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Improving Access & Linkage to Care in Underserved Populations & Baby Boomers

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Clinical Directors Network, Inc. (CDN)
Webcast Series
December 13, 2017

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Disclosures

- Dr. Miller receives grant funding from Gilead Sciences

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Objectives

1. Describe the burden of hepatitis C in the United States and recognize that it is common, deadly and curable

2. Identify barriers to HCV access and linkage to care, focusing on underserved populations and baby boomers

3. Outline solutions to improve access to care, highlighting patient navigation and novel models of care

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Polling Question

Who's participating?

The following best describes my practice/experience:

1. I have very few patients with HCV but want to learn
2. I screen for HCV but am not involved in treatment
3. I have experience treating HCV
4. I am non-clinical but work with clients with HCV infection

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Why is hepatitis C important?

1. Hepatitis C is common
2. Hepatitis C is deadly
3. Hepatitis C is curable

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HCV Prevalence Worldwide

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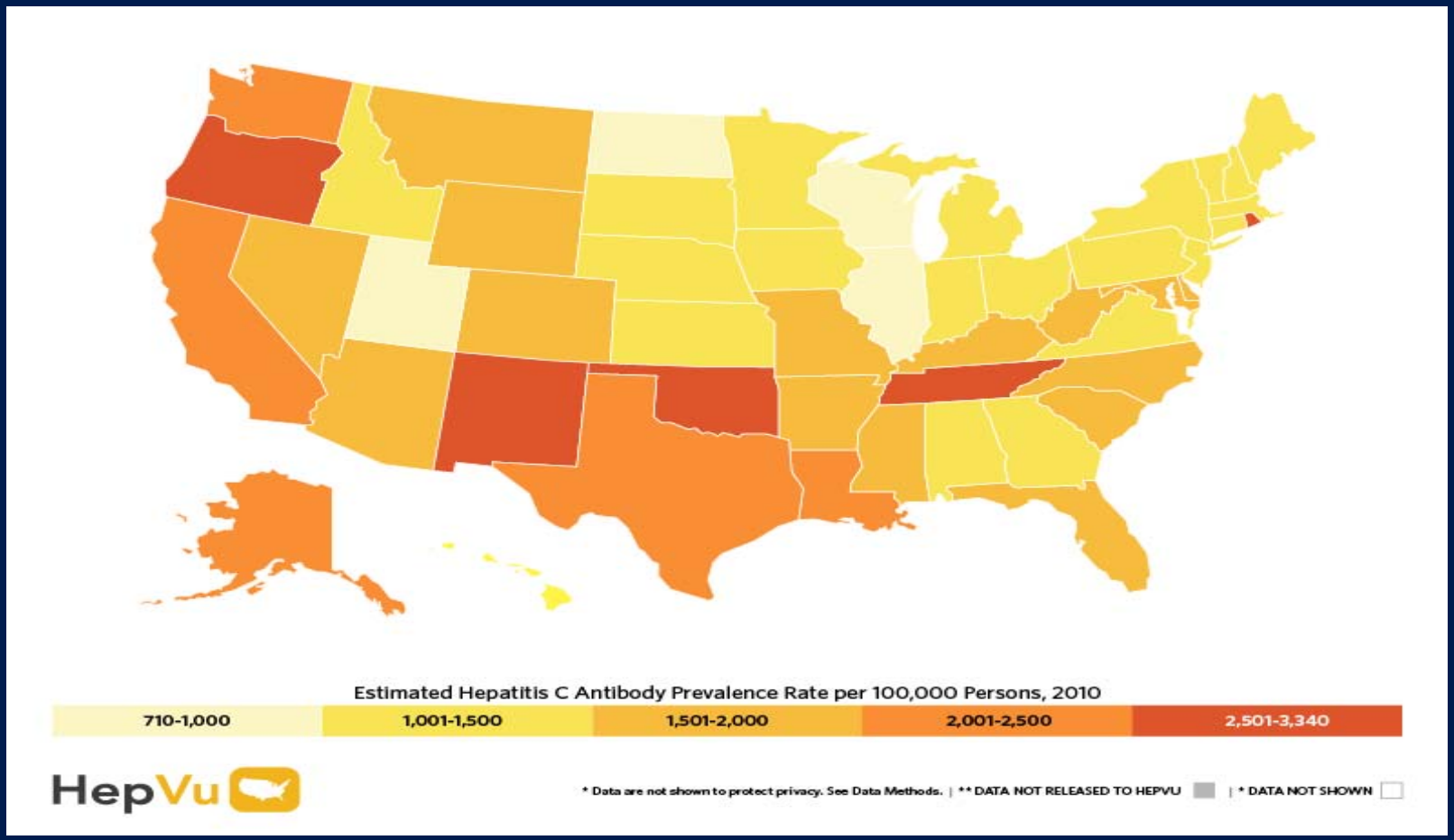
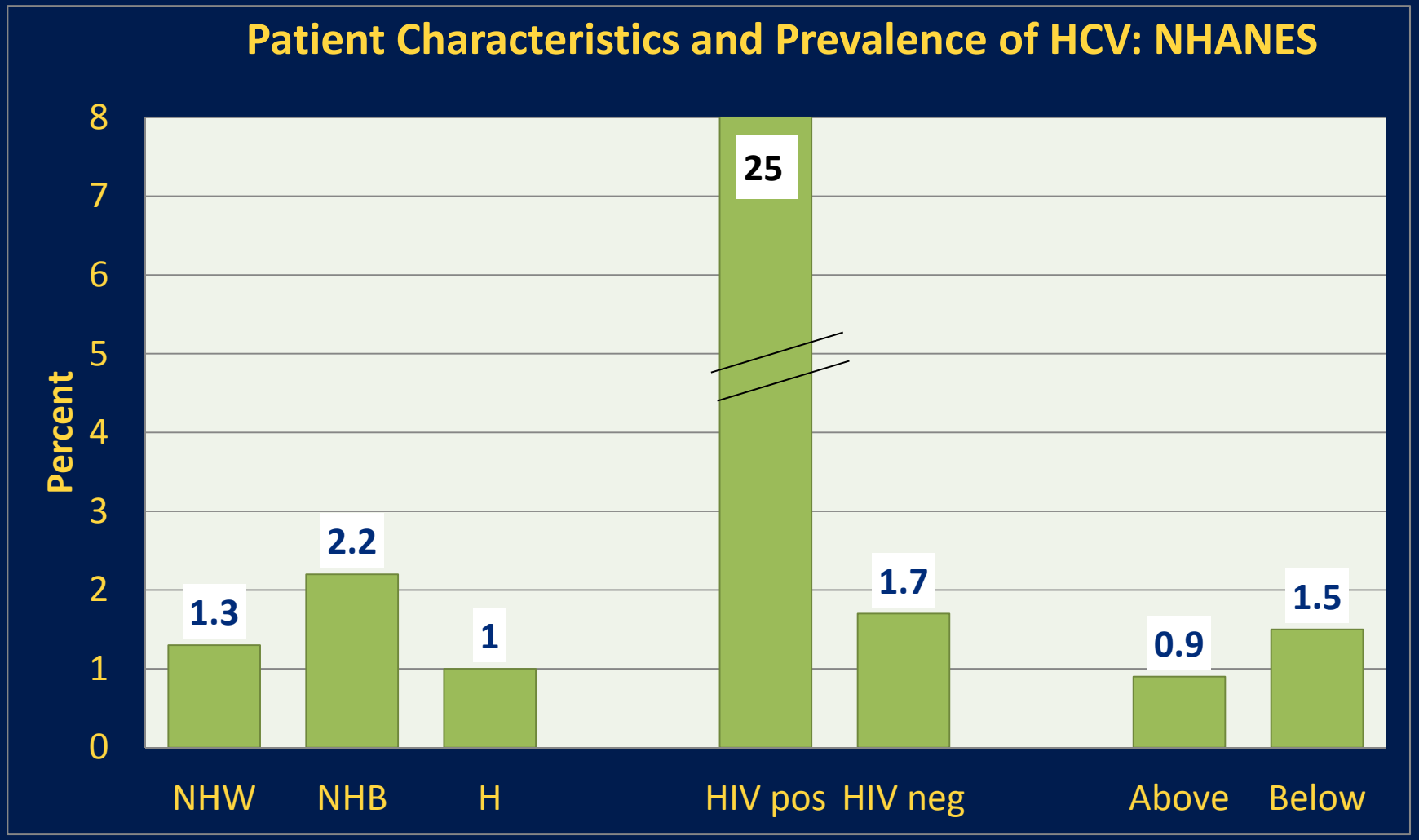
HCV Prevalence in the US



www.hepvu.org

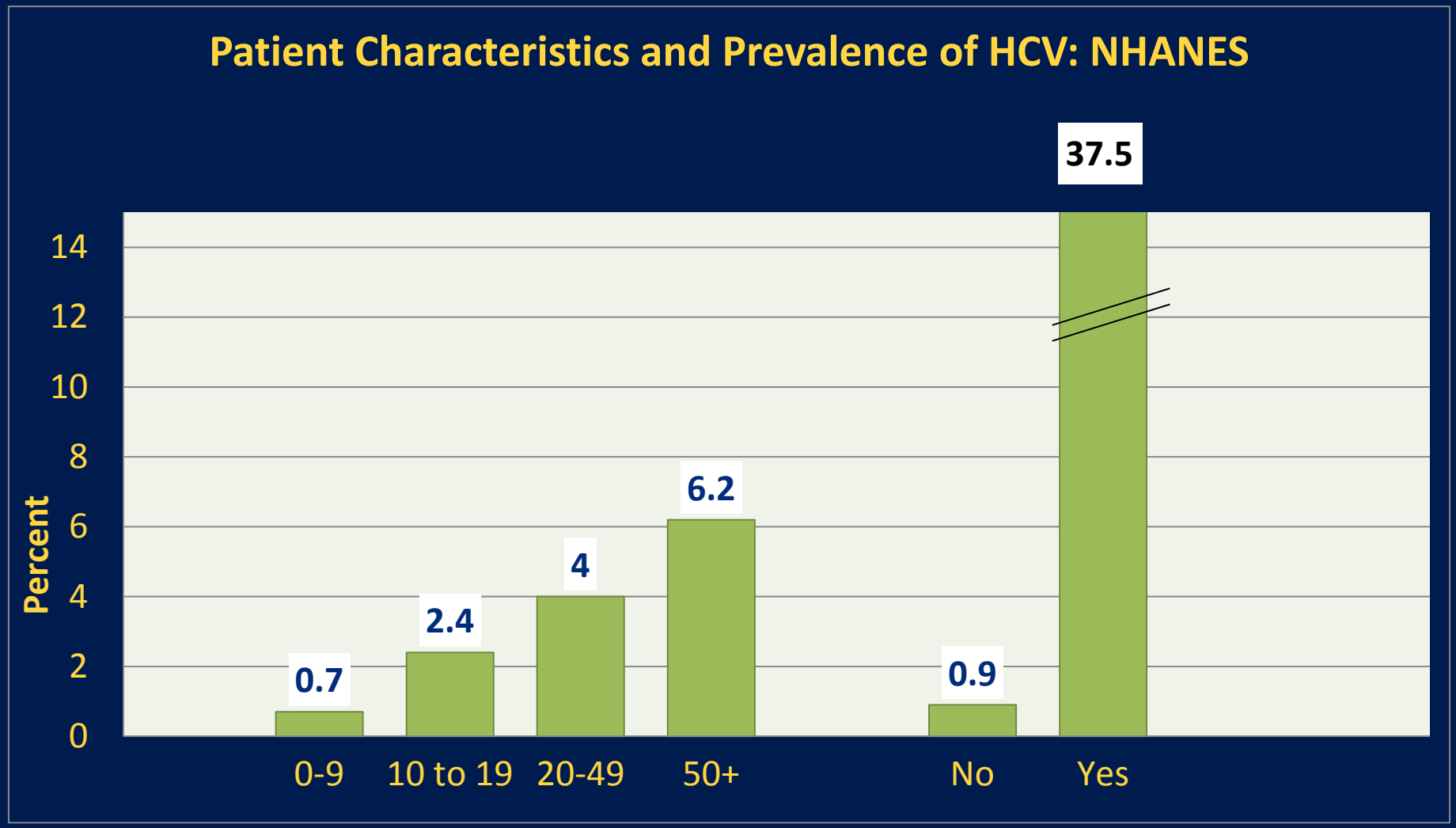
HCV Disproportionately Affects Subgroups



NHW: Non-Hispanic White
NHB: Non-Hispanic Black
H: Hispanic

Ditah et al. J Hepatol. 2014;60:691-8.

