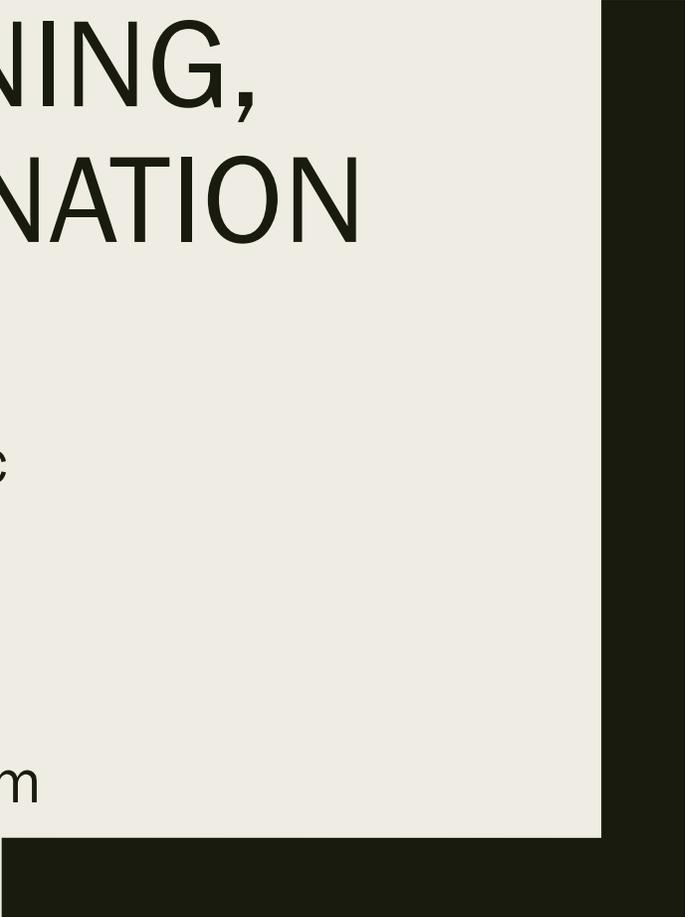




HCV IN 2018: SCREENING, TREATMENT AND ELIMINATION

Lesley Miller, MD
Medical Director, Grady Liver Clinic
Associate Professor of Medicine
Emory University

