

# New Technologies for Addressing Treatment Barriers and Treatment Adherence

**Jeffrey J. Weiss, PhD, MS**

Associate Professor of Medicine  
Director Hepatitis C Clinical & Research Program  
Division of General Internal Medicine  
Icahn School of Medicine at Mount Sinai

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PREP-C



# Disclosures

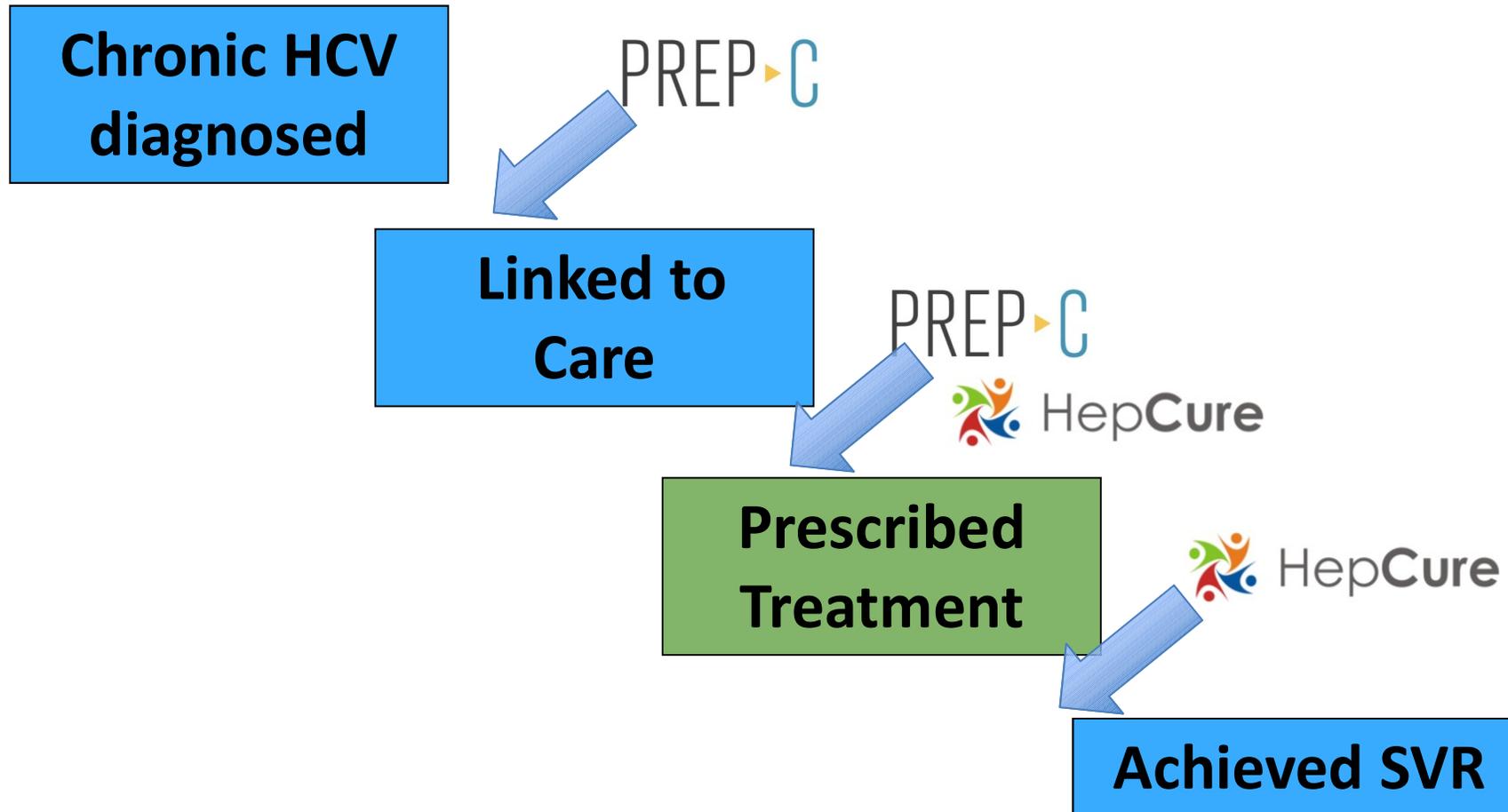
Consultant: AbbVie

Research Support: Gilead Sciences

# Web & Smartphone Open-access Tools to Aid in Achieving Full Benefits of DAAs

- Prepare patients to begin HCV treatment
- Actively engage patients in treatment process
- Increase communication between patients and providers during treatment
- Expand base of HCV treaters
- Track quality of HCV care provided

# HCV Cascade Intervention Opportunities



# Recommendations for the Management of Hepatitis C Virus Infection among People Who Inject Drugs

## RECOMMENDATION:

**Pre-therapeutic assessment should include an evaluation of housing, education, cultural issues, social functioning and support, finances, nutrition and drug and alcohol use. PWID should be linked into social services, and peer support if available.**

**Class I, Level B**

**Grebely et al. on behalf of INHSU. Intl J of  
Drug Policy 2015**

# Psychosocial Readiness Evaluation and Preparation for Hepatitis C treatment (PREP-C)

- Background
  - Developed in response to lack of guidelines and screening tools to meet clinicians' needs for assessing patient's psychosocial readiness to begin chronic HCV therapy
  - NYC DOHMH Hep C Task Force Working Group
- Description
  - Clinical interview (20 – 30 minutes)
  - Assessment of 9 areas of psychosocial functioning based on research findings and clinical experience
- Implementation
  - Piloted at Mount Sinai and revised for DAA treatment
  - Web based version now available [PrepC.org](http://PrepC.org)
  - Full and Abbreviated versions
  - Spanish version to be live October 2016