HCV Disproportionately Affects Subgroups



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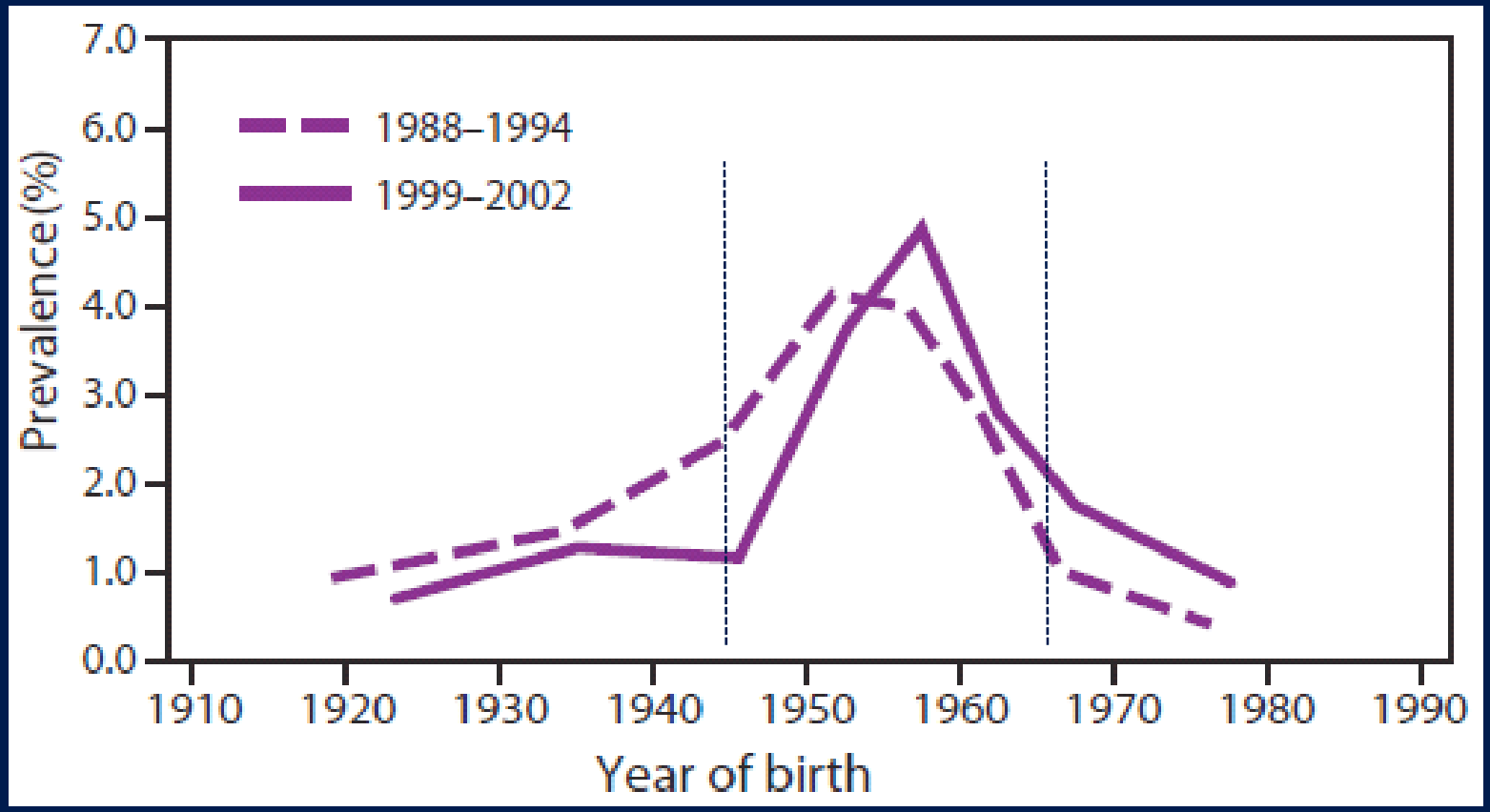
HCV Disproportionately Affects Baby Boomers



Smith BD, et al. *MMWR Recomm Rep*. 2012;61(RR-4):1-32.

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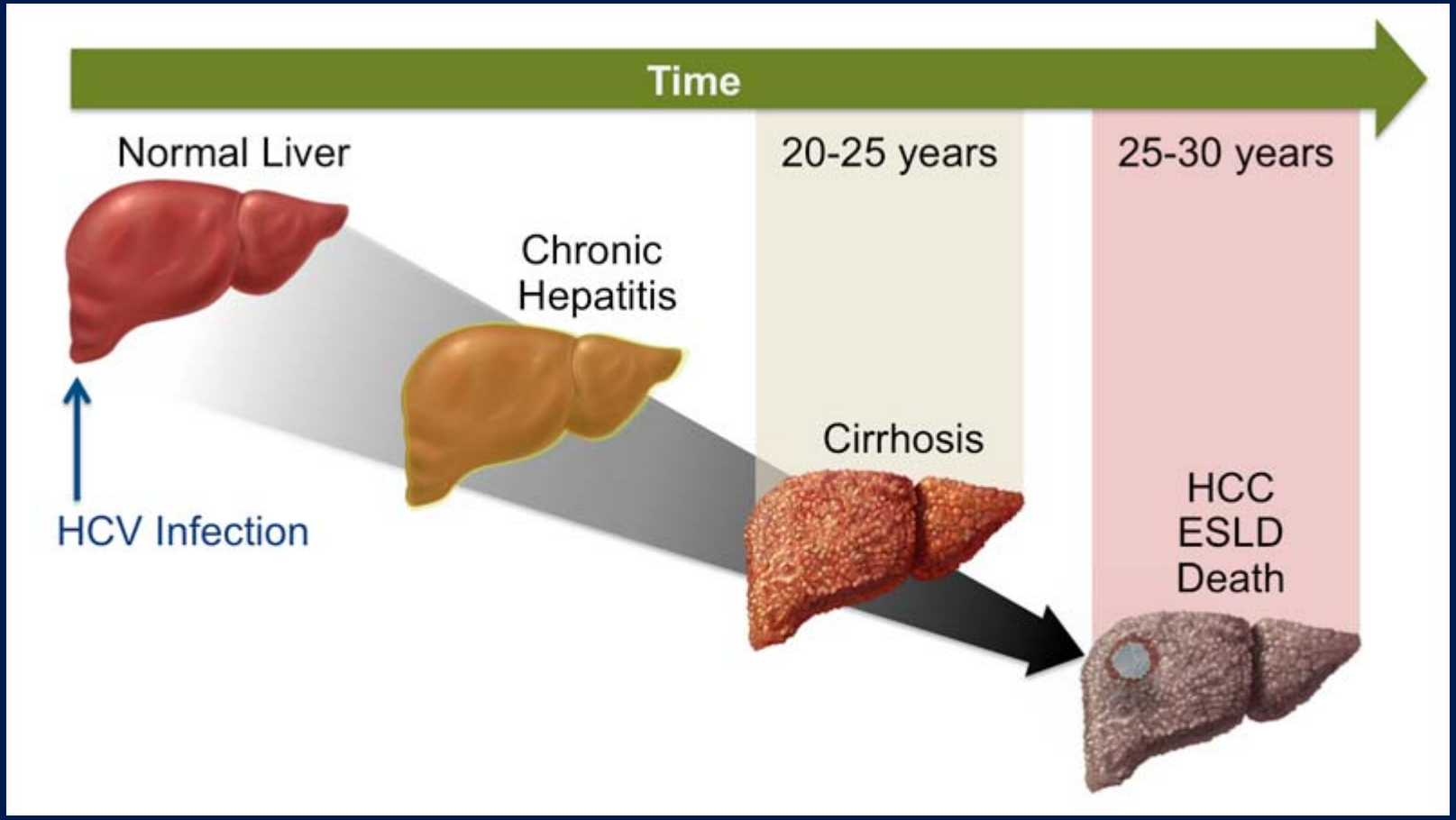
Hepatitis C is Deadly



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Hepatitis C is Deadly

www.hepvu.org

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Hepatitis C kills 20K Americans per year More than HIV, TB and 58 other infections COMBINED

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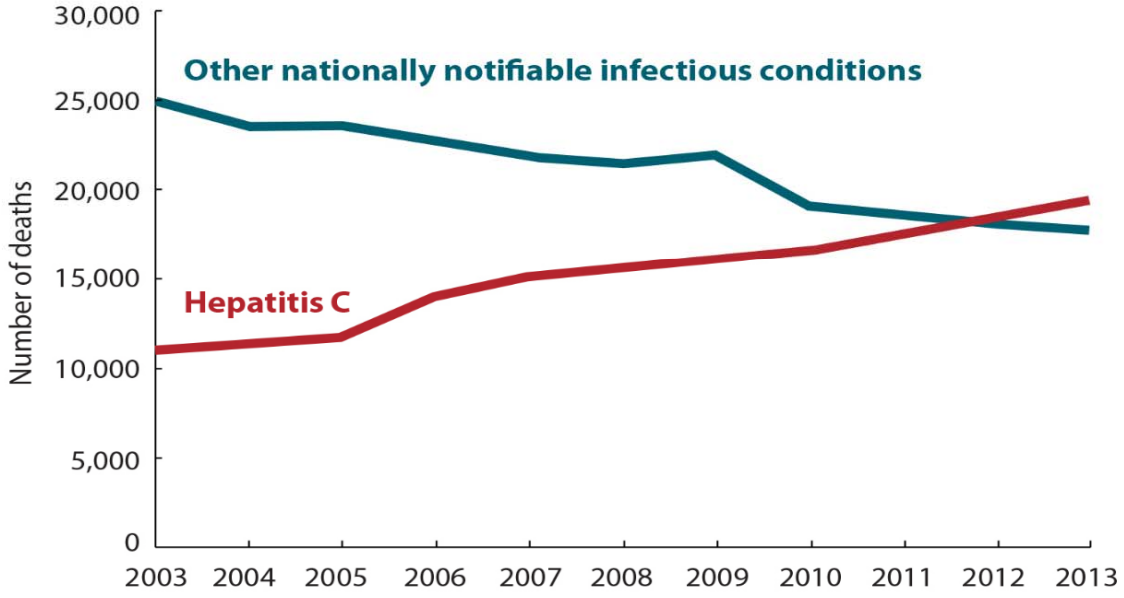
Annual number of hepatitis C-related deaths vs. other nationally notifiable infectious conditions in the US, 2003-2013



Source: Centers for Disease Control and Prevention

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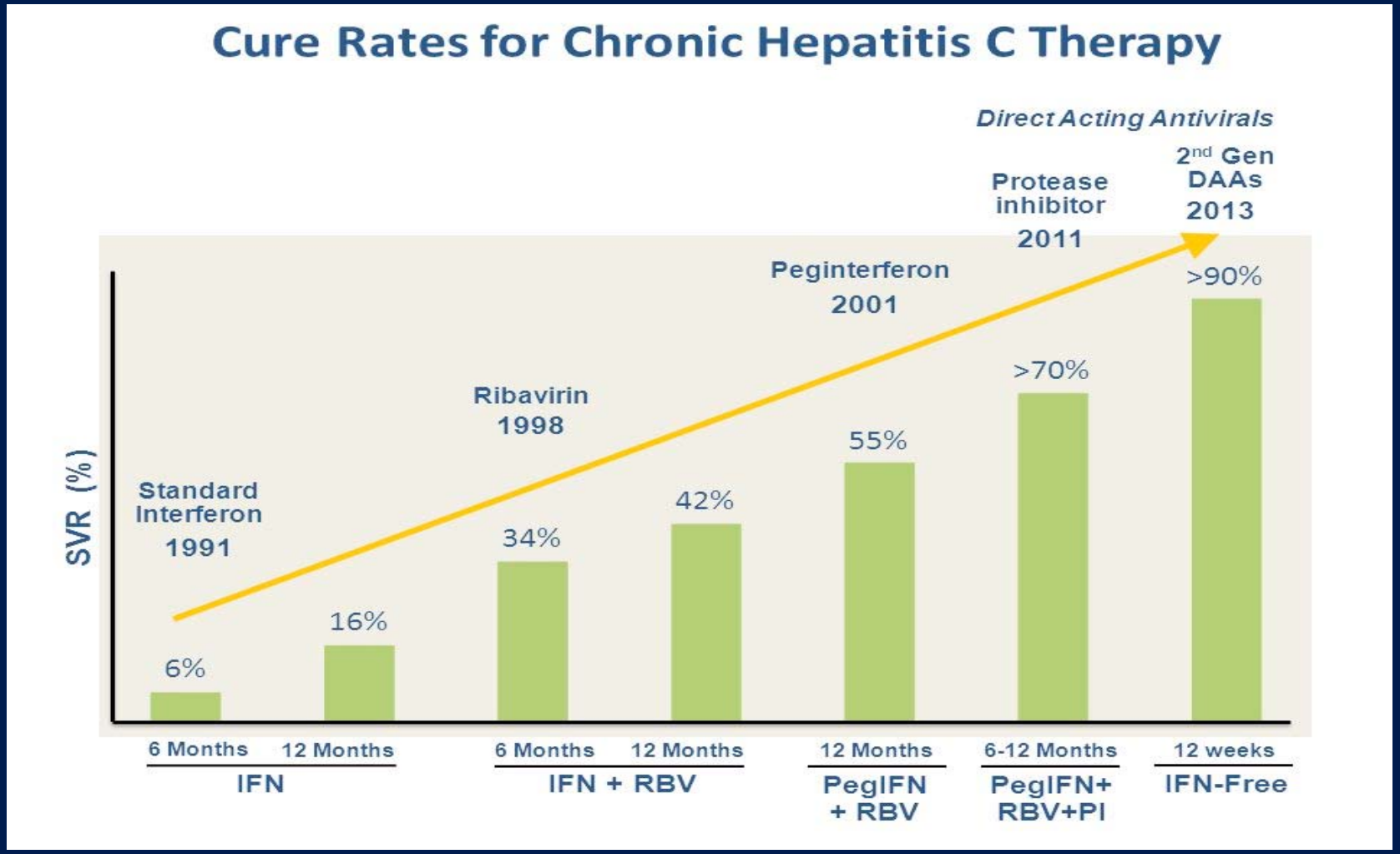
Hepatitis C is Curable!