Georgia Emerging Infections Program
15th Annual Meeting
April 27, 2018



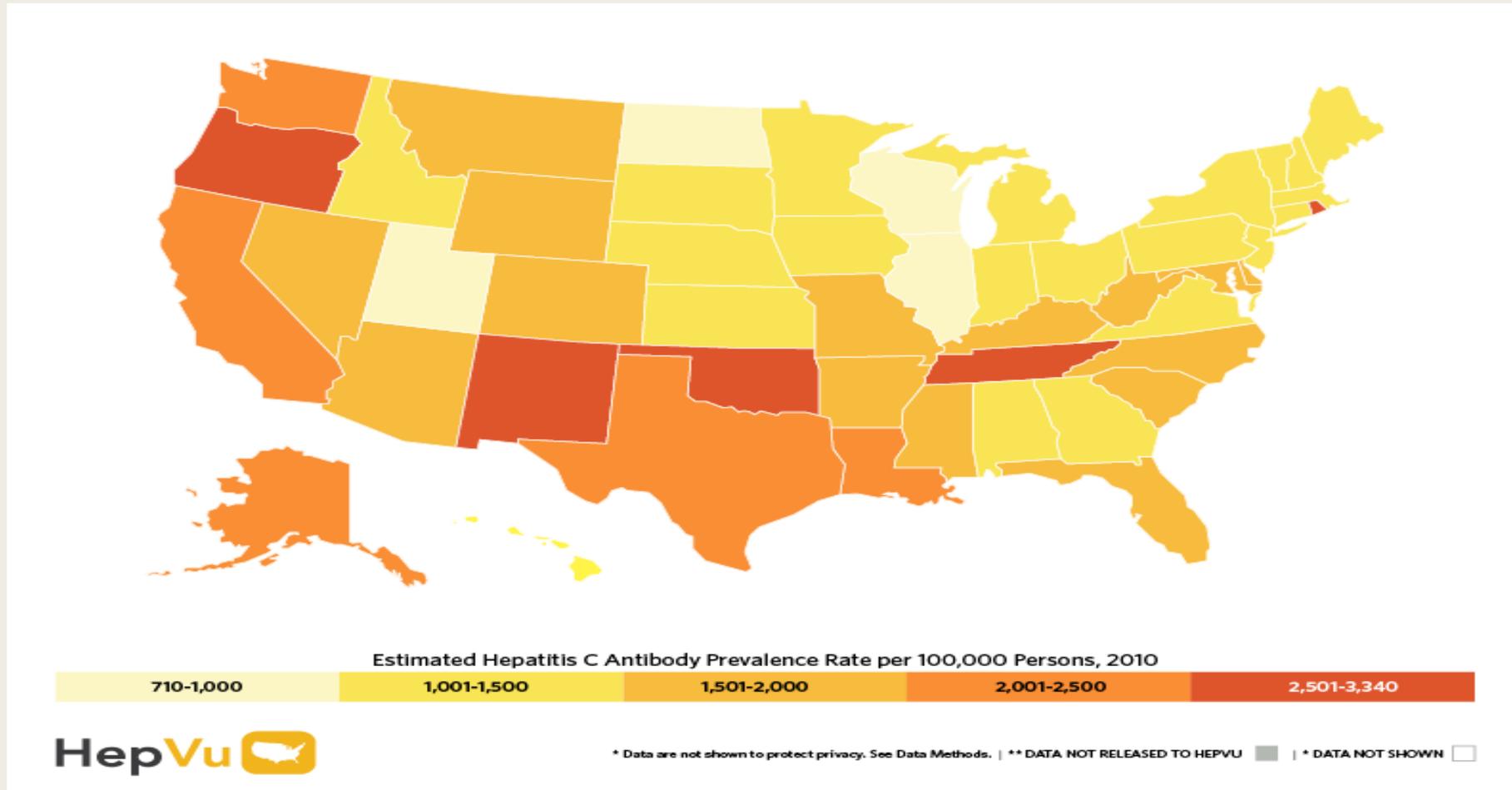
Outline

- The Scope and Impact of HCV
- HCV Screening and Linkage to Care
- HCV Treatment
- Can We Eliminate HCV?

