Overcoming Barriers to HCV Care

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Disclosures

Grant Support from Gilead Sciences, FOCUS program

Advisory Board, Gilead Sciences

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Epidemiology of HCV in the US

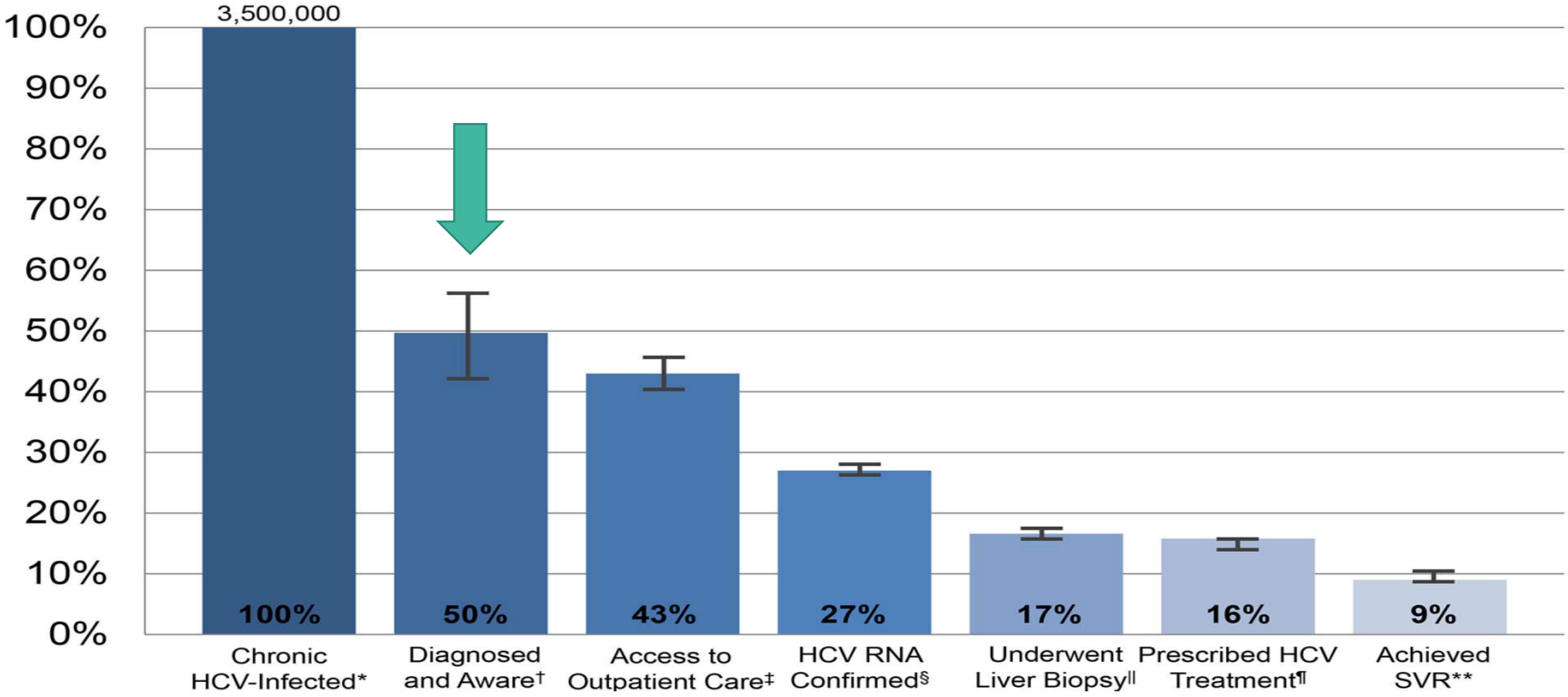
Most common blood-borne infection in the US

- 3.2 million to **5.2 million** persons chronically infected
- Birth cohort 1945-1965: **3.27%** antibody positive
  - Non-Hispanic blacks: **6.31%**
  - Non-Hispanic whites: **2.92%**
  - Mexican American/ other: **2.78%**

50% to 75% of individuals chronically infected with HCV are unaware of their infection

Smith BD. AASLD poster #394, 2011
Armstrong GL. Annals of Int Med, 2006 144; 705-714
Chak E. *Liver Internat*. 2011, 2:1090-1101

Treatment cascade for people with chronic HCV infection



Yehia B. PLoS One. 2014; 9(7) e101554.

Birth Cohort with high rates of HCV

FIGURE 1. Prevalence of hepatitis C virus antibody, by age at time of survey — National Health and Nutrition Examination Survey, United States, 1988–1994 and 1999–2002

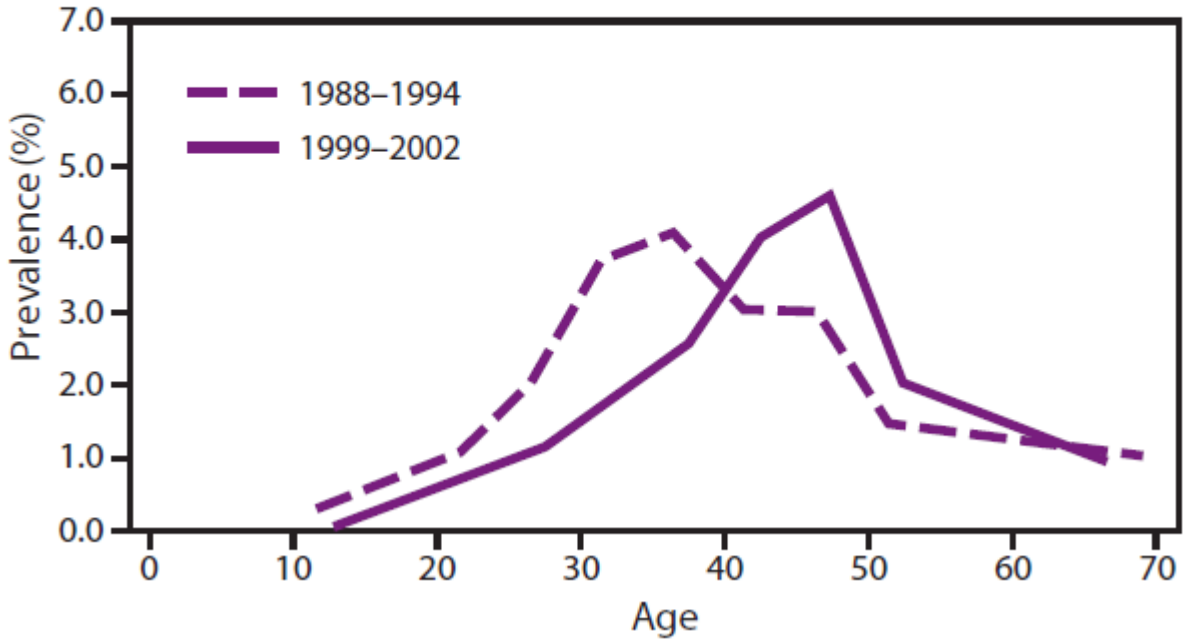
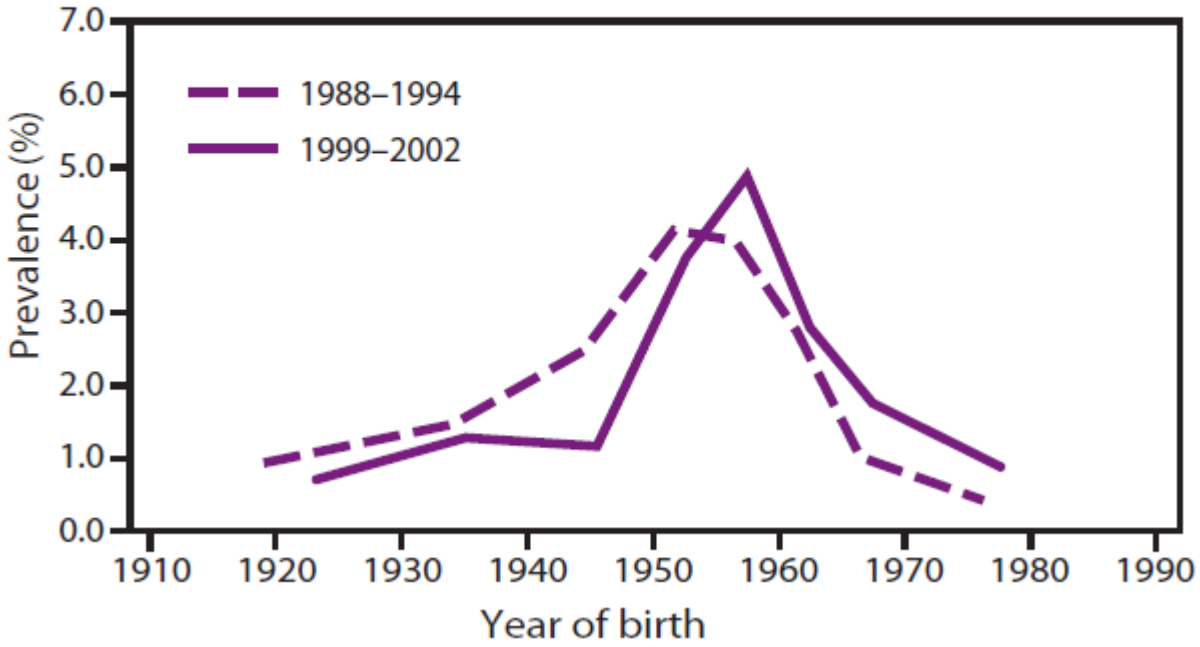


FIGURE 2. Prevalence of hepatitis C virus antibody, by year of birth — National Health and Nutrition Examination Survey, United States, 1988–1994 and 1999–2002



CDC. MMWR. August 17, 2012, Vol. 61 , No. 4
Armstrong GL et al. *Ann Internal Med*, 2006;144:705–14.

CDC Recommendations for HCV testing

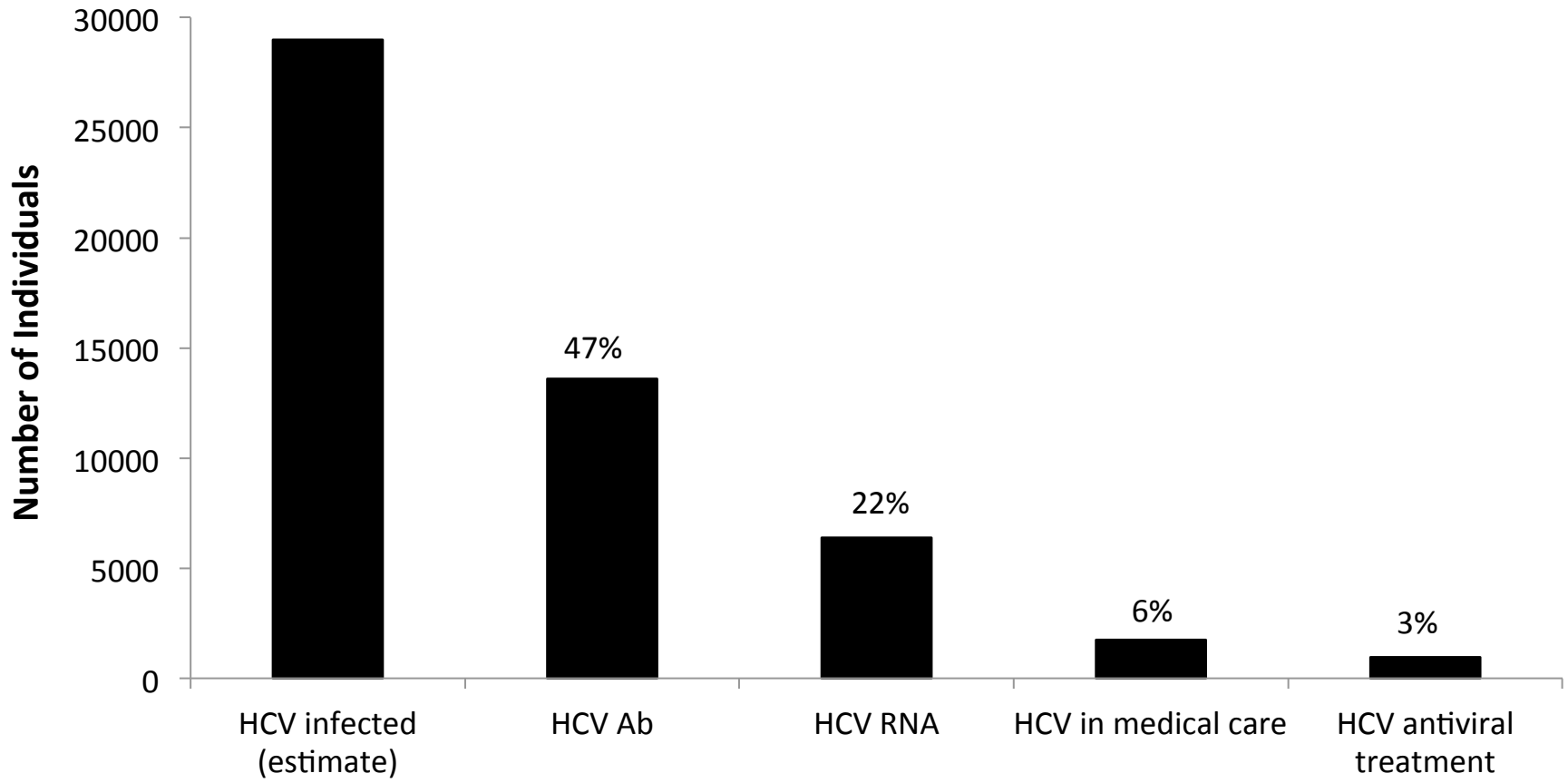
Birth Cohort based screening

- All individuals born between 1945 and 1965 should be tested at least once for HCV
- All individuals outside of this cohort with a HCV risk factor should be screened
- Cost-effective
- 1-time cohort screening would identify about **86%** of undiagnosed cases, compared with **21%** with risk-based screening

US Preventive Services Task Force: Grade B recommendation

Rein DB. *Ann Intern Med*. 2012;156(4):263-70
http://www.uspreventiveservicestaskforce.org/uspstf/uspshepc.htm
CDC. MMWR 2012;61(No. RR-4).