Nelson D. Hepatitis C virus, from discovery to cure. 2016

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HCV Screening

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Polling Question

What are your HCV screening practices?

1. I don't screen for HCV

2. I am aware of the screening guidelines, and screen when I remember

3. I work in a setting with screening prompts, so I screen the majority of patients

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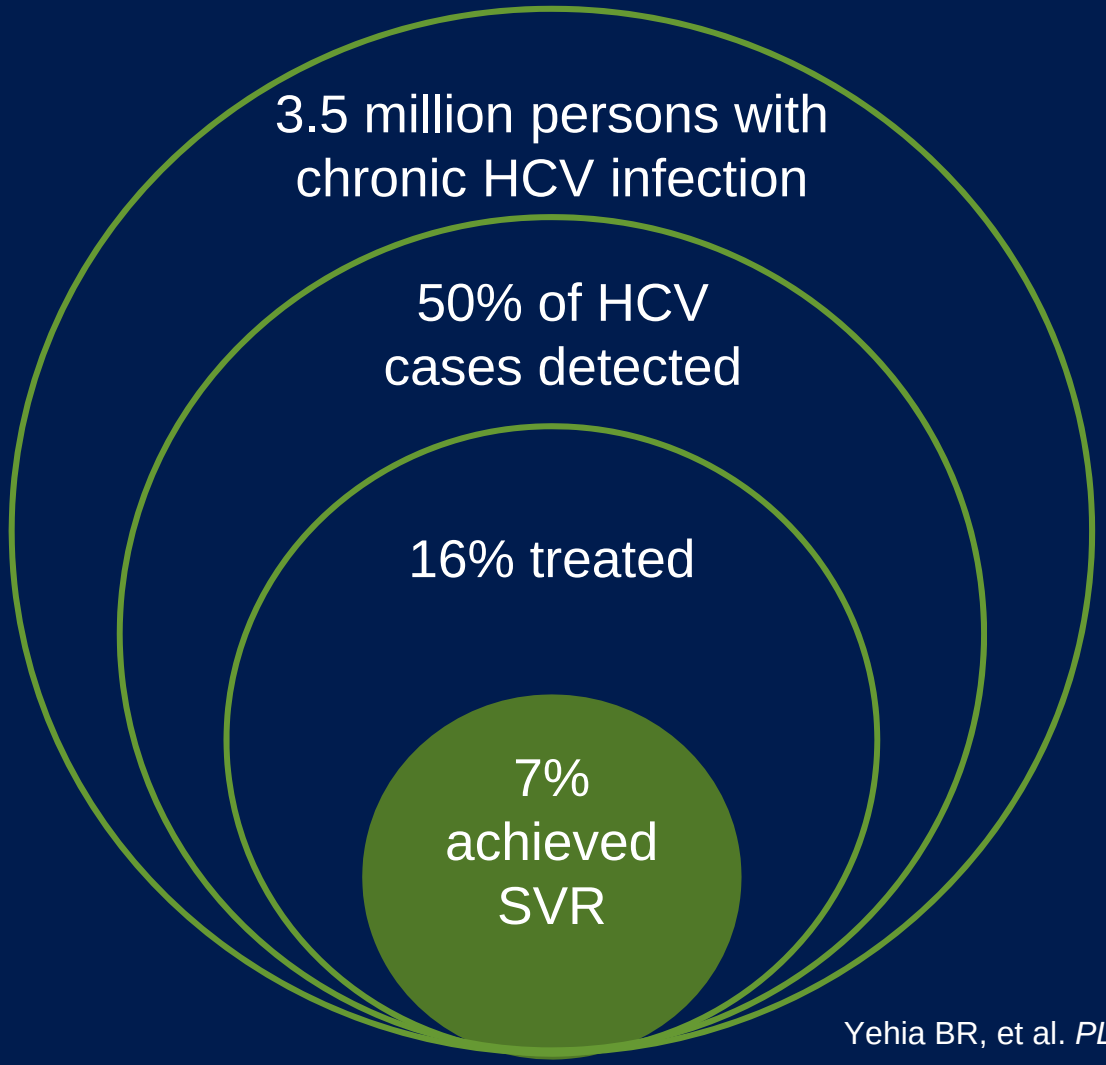
HCV Care Cascade



Yehia BR, et al. *PLoS One*. 2014;9:e101554.

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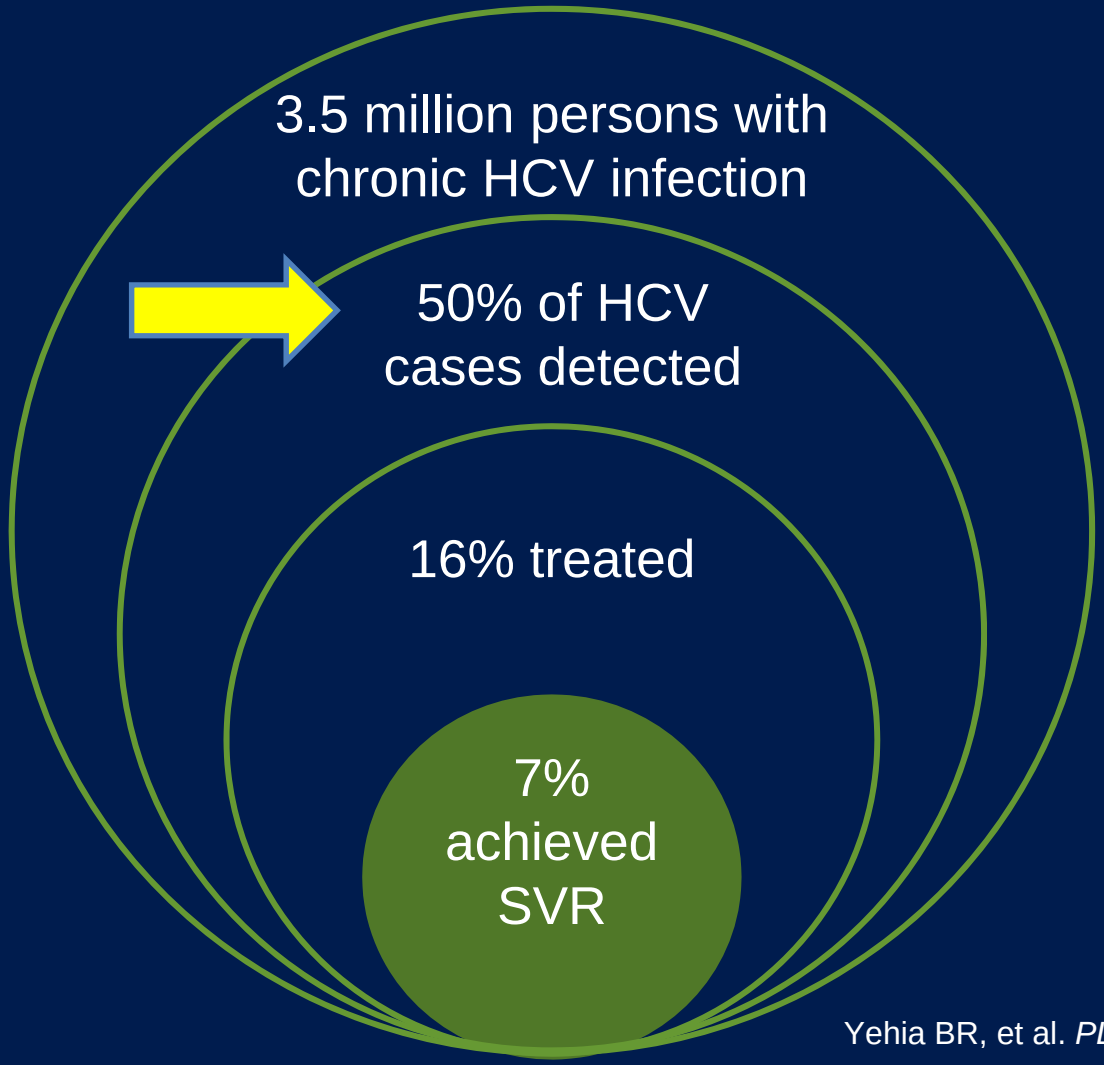

Yehia BR, et al. *PLoS One*. 2014;9:e101554.

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HCV Screening: Then and Now

- Pre-2012: CDC recommends risk-based HCV screening
- 2012: CDC adds recommendation for HCV screening for all persons born between 1945-1965
  - 50% of those with hep C unaware of diagnosis
  - 75% hep C patients born 1945-1965
  - Screening + treatment=cost effective

KNOW MORE HEPATITIS™

Rein DB et. Al. Ann Intern Med. 2012;156(4):263-270

Annals of Internal Medicine | CLINICAL GUIDELINE

Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

Annals of Internal Medicine

U.S. Preventive Services TASK FORCE
www.USPreventiveServicesTaskForce.org

SCREENING FOR HEPATITIS C VIRUS INFECTION IN ADULTS
CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Persons at high risk for infection and adults born between 1945 and 1965
Recommendation	Screen for hepatitis C virus (HCV) infection. Grade: B

Moyer, VA et. al. Ann Intern Med 2013; 159: 349-357

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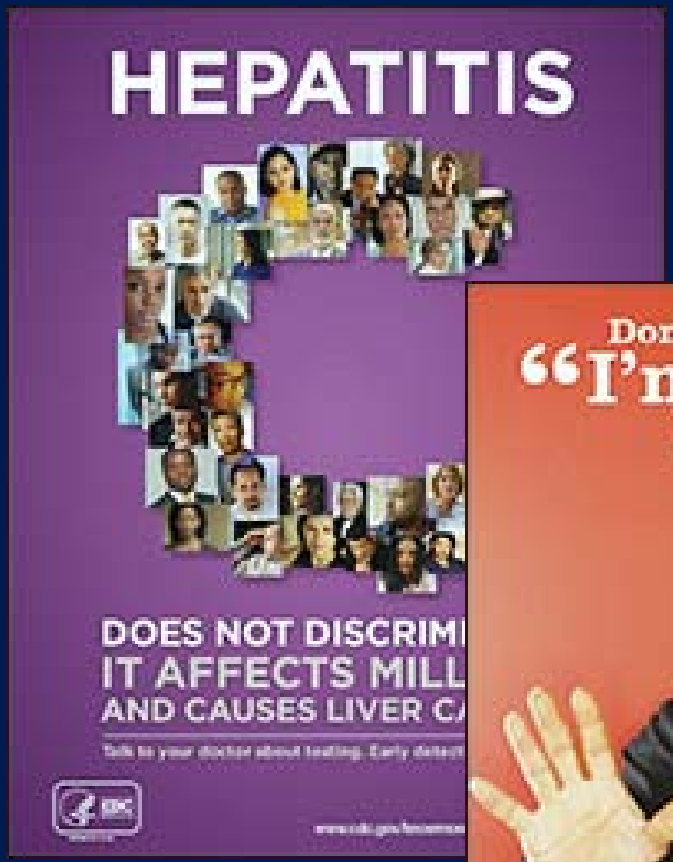
Who should be tested?

