One Size Does Not Fit All: HCV Care in Various Settings

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Session Learning Objectives

At the end of the session, you will be able to:

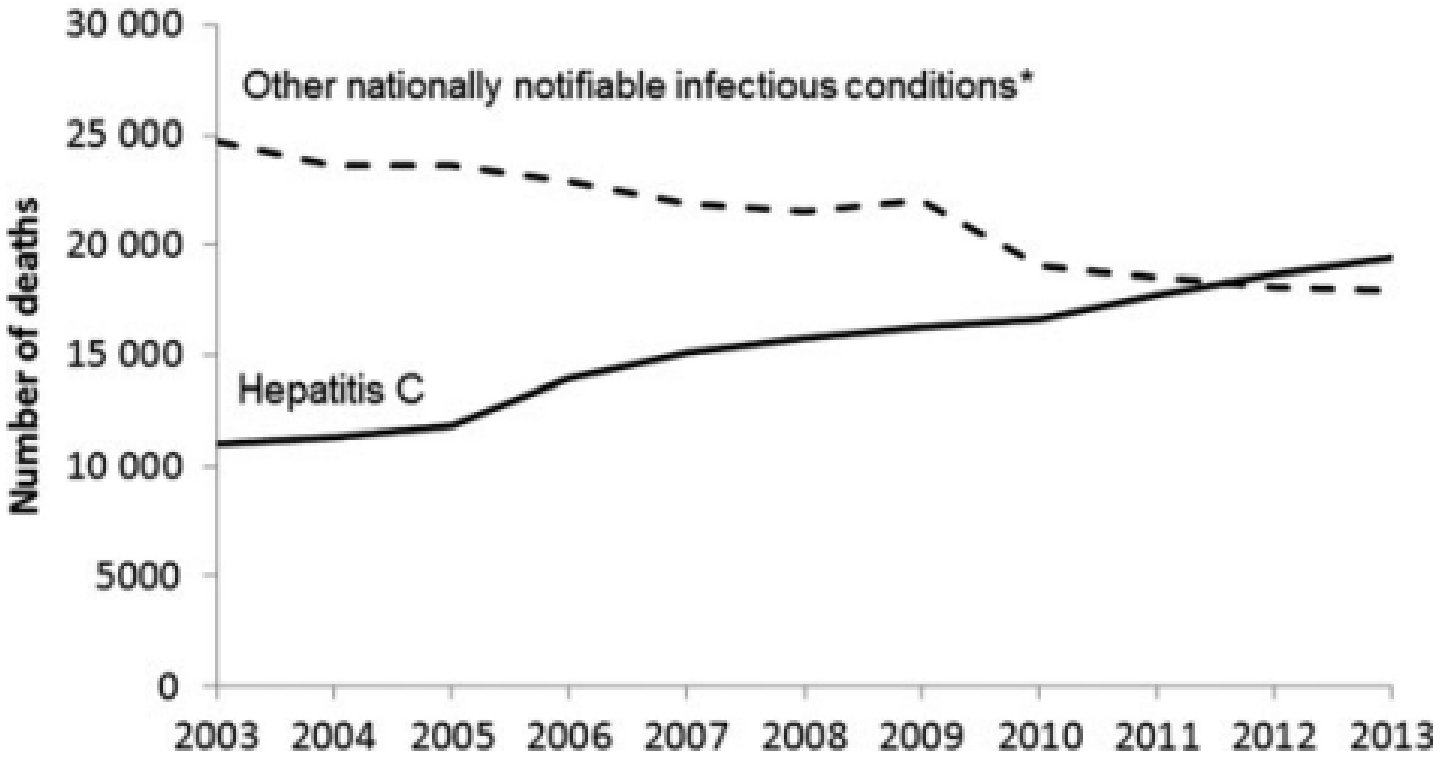
- Discuss challenges to HCV treatment for people who use drugs.
- Discuss the approach to HCV screening among people who use drugs.
- Discuss models to increase HCV treatment among people who use drugs.

Disclosure Information

Oluwaseun Falade-Nwulia MBBS, MPH

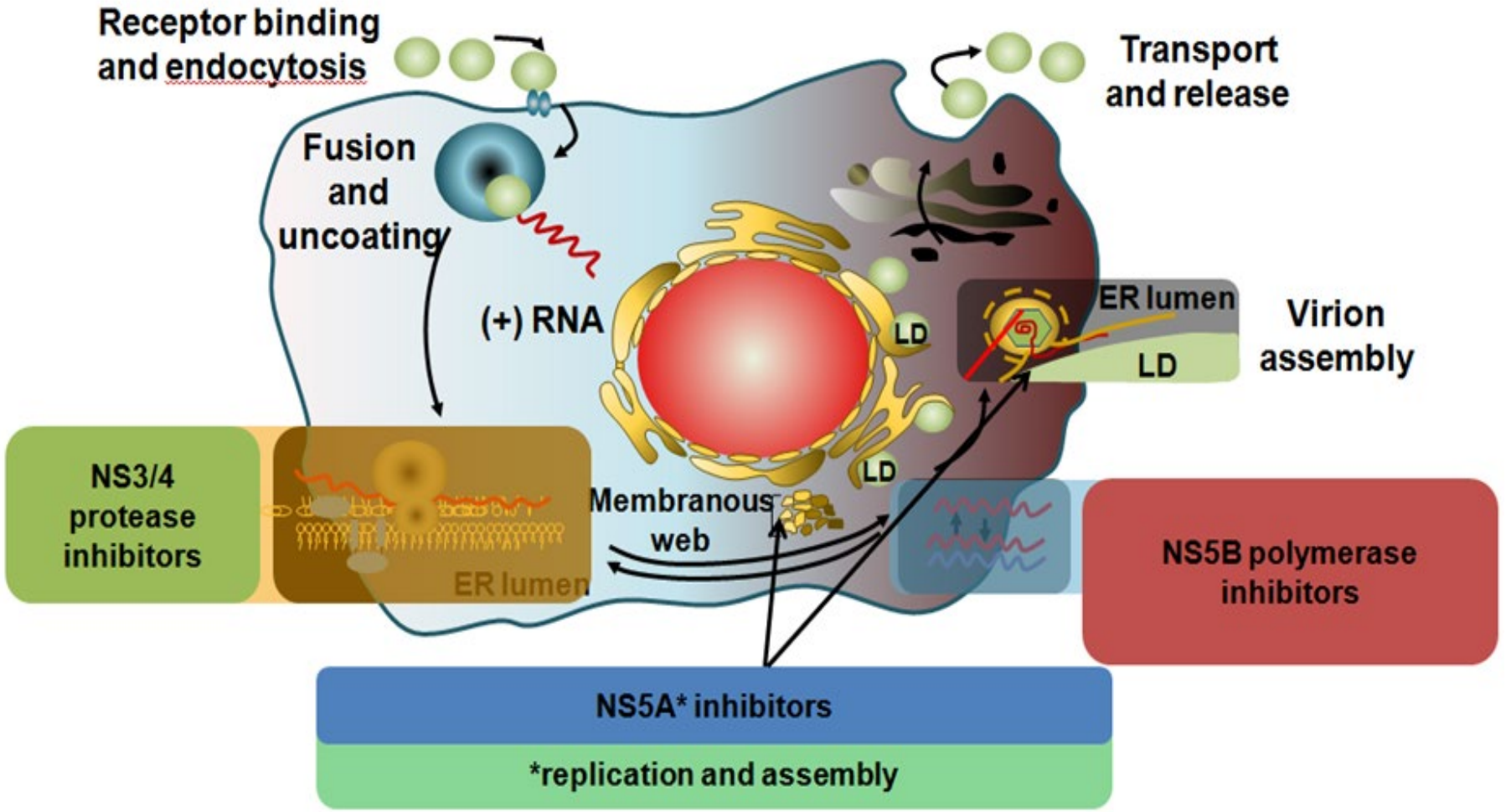
- Research funds paid to institution: Abbvie
- Medical advisory: Gilead