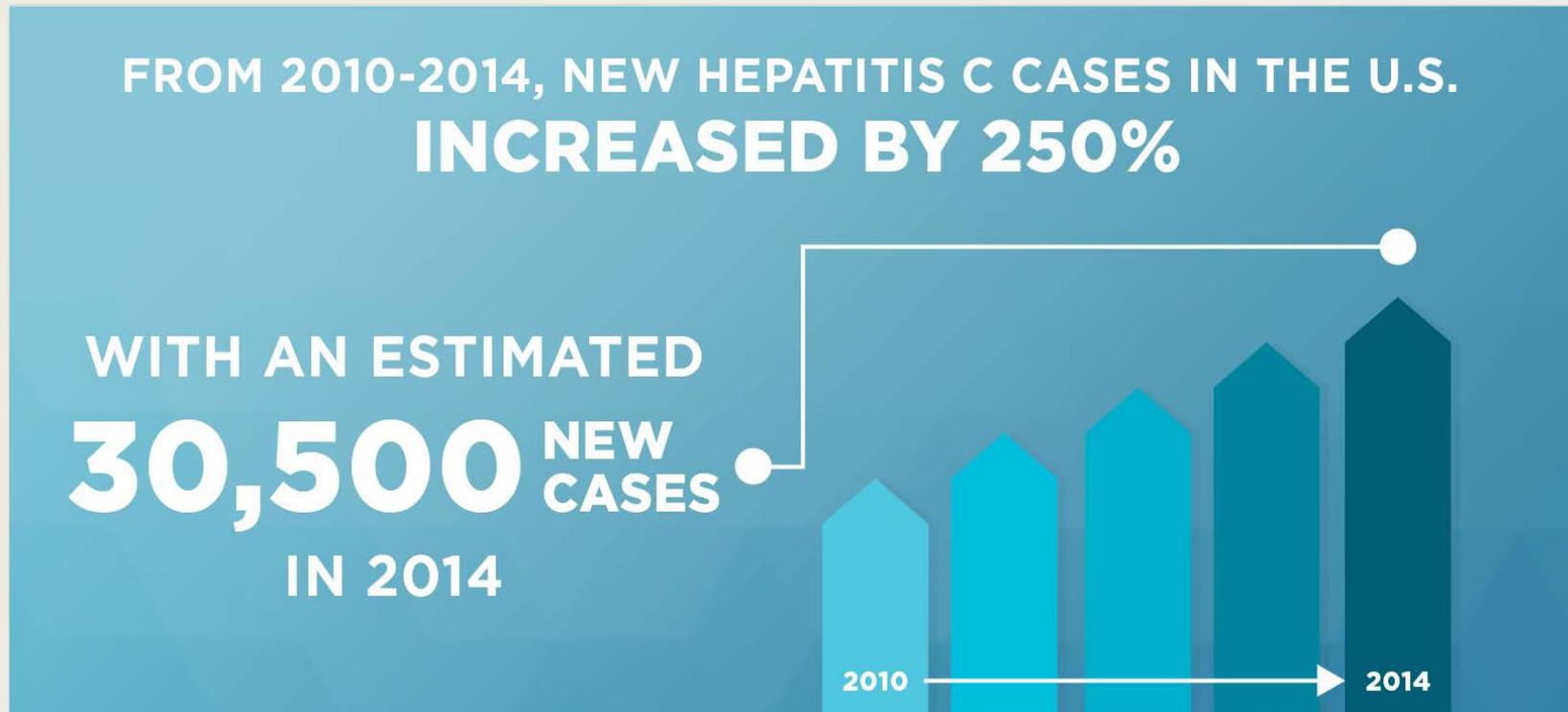
HCV in 2018

- HCV is *common, deadly and curable*
- HCV can be *eliminated*

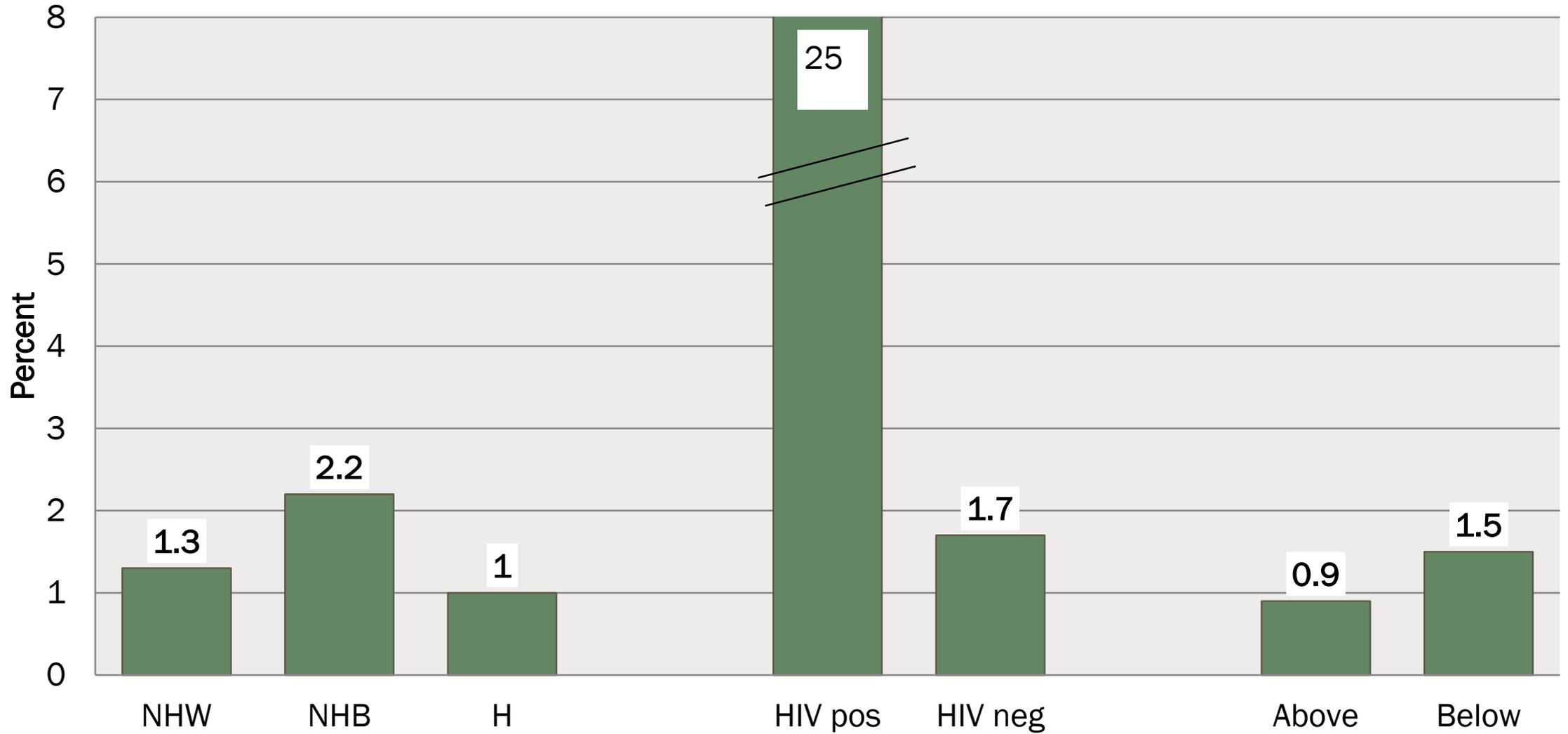