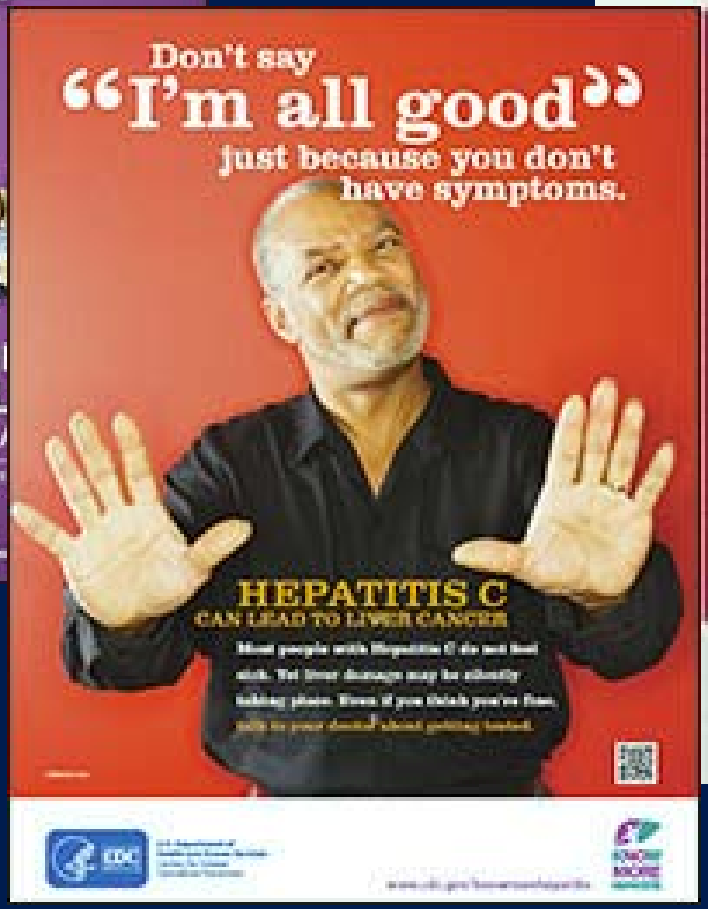
Persons born between 1945 and 1965

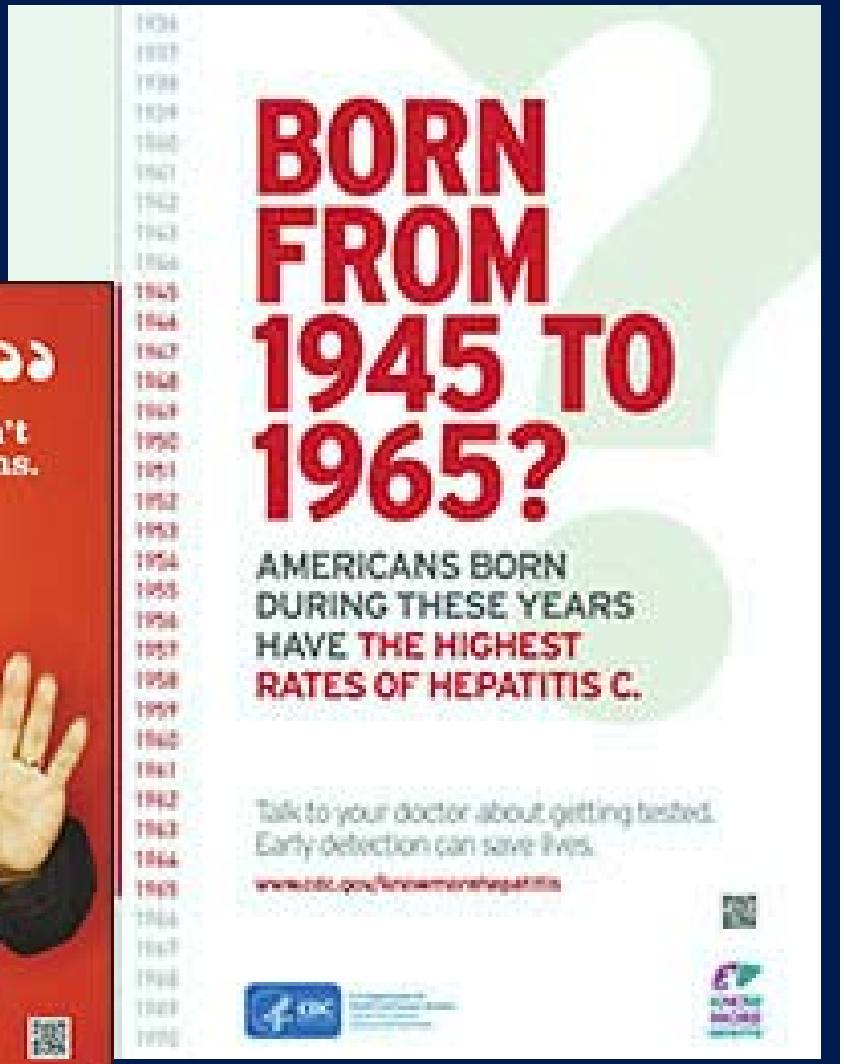
-PLUS-

- Current or past IVDU
- Persons with HIV
- Persons on hemodialysis
- Persons with unexplained high AST/ALT
- Recipients of transfusions/transplants before 1992
- Children born to HCV-infected mothers
- Health care workers after needle stick or mucosal exposure
- Sexual partners of HCV-infected persons

Ghany et al. Hepatology 2009;49:1335-1374
Centers for Disease Control and Prevention. MMWR 2012;61(No. RR-4):2-31.







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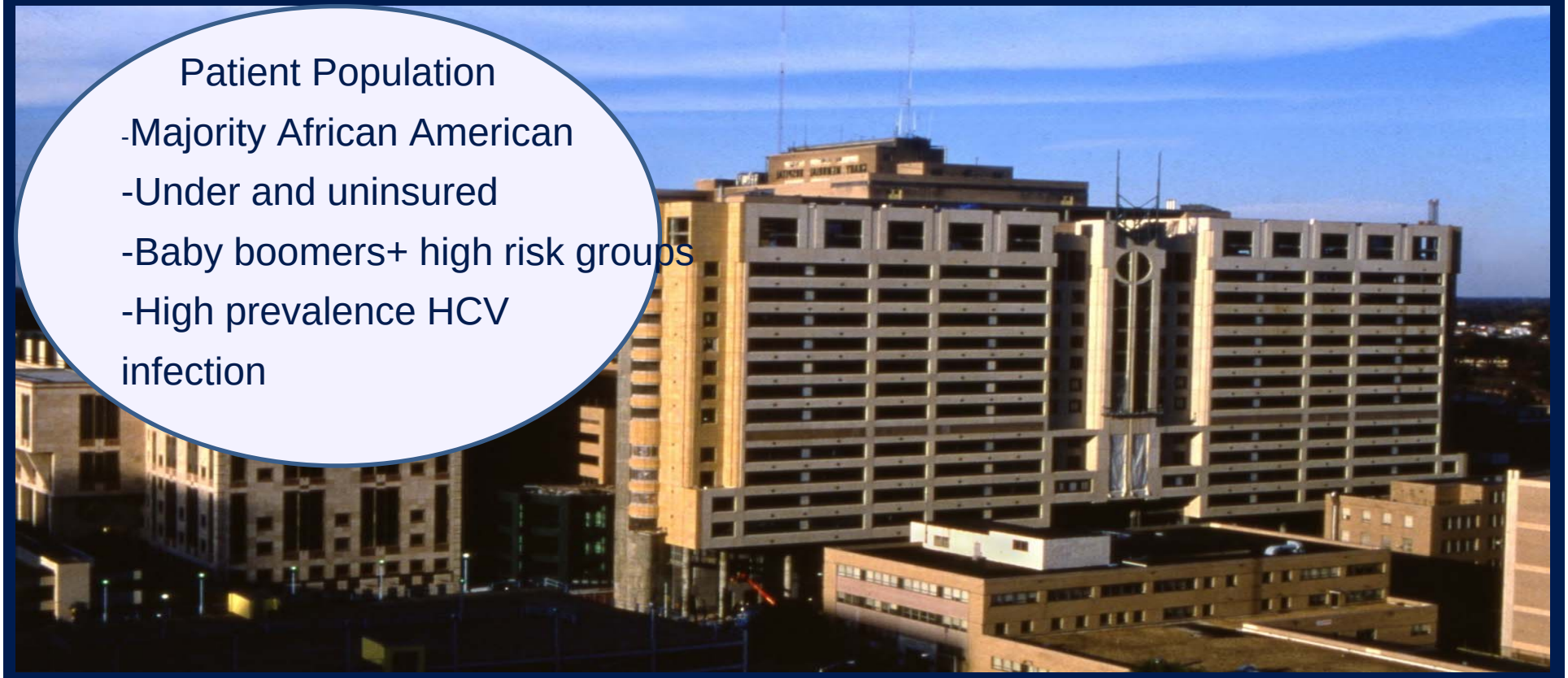
Why Screen at Grady?



Patient Population

-Majority African American

-Under and uninsured

-Baby boomers+ high risk groups

-High prevalence HCV infection

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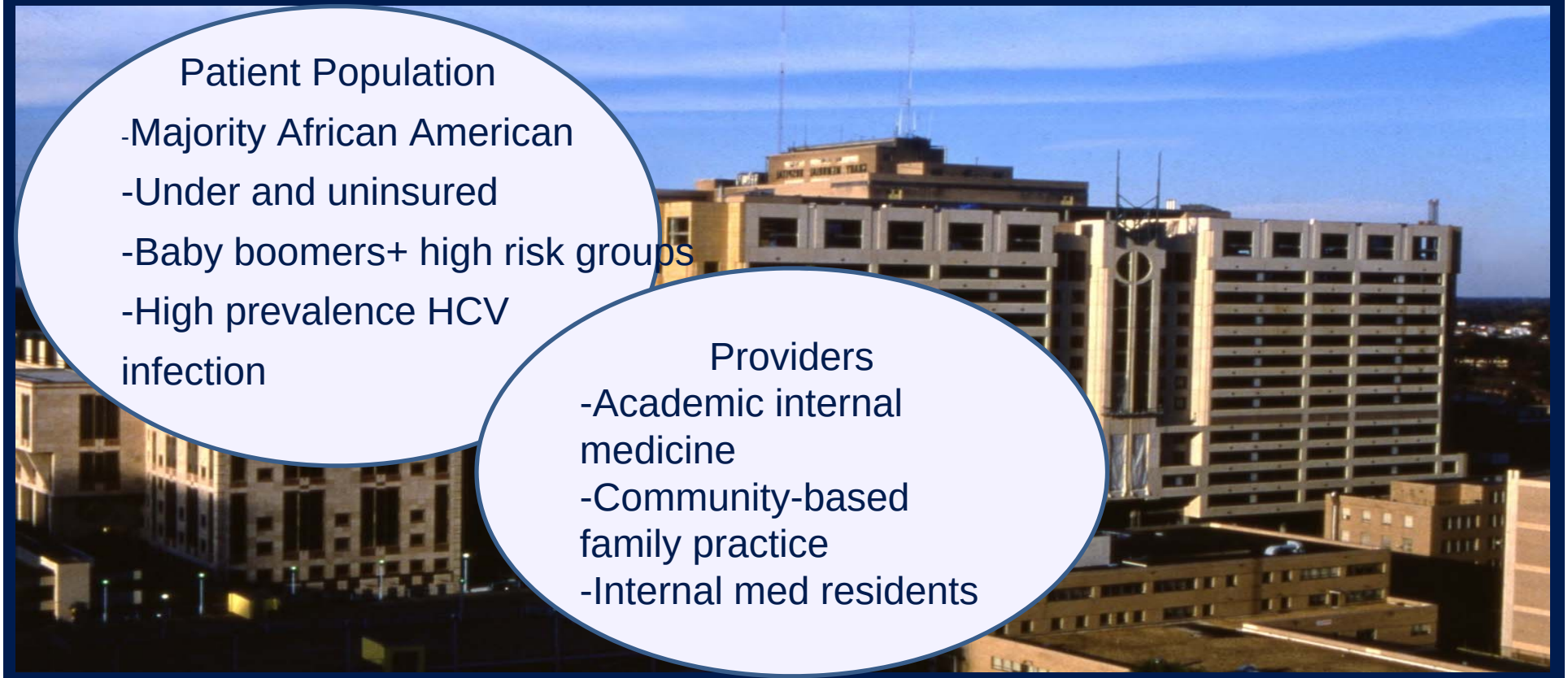
Why Screen at Grady?



Patient Population
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Providers
-Academic internal medicine
-Community-based family practice
-Internal med residents

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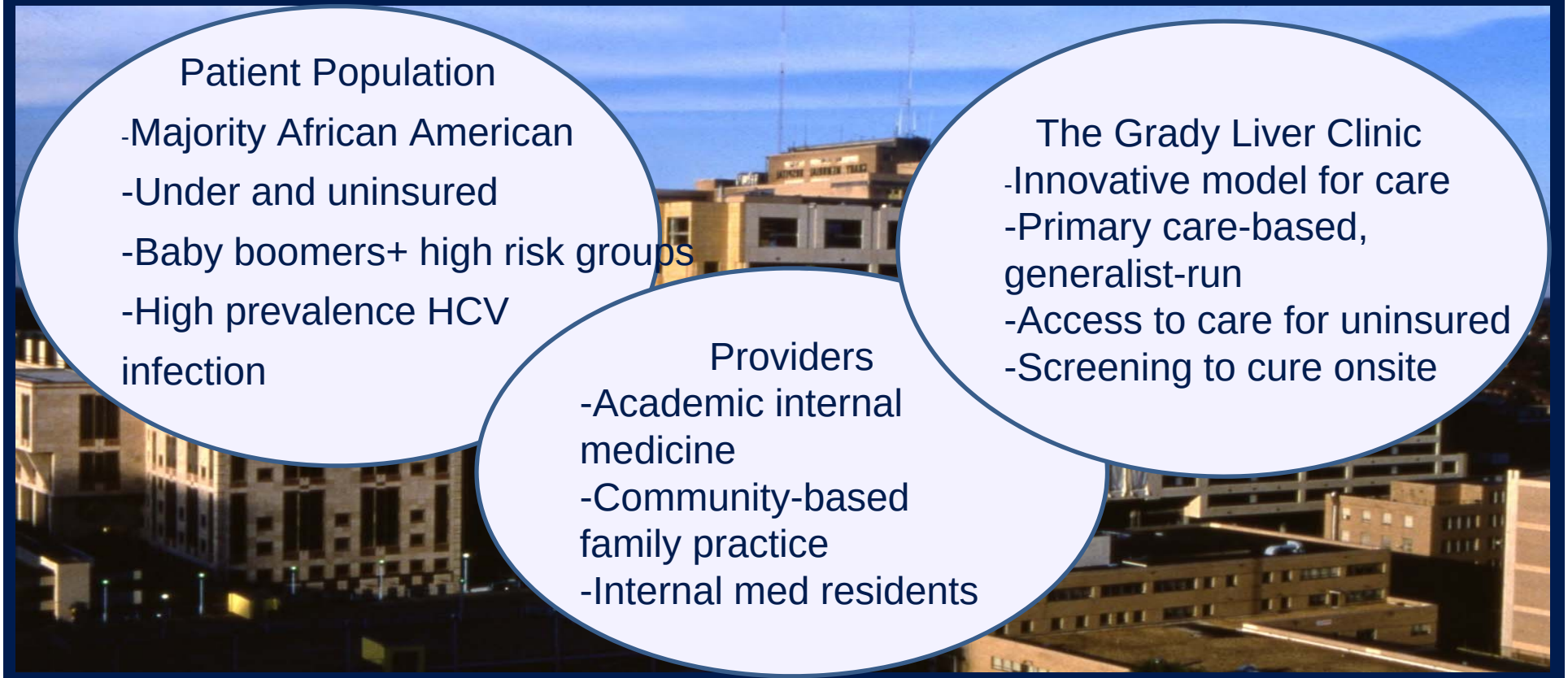
Why Screen at Grady?