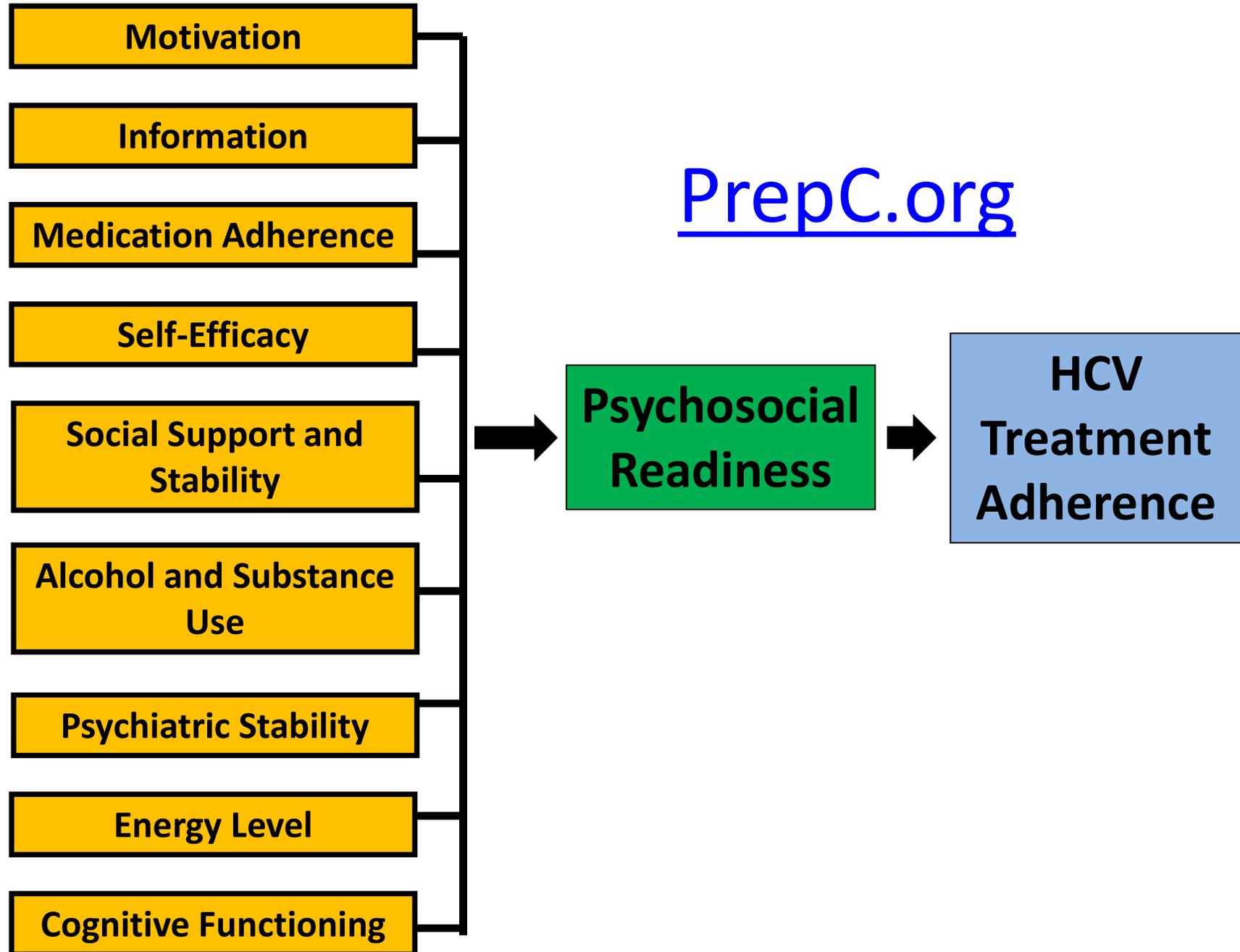
# Behavioral Medicine Framework



# Patient Readiness for HCV Treatment

PREP → C

**Developed to guide how best to prepare patients to succeed on treatment; not to decide who should go on treatment**



# Principles Guiding Development of PREP-C Assessment Tool

- Suitable to be administered by service providers from diverse disciplines
- Structured interview rather than self-report
- Not to be used to “screen people out” of treatment but to identify areas which can be improved
- Can be used with HCV mono-infected and HIV/HCV co-infected clients
- Provides opportunity for immediate intervention and provision of resources
- Leads to plan for (referral to) further evaluation and treatment
- Can be used in a diverse range of HCV treatment settings

# Goals of Using PREP-C

- Identify modifiable areas of psychosocial functioning which are predictive of HCV treatment adherence prior to HCV treatment initiation in order to be able to create a treatment plan to improve functioning in these areas prior to HCV treatment initiation