HCV is the Leading Infectious Disease Killer in the US



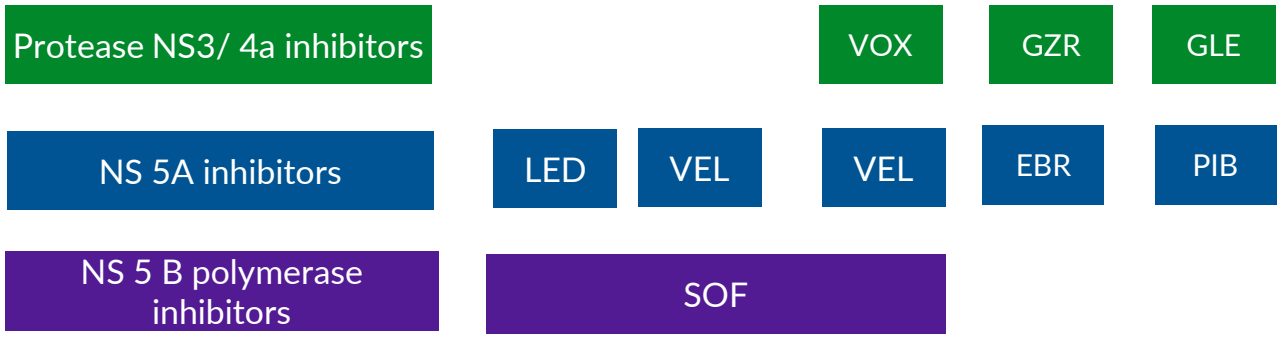
Ly et al CID 2016

HCV Life Cycle and DAA Targets



Adapted from Manns MP, et al. Nat Rev Drug Discov. 2007;6(12):991-1000.

Recommended combinations of oral DAA as applied to different HCV genotypes:



SVR 12 rates ≥ 95% across genotypes and populations

Combination Therapies
Preferred Regimens

Ledipasvir (LDV) + Sofosbuvir (SOF)
(FDC, GT1,4,5,6)

Pibrentasvir (PIB) + Glecaprevir (GLE)
(GT1, 2, 3, 4, 5, 6)

Velpatesvir (VEL) + Sofosbuvir (SOF)
(GT1, 2,3 ,4, 5, 6)

Velpatesvir (VEL) + Sofosbuvir (SOF) + Voxilaprevir
(GT1, 2,3 ,4, 5, 6)

Hcvguidelines.gov accessed 06/01/2022

WHO Global Health Sector HCV Strategy

Global Targets for 2030

Expand and enhance services. → *Decrease new infections.* → *Decrease deaths.* → **Reduce global suffering and costs.**

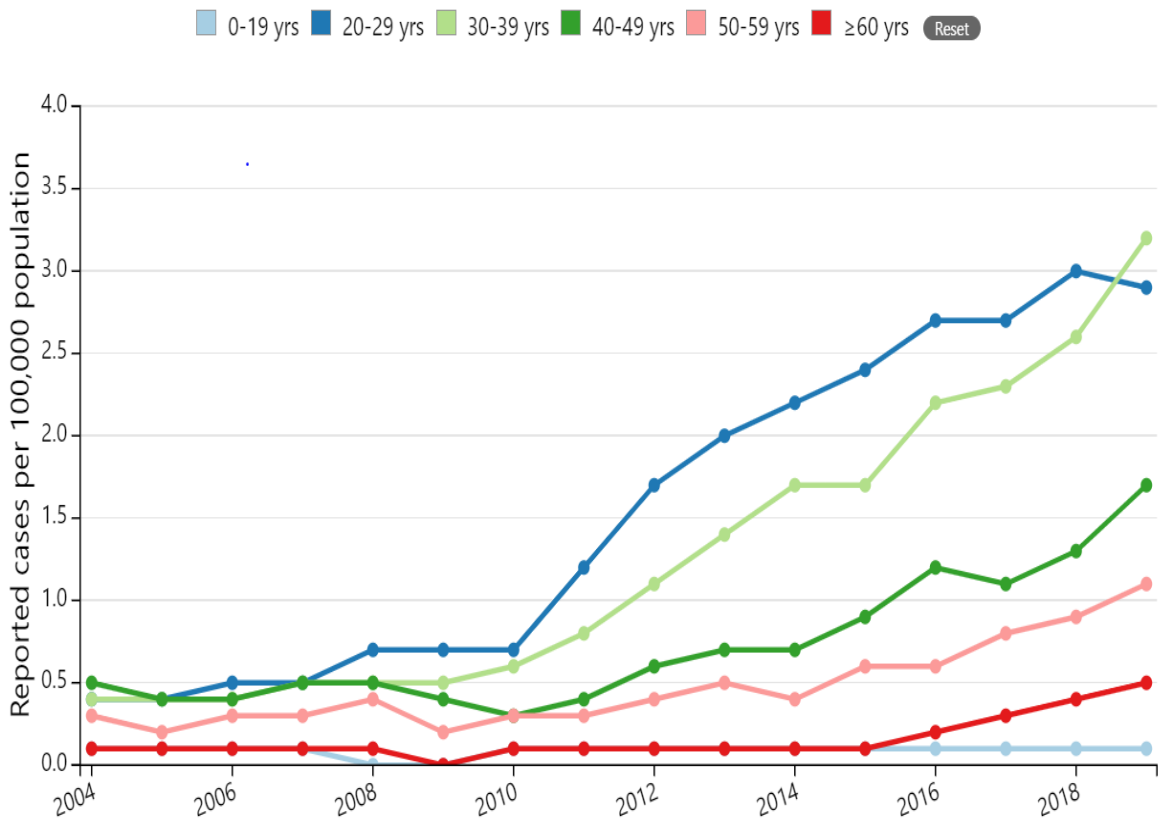
- **90%** diagnosed
- **80%** of eligible people treated
- **50%** of PWID covered by harm reduction services

