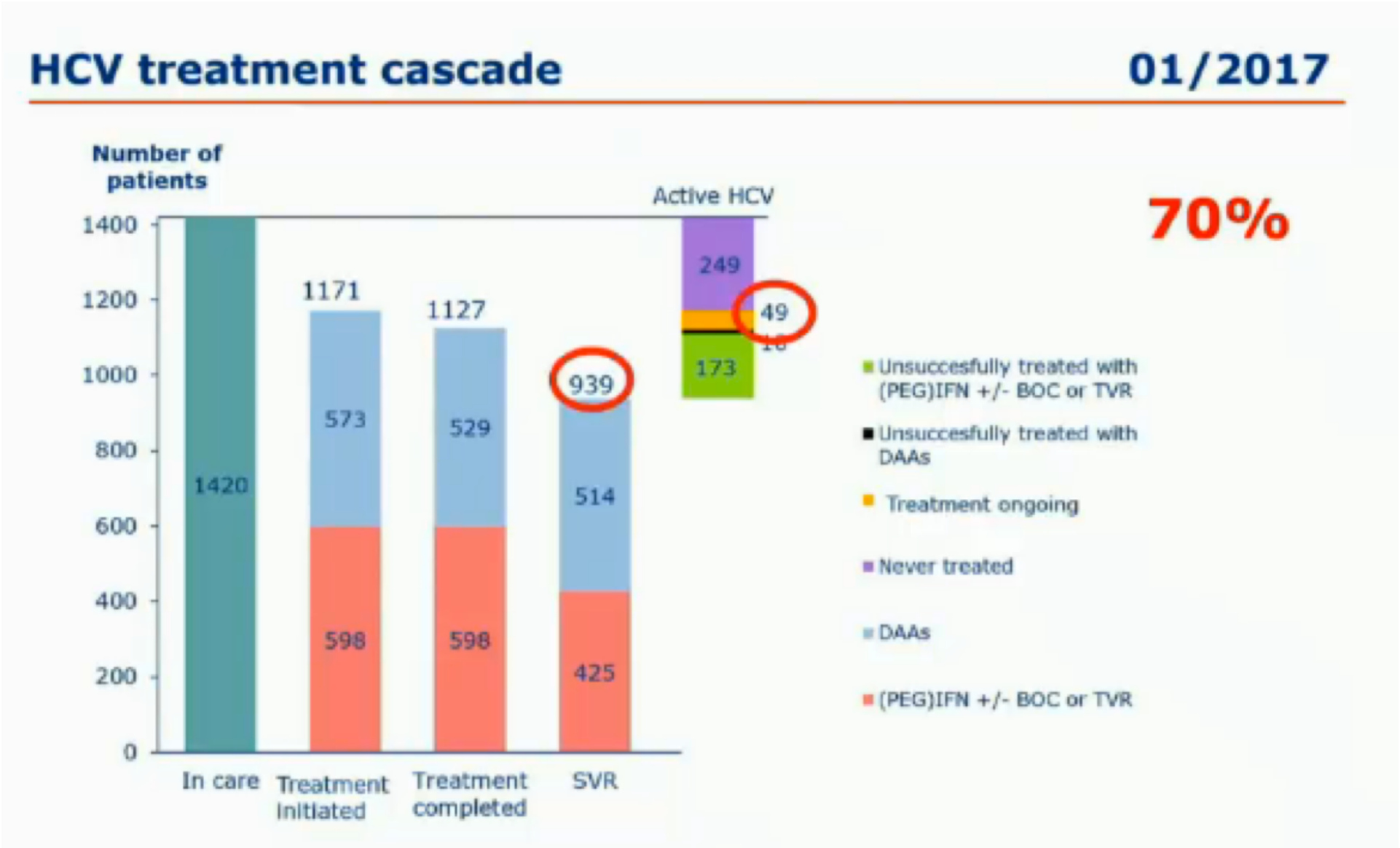
US Data on HIV+ MSM Reinfection



HCV Treatment as Prevention



Unrestricted access to DAA for HIV/HCV Co-infected in Netherlands



Acute HCV infection post universal access in Netherlands Reduced

Results:

2014

A-HCV **n = 93**

Genotype 1= 75 (81%)

Genotype 4= 18 (19%)

PYFU n = 8290

11.2/1000 PYFU
(95% CI 9-14)

1.1% per year

2016

A-HCV **n = 49**

Genotype 1= 34 (69%)

Genotype 4= 15 (31%)

PYFU n = 8961

5.5/1000 PYFU
(95% CI 4–7)

0,55% per year

Take Home Points

- Both MSM and PWID make up the HIV/HCV epidemic
- HIV/HCV leads to worsened liver outcomes
- Treating HIV/HCV leads to CURE!
- Drug-drug interactions are manageable
- Treatment reduces mortality and leads to prevention!

Questions


Thank You for Your Attendance!
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www.prn.org