

Enhancing Hepatitis C Care for People Experiencing Homelessness: A Patient-Centered Primary Care Approach

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Boston Health Care for the Homeless Program

5/29/14



BOSTON HEALTH CARE *for*
the HOMELESS PROGRAM

THE KRAFT CENTER

for Community Health

Empowering a new generation of community health leaders

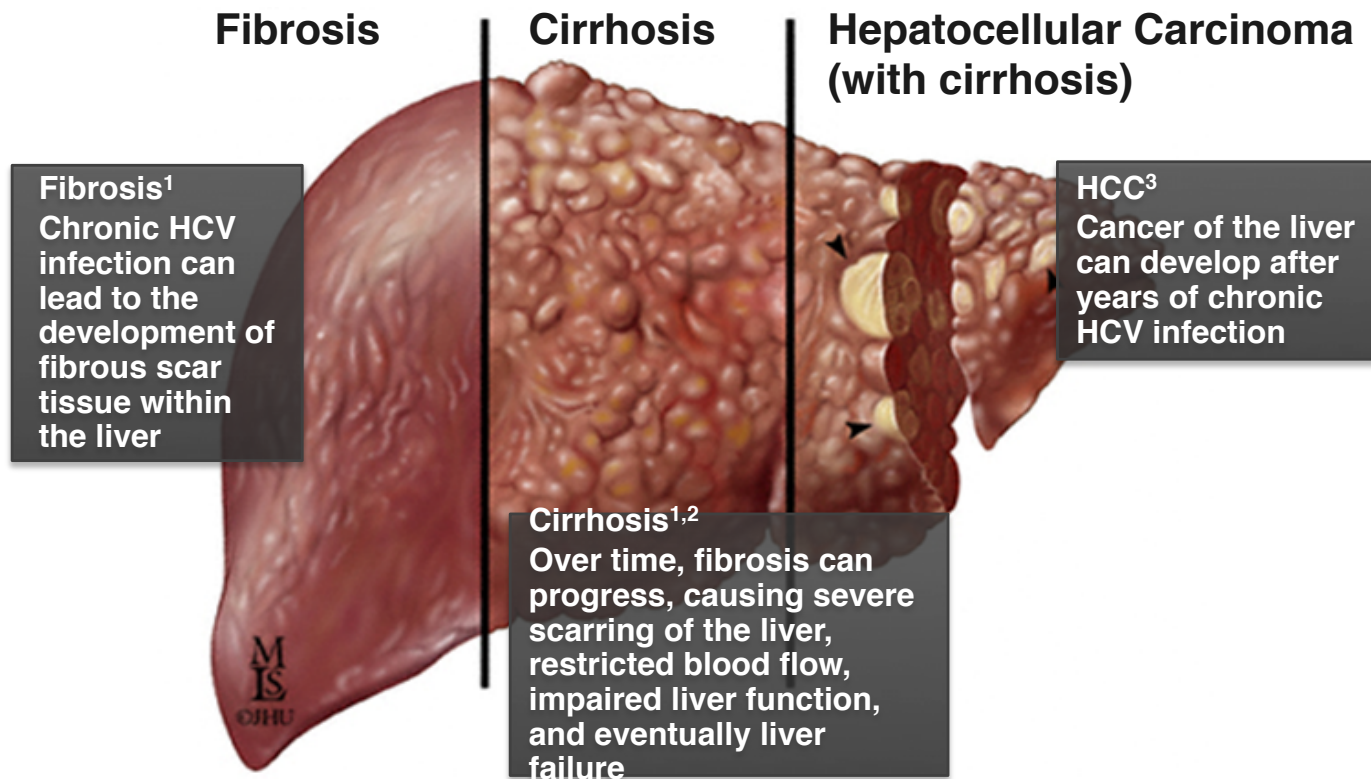
Outline

- **The Problem**
 - HCV in the US is epidemic
 - HCV disproportionately impacts marginalized populations
- **The Opportunity**
 - Rapidly evolving science affords cure at high rate
- **The Response**
 - Empower Health Care for the Homeless Programs to utilize opportunity

The Problem

- Hepatitis C (HCV)- High prevalence, communicable chronic illness
 - 1.0% US prevalence NHANES Survey (Denniston et al, 2014)
 - ~2.2-3.2 million Americans
 - **NHANES underreports persons who are incarcerated and homeless
 - 23% at BHCHP (Bharel et al, 2013)
 - 22-52% across Health Care for the Homeless Programs in the US (Strehlow et al, 2012)
 - 12-35% in incarcerated populations (Weinbaum et al, 2003)

Chronic HCV Infection



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Chronic liver disease includes fibrosis, cirrhosis, and hepatic decompensation; HCC=hepatocellular carcinoma.