Philadelphia Cascade of Care 2010-2013



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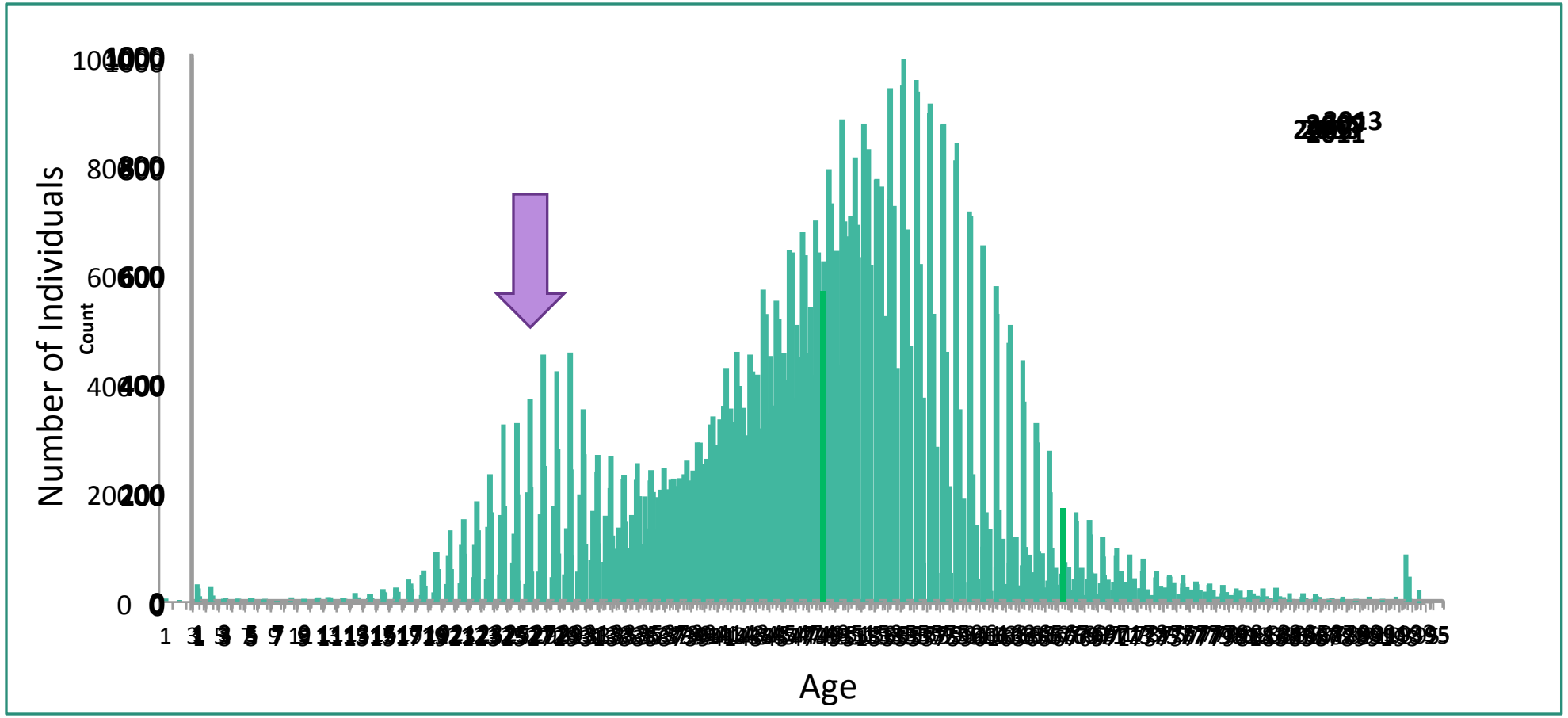
Viner et al. Hepatology. 2015 Mar;61(3):783-9.

A new population of young HCV cases is emerging in Philadelphia 2007-2103

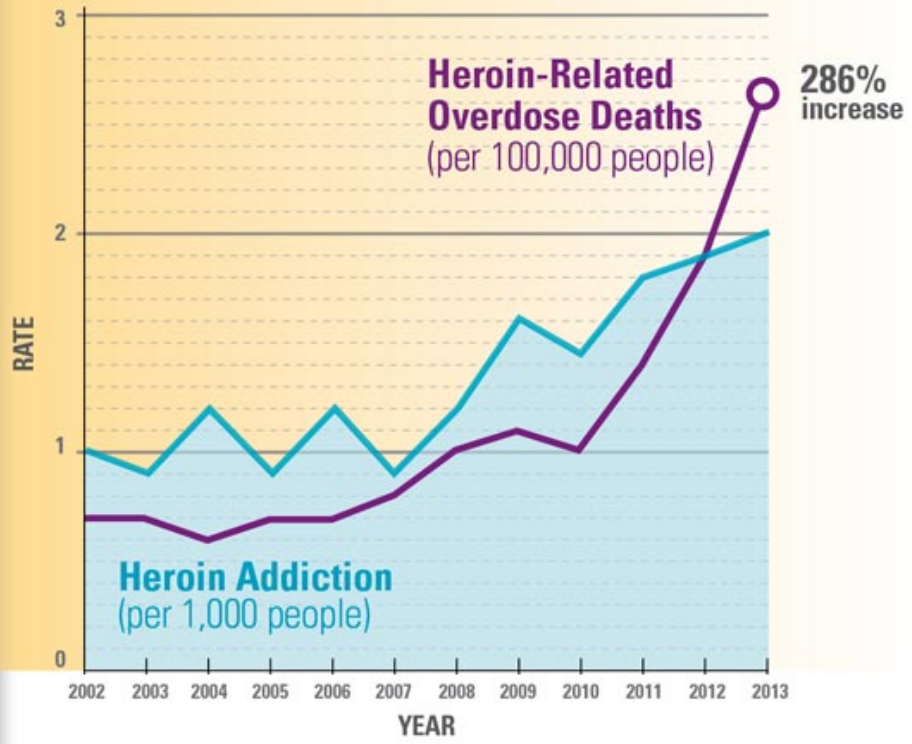


Data provided by Dr. Kendra Viner PhD from the Philadelphia Department of Public Health

Heroin Use Has INCREASED Among Most Demographic Groups

	2002-2004*	2011-2013*	% CHANGE
SEX			
Male	2.4	3.6	50%
Female	0.8	1.6	100%
AGE, YEARS			
12-17	1.8	1.6	--
18-25	3.5	7.3	109%
26 or older	1.2	1.9	58%
RACE/ETHNICITY			
Non-Hispanic white	1.4	3	114%
Other	2	1.7	--
ANNUAL HOUSEHOLD INCOME			
Less than $20,000	3.4	5.5	62%
$20,000–$49,999	1.3	2.3	77%
$50,000 or more	1	1.6	60%
HEALTH INSURANCE COVERAGE			
None	4.2	6.7	60%
Medicaid	4.3	4.7	--
Private or other	0.8	1.3	63%

Heroin Addiction and Overdose Deaths are Climbing

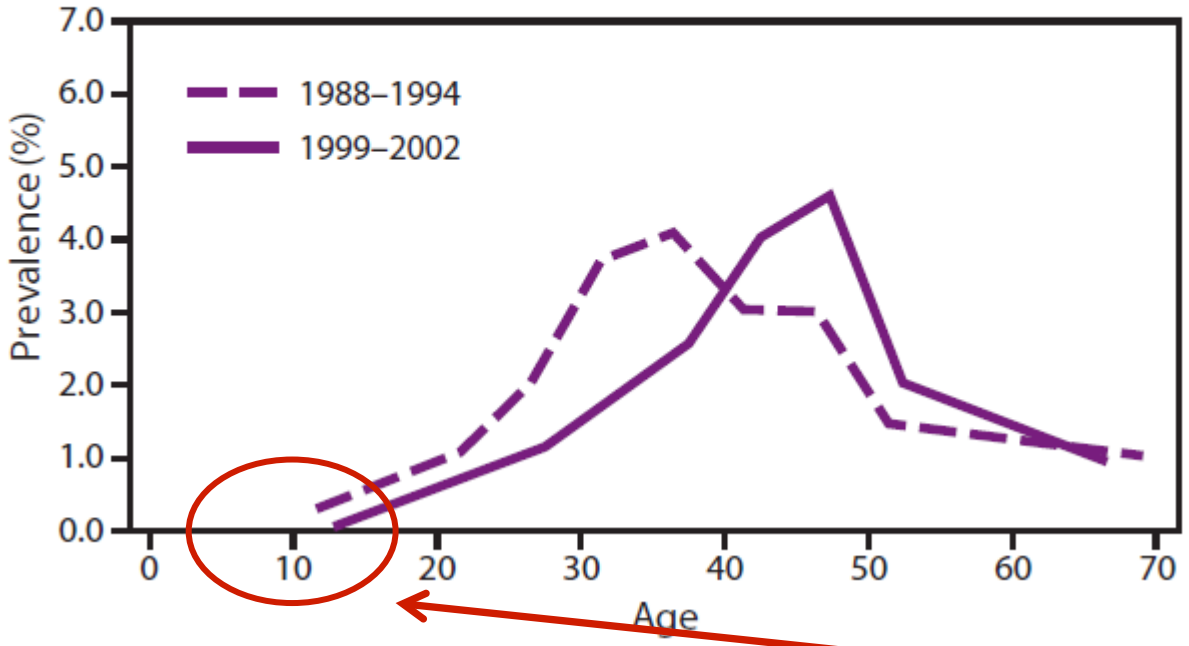


SOURCES: National Survey on Drug Use and Health (NSDUH), 2002-2013.
National Vital Statistics System, 2002-2013.

http://www.cdc.gov/vitalsigns/heroin/

Birth Cohort testing recommendations

FIGURE 1. Prevalence of hepatitis C virus antibody, by age at time of survey — National Health and Nutrition Examination Survey, United States, 1988–1994 and 1999–2002