Patient Population
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The Grady Liver Clinic
- Innovative model for care
- Primary care-based, generalist-run
- Access to care for uninsured
- Screening to cure onsite

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Evolution of Routine HCV Screening at Grady

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No Program

- *Pre-2012*
- *? Prevalence*

TILT-C

- *2012 – 2015*
- *30 months*
- *5,282 tested*
- *409 HCV Ab+*

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- *2015 – 2017*
- *23 months*
- *15,341 tested*
- *1,159 HCV Ab+*

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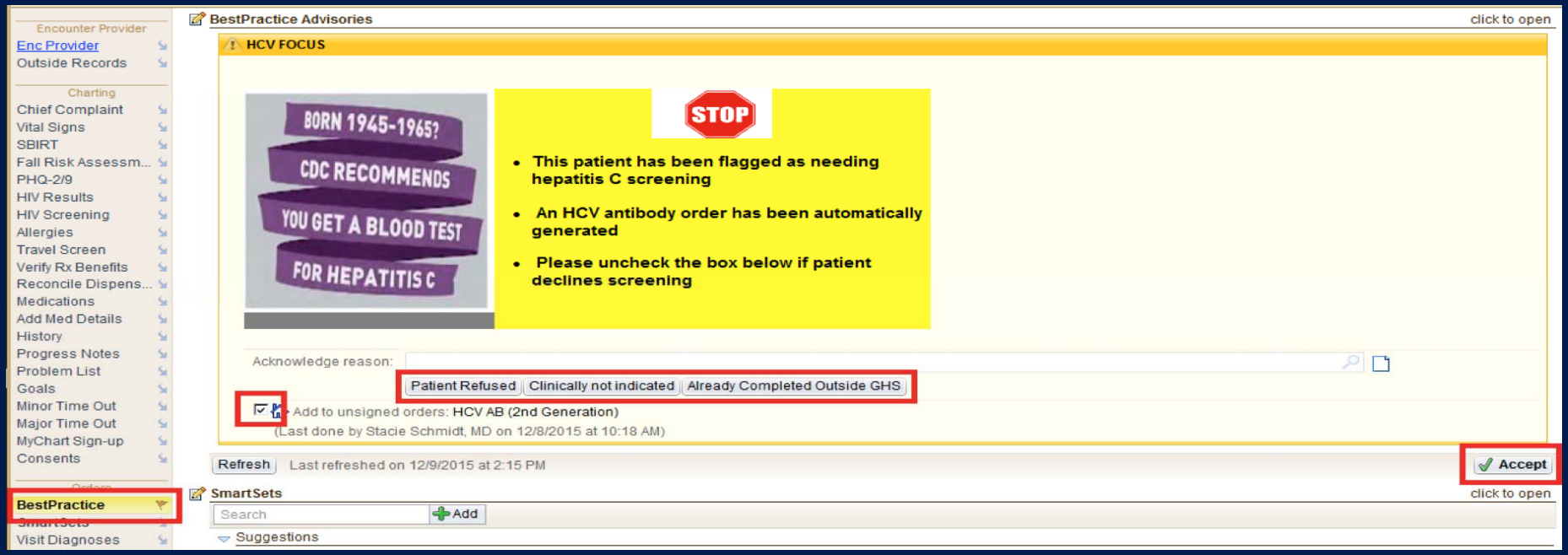
Creating an Epic Alert Boosted Screening Rates



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Patient Path for HCV Testing at Grady

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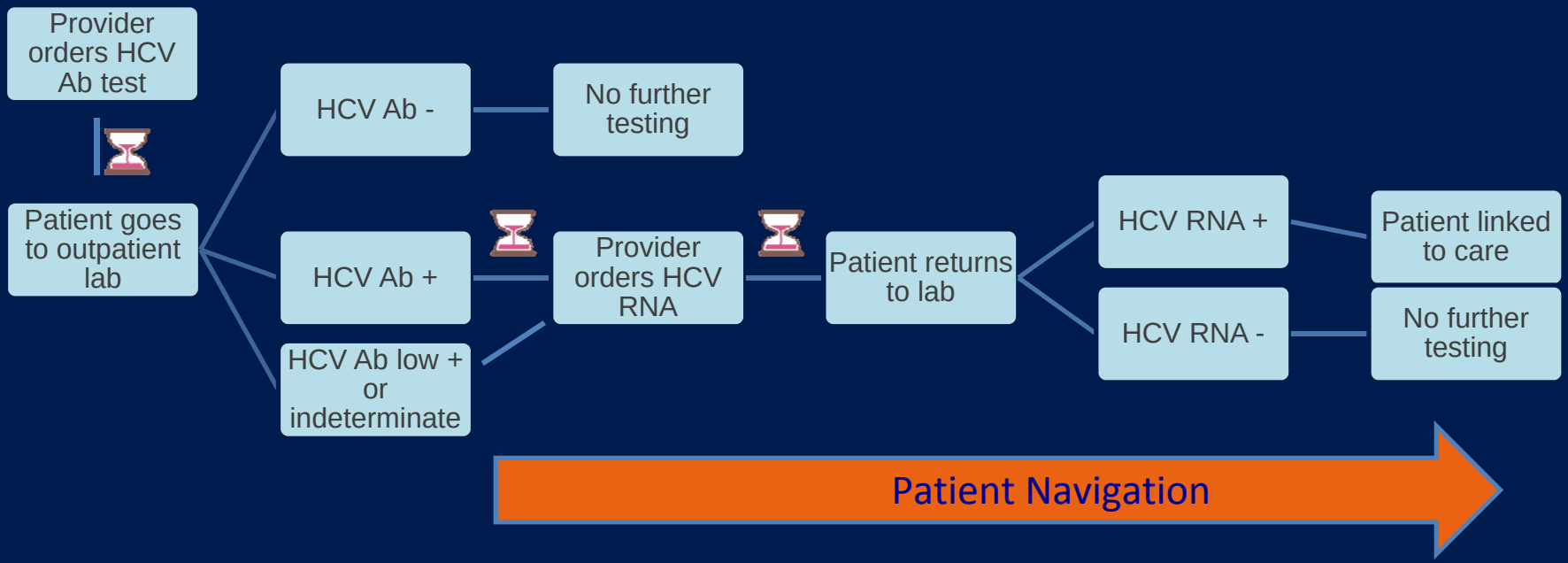

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Grady HCV Care Cascade

2012-2017

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- **7.6% prevalence**
- **75% tested**
- **66% viremic**
- **77% linked**

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Comparing HCV Screening Outcomes

	Emory/Grady (Atlanta)	UTHSC (San Antonio)	MedStar (DC)
Setting	Primary Care Low Income	Inpatient Safety Net	Primary Care
Population	Baby boomers (93% AA)	Baby boomers (58% Hispanic)	Baby boomers (86% AA)
Number tested	2,894	4,582	1,123
HCV Ab+	6.9%	6.9%	8.8%
HCV RNA+	71%	61%	62%

Turner BJ et al. Hepatology 2015;62(5):1388-95
Miller LS et al. Public Health Reports 2016; 131(2): 84-90
Geboy et al. Public Health Reports 2016; 131(2): 49-56

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Barriers to Screening

- Logistical challenges with implementation
- Provider time constraints
- Competing priorities for patients
- Stigma
- Cost of confirmatory testing
- Lack of linkage options

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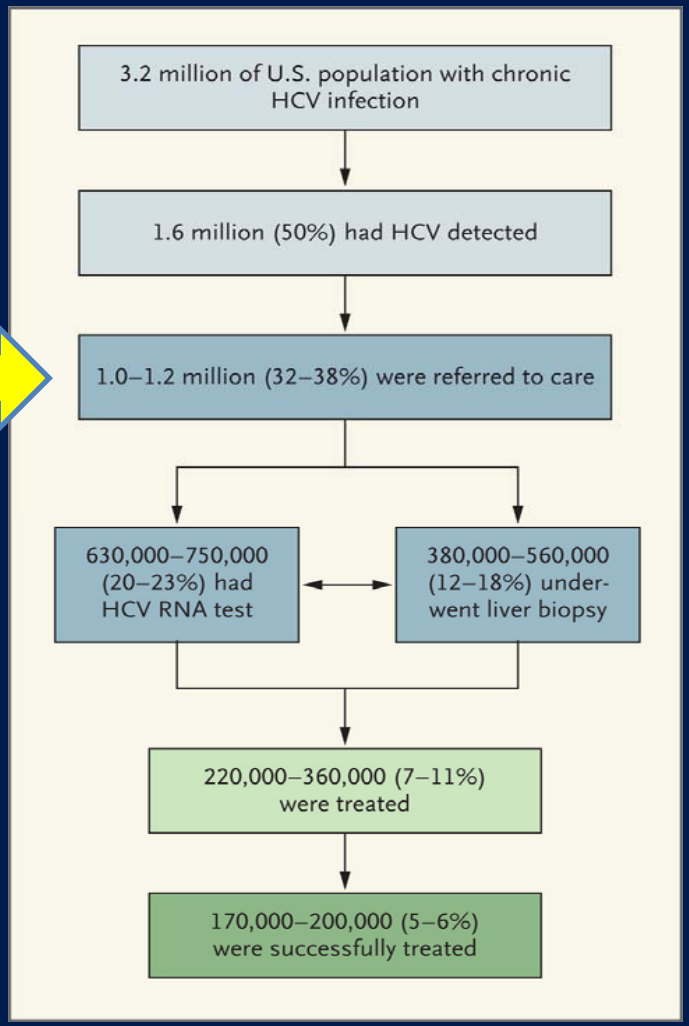
HCV Linkage to Care



Holmberg SD et al. N Engl J Med 2013;368:1859-1861.

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Linkage to HCV Care

"All persons with current active HCV infection should be linked to a practitioner who is prepared to provide comprehensive management"

Usual options:

- Gastroenterology and/or hepatology
- Infectious disease
- Primary care?

hcvguidelines.org accessed 12/6/17

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Barriers to Specialty Care

- Lack of access to specialists
  - Uninsured population
  - Geographic distance
  - Lack of availability of specialists
- Medical, substance abuse, psychiatric co-morbidities
- Cost of treatment

hcvguidelines.org accessed 12/6/17

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Strategies for Access to HCV Care

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- Co-localization of services
  - Corrections
  - Substance abuse treatment settings
  - Needle exchanges
- Integrated care
  - Multidisciplinary care coordination
  - Case management and navigation
- Primary care-based treatment

hcvguidelines.org accessed 12/6/17

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Models for HCV Treatment by PCPs

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- Project ECHO (telemedicine)
- HCV specialty clinic run by generalists
  - Grady Liver Clinic
  - Mt. Sinai REACH Program
- Advance practice provider-run free clinic
  - St. Mary's Health Center

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Benefits of HCV care by PCPs

- Pt comfort with provider and site
- Fewer logistical barriers
- Less fragmented care
- Outcomes as good or better than specialty care

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Excellent Treatment Outcomes by PCPS