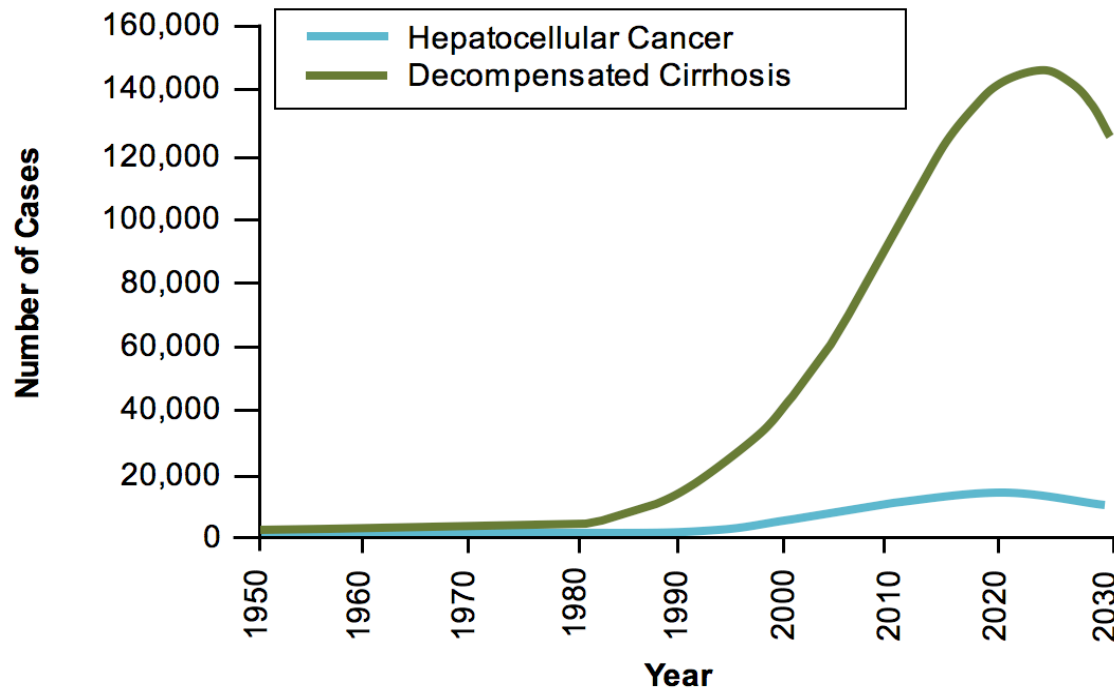
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<http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm>. Accessed May 8, 2012.

Projected Numbers of Decompensated Cirrhosis and Cases of HCC to Rise Through 2020



- Decompensated cirrhosis became more common after 1995 and is presently estimated at 11.7% of cirrhosis cases; the number of cases is expected to continue to increase through ~2020-2030
- HCC rose steeply after 1990. Based on the model, the incidence of HCV-related HCC is expected to peak in 2019 at almost 14,000 cases per year if the risk in HCV-infected persons with fibrosis remains the same

HCC=hepatocellular cancer; HCV=hepatitis C virus.

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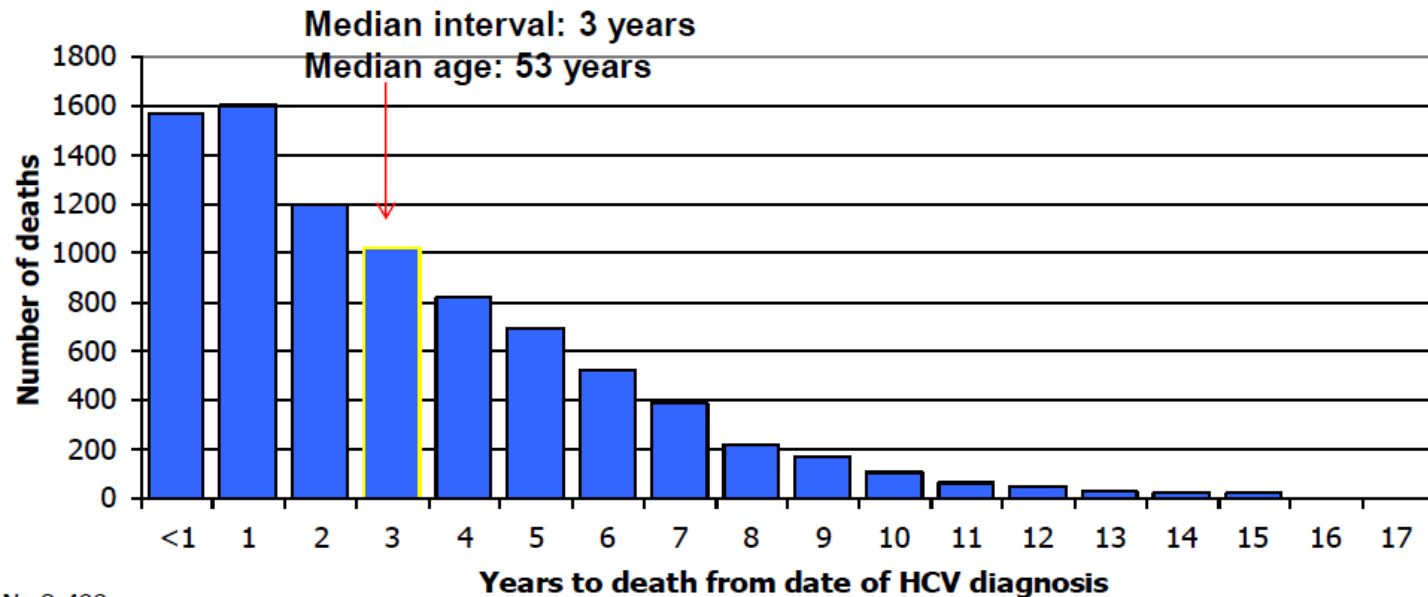
Reprinted from *Gastroenterology*, 138(2), Davis GL, et al, Aging of Hepatitis C Virus (HCV)-Infected Persons in the United States: A Multiple Cohort Model of HCV Prevalence and Disease Progression, Page Nos. (513-521), Copyright (2010) © with permission from Elsevier.

Adapted from Davis GL, et al. *Gastroenterology*. 2010;138(2):513-521

Mortality among HCV cases in Massachusetts

Lijewski, et al, 2012

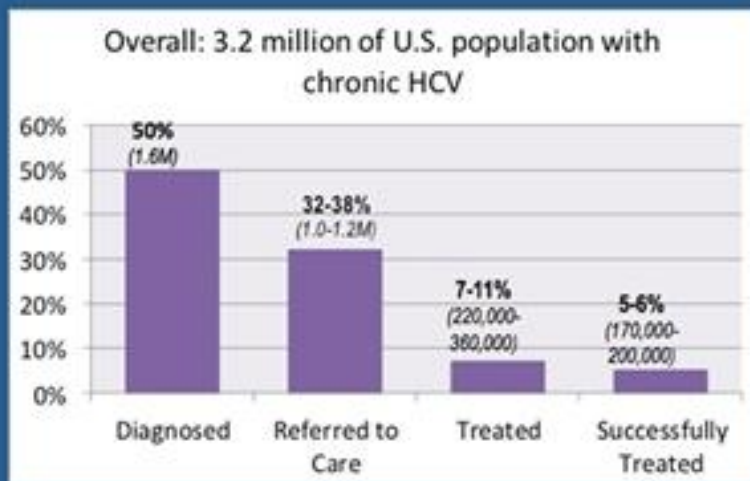
Timing of mortality among known HCV cases in Massachusetts, 1992-2009



N=8,499

76,122 HCV diagnoses were reported to the MDPH between 1992 and 2009, 8,499 of these reported HCV cases died and are represented in the figure. Data as of 1/11/2011.