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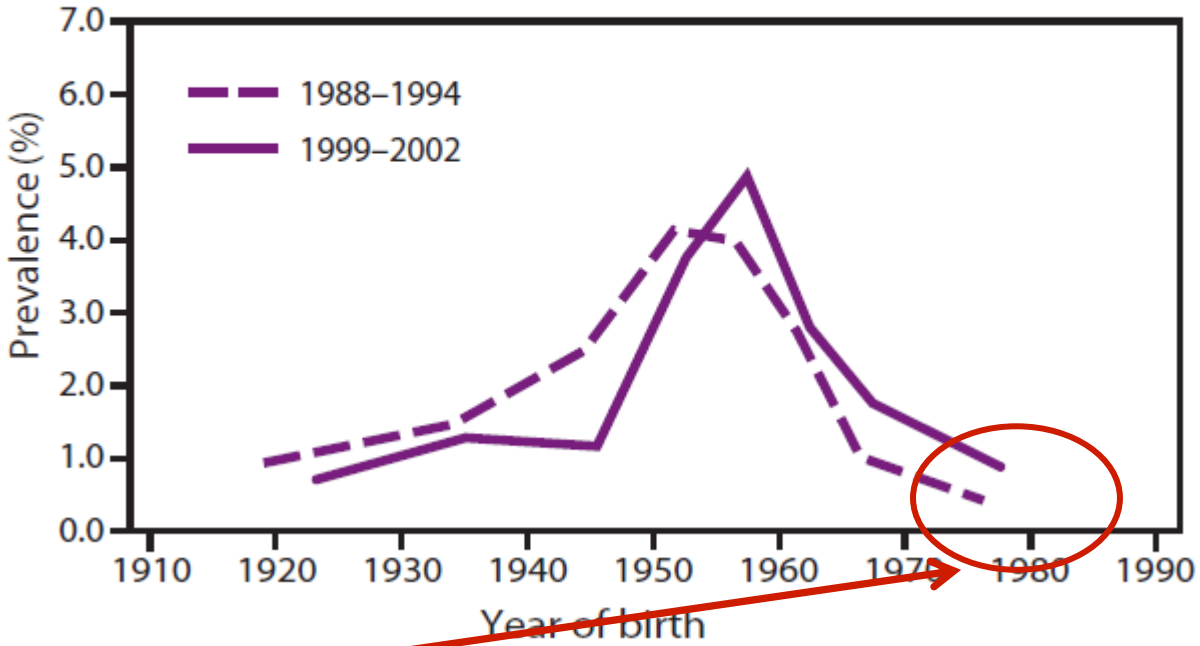
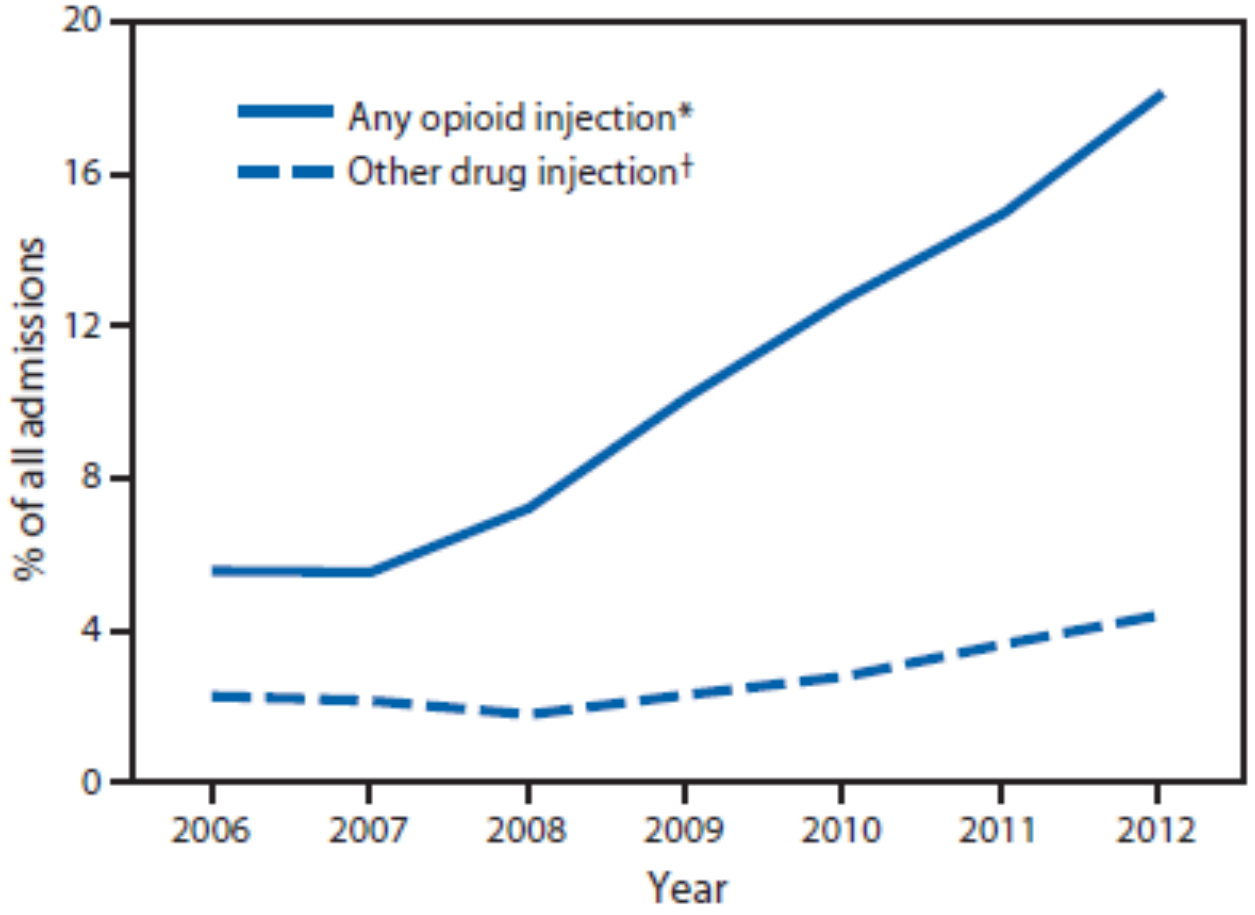


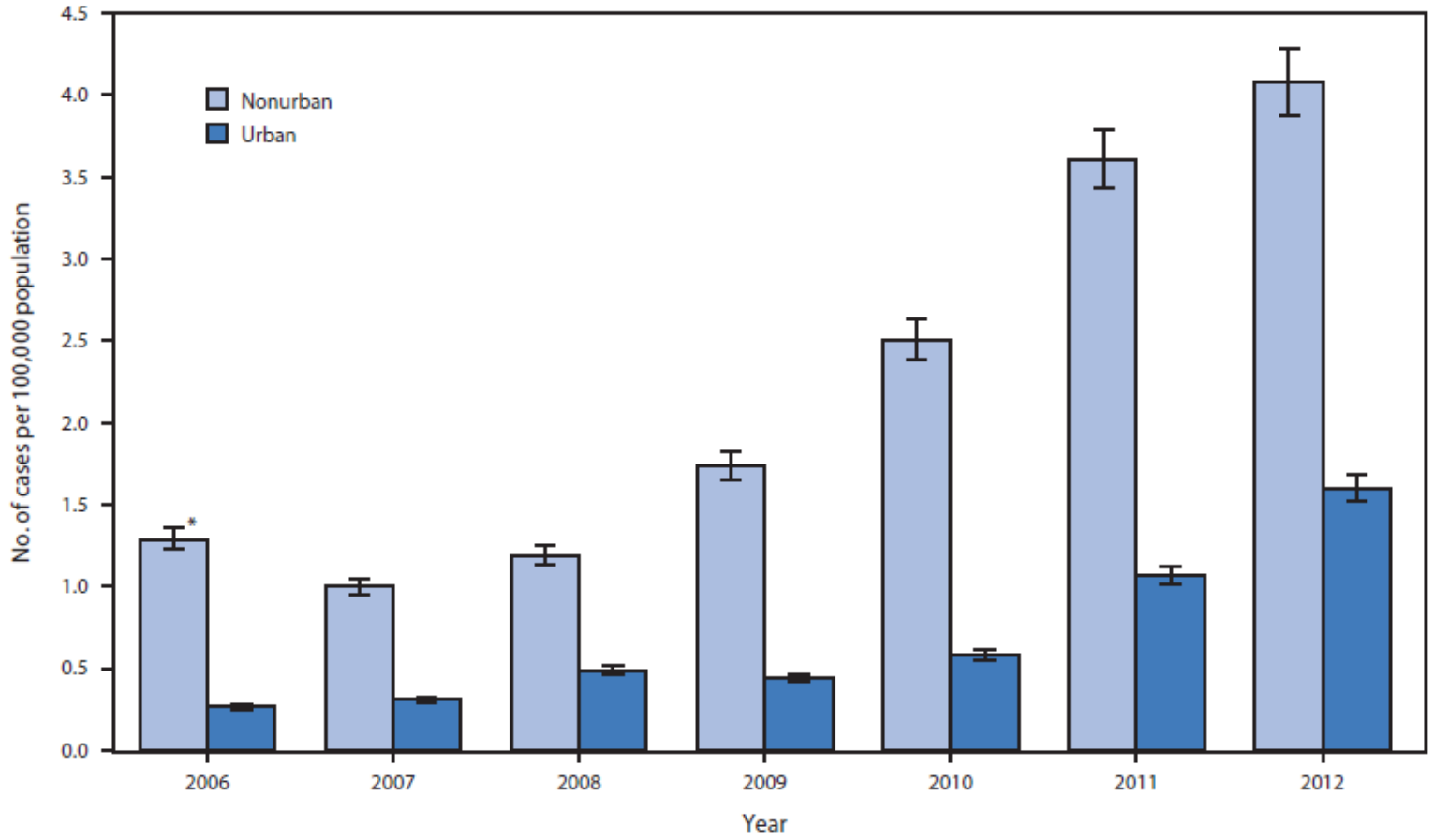
Opioid epidemic

CDC. MMWR. August 17, 2012, Vol. 61 , No. 4
Armstrong GL et al. *Ann Internal Med*, 2006;144:705–14.

Percentage of all admissions to substance abuse treatment centers by persons aged 12-29 yrs (N=217,789) by year - Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012



Incidence of acute hepatitis C among persons aged </= 30 years, by urbanicity and year - Kentucky, Tennessee, Virginia and West Virginia 2006-20012



* 95% confidence interval.

New cases of HCV and deaths from old infections are both on the rise

Estimated Actual New Cases of HCV (range)		
2011 (estimated)*	**2012 (estimated)***	**2013 (estimated)***
16,500 (7,200-43,400)	24,700 (19,600-84,400)	29,700 (23,500-101,400)

* Actual acute cases estimated to be 13.9 times the number of reported cases in any year

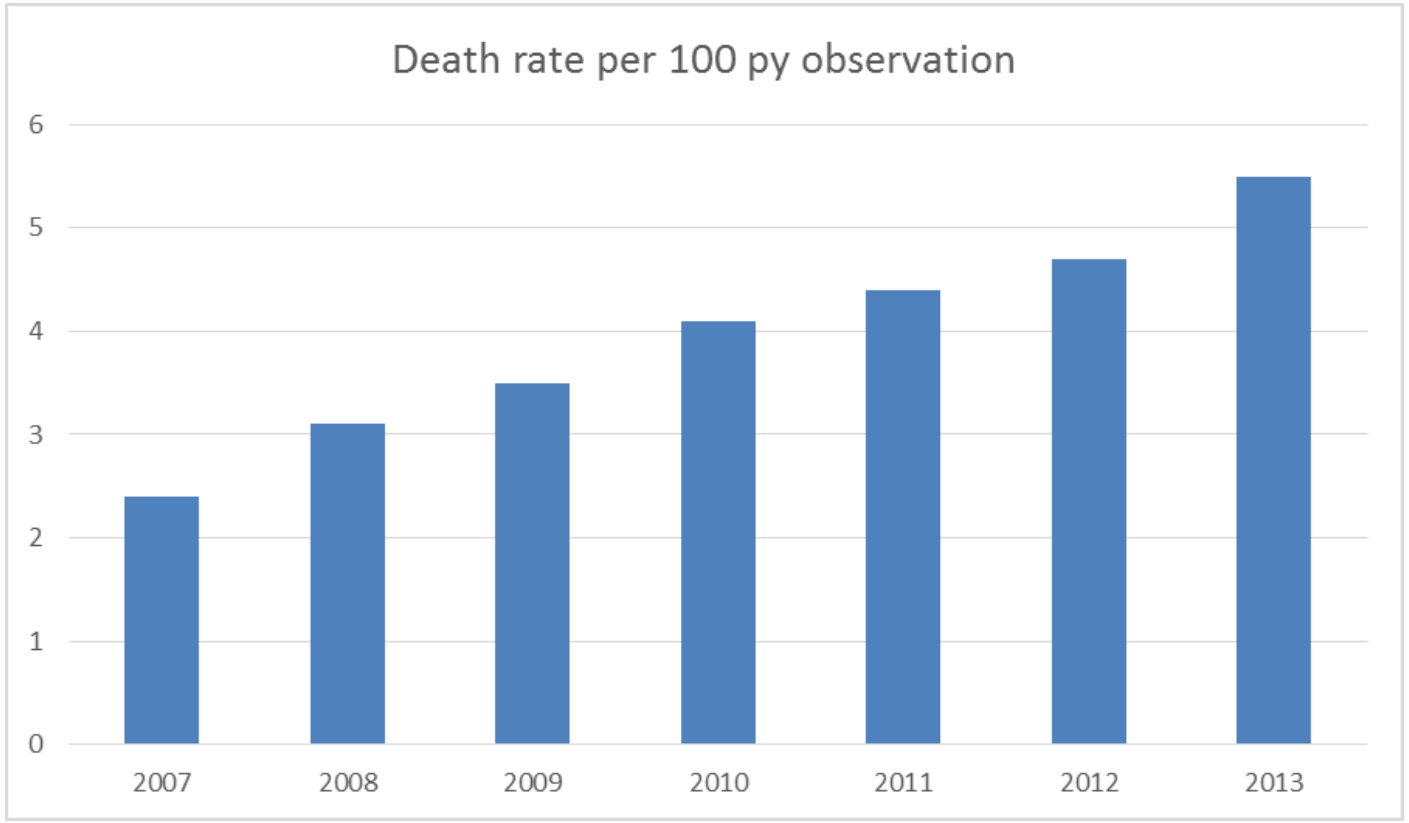
Est. No. of Chronic Cases In the United States	No. of Death Certificates listing HCV as a Cause of Death			
	2010	**2011**	**2012**	**2013***
2.7- 3.9 million	16,627†	17,721†	18,650†	19,368†