- **90%** reduction in HCV incidence

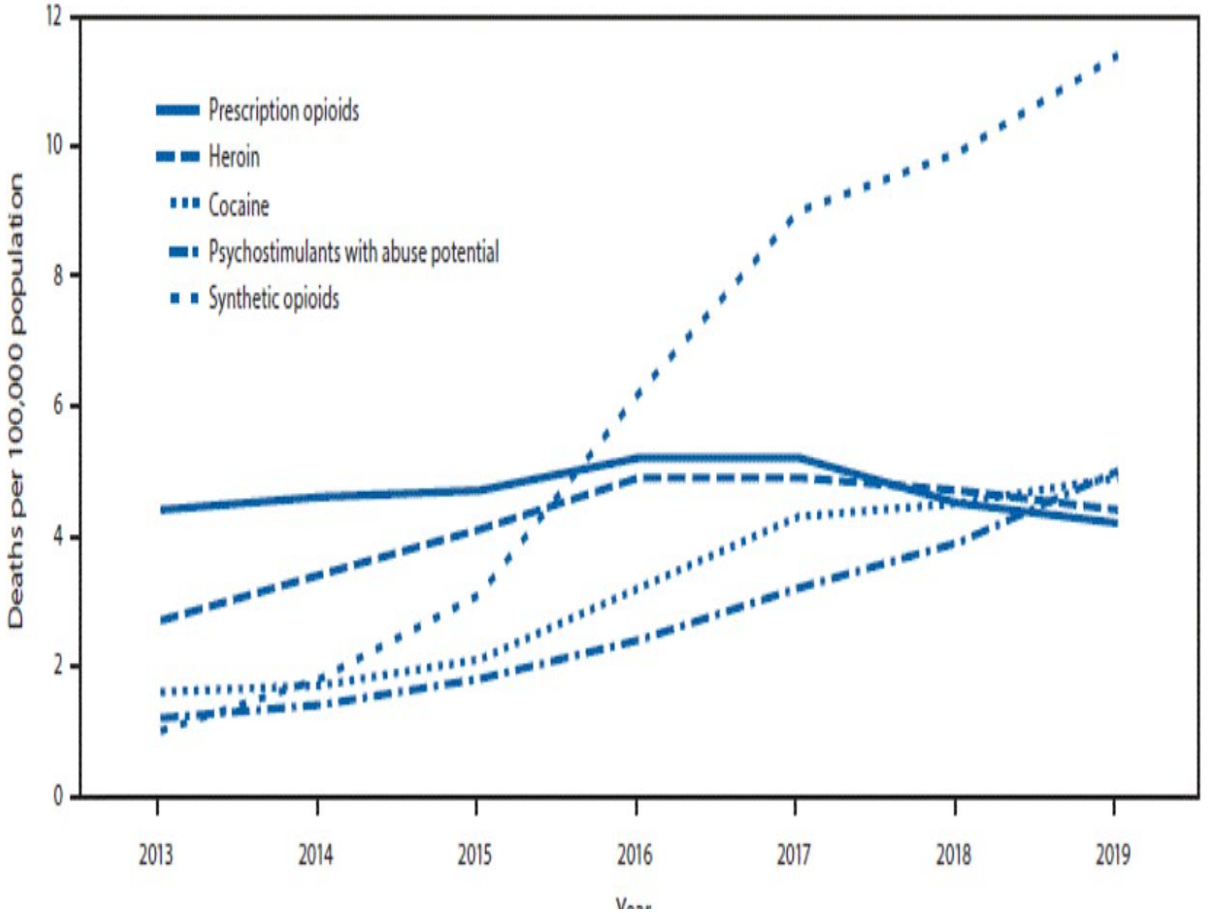
- **65%** reduction in HCV-related deaths (relative to 2015)

WHO. Draft global health sector strategy on viral hepatitis, 2016–2021. Available at: www.who.int/hepatitis/news-events/strategy2016-2021/Draft_global_health_sector_strategy_viral_hepatitis_13nov.pdf?ua=1 (accessed January 2016)

Rising HCV incidence in the US driven by the opioid epidemic:



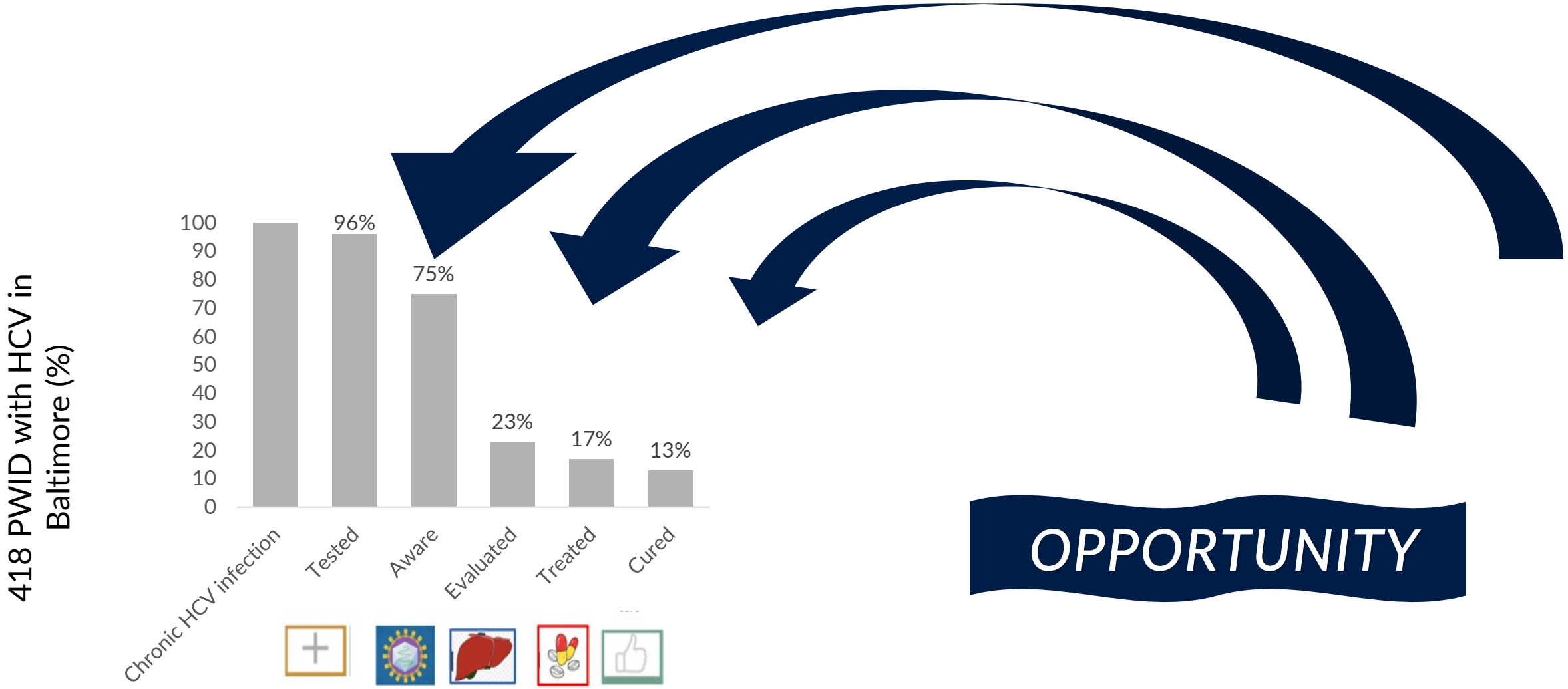
Incident HCV 2004-2018



Overdose deaths 2013-2019

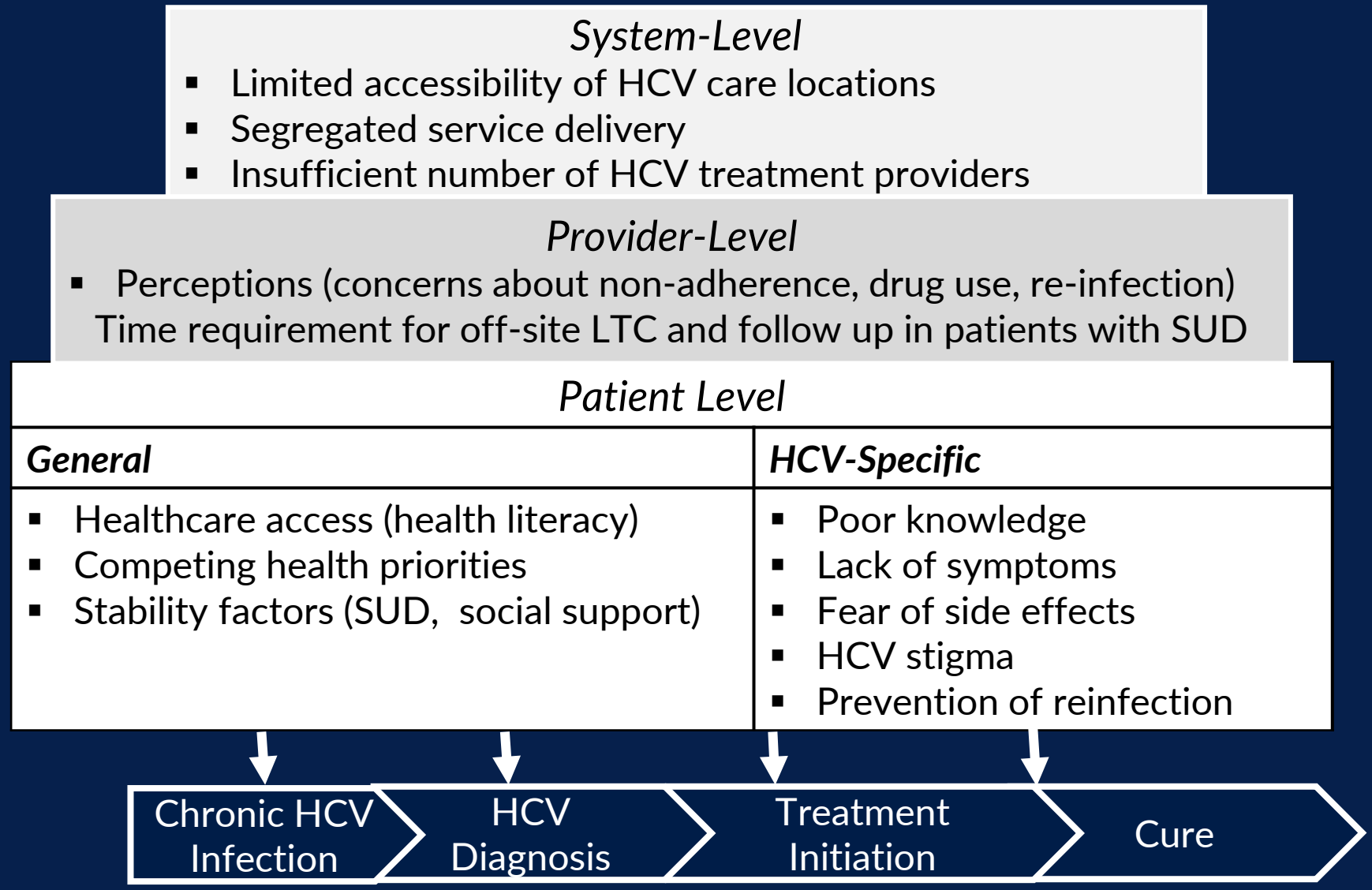
Figure 3.4 of 2019 Viral Hepatitis Surveillance report | CDC, Mattson et al MMWR 2021,

Hepatitis C Care Continuum Among PWID in Baltimore



Falade-Nwulia et al Liv Int 2020

Barriers To HCV Treatment For People Who Use Drugs



US Preventive Services Task Force: Recommendations For HCV Testing Updated March 2020

The USPSTF recommends screening **adults 18 to 79 years of age** for HCV infection.	**Grade B***

* Moderate certainty that HCV screening in adults aged 18-79 years has substantial net benefit

AASLD/IDSA HCV Screening Recommendations

Recommendations for One-Time HCV Testing	*Rating*
One-time, routine, opt-out testing recommended for all persons 18 years of age or older.	I, B
One-time testing recommended for all persons younger than 18 years of age with exposures, activities, or conditions/circumstances associated with increase HCV infection risk.	I, B
Prenatal testing as part of routine prenatal care recommended for each pregnancy.	I,B
Periodic repeat testing should be offered to all individuals with exposures, activities, or conditions/circumstances associated with increased HCV exposure risk.	IIa, C
Annual testing recommended for: all individuals who inject drugs; men with HIV infection who have unprotected sex with men; men who have sex with men and are taking HIV pre-exposure prophylaxis.	IIa, C

When antibody status is unknown use reflexive HCV antibody to RNA testing.