U.S. HCV Treatment Cascade



(Holmberg et al., "Hepatitis C in the U.S." *N Engl J Med* 2013; 368: 1859-1861)

Cascade of care describes scope of missed opportunities (Holmberg et al, 2013)

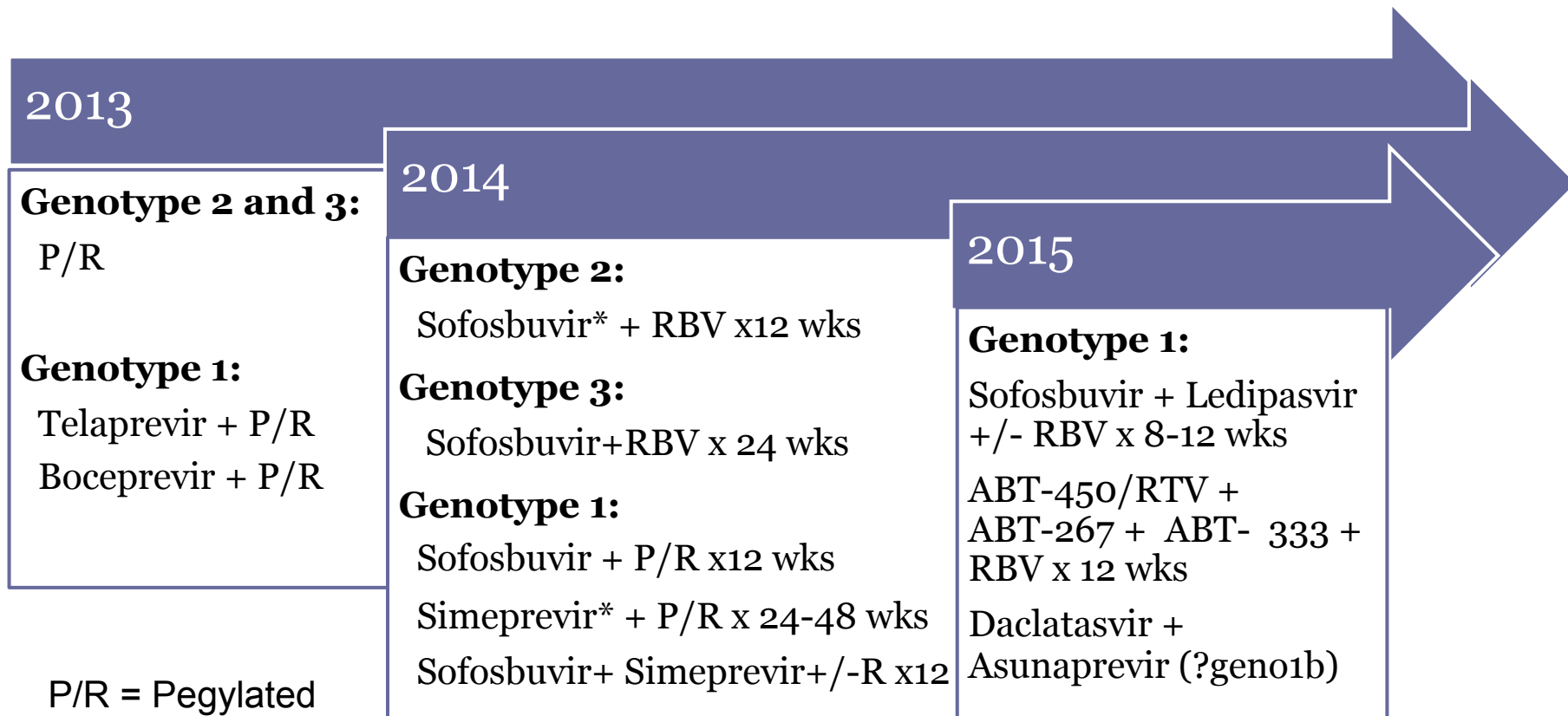
Historic HCV care limitations

- Barriers to HCV care:
 - Access
 - Attitude
 - Competing Priorities
 - Expertise
- 3% of BHCHP patients with hepatitis C ever started on treatment (Ard and Bharel, unpublished data)

The Opportunity

- The advent of very tolerable, highly efficacious direct-acting antiviral (DAA) medications to treat HCV enables broad application of curative treatment to previously hard to reach/hard to treat groups

Rapid Evolution of HCV Regimens: Easier to Tolerate, Higher SVR, All Oral for Most Patients by Late 2014