* Underlying or contributing cause of death in most recent year available (2013)

†Current information indicates these represent a fraction of deaths attributable in whole or in part to chronic hepatitis C

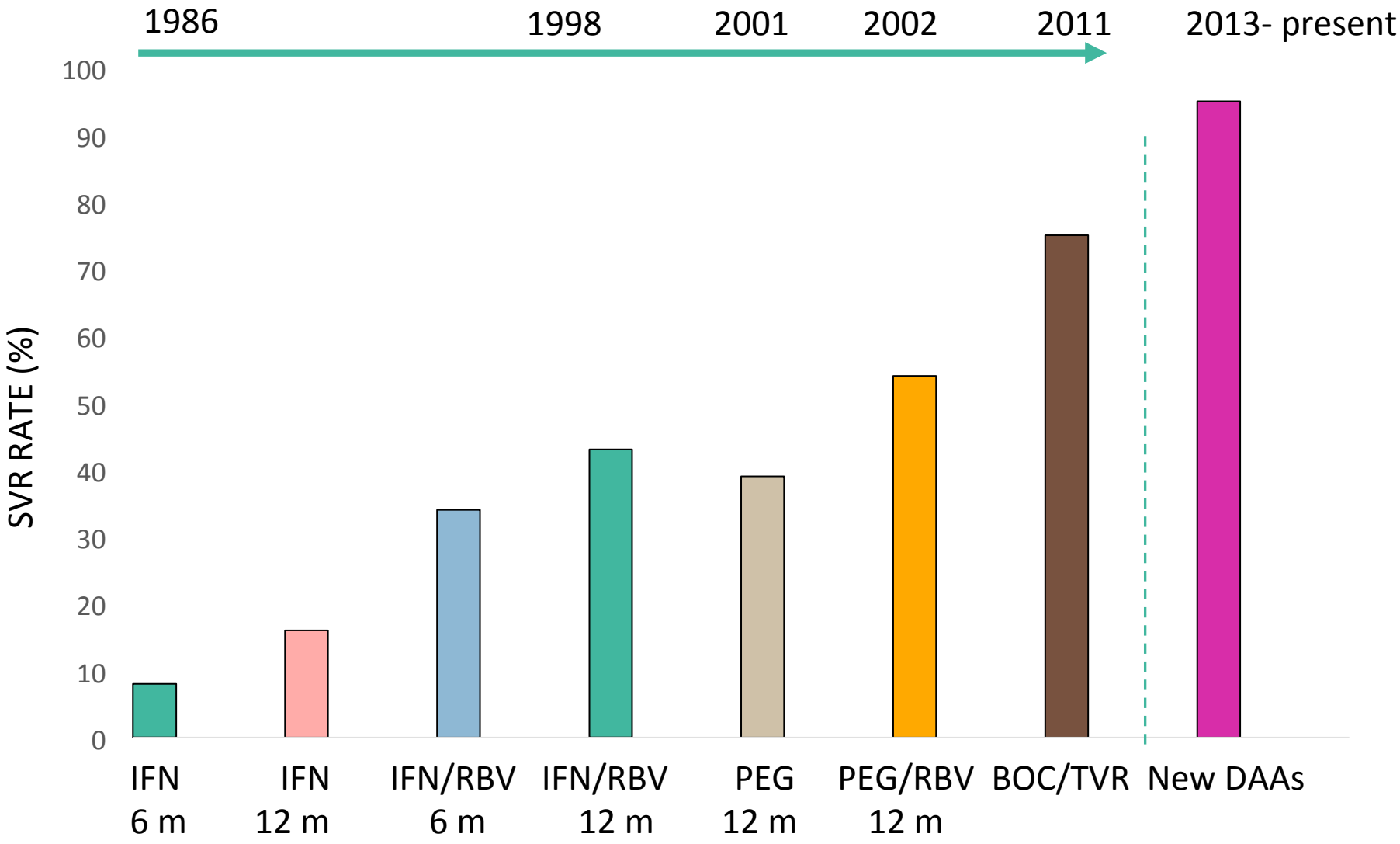
http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm

The Chronic Hepatitis Cohort Study (CHeCS)
Doubling of mortality rate, 2007-2013



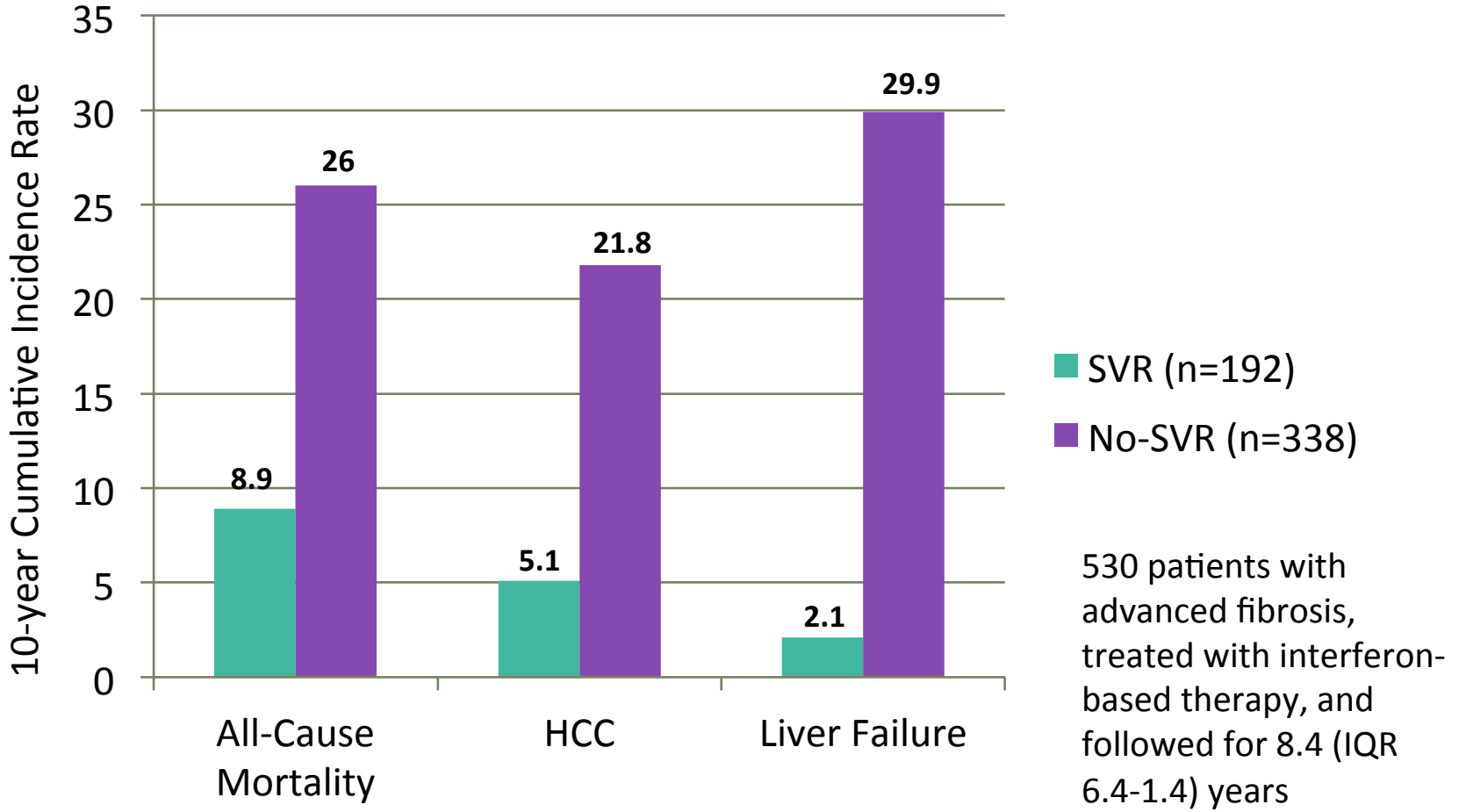
Slide courtesy of S. Holmberg, presented at IDSA 2015

Evolving HCV Treatment



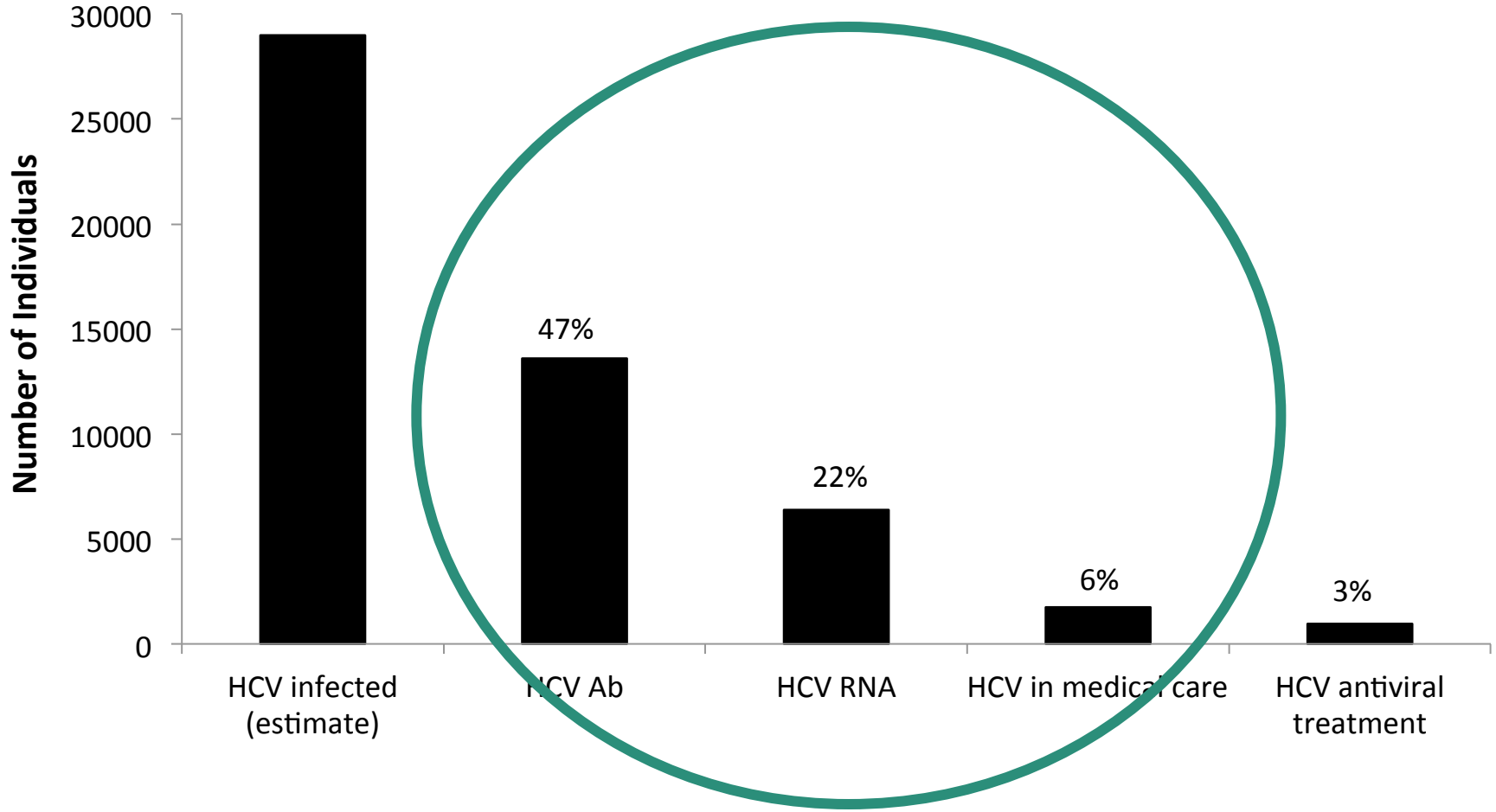
Adapted from Strader DB. Clin Liver Disease 2012, 1:1; 6-11.

SVR (Cure) Associated with Decreased All-Cause Mortality



530 patients with advanced fibrosis, treated with interferon-based therapy, and followed for 8.4 (IQR 6.4-1.4) years

Philadelphia Cascade of Care 2010-2013



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Viner et al. Hepatology. 2015 Mar;61(3):783-9.

Community based testing

A testing and linkage to care campaign that stimulates demand for and provides HIV and HCV testing across an entire zip code.