HCV is common



HCV incidence is increasing



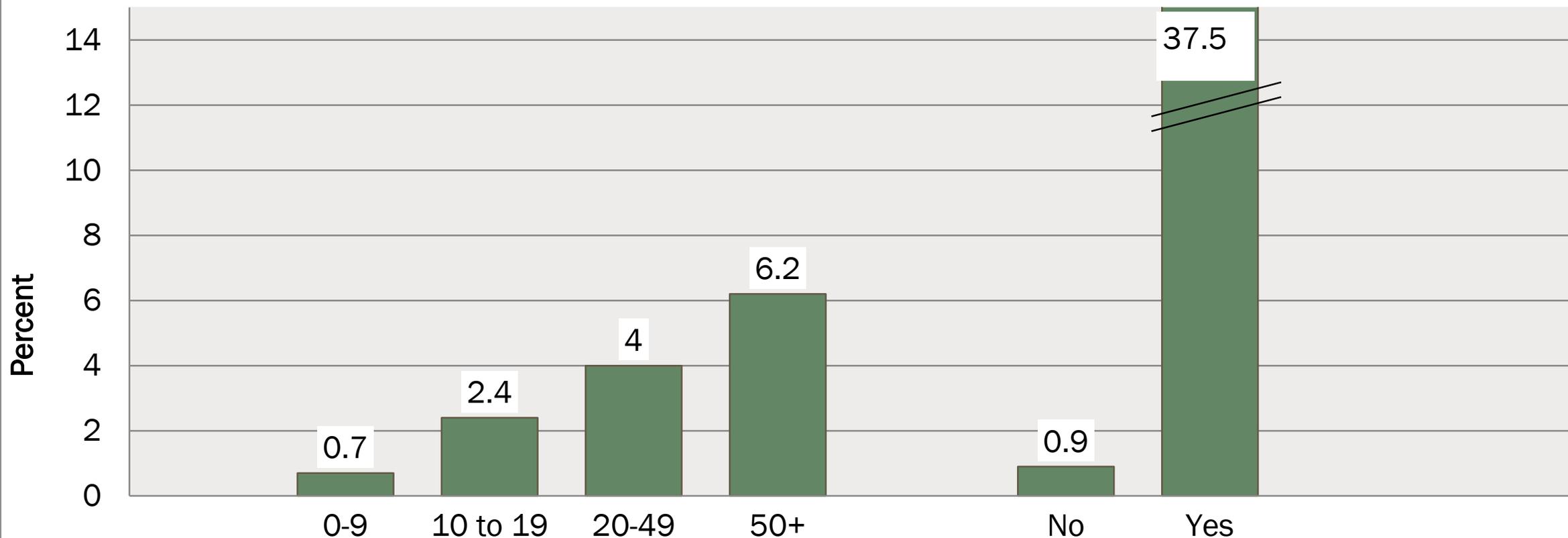
Patient Characteristics and Prevalence of HCV: NHANES