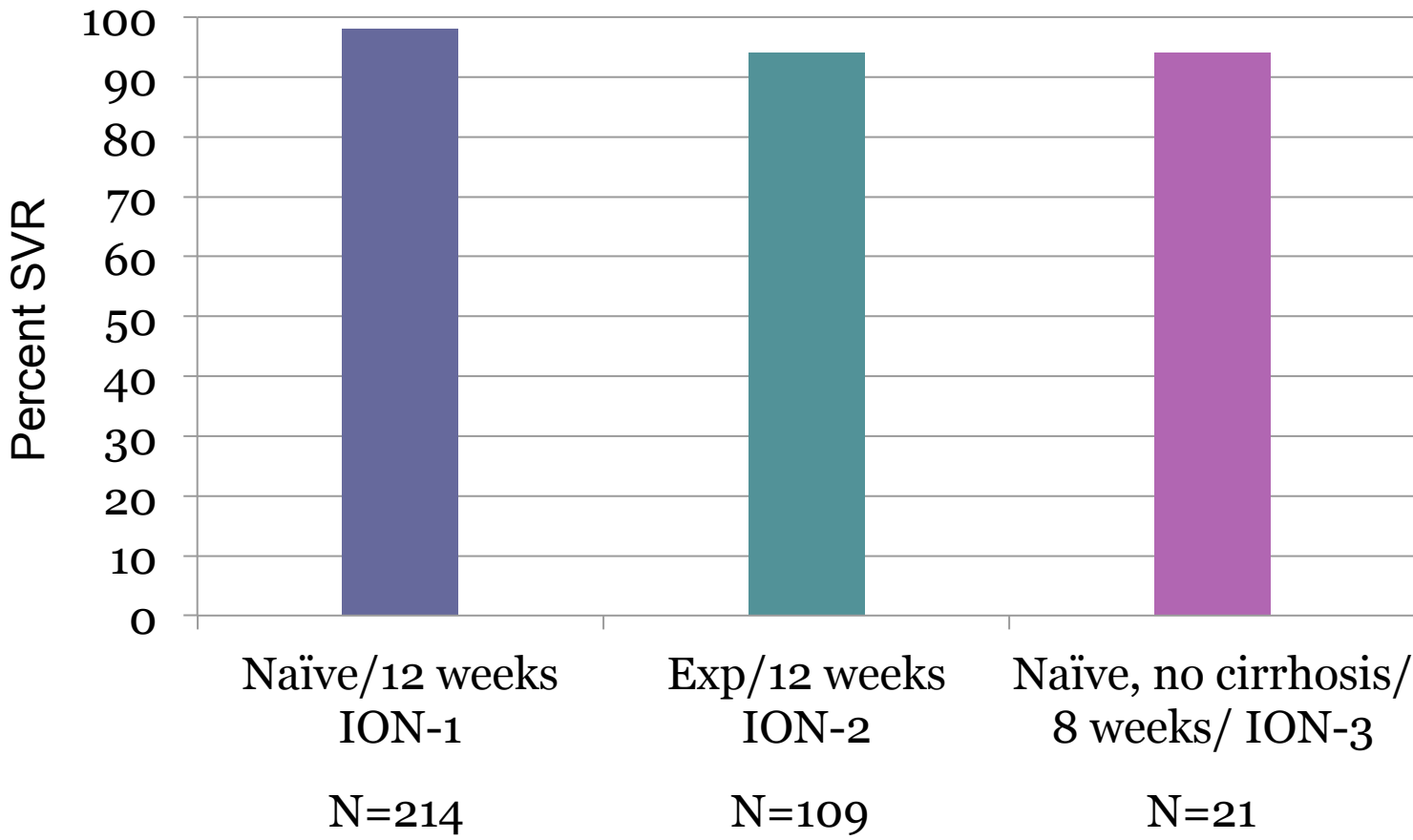


P/R = Pegylated interferon alfa plus ribavirin

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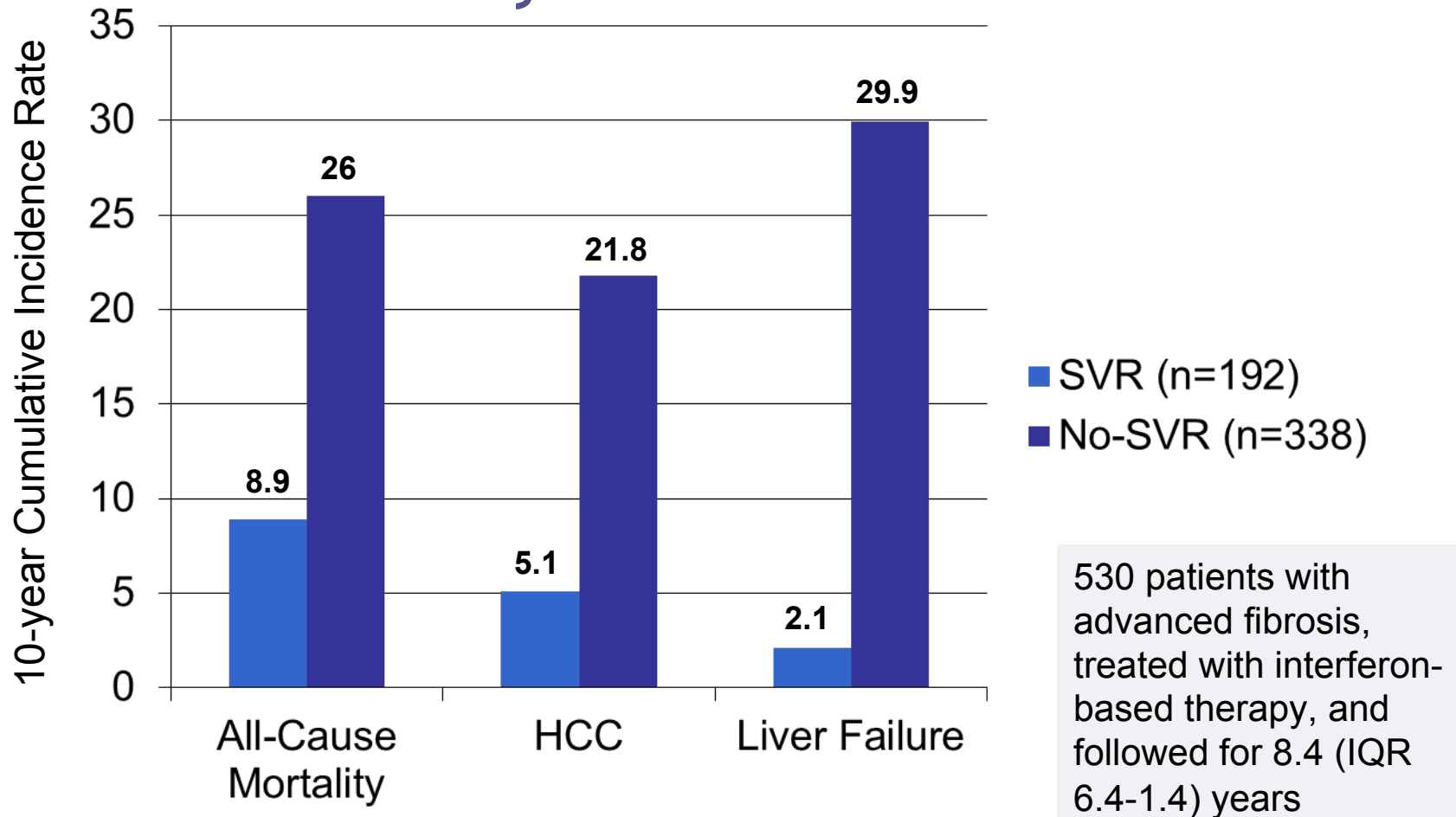
*Approval for SMV 11/26/13 and SOF 12/6/13