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Female	49.1
African American	91.0
Single	81.1
Age	
<47	71.0
47-67	29.0
Education	
Less than high school	17.6
High school degree/GED	50.9
At least some college	31.5
Income	
Less than $10,000	46.4
$10,000 - $14,999	18.7
$15,000 - $29,999	17.8
> $30,000	17.1
Self-identified sexual orientation	
Heterosexual	89.0
Gay/Lesbian	4.9
Bisexual	6.1
Ever incarcerated	36.3

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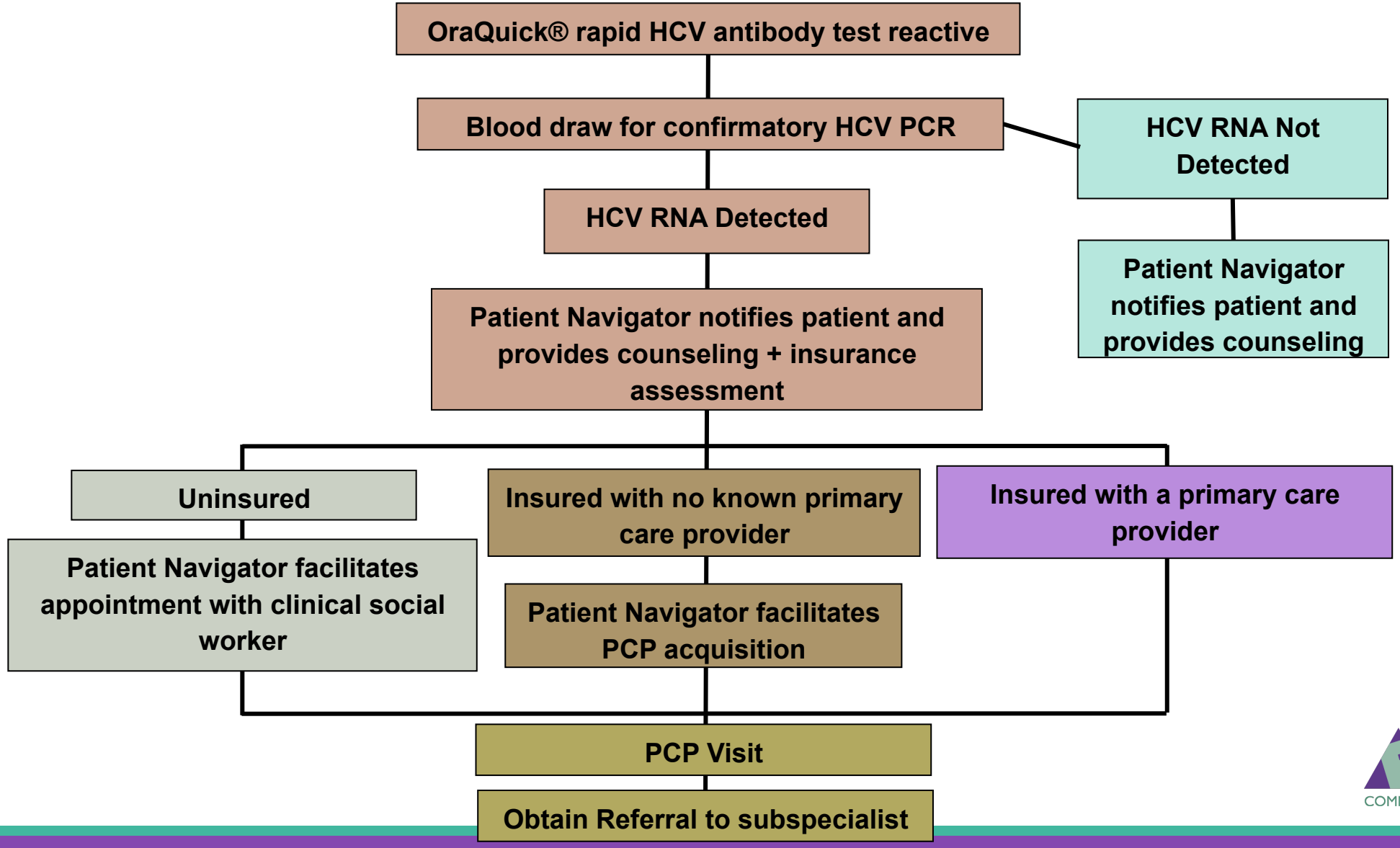
Do One Thing baseline population characteristics n=1,301

Trooskin S et al. JGIM. 2015 Jul;30(7):950-7.

Testing and Linkage to Care Protocol



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HCV Patients

1,301 participants were tested for HCV

- 3.9% anti-HCV seroprevalence
- 2.8% chronically infected

8% of anti-HCV positive participants were already engaged in HCV care

Of those chronically infected individuals:

- 58% aware of infection but not engaged in care
- 36% uninsured
- 58% had an Audit-C score commensurate with alcohol use disorder
- 80% participants had serious co-morbidities such as mental illness and addiction

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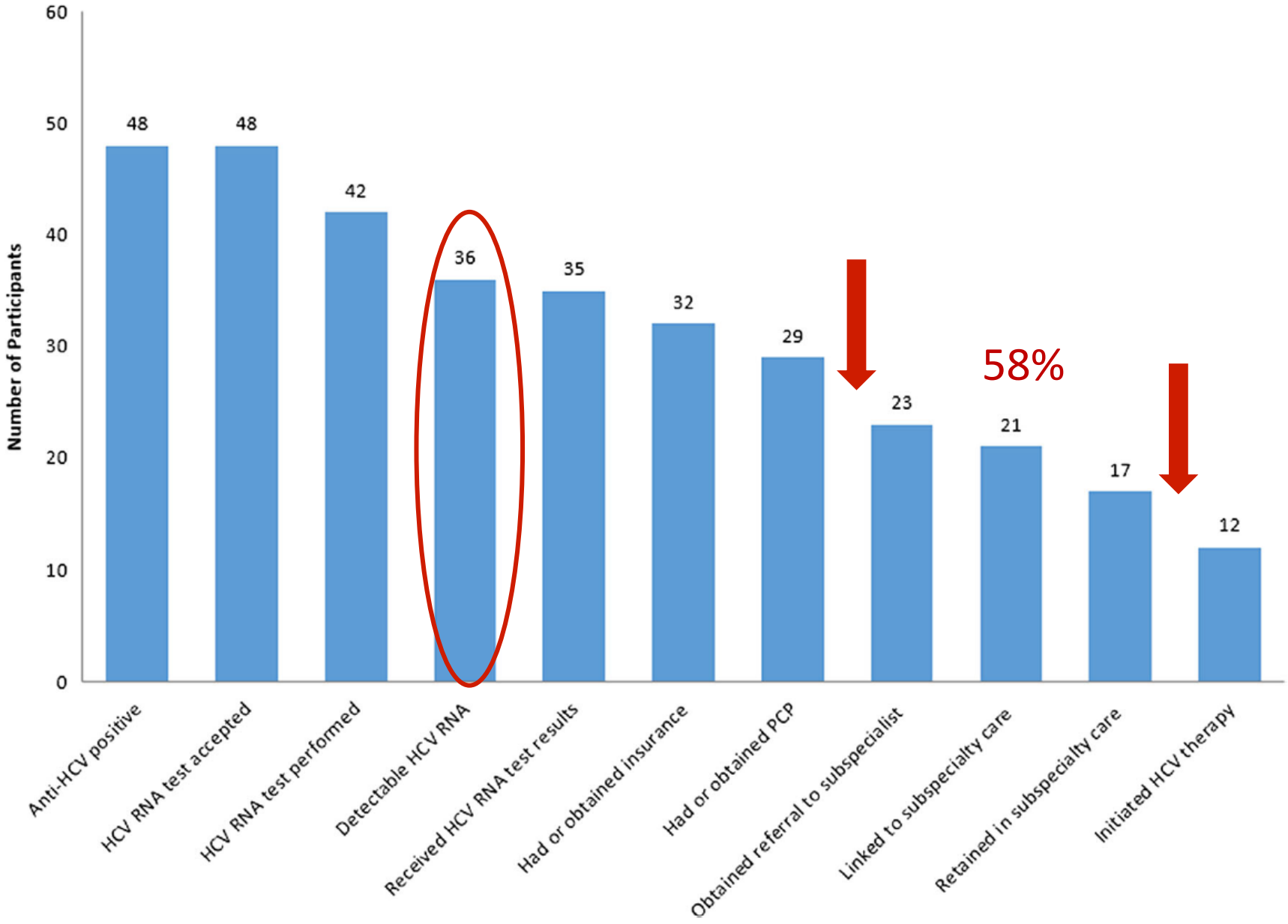

Do One Thing Campaign HCV Testing and Linkage to Care Cascade n=1,301

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Trooskin S et al. JGIM. 2015 Jul;30(7):950-7.

Lessons Learned from *Do One Thing*

The HCV care continuum is complex

Multiple barriers exist

- Referrals
- Obtaining medication for patients/ payer restrictions

Patient navigation is key when patients are tested via outreach

Outreach testing and community engagement is a way to re-engage individuals living with HCV not currently in care

Immediate blood draw for PCR confirmatory testing is necessary

- Local hospital labs can partner to process and test specimens on nights and weekends

These informed our design of C A Difference

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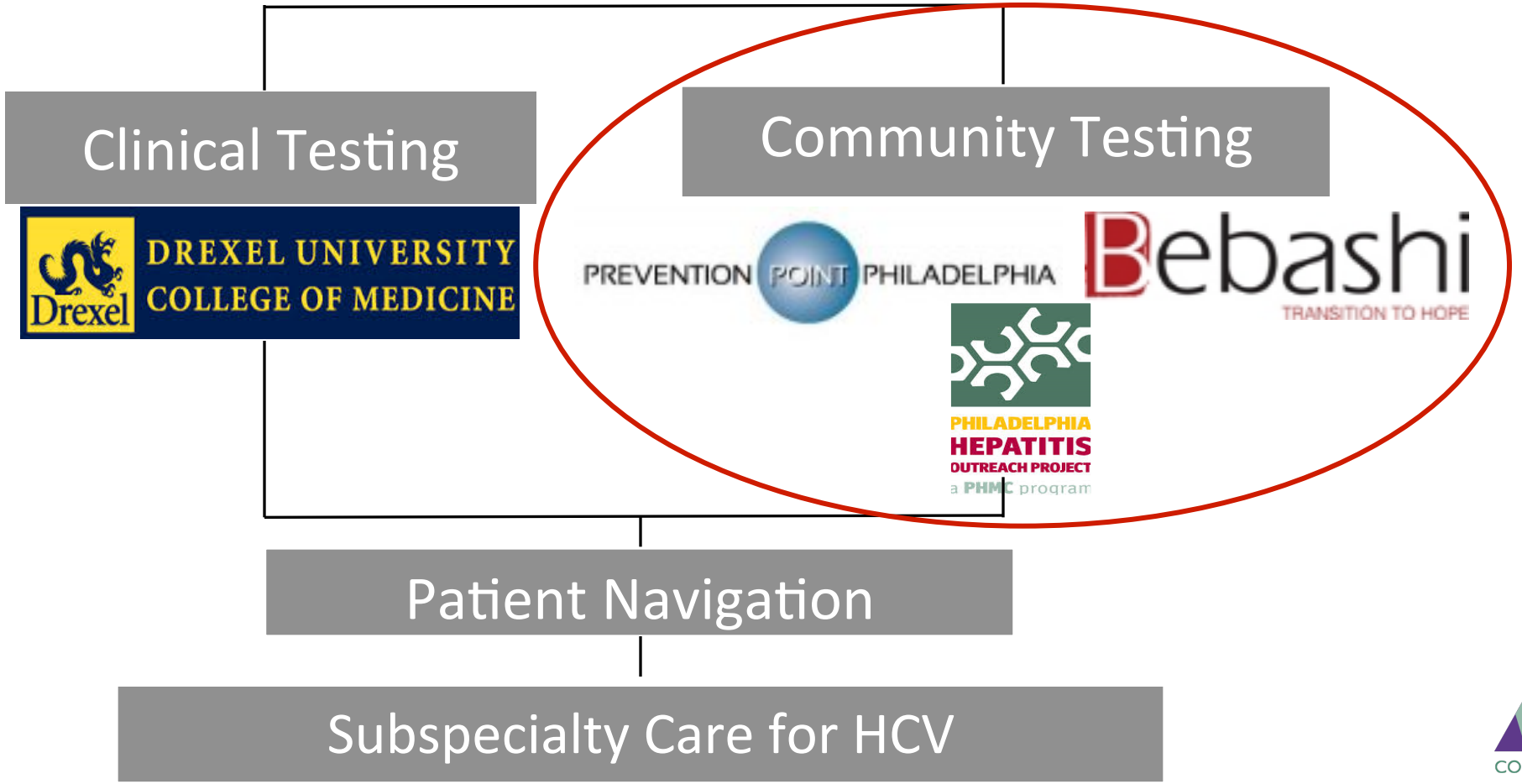
C a Difference