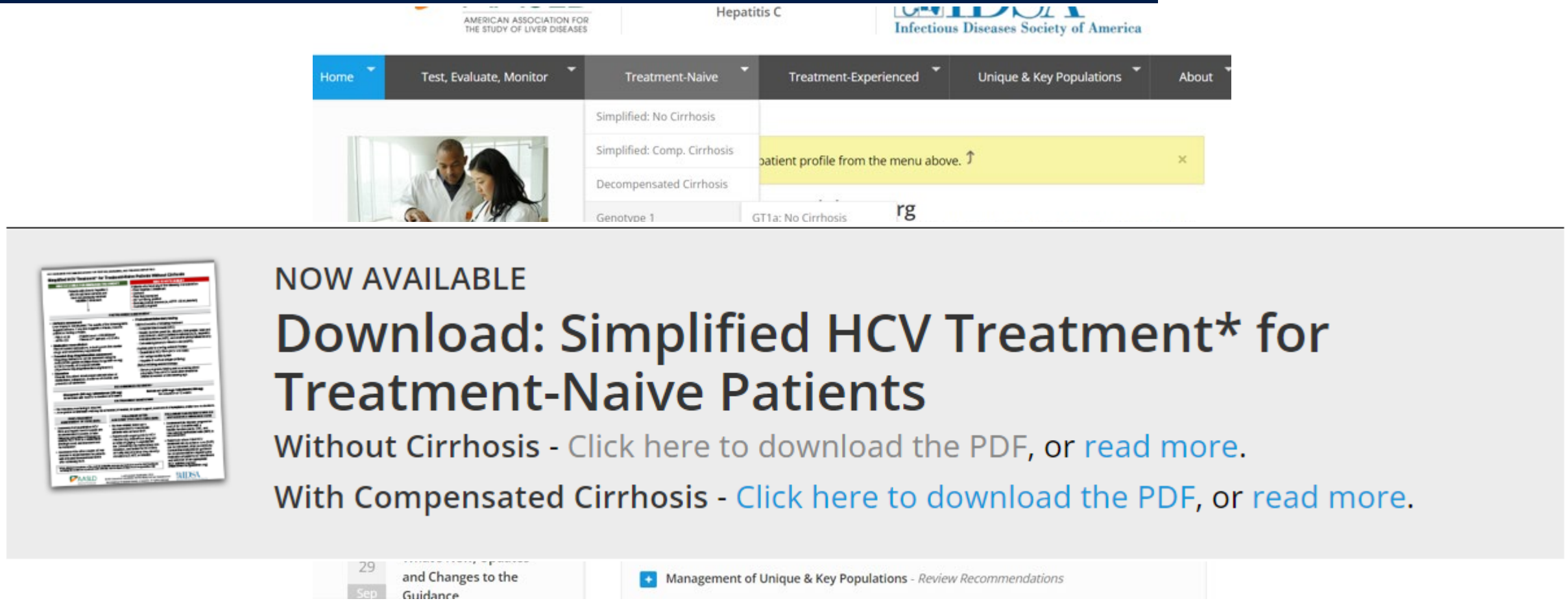
Hcvguidelines.org accessed March 25, 2022

HCV Should Be Treated as Soon as Possible

Recommendations for Medical Management and Monitoring of Acute HCV Infection	
Recommended	*Rating*
After the initial diagnosis of acute HCV with viremia (defined as quantifiable RNA), HCV treatment should be initiated without awaiting spontaneous resolution.	I, B

Hcvguidelines.org accessed March 25, 2022

Complex HCV Treatment Regimens Are No Longer a Barrier to HCV Treatment



hcvguidelines.gov accessed March 25, 2022

Simplified HCV Treatment Algorithm for Patients Without Cirrhosis

PRETREATMENT ASSESSMENT*

- **Calculate FIB-4 score.**
- **Cirrhosis assessment**: Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or any of the following findings from a previously performed test.
  - Transient elastography indicating cirrhosis (eg, FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (eg, FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (eg, liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm³, etc)
  - Prior liver biopsy showing cirrhosis
- **Medication reconciliation:** Record current medications, including over-the-counter drugs, and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.

- **Pretreatment laboratory testing**

Within 6 months of initiating treatment:

  - Complete blood count (CBC)
  - Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
  - Calculated glomerular filtration rate (eGFR)

Any time prior to starting antiviral therapy:

  - Quantitative HCV RNA (HCV viral load)
  - HIV antigen/antibody test
  - Hepatitis B surface antigen

Before initiating antiviral therapy:

  - Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg)
taken with food for a duration of 8 weeks

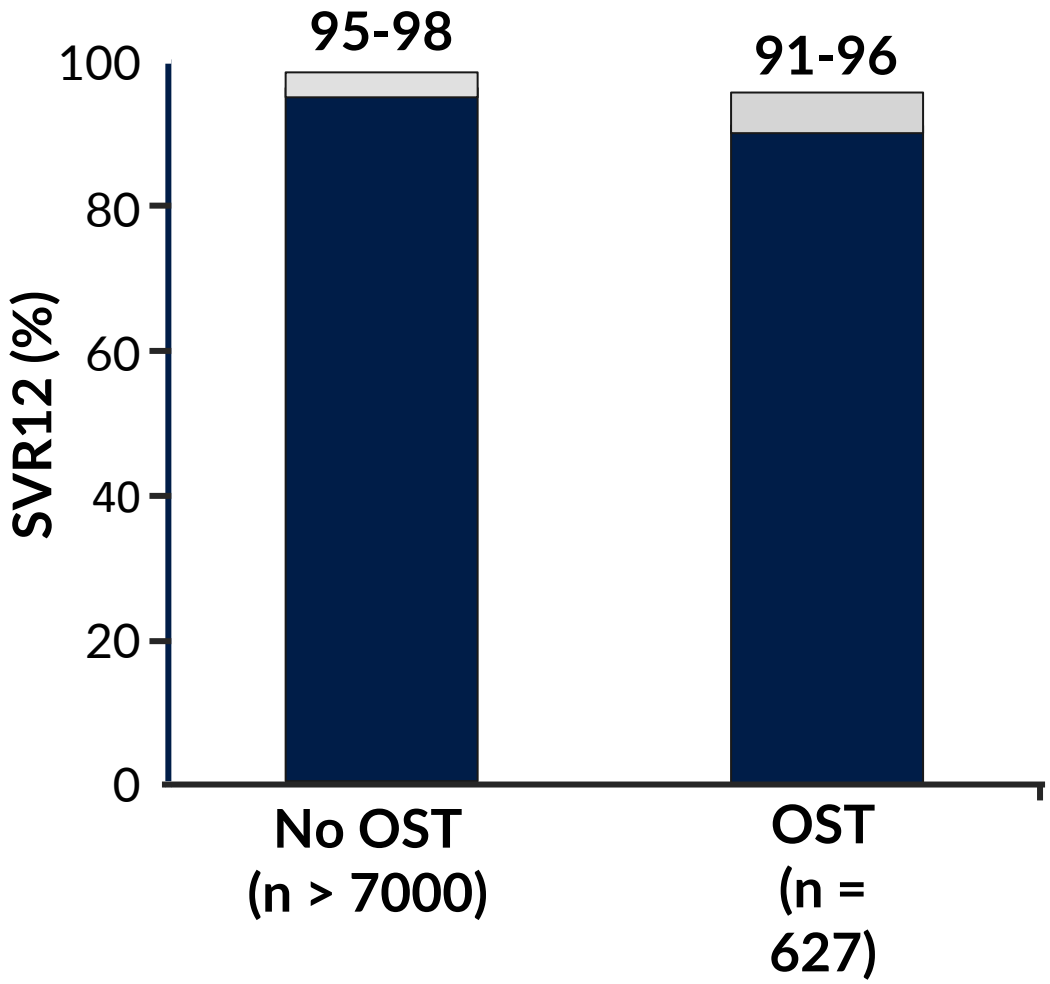
Sofosbuvir (400 mg) / velpatasvir (100 mg)
for a duration of 12 weeks