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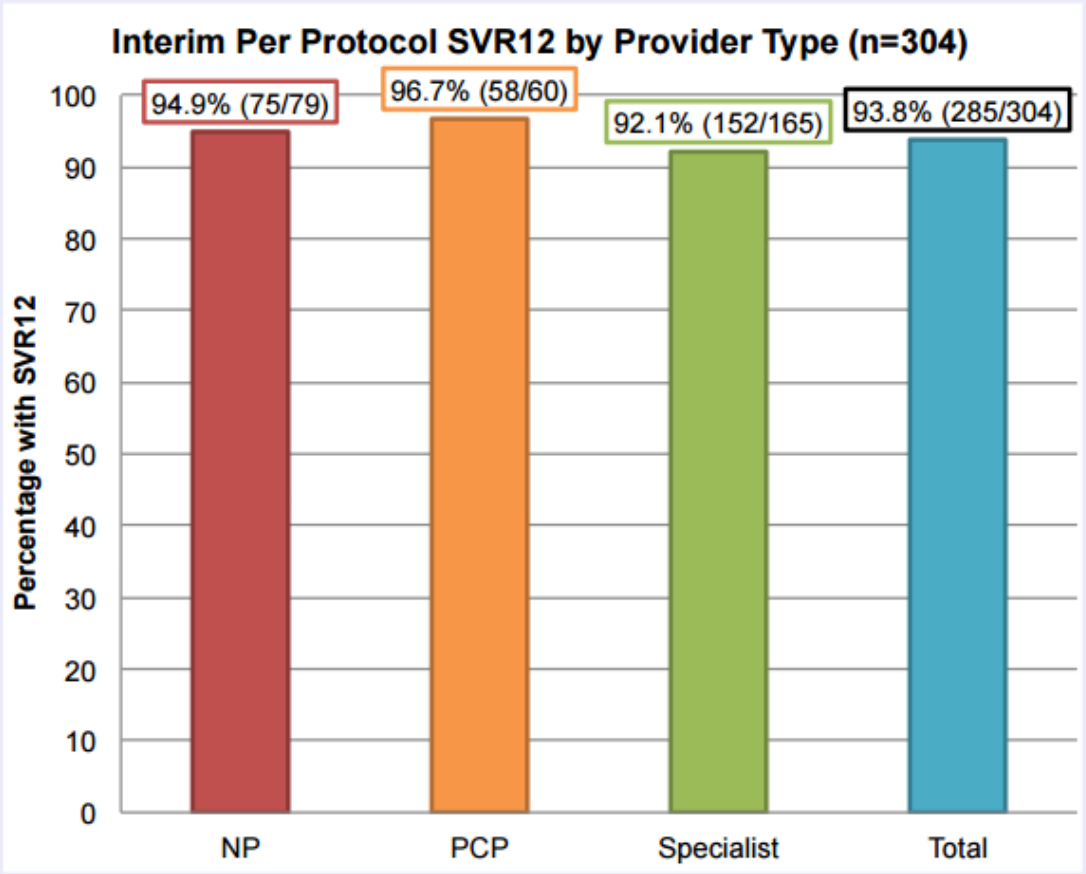

Figure 1. Interim Per Protocol SVR12 by Provider Type. Of 304 patients with available SVR12 results, 93.8% achieved SVR12. There was no significant difference in SVR12 between patients treated by NPs, PCPs, and specialist physicians

Kattakuhzy et. al. CROI abstract 538LB Feb 2016

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Access to Care: Grady Liver Clinic

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Grady Memorial Hospital

Grady Memorial Hospital

- 1,000 bed, urban, safety net hospital
- Largely un-and underinsured, African American population
- Teaching site for Emory and Morehouse SOM
- Home to Primary Care Center (PCC)
  - 60K annual visits
  - Medical Home
  - Resident and faculty providers

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Grady Liver Clinic: Goals

- Provide access to comprehensive care for underserved patients with hepatitis C
- Evaluate co-morbidities and assess readiness for hepatitis C treatment
- Initiate and monitor patients on antiviral therapy

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Grady Liver Clinic: Model

Structure:

- Primary site at Grady treating hepatitis C
- Three half-day sessions per week
- 80 new referrals per month
- 2,500 patient visits annually
- Start with group education session

Staffing:

- 1-2 attendings per clinic, 6 faculty in pool
- 2 Clinical Pharmacists and 1 Patient Assistance Analyst
- Internal Medicine and Psychiatry residents, GI fellows
- CDC volunteers
- PCC staff (nursing, CA, practice manager)
- Patient Navigator
- Program Coordinator
- Nurse Practitioner

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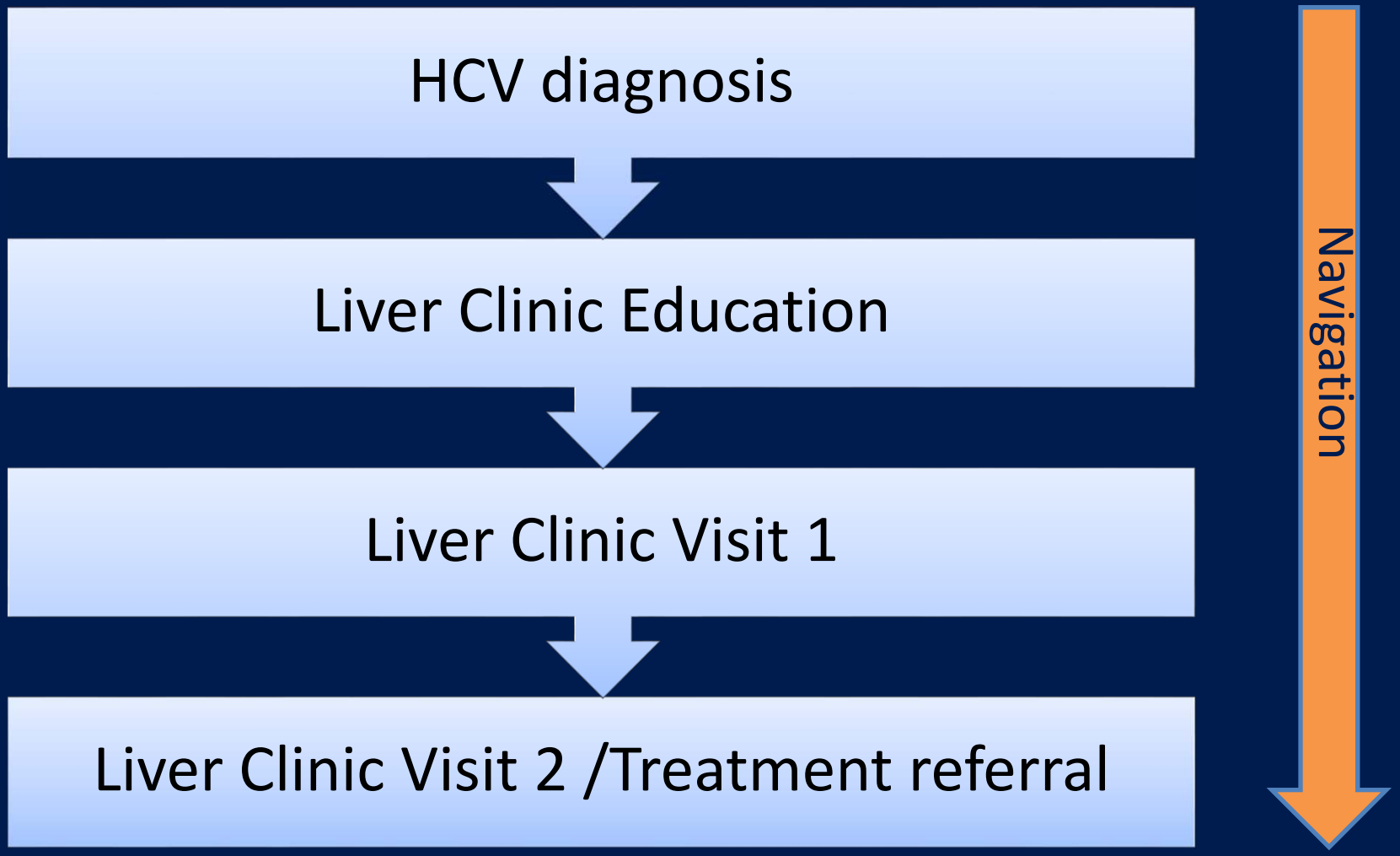
Liver Clinic Sequence



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HCV Work-up

HCV RNA +

Genotype Testing	HAV HBV HIV testing	Liver Fibrosis Assessment	Co-morbidity Assessment (CKD, Meds)

Medication Choice

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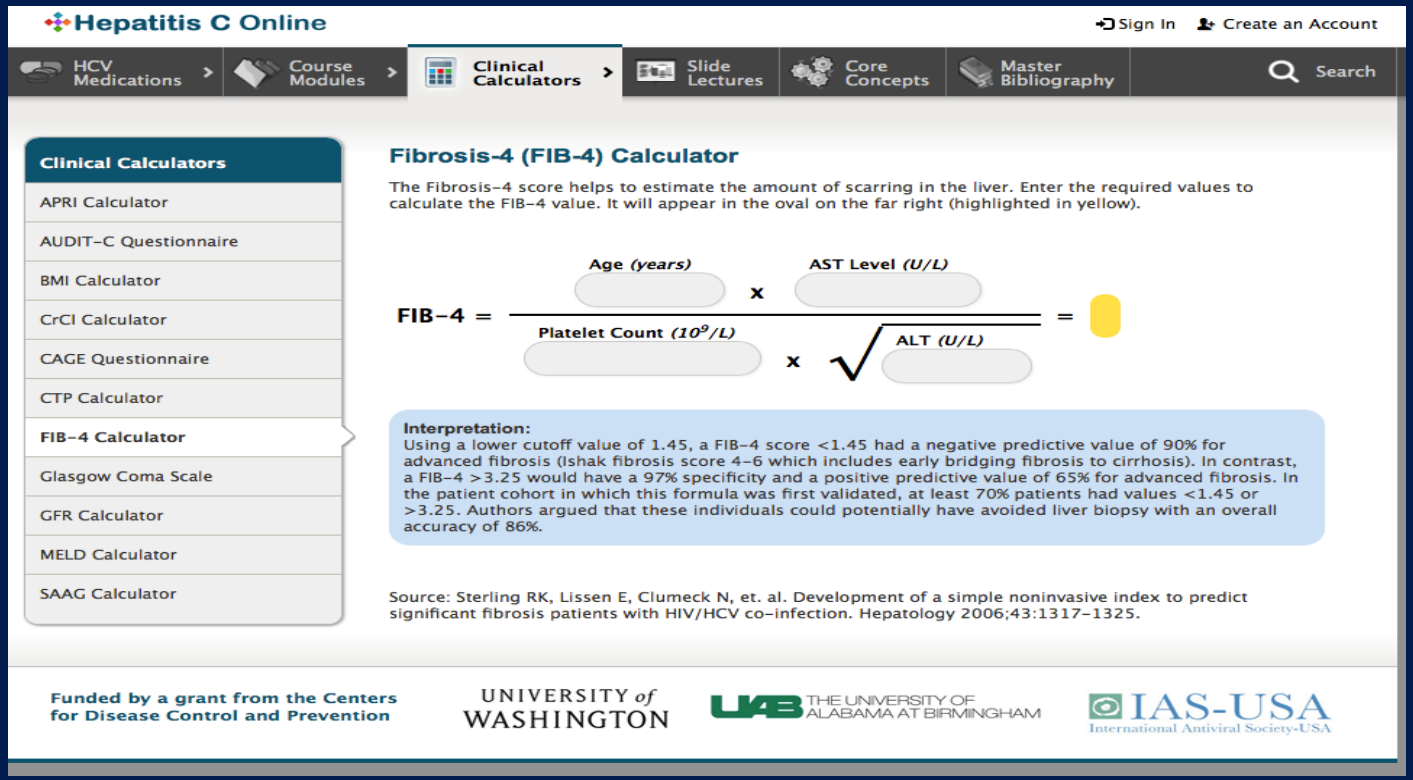
FIB-4 Score



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Recommended HCV Medications

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Ledipasvir/ sofosbuvir		SVR >90%
Elbasvir/ grazoprevir		SVR>90%
Velapatasvir/ sofosbuvir		SVR>90%
Sofosbuvir/ Velpatasvir/ Voxilaprevir		SVR>90%
Glecaprevir/ Pibrentasvir		SVR>90%

~0ne pill daily

~8-12 week course

Well-tolerated

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Grady Liver Clinic Treatment Timeline

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Treatment Start
- -Lab visit
- -Office visit
- -Medicine given

Week 4
- -Lab visit
- -Office visit
- -Medication given

Week 8
- -Lab visit
- -Office visit
- -Medication given

Week 12
- -Phone visit
- -Treatment ends

12 weeks after treatment
- -Phone reminder
- -Lab visit
- -Phone call with results

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Grady Liver Clinic
HCV Treatment and Cure Rates