VISUALIZING A FUTURE FREE OF HEPATITIS C



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Integrated Community Based HCV Testing: Lessons Learned

Integrating HCV testing into existing HIV and STI testing programs has advantages

- Sustainability from diversified funding sources
- Reaches individuals at greatest risk
- 1183 tested, anti-HCV seroprevalence 11.5%

Education is required for staff

- Testers should be trained phlebotomists

Communication is key when community testers do not also act as the patient navigator

Maintaining a low patient navigator to patient ratio is critical

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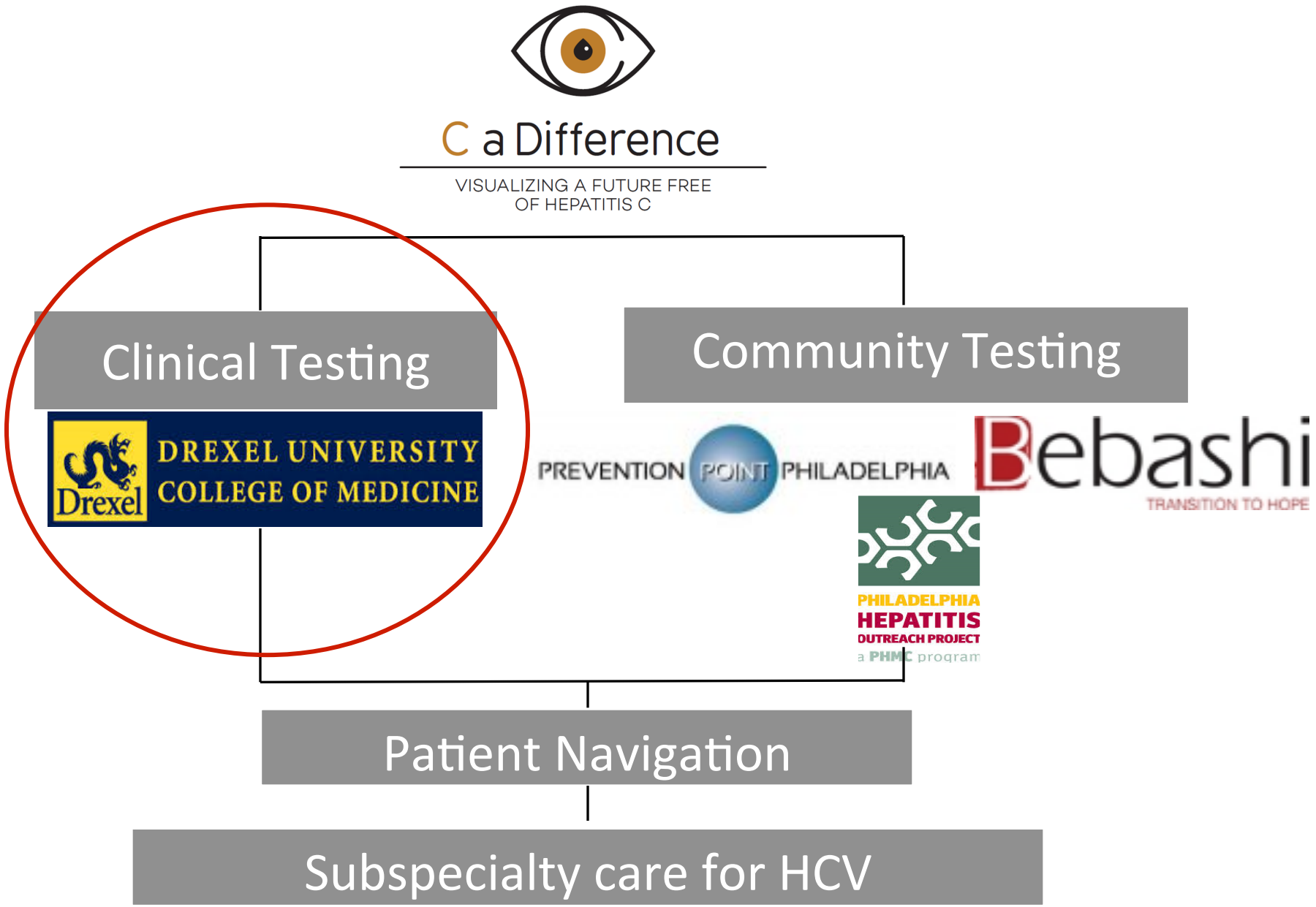

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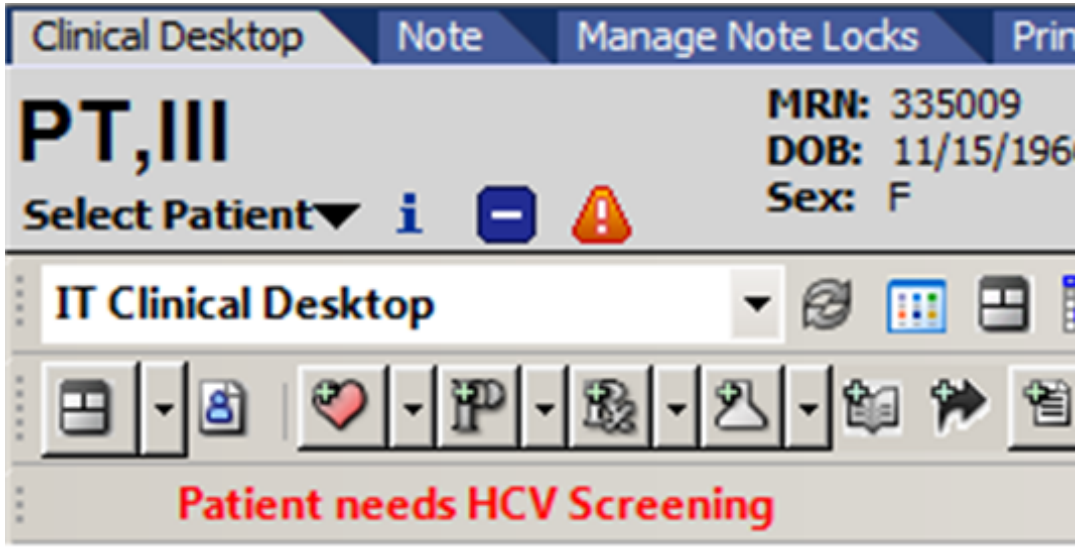

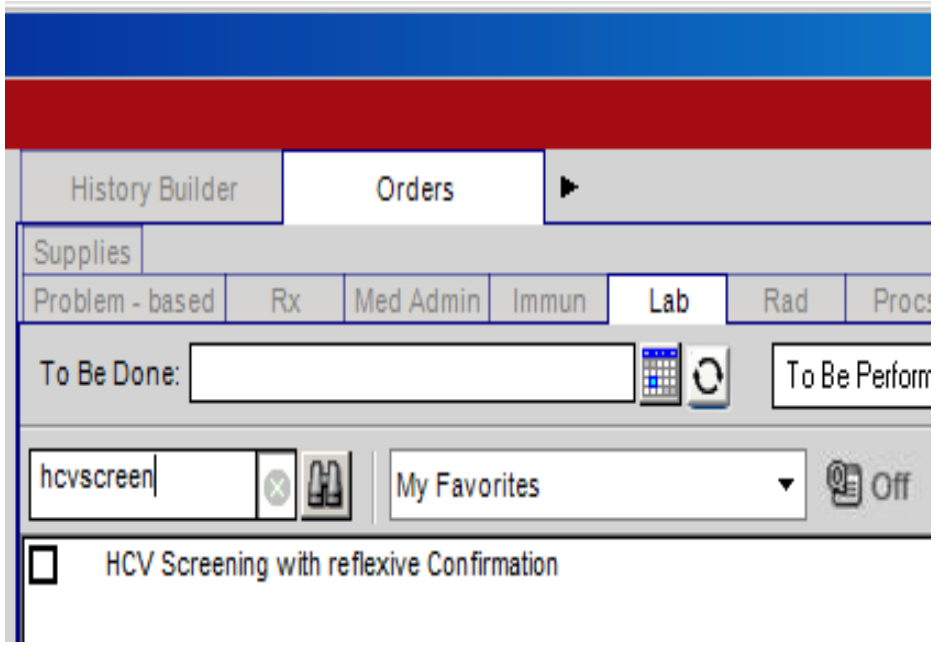

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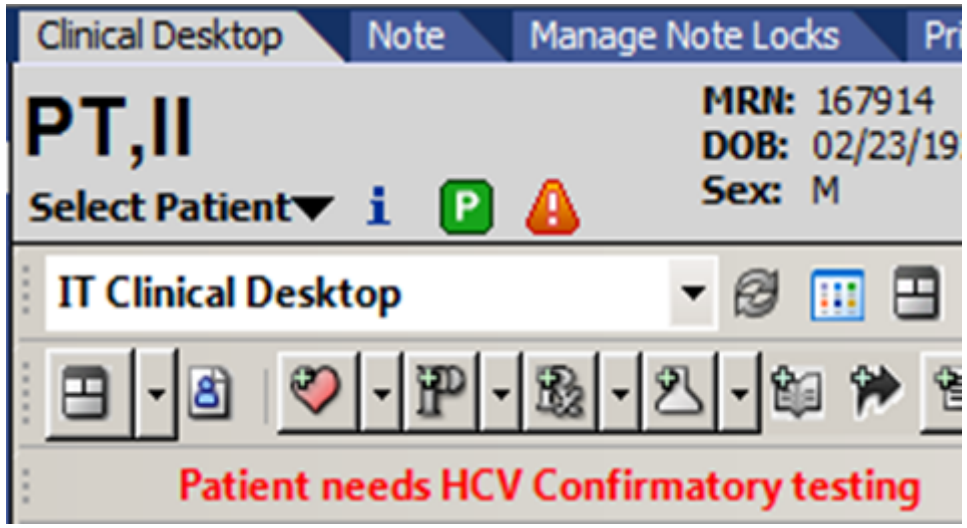