SVR-12 in Genotype 1 Patients Treated with Sofosbuvir+Ledipasvir (FDC)



Gilead Phase 3 Program:
-Genotypes 1a and 1b combined for all studies
-ION-1 with 15.7% cirrhosis
-ION-2 with 20% cirrhosis
-Filed with FDA 2/10/14 so we anticipate approval in mid-Oct 2014

SVR (Cure) Associated with Decreased All-Cause Mortality



Treatment in the community

- Established models of HCV treatment in community settings
 - Project ECHO (Arora et al, 2012)
 - Treatment linked to opiate substitution therapy
 - Homegrown efforts
 - MGH Charlestown, BMC GIM, GLFHC
 - At BHCHP
 - HRSA SPNS Ryan White HCV Treatment Expansion Initiative

As treatments become less nuanced and less toxic, PCMH and HCH programs offer excellent frames to enable integrated services for HCV treatment

HCV at BHCHP

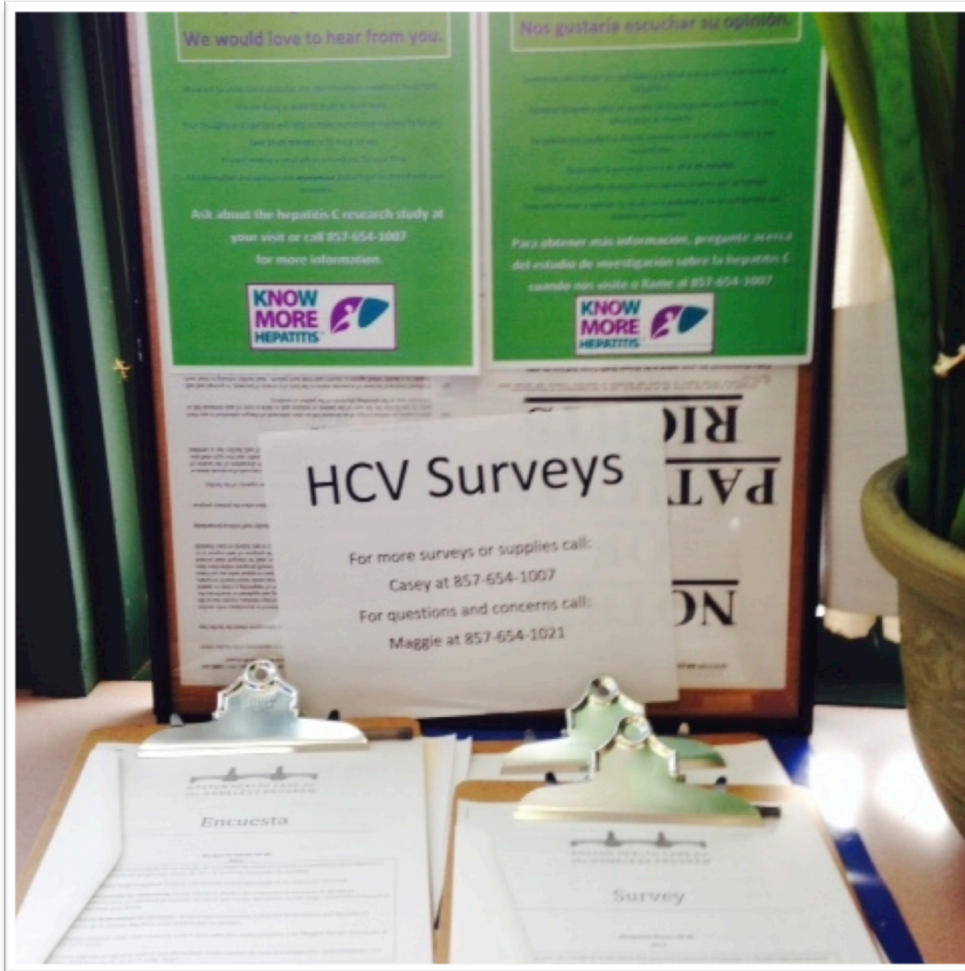
- Implementation of HCV treatment required assessment of:
 - current patient needs
 - Anecdotal experience during SPNS suggested poor uptake of HCV treatment
 - Fears about side effects
 - Lack of perceived need for treatment
 - Competing priorities
 - current standards of HCV care in primary care
 - capacity to treat patients with limited resource allocation

HCV Needs Assessment Survey

- Objectives:
 - Conduct an survey of BHCHP patients with HCV to elucidate the knowledge level and unique concerns of homeless persons around HCV treatment
 - Utilize survey data to establish a tailored, comprehensive HCV treatment program that promotes cure in people experiencing homelessness, despite barriers

HCV Needs Assessment Survey

- 32-item self-administered questionnaire
- English and Spanish
- Administered from October 2013-January 2014
 - Jean Yawkey Place – PCMH-recognized clinic
 - Barbara McInnis House – medical respite center
 - Pine St. Inn – shelter clinic
 - Saint Francis House – shelter clinic



What concerns you most about living with hepatitis C?