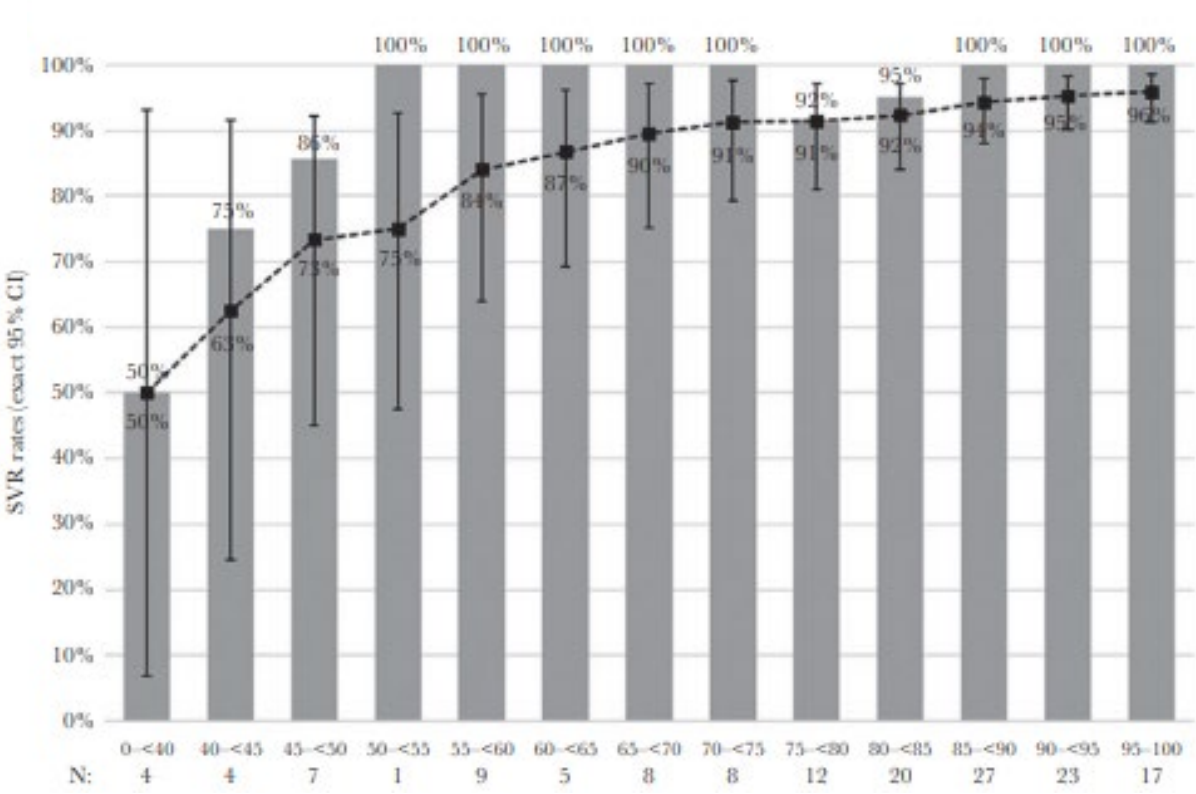
ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.

hcvguidelines.gov accessed March 25, 2022

HCV Treatment Outcomes Among PWID





HCV SVR by electronic blister pack adherence measurement rate

Zeuzem et al . Ann Intern Med. 2015, Feld et al NEJM. 2014, Grebely. EASL 2017, Grebely. CID, Grebely. CID. 2016, Puoti. AASLD 2014, Norton et al OFID 2020

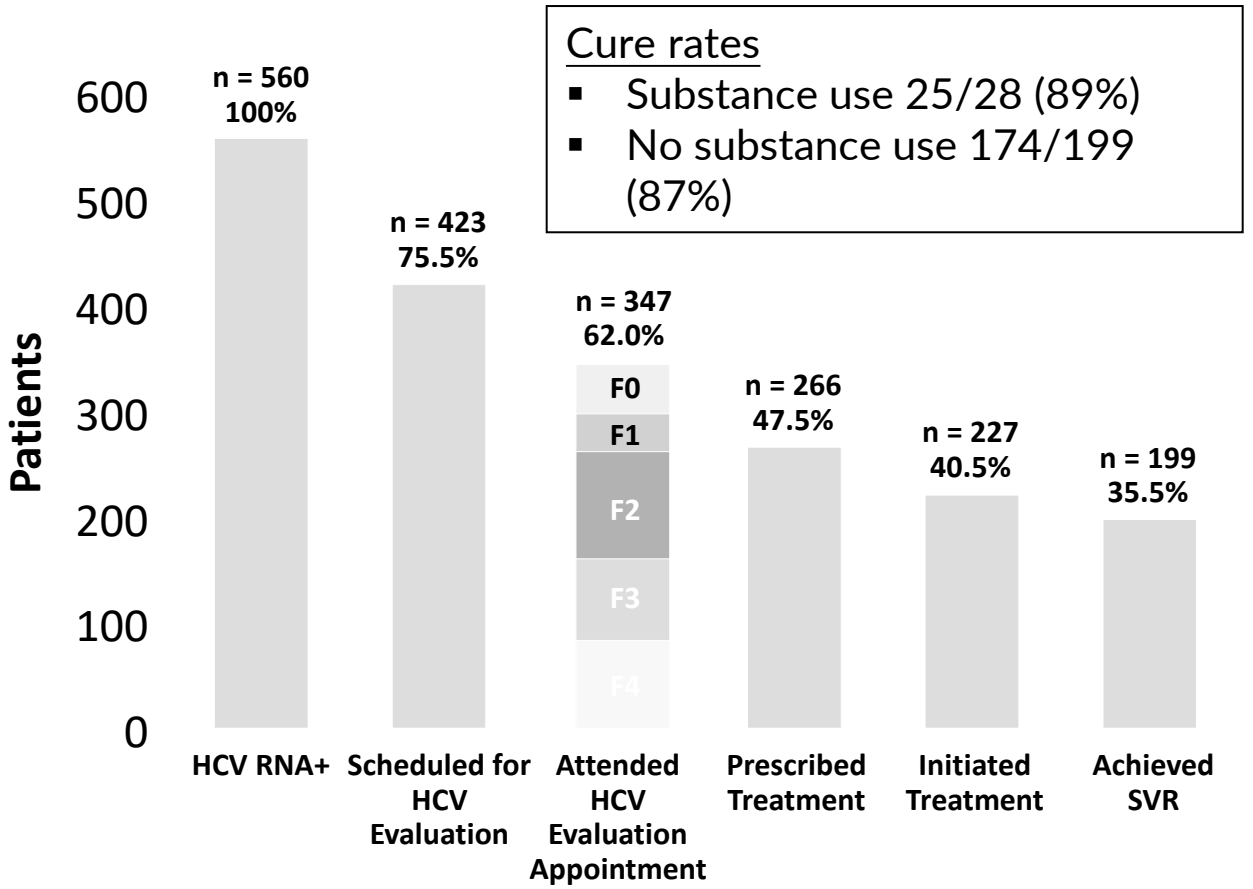
Local Health Department HCV Testing LTC and treatment