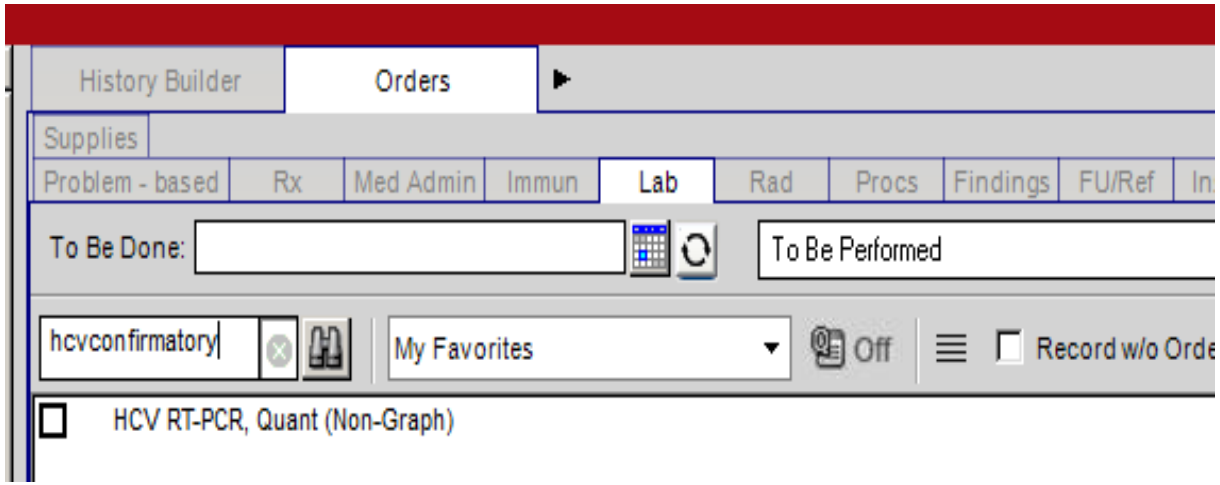

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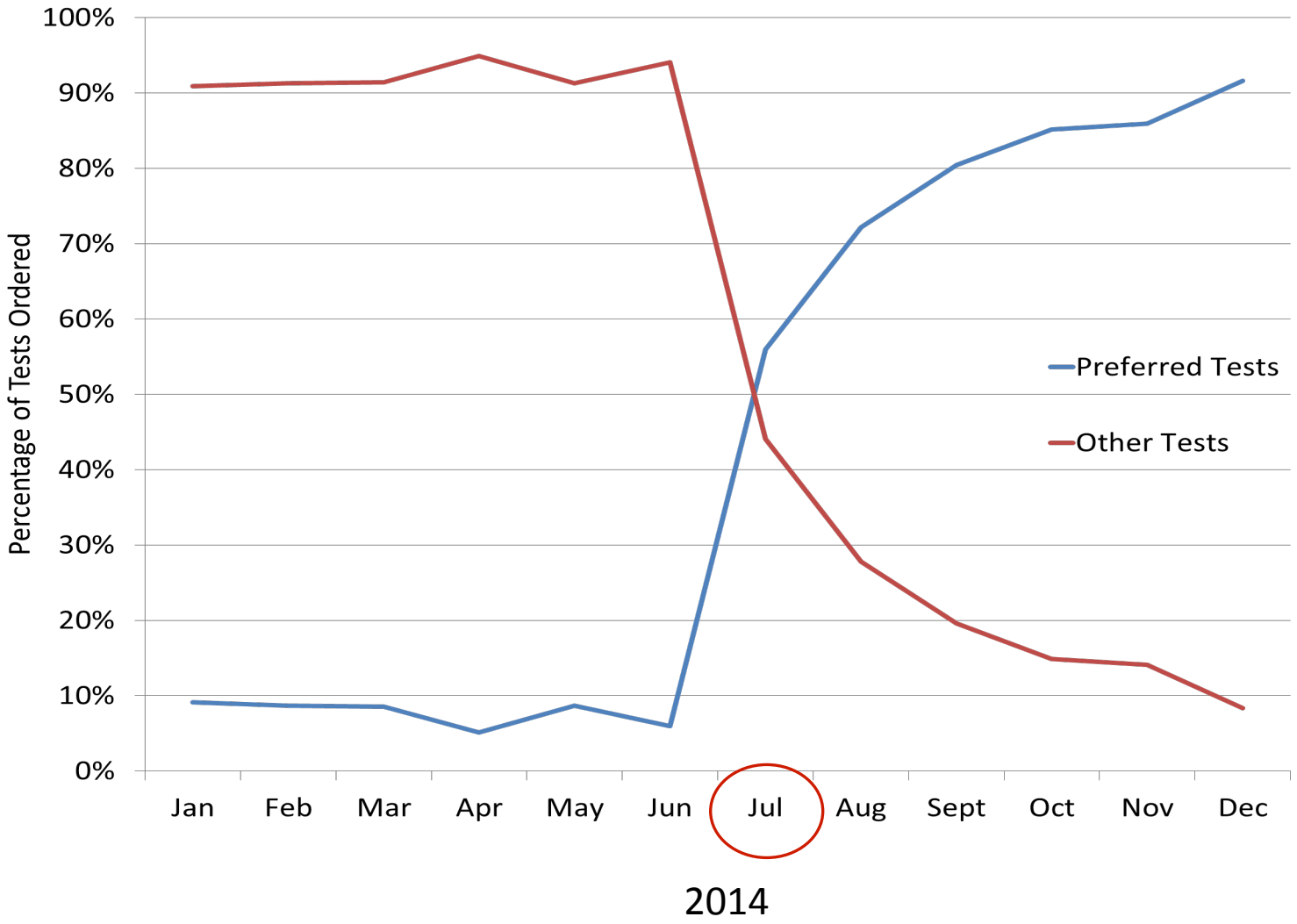
Impact of HCV Testing Prompts on Type of HCV Screening Test Ordered



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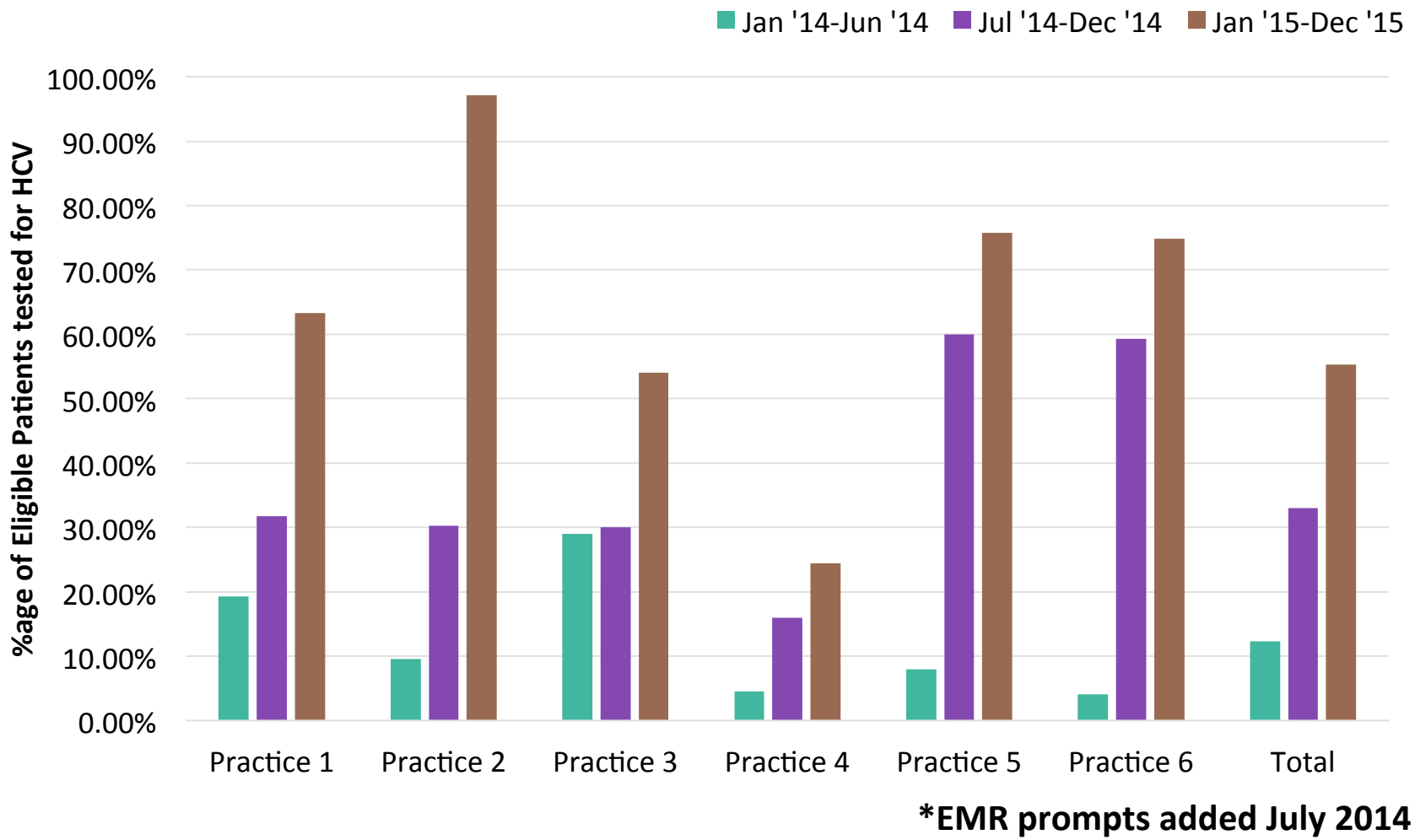
Impact of EMR prompts on Percentage of Eligible Baby Boomers Tested for HCV



***EMR prompts added July 2014**

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Integrating HCV Testing into primary care: Lessons Learned

The prevalence of HCV is high in urban primary care practices
- 6029 patients tested, anti-hcv seroprevalence 8.23%

PCPs are busy! Testing has to be easy and meaningful
- Eliminate outdated or less useful tests from testing menus

Educate the providers and their staff & provide feedback

Get to know your IT staff
- Learn what your EMR can and cannot do
- The more that testing can be automated, the better
- QC must be a part of the process

The role of the navigator often differs in a clinical testing model

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Next steps

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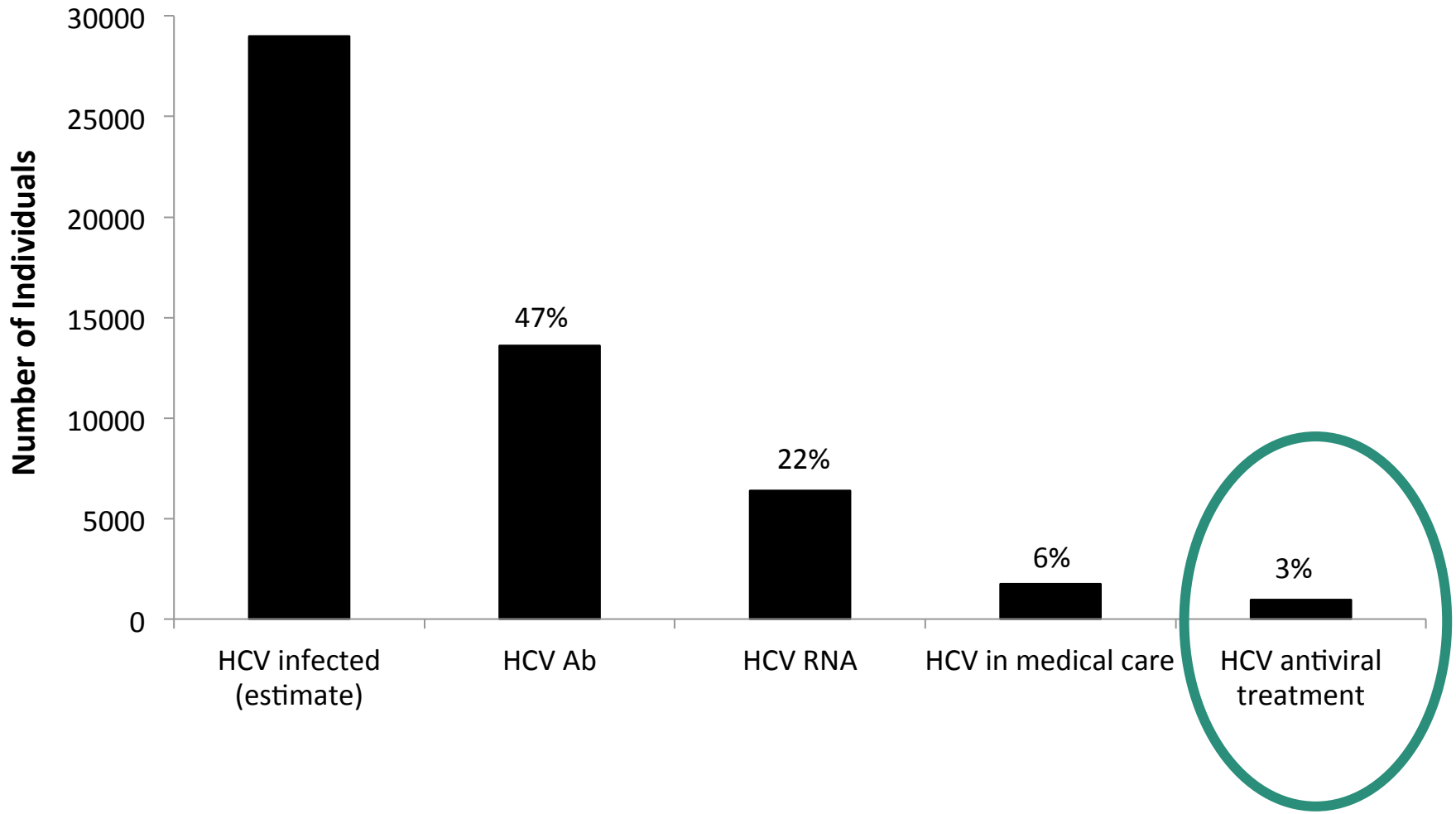
The Jonathan Lax Treatment Center
The Youth Health Empowerment Project
The John Bell Health Center

PHILADELPHIA FIGHT

INSTITUTE FOR COMMUNITY JUSTICE
A Program of Philadelphia FIGHT

<u>COMMUNITY BASED TESTING</u>
Syringe Exchange Program
Drug Treatment Programs
Homeless shelters
Opioid substitution programs
Senior Centers

Philadelphia Cascade of Care 2010-2013



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Viner et al. Hepatology. 2015 Mar;61(3):783-9.

AASLD/IDSA: Who should be treated?

Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.