- Identify non-modifiable areas of psychosocial functioning which are predictive of HCV treatment adherence prior to HCV treatment initiation in order to be able to plan for and take these factors into account during treatment
- Level of support and resources available in treatment setting can be used to inform evaluation of readiness

## Healthcare Provider Portal

Enter Patient ID  **SEARCH** **ADD NEW PATIENT**

Sort by: Patient ID ▲ Date Created ▼ Date Last Edited ▼

**124** » PATIENT INFO » ABBREVIATED 09/08/15 3:22 PM 09/08/15 3:46 PM

1	2	3	4	5	6	7	8	9	SCORE	NEW EVAL
M	I	MA	SE	SS	SU	PS	EL	CF		

**123** » PATIENT INFO » ABBREVIATED 09/02/15 9:08 AM 09/20/15 3:30 PM

1	2	3	4	5	6	7	8	9	SCORE	NEW EVAL
M	I	MA	SE	SS	SU	PS	EL	CF		

Under evaluation to begin HCV treatment

**122** » PATIENT INFO » ABBREVIATED 08/19/15 10:18 AM 08/22/15 5:07 PM

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M	I	MA	SE	SS	SU	PS	EL	CF		

**121** » PATIENT INFO » ABBREVIATED 08/18/15 4:16 PM 08/22/15 4:37 PM

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**120** » PATIENT INFO » ABBREVIATED 07/28/15 3:08 PM 08/18/15 12:57 PM