- Rapid HCV testing provided by a patient navigator
  - provided initial information about HCV testing and possible results
  - performed HCV rapid test
  - discussed availability of oral treatments which cure HCV infection
  - offered linkage to care services
  - confirmed contact information
  - insurance evaluation and navigation as needed
  - reminders to attend HCV evaluation and treatment appointments
  - community outreach
- City wide HCV linkage to care services

https://www.cdc.gov/nchhstp/docs/successstories/HepC-in-Maryland.pdf accessed May 2021

Hepatitis Testing and Treatment in BCHD: Baseline Characteristics and Outcomes

Characteristic	*n (%)*
Total	560 (100.0)
Race	
▪ Black/African American	451 (80.5)
▪ White/other	109 (19.5)
Age, years	
▪ 20–39/40–59	76 (13.6)/343 (61.3)
▪ ≥60	141 (25.2)
Male/Female	361 (64.5)/199 (35.5)
Insurance status	
▪ Medicaid/Medicare	367 (65.5)/70 (12.5)
▪ Private/Unknown	72 (12.9)/51 (9.1)
Illicit substance use in prior 12 months	109 (19.5)
HIV coinfection	45 (8.0)



- Fibrosis and other restrictions to HCV treatment coverage remain a barrier to HCV treatment

Rosecrans. A … Smith J, Irvin R.. Falade-Nwulia Am J Prev Med. 2020;59:420.

Partnering with Syringe Service Programs

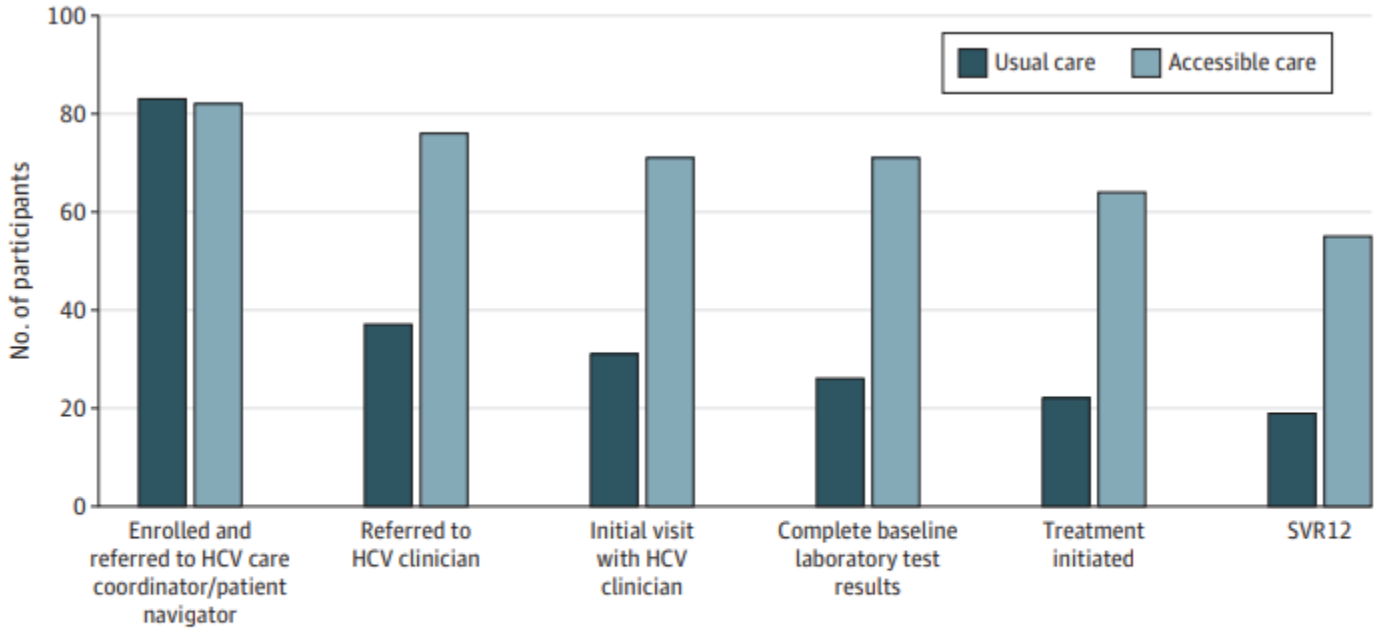
Mobile HCV Treatment Services

Telemedicine Based HCV Treatment Services

Telemedicine Based Integrated HCV And OUD Treatment

- Patient centered care grounded in best practices of addiction medicine
  - Integrated HCV and OUD treatment
  - Overdose prevention
  - Evaluation for mental and behavioral health concerns
- Motivational interviewing
- Peers a critical part of
- Multidisciplinary team

SSP Based + Patient Navigation Vs Facilitated Referral For HCV Care

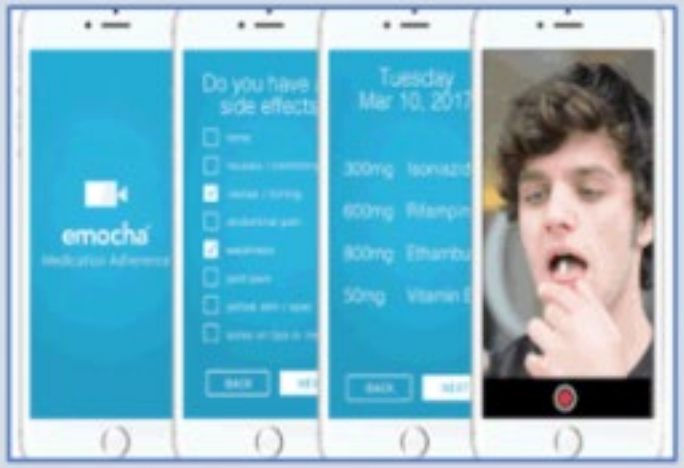


	Of those enrolled, referred and attended initial visit	Of those who attended initial visit with HCV clinician, completed laboratory testing and initiated treatment	SVR12, %
Usual care	37	71	86
Accessible care	87	90	86
P	<.001	.01	.96