“My concerns about having hep C is that if I don't protect myself either I can die of it and I can infect others.”
- study respondent

“I honestly don't think about it enough.”
- study respondent

“Not being able to have a serious relationship with someone who is not infected and may be biased.”
- study respondent

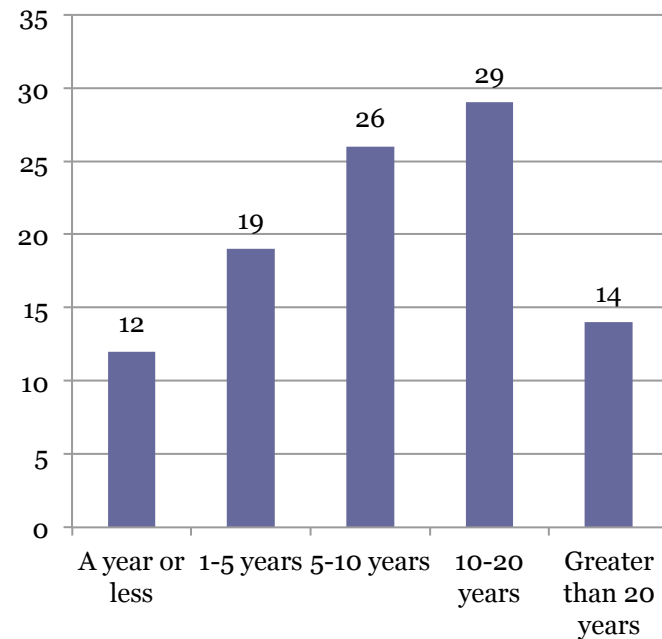
“Dieing of liver cancer.”
study respondent

HCV Needs Assessment

Table 1. Demographic Characteristics N=240

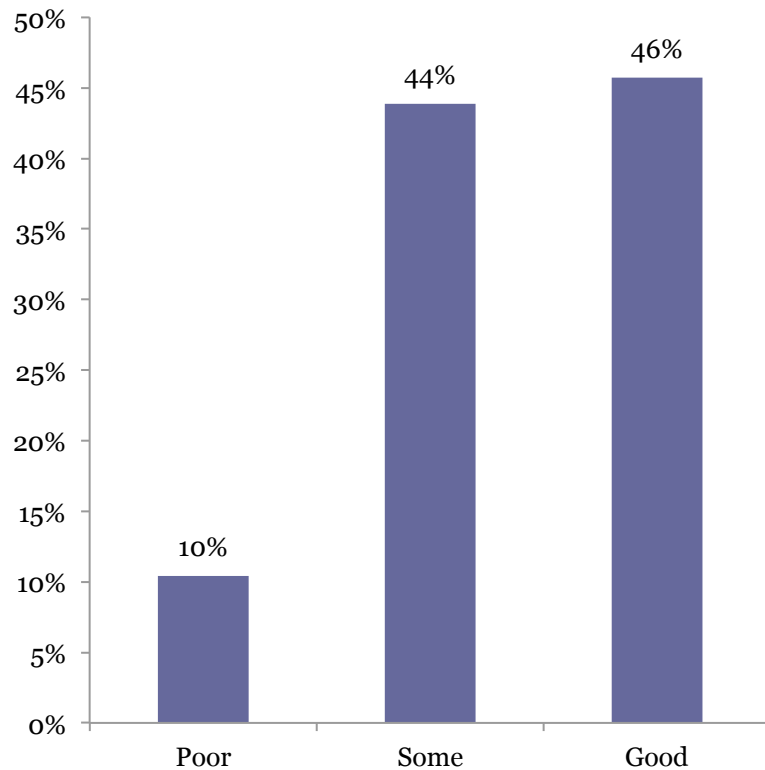
General Demographics	N	%
Gender		
Male	177	80.1
Female	40	18.1
Ethnicity		
Hispanic or Latino	47	21.3
Race		
White	118	49
Black or African American	59	25
American Indian or Alaska Native	7	3
More than one race/mixed race	9	4
Other	32	13
Prefer Not to answer	4	2
Housing Status		
Shelter	147	66
Street	43	19
Housed	57	26
Other	34	15
Self-reported Substance Abuse		
Use of any drugs in the past month	91	41.2
Use of Injected Drugs in the past month	43	19.6
Excessive alcohol use in the past week	39	17.7
Attendance of methadone or suboxone clinic	71	32.6

Figure 1. Duration of known HCV infection N=225



HCV Knowledge Level

Figure 2. Hepatitis C knowledge level of survey respondents based on a seven item exercise N=240



Examples of knowledge questions:

- Can hepatitis C be spread through sharing needles or works?
- Is there a hepatitis C vaccine?
- Can hepatitis C cause cirrhosis?
- Does having HIV infection increase the risk of liver damage if you have hepatitis C?
- Is there a treatment that can cure hepatitis C infection?