Poverty Index Ratio

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

Patient Characteristics and Prevalence of HCV: NHANES



**# lifetime
sexual partners**

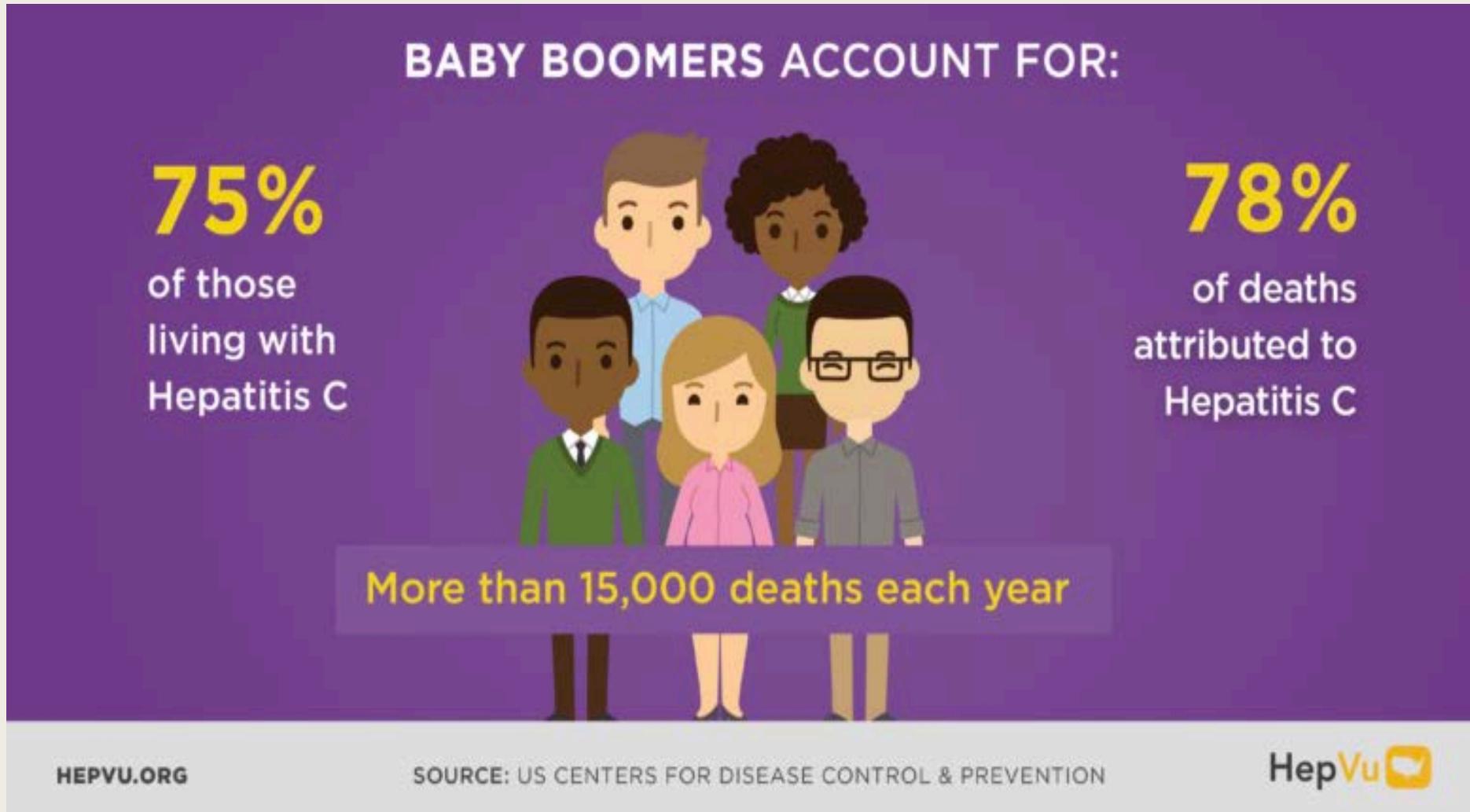
Lifetime drug use

Quiz time

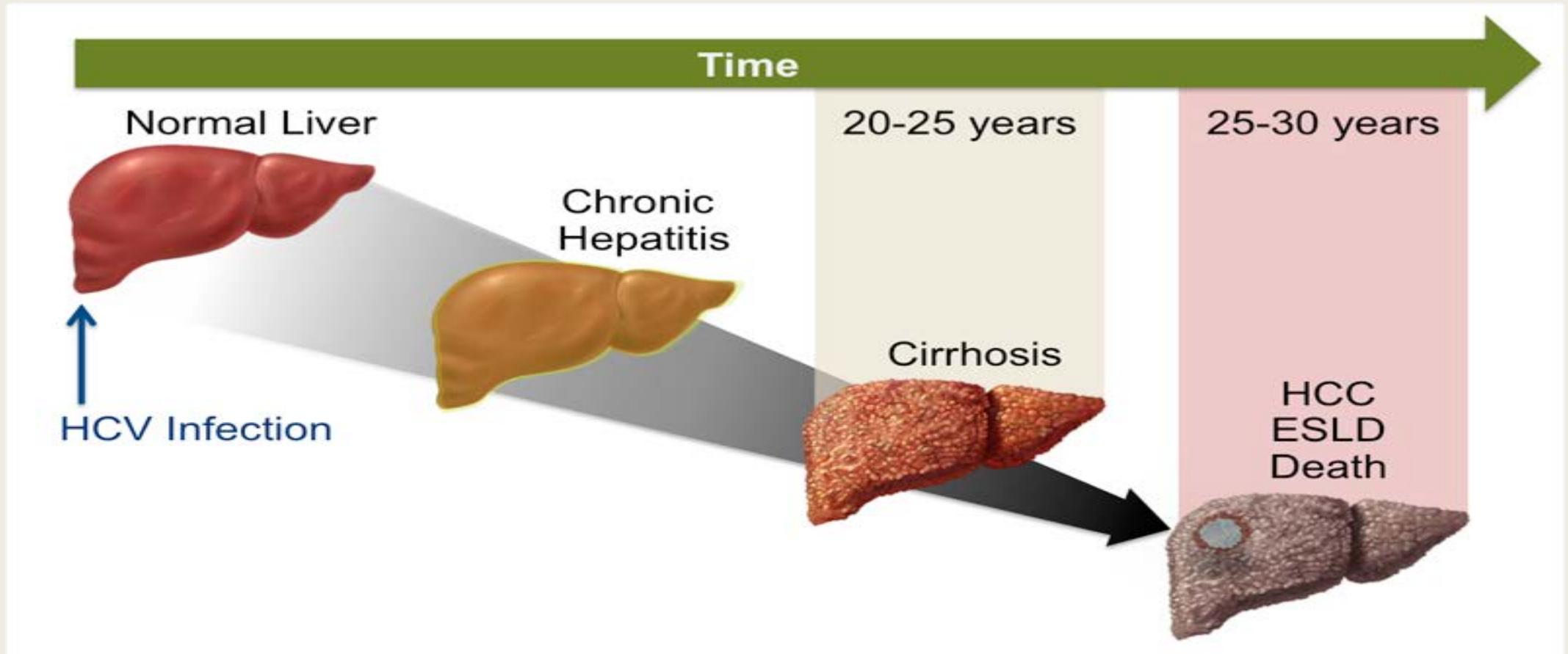
Which birth cohort has the highest prevalence of hepatitis C in the US?