Echardt et al JAMA Internal Medicine 2020

Real Hepatitis Outcomes

Modified Directly Observed Therapy (mDOT)



Patient Navigation (PN)

CHECK HEP NEW YORK CITY

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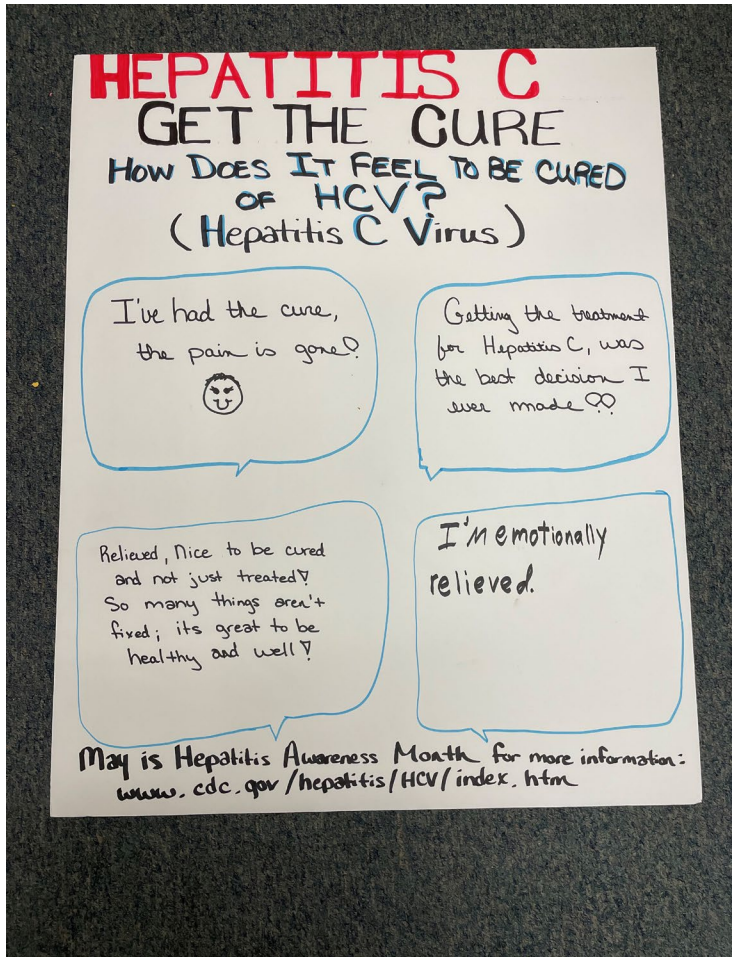
Shruti H. Mehta, PhD, MPH
Brianna L. Norton, DO, MPH
Kimberly A. Page, PhD, MPH
Lynn E. Taylor, MD, FAASLD
Judith I. Tsui, MD, MPH

Peer-Based Approaches to HCV Linkage

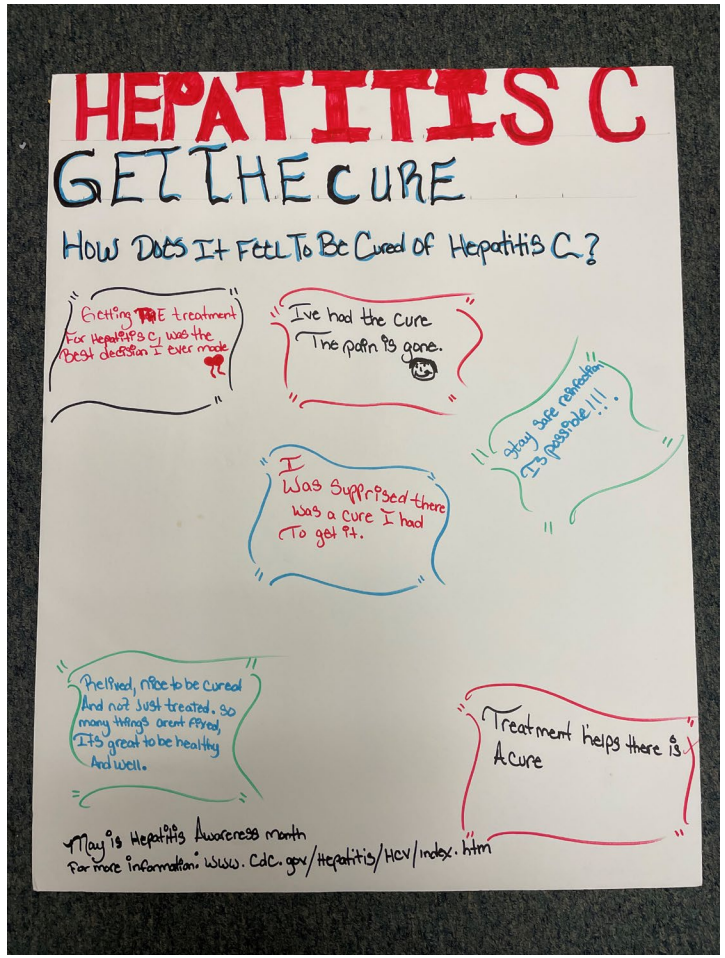
Quote from an HCV treated PWID:

"I took the meds, I got cured, and I started telling everybody about it. It just seemed like it uplifted me a little bit, and I was smiling about it. I know a lot of people I did drugs with knew they had it, but they didn't know about the cure. I would tell them about it. That felt good."

How it Felt to Get Treated and Cured of HCV



- "I've had the cure; the pain is gone!"
- "Getting the treatment for Hepatitis C was the best decision I ever made!"
- "Relieved. Nice to be cured and not just treated! So many things aren't fixed, it's great to be healthy and well."
- "I'm emotionally relieved."



Echardt et al JAMA Internal Medicine 2020

Final Takeaways

- HCV infection is associated with significant morbidity and mortality.
- People who use drugs have high HCV incidence.
- Integrated care models increase HCV treatment uptake.
- Peer facilitated strategies enhance linkage and retention in care.
- Public, private, academic, community and other partnerships will be critical to advancing HCV care equity for people who use drugs.

Thank You!

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