Treatment factors and preferences

Table 2. Respondents' motivating factors for HCV treatment N=240

Motivating factors (total) N=240	N	%
Taking care of your health *	146	60.8
Your provider says you should get treated *	107	44.6
You are clean	94	39.2
Treatment that doesn't make you sick	91	37.9
Feeling sick from hepatitis C	84	35
Housing is stable	63	26.3
Loved ones say you should get treated	53	22.1
Other	36	15



* statistically significant with a p value of ≤ 0.05

Table 3. Respondents' preferred location for HCV treatment N=240

Where would you feel most comfortable receiving treatment for hepatitis c?	N	%
Primary Care office	127	53%
Liver doctor's office	88	37%
Suboxone/methadone clinic	17	7%
Other healthcare setting	11	5%
Anywhere/Not sure/Other	22	10%



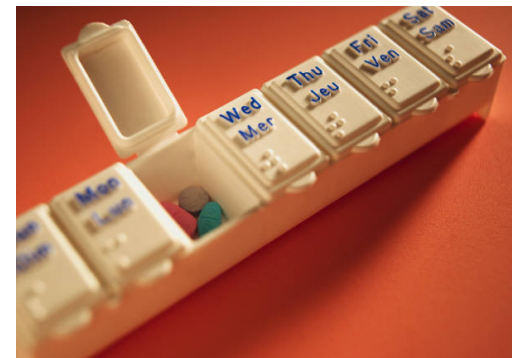
Treatment factors

86% report **interest** in HCV treatment

74% are **confident** they could complete HCV treatment

Table 4. Wishes for additional support services to assist with hepatitis C treatment

	N	%
Barbara McInnis House/respice center	143	60
Help with medication	86	36
Behavioral Health (psychiatry and counseling)	82	34
Case management	81	34
Help with housing	79	33
Support groups	72	30
Substance abuse treatment	65	27
Nutritional/meal support	58	24
Other	31	13



HCV Needs Assessment Survey

Conclusions

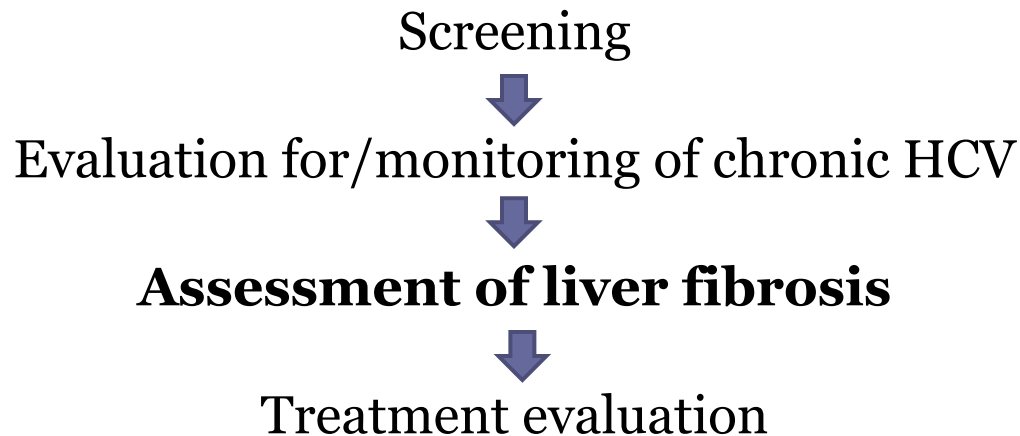
- **First of its kind HCV needs-assessment in a homeless health care setting**
 - Homeless persons have high levels of knowledge about HCV
 - The majority of homeless persons desire HCV treatment and are confident they can complete treatment
 - Primary care teams fulfill an essential role
 - Educating along continuum of prevention → cure
 - Motivating individuals to receive treatment
 - Preferred location for treatment

Next Steps

- Empower primary care teams
 - Implement health center-specific guidelines for screening and routine care for this special population
- Increase capacity to cure
 - Provide person-centered HCV treatment by expert staff on site
- Share successful models for HCV treatment in this special population with local and national partners

Primary Care HCV care guidelines

- Developed based on review of current guidance
- Tailored to high prevalence, limited resource setting



Screening

- **All** patients at BHCHP should receive **one-time screening for hepatitis C by hepatitis C antibody testing** regardless of risk factors.
- Follow-up annual antibody screening should be conducted for patients who are at high risk to acquire HCV.
- Patients with a previous exposure to HCV (HCV antibody positivity) but an undetectable HCV viral load due to spontaneous viral clearance or treatment, should undergo annual screening with HCV viral load if they have ongoing risk factors as HCV antibody-positivity is not protective against reinfection.

Evaluation of chronic HCV

	Baseline	Q6mo ***cirrhosis only	Annually	only w/symptoms
HCV viral load (RNA)	X			
HCV genotype	X			
CBC/diff	X	X	X	
PT/INR	X	X	X	
BMP/LFTs	X	X	X	
Abd U/S	X	X		
Cryoglobulins				X
Fib-4 index	X		X	
HIV Antibody	X		X if risk factors	
HAV screening	X			
HBV screening	X			
Endoscopy	At time of cirrhosis diagnosis- FU based on results			

Preventive Screening

- **Hepatitis A Screen**
 - HAV Ab (-) → Vaccinate
 - HAV Ab (+) → Immune
- **Hepatitis B Screen**
 - HBsAb (-) & HBsAg (-) → Vaccinate
 - HBsAb (+) & HBsAg (-) → Immune
 - HBsAb (-) & HBsAg (+) → Co-infection w/HBV
- **HIV Screen**
 - HIV Ab (+) → Co-infection w/HIV