Rating: Class I, Level A

Current Challenges in HCV Care: Wholesale Acquisition Costs

◦ LED/ SOF) x 8 weeks	$63,000
◦ LED/ SOF x 12 weeks	$94,500
◦ VEL/ SOF x 12 weeks	$74,760
◦ ELB/ GRA x 12 weeks	$54,600
◦ PrOD x 12 weeks	$83,319
◦ SIM/SOF x 12 weeks	$150,360
◦ DAC/ SOF x 12 weeks	$148,000

◦ WAC does not include negotiated discounts and rebates

◦

Arlene Price, Janssen (Personal Communication)
http://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug

Hagan LM et al. Hepatology 60, 37-45, July 2014.
www.fairpricingcoalition.org

Current Challenges in HCV Care

Restrictive criteria for drug approval for many payers

- Sobriety requirement
- Prescriber requirement
- Disease severity requirement
- HIV may not be a mitigating factor

Arduous prior authorization process for providers

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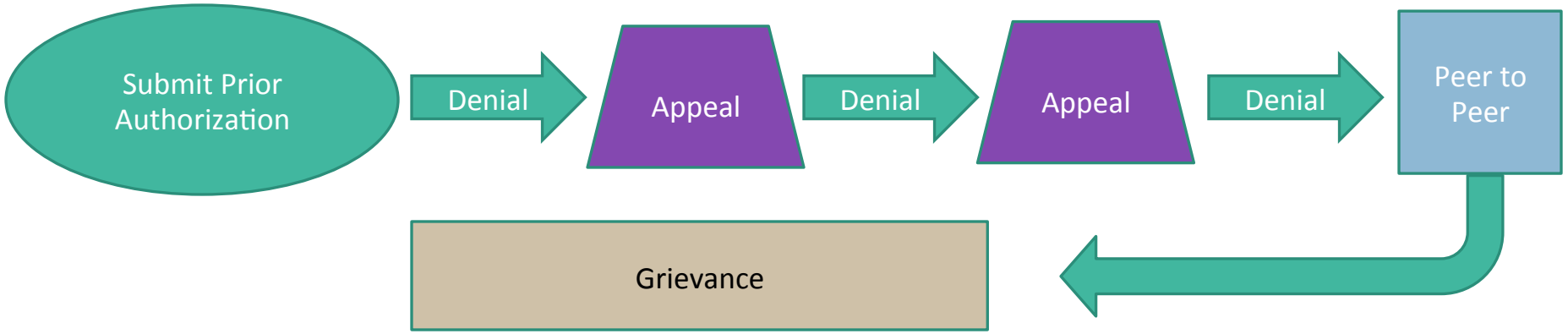
Barua S et al., *Ann Intern Med.* 2015;163(3):215-223
Canary LA et al., *Ann Intern Med.* 2015;163(3):226-228

Current Challenges in HCV Care



Approximately 8 hrs of staff time per patient

1 to 4 months to go through the process

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When insurance will not cover drugs what are the options?

Wait for new drugs to be approved

- No guarantee that those will be covered/ patient will qualify

Wait until patient qualifies

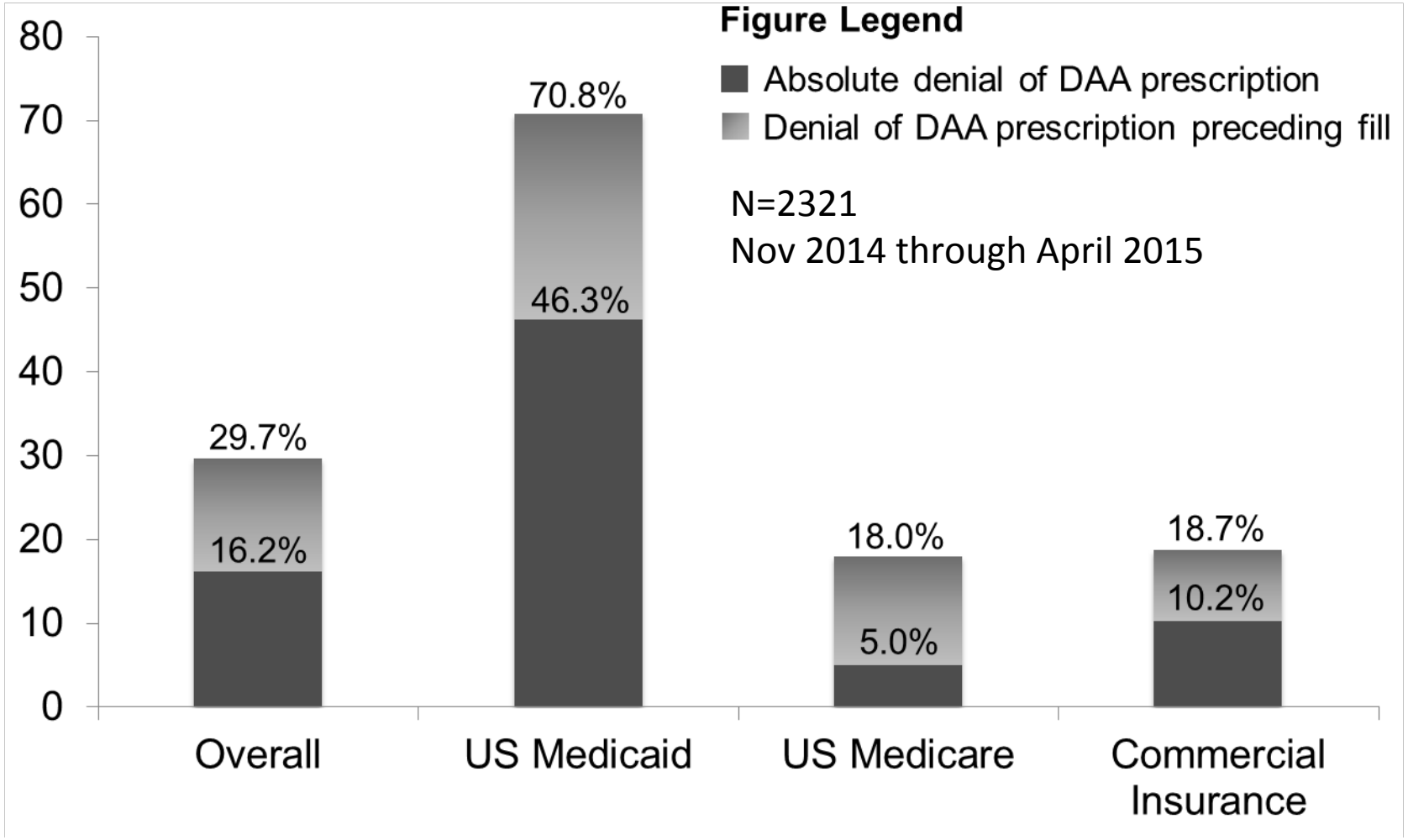
- Sobriety
- Worsening fibrosis

Take legal action

Apply to patient assistance programs to obtain free drug

- There is only one company that does this currently
- Financial information to qualify
- Proof that patient does not qualify for insurance
- Challenging to navigate

Incidence of Absolute Denial of DAA Therapy, By Insurance



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LoRe et al. Clin Gastro and Hep. 2016; 14 (7) 1035-1043.

Advocacy in Philadelphia

Philadelphia-area collective dedicated to improving the continuum of hepatitis C prevention, care, and support services in Philadelphia

HepCAP
HEPATITIS C ALLIES OF PHILADELPHIA

The HEALTH FEDERATION of Philadelphia

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St. Christopher's Hospital for Children

gsk GlaxoSmithKline

MERCK

OraSure Technologies, Inc.

The HEALTH FEDERATION of Philadelphia

AMERICAN LIVER FOUNDATION
Your Liver. Your Life.

Jefferson University Hospitals

project SAFE

OFFICE OF HIV PLANNING PHILADELPHIA
WWW.HIVPHILLY.ORG

PREVENTION POINT PHILADELPHIA

Penn Medicine

Genentech

Bebashi
Transition to Hope

CONGRESO
Strengthening Latino Communities

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VERTEX

We are the Drug Policy Alliance.

mazzoni center
LGBT HEALTH & WELL-BEING

PHMC
a nonprofit institute for public health

HEPCAP
HEPATITIS C ALLIES OF PHILADELPHIA

USciences
University of the Sciences

abbvie

PDPH
PHILADELPHIA
Department of Public Health

Hep B United
PHILADELPHIA

Bristol-Myers Squibb

Temple University Hospital
Temple University Health System

KENSINGTON HOSPITAL

Einstein
HEALTHCARE NETWORK

ActionAIDS
FRIENDS FOR LIFE

BURMANS

HepTREC

GILEAD

GPHA Greater Philadelphia Health Action, Inc.

THE CONSORTIUM

MANNA

GAUDENZIA

GALAEI

Drexel DREXEL UNIVERSITY COLLEGE OF MEDICINE

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

The Children's Hospital of Philadelphia®

HepCAP

Bimonthly public meetings

- Scientific updates
- Local Epidemiology
- Access to care: challenges and best practices
- Advocacy

Primary Care Provider Education

Coalition and Relationship building

- May 1 2015 State Wide HCV Summit
- State Medicaid, P&T

Changes to State Medicaid Rx Restrictions

2014

F3/F4

No exception for HIV patients

No drugs or alcohol for 6 months

Specialist Physician

2015/ 2016

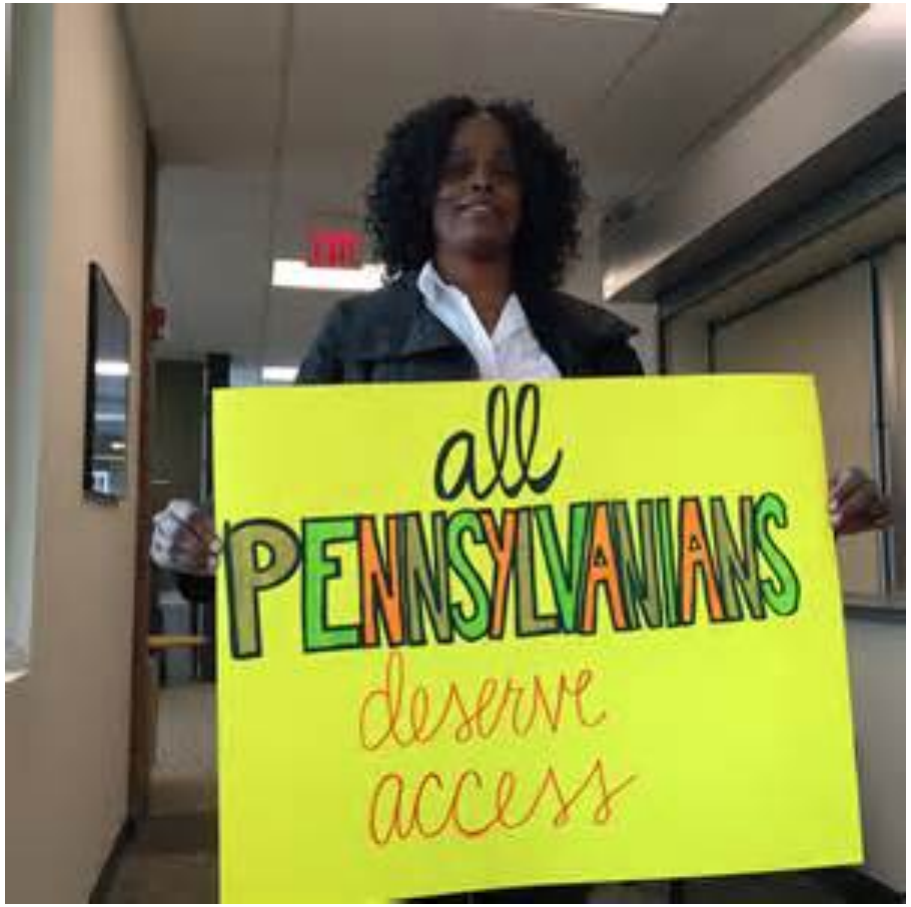
F2 for HCV Mono infected patients

F0 for HIV/HCV Coinfection or anyone with extrahepatic manifestation

No sobriety requirement

Experienced provider


PA
TREATED
I
a
CURE
TESTED
TREATED
Deliver us
from EVIL
HCV
treatment
restrictions


all
PENNSYLVANIANS
deserve
access

You can help improve the cascade!

Locally:

Come to the next HepCAP meeting

- Wednesday December 7th 2016 @ 5:30pm, Department of Public Health 500 S Broad Street

Nationally:

www.NVHR.org

NVHR
National Viral Hepatitis Roundtable

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Home › Hepatitis C Baby Boomer Homepage

Welcome to the NVHR Hepatitis C Resources Page

SHARE

NVHR's program aims to increase the number of people born 1945-1965 (baby boomers) and other communities at risk tested for hepatitis C. This page has information for providers, patients, and organizations and highlights the work of our community partners.

Implementing EMR Prompts

Allscripts EMR

Allscripts™

Epic EMR Prompts

PROGRAM QUICKLINKS

- **Hepatitis C Baby Boomer Homepage**
- Implementing Electronic Medical Record Prompts
- AllScripts EMR
- Epic EMR Prompts
- Provider Training
- Research Articles and Presentations
- Patient Resources
- NVHR Fact Sheets
- Testing Day Events and

Thank you!

Do One Thing Team
- Amy Nunn ScD, Brown University

C a Difference Team
- Lora Magaldi, MA C a Difference Project Coordinator
- Carla Coleman, MBA Linkage Coordinator
- Ta-Wanda Preston, Outreach specialist
- Students, volunteers, patients

Alex Shirreffs MPH, Government Co-Chair of HepCAP
- HepCAP members

NVHR
- Ryan Clary
- Tina Broder
- Emily Stets

Gilead FOCUS and Prevent Cancer Foundation

PHILADELPHIA FIGHT COMMUNITY HEALTH CENTERS