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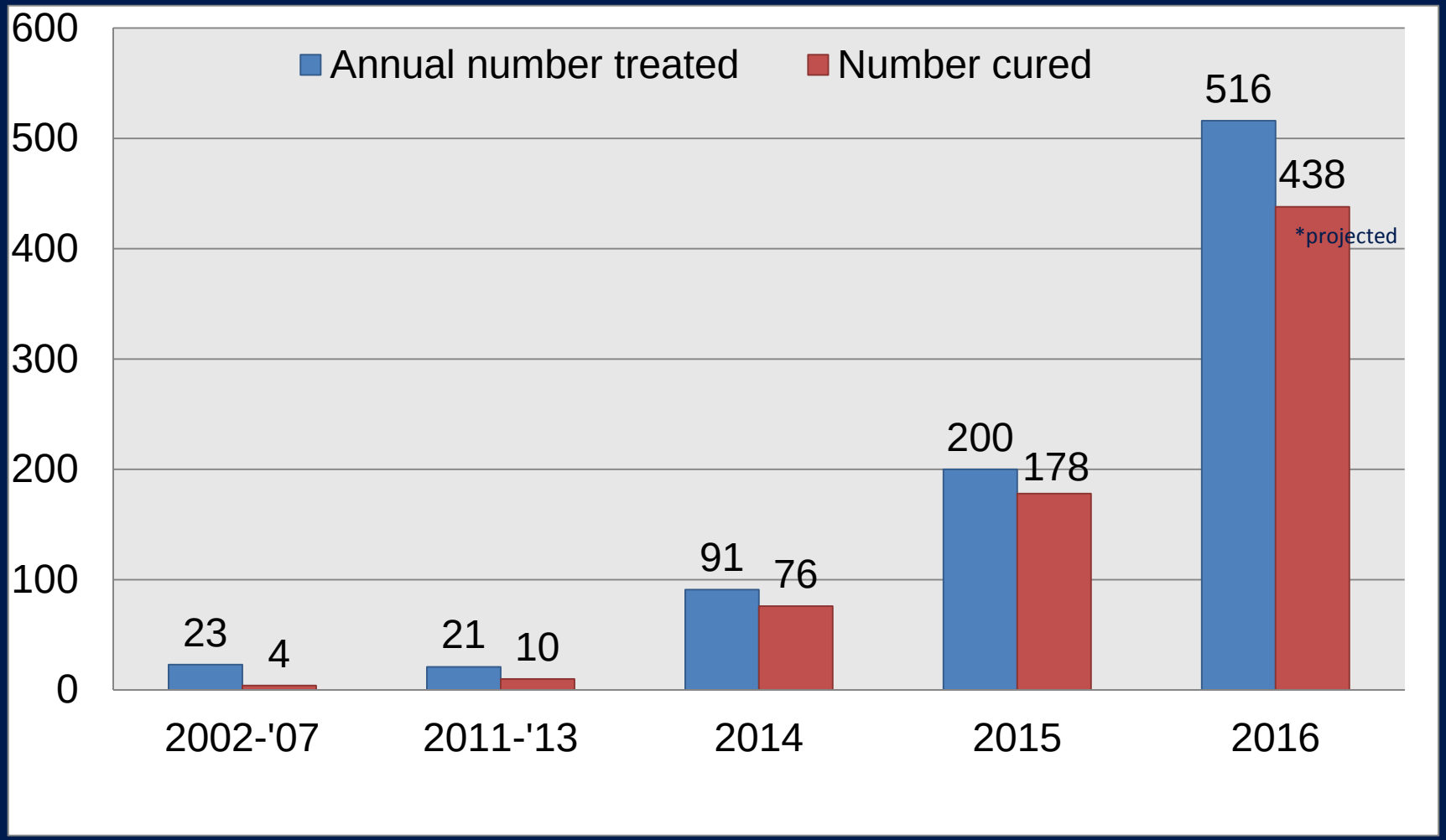

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Facilitators of Successful Linkage

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- Reflex RNA testing
- Patient navigation
- Fast tracking newly diagnosed
- Group education
- Investing resources into program via 340b

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Mt. Sinai REACH Program

- REACH Program (Respectful & Equitable Access to Comprehensive Healthcare) launched in 2002
- New York City, primarily Hispanic and African American, low SES patient population
- Offers community HCV testing, linkage to care and treatment and is staffed by:
    - Medical providers, Nurse
    - Behavioral Health providers
    - Patient navigators
- Patients recruited from primary care sites and community-based outreach and testing program

Parrella et al. APHA Poster, November 2017

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REACH Program Treatment Cascade

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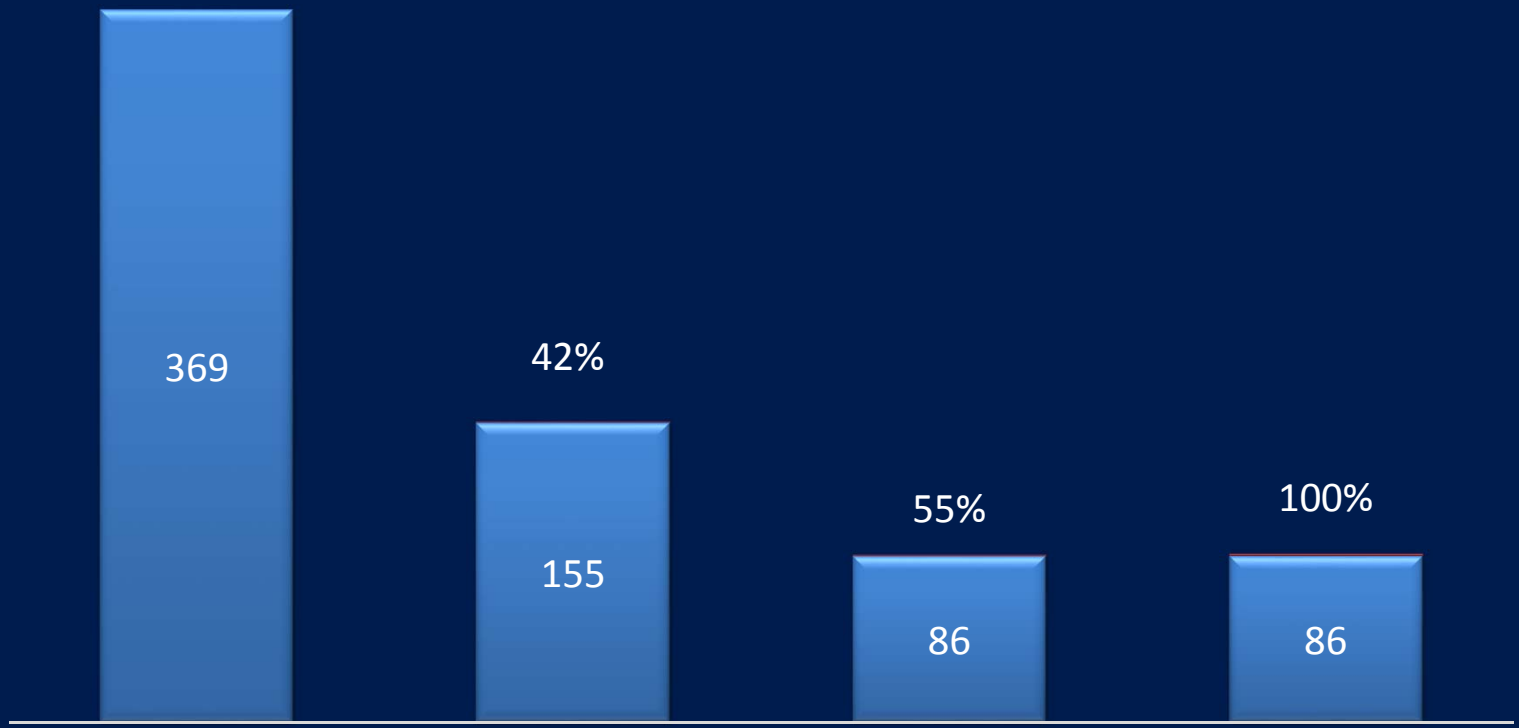

Parrella et al. APHA Poster, November 2017

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St. Mary's Health Center

Clinic Birth-Cohort (1945-1965) Patients Undergoing HCV Testing

	Baseline 2014	2015 Program Implementation	2016 Jan-July
Total Age-Cohort Patients (1945-1965) seen in calendar year	380	577	431
Number and % of Age-Cohort Patients with one-time Age-Cohort Testing	5.0% (19)	67.8% (391)	70.7% (305)
HVC+ (RNA detected following CDC testing algorithm)	4	19	23

As of 2016, the clinic increased age-cohort one-time HCV testing 65.7% from 2014 baseline.

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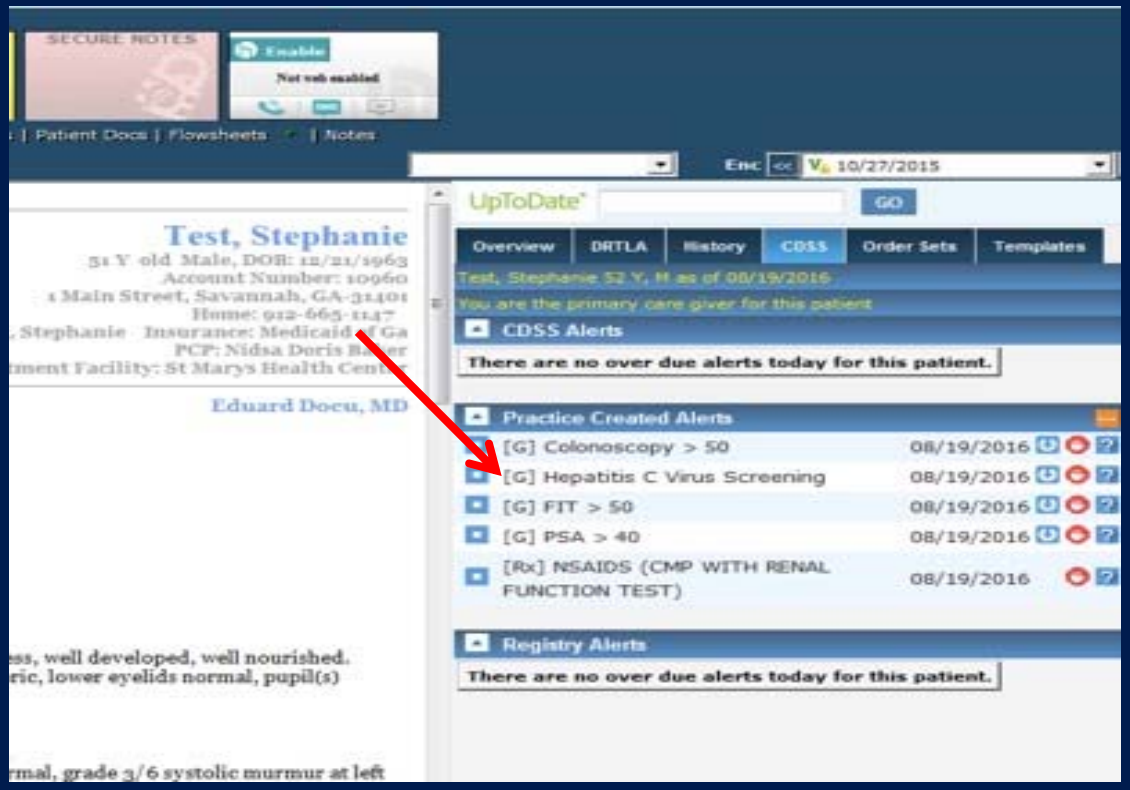
EMR Alerts



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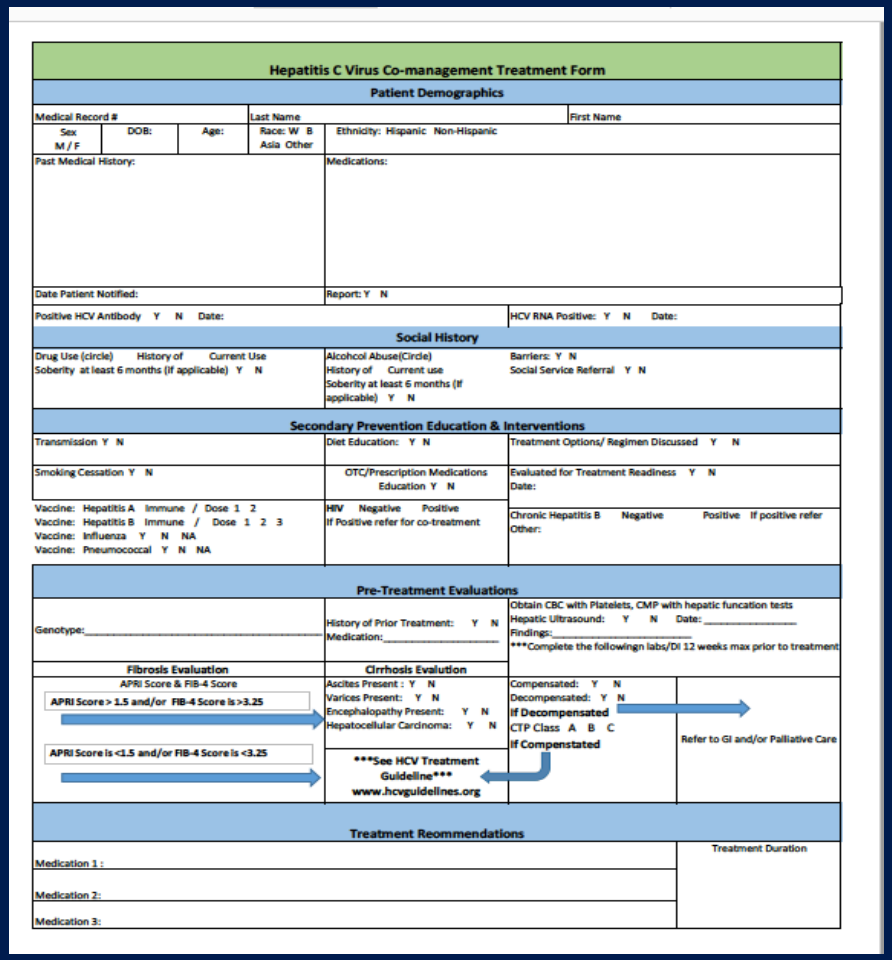
HCV Management Form



Hepatitis C Virus Co-management Treatment Form

Patient Demographics

Medical Record # | Last Name | First Name

Sex M / F | DOB: | Age: | Race: W B Asia Other | Ethnicity: Hispanic Non-Hispanic