Preventive Immunizations

- Influenza vaccination
- Pneumococcal vaccination

Alcohol Use → Brief Intervention/Referral if indicated

Fibrosis Assessment

Selected Noninvasive Systems to Assess Liver Fibrosis in Chronic Hepatitis C

Marker	Description	Performance
AST to platelet ratio index (APRI)	(AST level/ULN x 100)/ platelet count	Threshold of 0.7 has a sensitivity of 77% and specificity of 72% for significant fibrosis (Metavir stage 3 or 4) ¹³
FIB-4 index	$(\text{Age (yrs)} \times \text{AST (IU/mL)}) / (\text{platelets (x 1000)} \times \text{ALT (IU/mL)})^{1/2}$	Index of > 3.25 has PPV of 82% with a specificity of 98% for significant fibrosis (Metavir stage 3 or 4) ¹⁴
<i>FibroTest</i>	Calculation including age, haptoglobin, alpha-2-macroglobulin, apolipoprotein A1, GGT, and total bilirubin	Sensitivity of 75% and specificity of 85% to detect Metavir stage 2 or greater ¹⁵
<i>FibroScan</i>	Ultrasound device that uses transient elastography to assesses liver shear wave velocity (meters/second) that is converted to equivalent liver stiffness (kilopascals) at 50 Hz, which correlates with hepatic fibrosis stage	Threshold for diagnosis of cirrhosis 12.5 KPa with sensitivity of 87% and specificity of 91% ^{16,17}

18

In the interest of applying an accurate, easily administered, cost-effective measure that enables BHCHP to identify the highest risk patients for morbidity and mortality to the large population of patients with HCV at BHCHP, the Fib-4 index is chosen as the preferred fibrosis staging instrument.

Fib-4 index = $(\text{age (yrs)} \times \text{AST (IU/mL)}) / (\text{platelets (x1000)} \times \text{ALT (IU/mL)})^{1/2}$

Assessment of liver fibrosis and cirrhosis management at BHCHP

Liver Fibrosis Assessment

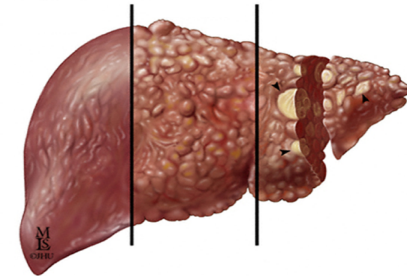
- Goal - to predict advanced fibrosis and cirrhosis
- Liver function tests, platelets and INR are **late** predictors of cirrhosis and are not useful in early fibrosis

Fib-4 index- a validated calculation to predict fibrosis using age, ALT, AST and platelet levels. Recommended annually.

- <1.45= highly suggestive of minimal fibrosis (F0-F1)
- >3.25=highly suggestive of advanced fibrosis (F3-F4)
- 1.46-3.24= indeterminate level of fibrosis

Reference: Metavir scale of fibrosis

- F0 = no fibrosis.
- F1 = portal fibrosis w/o septa.
- F2 = few septa.
- F3 = numerous septa w/o cirrhosis
- F4 = cirrhosis.



Cirrhosis Management- Consider Fib-4 scores >3.25 highly suggestive of cirrhosis and implement cirrhosis monitoring by:

- Screen for HCC with abdominal u/s q6 months
 - AFP testing lacks adequate sensitivity/specificity to be an effective surveillance tool and is no longer recommended
- Screen for esophageal varices with endoscopy
- Recommend referral to GI for management of complications r/t decompensated cirrhosis
 - Ascites
 - esophageal varices
 - portal hypertension

HCV Education in Primary Care

Guidance for Patients

HCV Infection is a blood-borne virus that affects the liver and, for some people, can cause scarring, cirrhosis and liver cancer over the course of many years.

Risk factors for disease progression include alcohol consumption, HIV coinfection, concomitant liver disease, obesity, age, genetic factors

Patient Education

- Avoid sharing toothbrushes and dental or shaving equipment and cover any cut or sore in order to prevent contact of their blood with others.
- Stop using illicit drugs. Get treatment for substance abuse. **Those who continue to inject drugs should avoid reusing or sharing syringes, needles, water, cotton or other paraphernalia**; use only sterile syringes from a reliable source (e.g., pharmacy, needle exchange); use a new sterile syringe to prepare and inject drugs; use sterile water to prepare drugs – otherwise use clean water from a reliable source (e.g. tap); clean the injection site with a new alcohol swab; and dispose of syringes and needles after one use in a safe, puncture-proof container.
- Do not donate blood, body organs, other tissue, or semen.
- If the patient has high risk sexual behavior (including multiple sex partners, anal sex or rough sex/fisting), recommend barrier precautions (e.g., latex condoms or gloves) and “safer” sex. Otherwise, the risk of sexual transmission of HCV is low, and the infection itself is not a reason to change sexual practices (i.e., those in long-term relationships need not start using barrier precautions).
- To protect the liver from further harm: do not drink alcohol; do not start any new medicines, including over-the-counter and herbal medicines, without checking with their provider.

BHCHP HCV Consult Service

- Started in 1/14 by NP, MD and RN with some experience in HCV treatment and >50 hours of CME
- Key elements
 - Specialty back-up
 - ID/GI/pharmacy
 - Administrative buy-in
 - Insurance expertise
 - Adherence support
 - Med storage
 - Frequent and flexible patient check-ins

50 patients seen since 1/27/14
7 patients treated
5/5 in first group achieved RVR

HCV Treatment in primary care of persons experiencing homelessness

Treatment - Who is appropriate for treatment?

- Urgency of treatment should be based on likelihood of **advanced fibrosis (F3-F4)**.
- If a patient is highly motivated, and understands there are future treatment options but wants treatment now, they should be evaluated for treatment candidacy
- **Refer to BHCHP HCV Consult Service for education, treatment evaluation and initiation**



What about cost?

Other
concerns?

What about reinfection?

Resources

- Treatment Guidelines
 - AASLD and IDSA guidelines www.hcvguidelines.org
 - Hepatitis C Online University of Washington
<http://www.hepatitisc.uw.edu/browse/all/lectures>
 - Clinical Care Options Hepatitis
www.clinicaloptions.com
- Hepatitis C news and conference proceedings
 - www.natap.org
 - www.hivandhepatitis.com
- Advocacy and patient education
 - HepMag www.hepmag.com
 - Hcvadvocate.org
 - National Viral Hepatitis Roundtable www.nvhr.org

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- MA Viral Hepatitis Coalition
- MA Department of Public Health Division of Viral Hepatitis

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