### Training

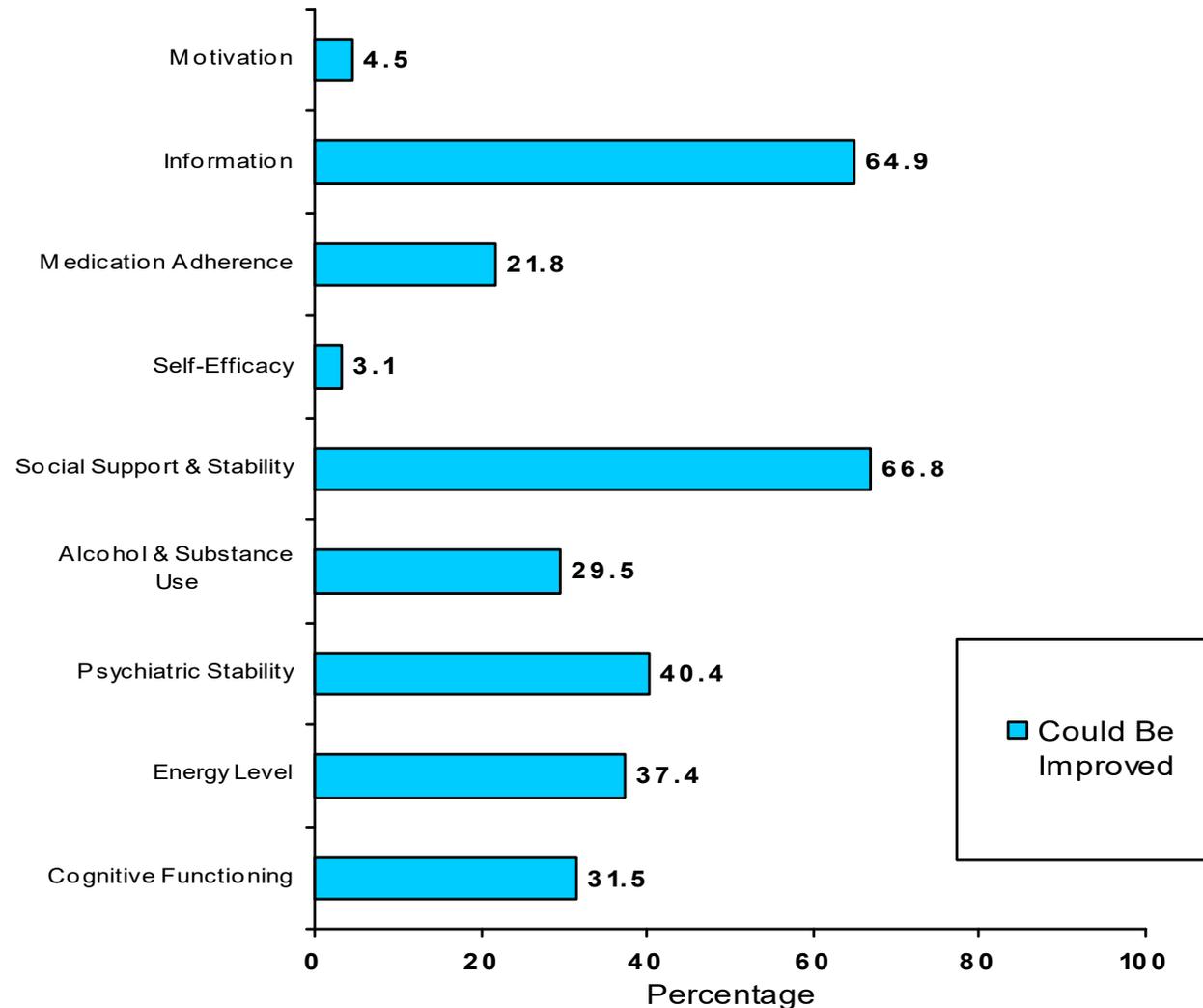
- Mock Patient Interview Documentation for Medical Record - 2012
- Directions for Using PREP-C
- Video of Mock Patient PREP-C Interview - Psychologist - 2012
- Video of Mock Patient PREP-C Interview - Nurse Practitioner - 2012
- Training Overview Slide Presentation
- Video of Mock Patient Prep-C Interview – Full Version – Nurse – 2015
- Video of Mock Patient Prep-C Interview – Abbreviated Version – Psychologist – 2015