Past Medical History: | Medications:

Date Patient Notified: | Report: Y N

Positive HCV Antibody Y N Date: | HCV RNA Positive: Y N Date:

Social History

Drug Use (circle) History of Current Use
Soberity at least 6 months (If applicable) Y N

Alcohol Abuse(Circle)
History of Current use
Soberity at least 6 months (If applicable) Y N

Barriers: Y N
Social Service Referral Y N

Secondary Prevention Education & Interventions

Transmission Y N | Diet Education: Y N | Treatment Options/ Regimen Discussed Y N

Smoking Cessation Y N | OTC/Prescription Medications Education Y N | Evaluated for Treatment Readiness Y N Date:

Vaccine: Hepatitis A Immune / Dose 1 2
Vaccine: Hepatitis B Immune / Dose 1 2 3
Vaccine: Influenza Y N NA
Vaccine: Pneumococcal Y N NA

HIV Negative Positive
If Positive refer for co-treatment

Chronic Hepatitis B Negative Positive If positive refer
Other:

Pre-Treatment Evaluations

Genotype:_____

History of Prior Treatment: Y N
Medication:_____

Obtain CBC with Platelets, CMP with hepatic funcation tests
Hepatic Ultrasound: Y N Date: _____
Findings:_____
***Complete the followingn labs/DI 12 weeks max prior to treatment

Fibrosis Evaluation
APRI Score & FIB-4 Score

APRI Score > 1.5 and/or FIB-4 Score is >3.25 → **Cirrhosis Evalution**

Ascites Present : Y N
Varices Present: Y N
Encephalopathy Present: Y N
Hepatocellular Carcinoma: Y N

Compensated: Y N
Decompensated: Y N
If Decompensated
CTP Class A B C → Refer to GI and/or Palliative Care
If Compenstated

APRI Score is <1.5 and/or FIB-4 Score is <3.25 → ***See HCV Treatment Guideline*** www.hcvguidelines.org

Treatment Reommendations

Medication 1 :
Medication 2:
Medication 3:

Treatment Duration

Home Medications Adjustments:

Treatment Monitoring

Treatment Start Date:	Projected End Date:	4 weeks	8 weeks	12 week	16 weeks	20 weeks	24 weeks	Completion Date:	12 Weeks Post	24 Weeks Post	
		Date	Date	Date:	Date:	Date:	Date:				
Labs	Baseline							Post Treatment Labs	Date:	Date	
Hemoglobin											
Platelets											
Creatinine											
Calculated GFR											
AST											
ALT											
Viral Load											

Consider Hepatic Ultrasound every 6 months if high risk of developing HCC

Patient's Name:
DOB:

Developed by: St. Joseph's/Candler Health System, St. Mary's Health Center, Lewis Cancer & Research Pavilion, Emory University School of Medicine

Updated 5/3/2016

Provider(s):


St Joseph's Candler
Historic District
COMMUNITY
OUTREACH
OFFICE HOURS


St. Joseph's Candler
St. Mary's Health Center
Historic District
COMMUNITY
OUTREACH
OFFICE HOURS
St. Mary's Health Center and the Good Samaritan Clinic
Hepatitis C Screening, Secondary Prevention, and Treatment Guidelines
Sarah Dobra JD, MPH, Lewis Cancer & Research Pavilion
Nidsa Baker, ANP-BC, St. Mary's Health Center
Lesley Miller , MD, Division of General Medicine and Geriatrics, Department of Medicine, Emory University School of Medicine
2015
St. Joseph's/Candler Health System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St. Joseph's Candler
St. Mary's Health Center
Historic District
COMMUNITY OUTREACH
OFFICE HOURS
Hepatitis C Virus Infection

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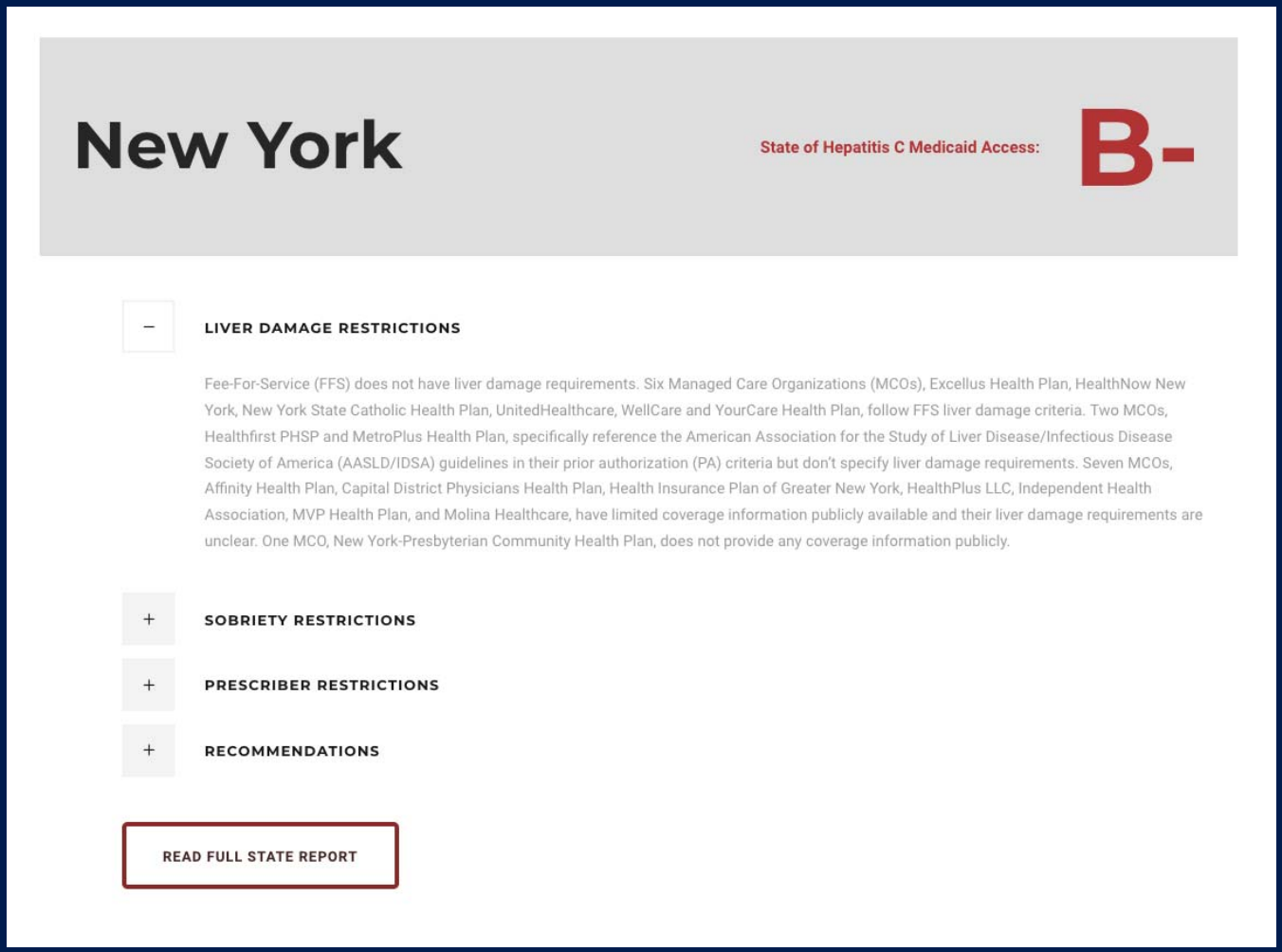
Department of Medicine

Systemic Barriers to Access to HCV Treatment

Grady

- High cost & uninsured patient population
  - Patient Assistance programs
  - Co-pay assistance
  - Dedicated staff for prior authorization & patient assistance program applications
- Medication restrictions based on:
    - Fibrosis stage
    - Substance use
    - Provider type

State of Medicaid Access Report



New York

State of Hepatitis C Medicaid Access: **B-**

− LIVER DAMAGE RESTRICTIONS

Fee-For-Service (FFS) does not have liver damage requirements. Six Managed Care Organizations (MCOs), Excellus Health Plan, HealthNow New York, New York State Catholic Health Plan, UnitedHealthcare, WellCare and YourCare Health Plan, follow FFS liver damage criteria. Two MCOs, Healthfirst PHSP and MetroPlus Health Plan, specifically reference the American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA) guidelines in their prior authorization (PA) criteria but don't specify liver damage requirements. Seven MCOs, Affinity Health Plan, Capital District Physicians Health Plan, Health Insurance Plan of Greater New York, HealthPlus LLC, Independent Health Association, MVP Health Plan, and Molina Healthcare, have limited coverage information publicly available and their liver damage requirements are unclear. One MCO, New York-Presbyterian Community Health Plan, does not provide any coverage information publicly.

\+ SOBRIETY RESTRICTIONS

\+ PRESCRIBER RESTRICTIONS

\+ RECOMMENDATIONS

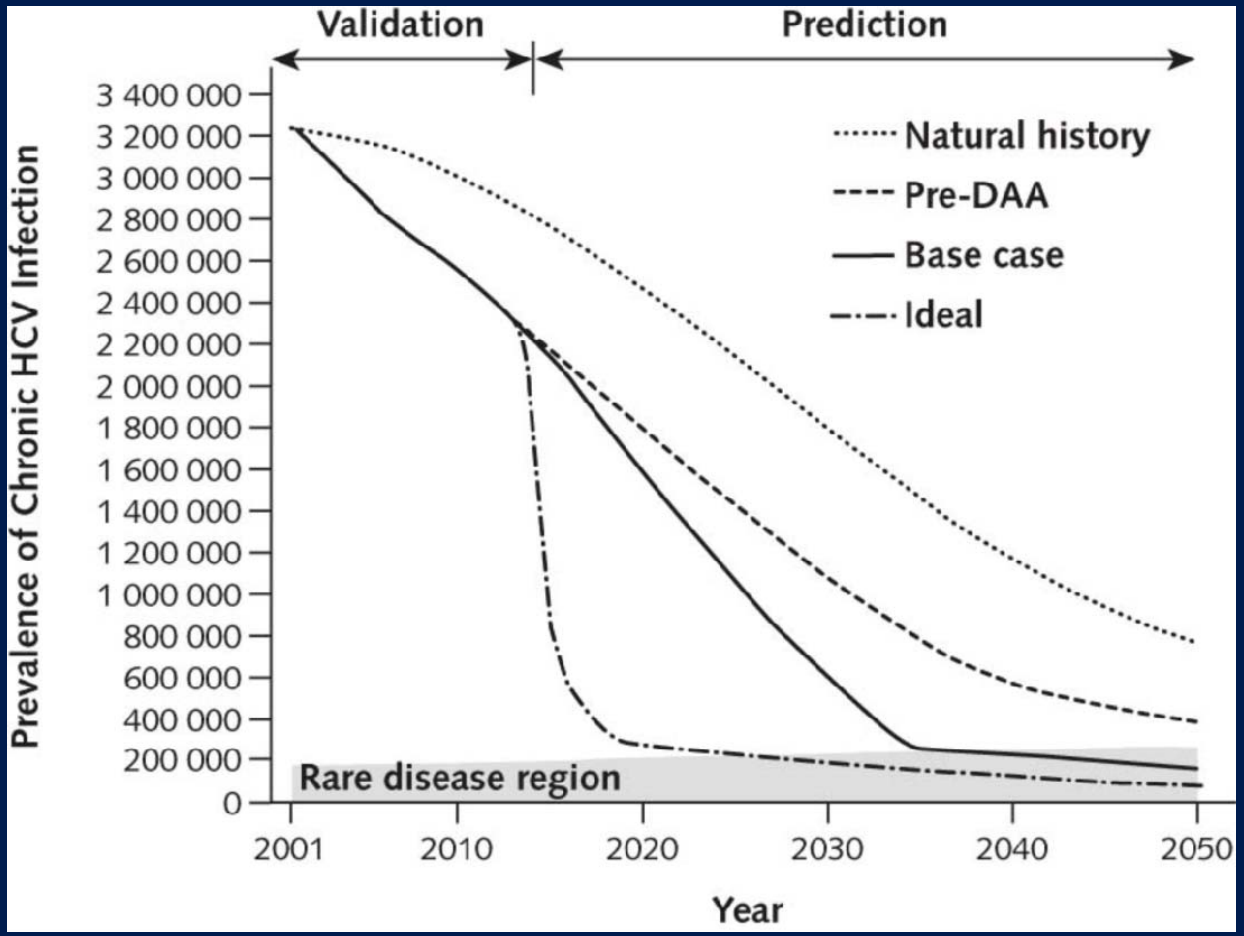
READ FULL STATE REPORT

https://stateofhepc.org/report/#findstate

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

From: The Changing Burden of Hepatitis C Virus Infection in the United States: Model-Based Predictions

Ann Intern Med. 2014;161(3):170-180. doi:10.7326/M14-0095



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Summary

- Hepatitis C is common, deadly and curable
- All baby boomers need one time screening for HCV and those with chronic infection should be referred to care
- Barriers to specialty care are common for underserved populations
- Novel models of care, including treatment by PCPs, address these barriers
- We can achieve HCV elimination with a combination of screening, linkage to care, and treatment

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Thank you!

Questions?