## PREP-C Patient Characteristics (n=349)

### March 2015-June 2016

<b>Age in yrs mean (sd)</b>	57.9 (10.2)
<b>Race/Ethnicity (%)</b>	
Black	38.1
Hispanic	35.5
White	20.6
Other	5.7
<b>Gender - males (%)</b>	66.2
<b>HIV-positive (%)</b>	10.0
<b>Medicaid or Medicare insurance (%)</b>	100.0
<b>Ever injected drugs (%)</b>	64.8
<b>Injected drugs in last year (%)</b>	11.2
<b>On OST (%)</b>	35.2
<b>Heroin use in last year (%)</b>	14.0
<b>Cocaine/Crack use in last year (%)</b>	6.0
<b>Non-prescribed benzo use in last year (%)</b>	5.4

# Psychosocial Domains to Target for Improvement - % Requiring Intervention per Domain



# Intersection of Psychiatric and Substance Use Disorders (N = 349)

	Psychiatric Status Could be Improved	Psychiatric Status Satisfactory
Substance Use Could be Improved	61/349 (17%)	42/349 (12%)
Substance Use Satisfactory	80/349 (23%)	166/349 (48%)

# Cost-effectiveness

- The cost of the PrepC assessment and intervention is less than one



**But not yet a reimbursable service**

# Intervention to Improve Hepatitis C (HCV) Treatment Uptake and Adherence in HIV/HCV Co-infection (NIMH R34-MH099930)

## Study Aims:

1. To formally adapt existing behavioral medicine interventions based on PREP-C assessment to target individual **patient-level barriers** to HCV treatment initiation in HIV/HCV co-infected patients who are medically eligible for HCV treatment
2. To conduct a pilot randomized clinical trial on HIV/HCV co-infected patients comparing the nurse-administered PREP-C intervention with attention control in order to evaluate patient acceptance, satisfaction, enrollment, retention as well as preliminary efficacy (initiation of HCV treatment within 6 mos. of randomization and persistence and adherence to the first 12 weeks of treatment in those who did initiate treatment)

**Table 1: PREP-C Intervention Session Schedule**

<b>Week</b>	<b>Training Module</b>
1	(1) Administration of web-based PREP-C Interview
2	(2) HCV Psycho-Education
3	(3) Motivation and Behavioral Skills I
4	(4) Motivation and Behavioral Skills II

**Table 2: Attention Control Session Schedule**

<b>Week</b>	<b>Training Module</b>
1	(1) Administration of web based SCID-II Interview
2	(2) HIV and ARV Therapy
3	(3) Adherence, Resistance and ARV Therapy
4	(4) Psychiatric and Medical Comorbid Conditions

**HepCure Toolkit:  
Provider Dashboard, Patient App, Tele-Education**



*HepCure.org*



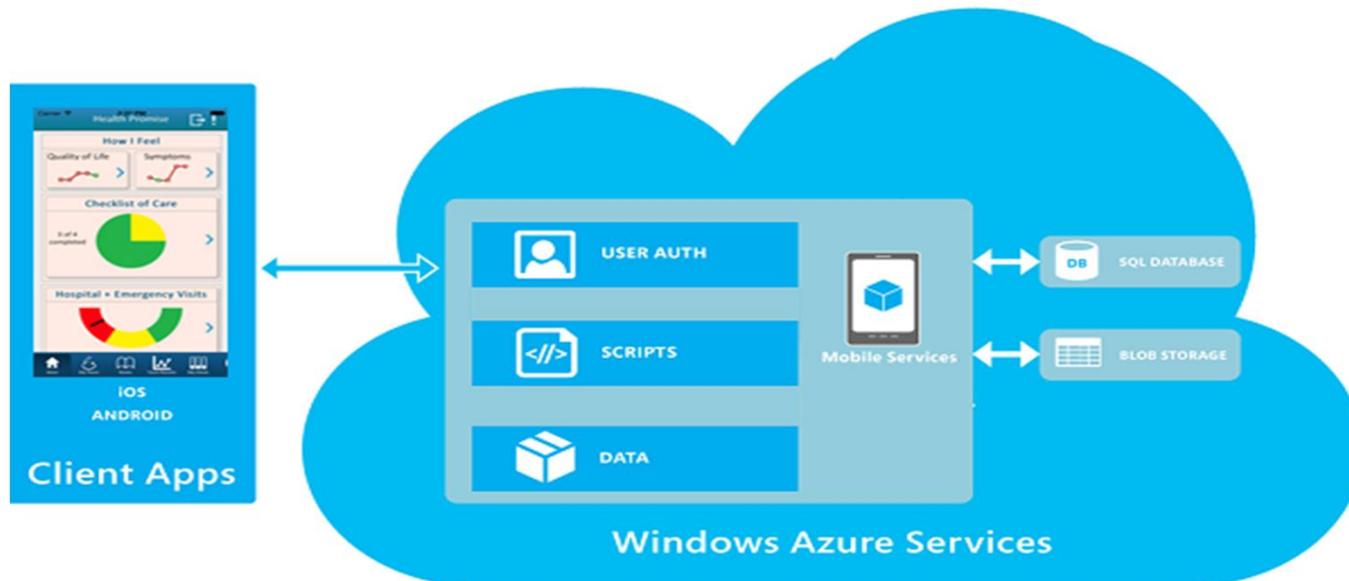
## Toolkit Goals

- **Engage patients**
  - Patients are primary stakeholders in their health
  - Places patient at center to improve adherence and quality of care through enhanced communication with provider
- **Expand the workforce**
  - Train primary care and other subspecialty providers evaluate and treat patients with HCV
- **Enable improved outcomes**
  - link health-care providers from community practices with specialists experienced in treating HCV
  - provide weekly tele-education and case conferencing
  - create archived training modules
  - real time quality improvement dashboard



## Security

- Windows Azure Services Cloud platform
  - Secure SSL encryption, HIPAA Adherent platform
  - Data is not stored in devices to prevent loss if stolen
- Review and sign agreement with Mount Sinai
- Terms of Use and Privacy Policy available



# Features of the HepCure Dashboard for Providers

- Organize and track your panel of HCV patients
- Patients can be shared with other providers for view or edit
- Treatment decision support algorithms to help determine the best options based in AASLD/IDSA treatment guidances
- Population health management by tracking HCV quality indicators
- Link to patients who are using the HepCure mobile app to better track symptoms and adherence
- Release labs to patients on the HepCure mobile app
- Track treatment progress
- Tele-education via weekly case-based webinars
- Submit cases for consultation with liver experts
- Provider resources

Remember Me

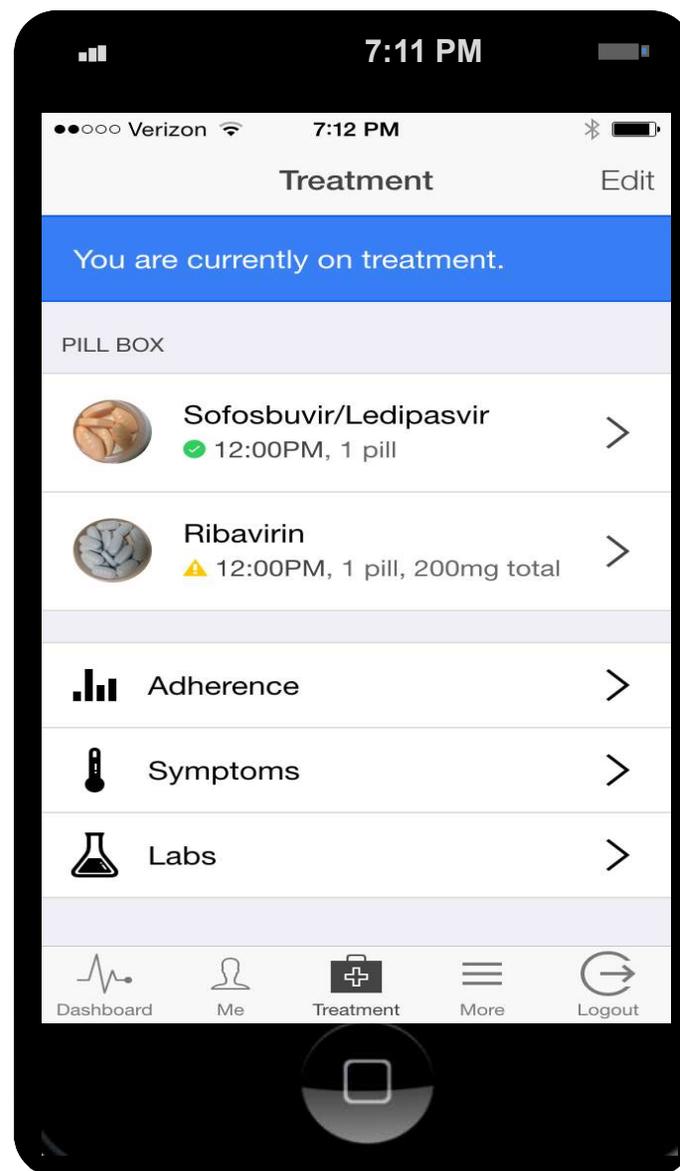
 Login

[← Forgot password](#) [Register →](#)



# HepCure Patient Mobile App

- Find out what treatment options are available
- Self-assess treatment readiness
- Enter appointments in smart device native calendar
- Set medication reminders
- Track Adherence
- Track Symptoms
- Enter Labs
- Educational Resources



# AdhereTech

**Patented Smart Pill Bottles  
to Track & Improve Adherence**



# RCT to Evaluate HepCure

- Patients on once daily STR for 12 weeks
- ❖ *Arm 1: Standard of care (passive monitoring of adherence with AdhereTech bottle) [n=33]*
- ❖ *Arm 2: HepCure dashboard + HepCure patient app (passive monitoring of adherence with AdhereTech bottle) [n=33]*
- ❖ *Arm 3: HepCure dashboard + HepCure patient app + AdhereTech reminders enabled [n=33]*
- Primary Outcome: Medication Adherence
- Secondary Outcomes: Sustained Virological Response, Patient Activation
- Qualitative data from patients and providers on use of HepCure patient app and provider dashboard

# Considerations for HepCure Use

- Smart phone availability to patients
- Literacy of patient population
- Number of languages for providers/patients
- Geographic spread of providers
- Reliable internet connectivity for providers
- Integration into existing systems/EMRs
- Monitoring & Evaluation requirements

# Concluding thoughts

- Multiple potential barriers to patient adherence in the real world including substance use
- Multiple potential barriers to providers treating patients with substance use for HCV
- Web-based tools can be part of the solution and help to optimize patient outcomes
- Essential to adapt web-based tools for the local context and patient population

# Acknowledgments

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**Thank you to our patients & research subjects**



# Learn More at [HepCure.org](https://HepCure.org)



## Primary Care Providers and Hepatologists come together to cure Hep C

An innovative project of Mount Sinai Medical Center in New York City, HepCure is improving provider knowledge & patient engagement for chronic disease management in persons infected with the Hepatitis C Virus (HCV). The project is designed to address barriers for the effective care and treatment of HCV by providing web-based and smartphone enabled resources, navigation, consultation, and support for both patients and providers. The HepCure project draws upon the experience base that has been developed at the Mount Sinai Liver Diseases Outpatient Hepatology