- A. 1925-1945
- B. 1935-1955
- C. 1945-1965
- D. 1975-1995

HCV disproportionately affects baby boomers



HCV is deadly



HCV natural history

Of every 100 people infected with Hepatitis C, **75-85 people will develop Chronic Hepatitis C**. If left untreated:



60-70 PEOPLE will develop
CHRONIC LIVER DISEASE



5-20 PEOPLE will develop
CIRRHOSIS over a period of 20-30 years



1-5 PEOPLE will die from
CIRRHOSIS or **LIVER CANCER**

Quiz time

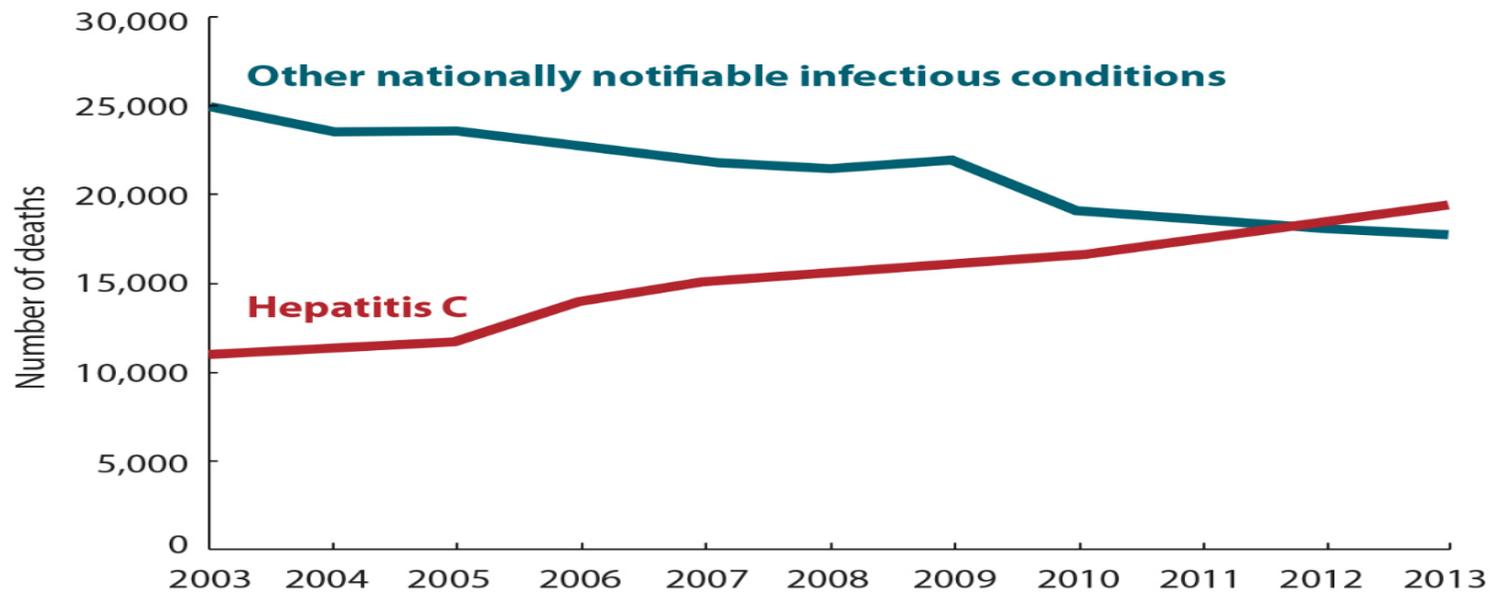
HIV kills more Americans than HCV?

A. True

B. False

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

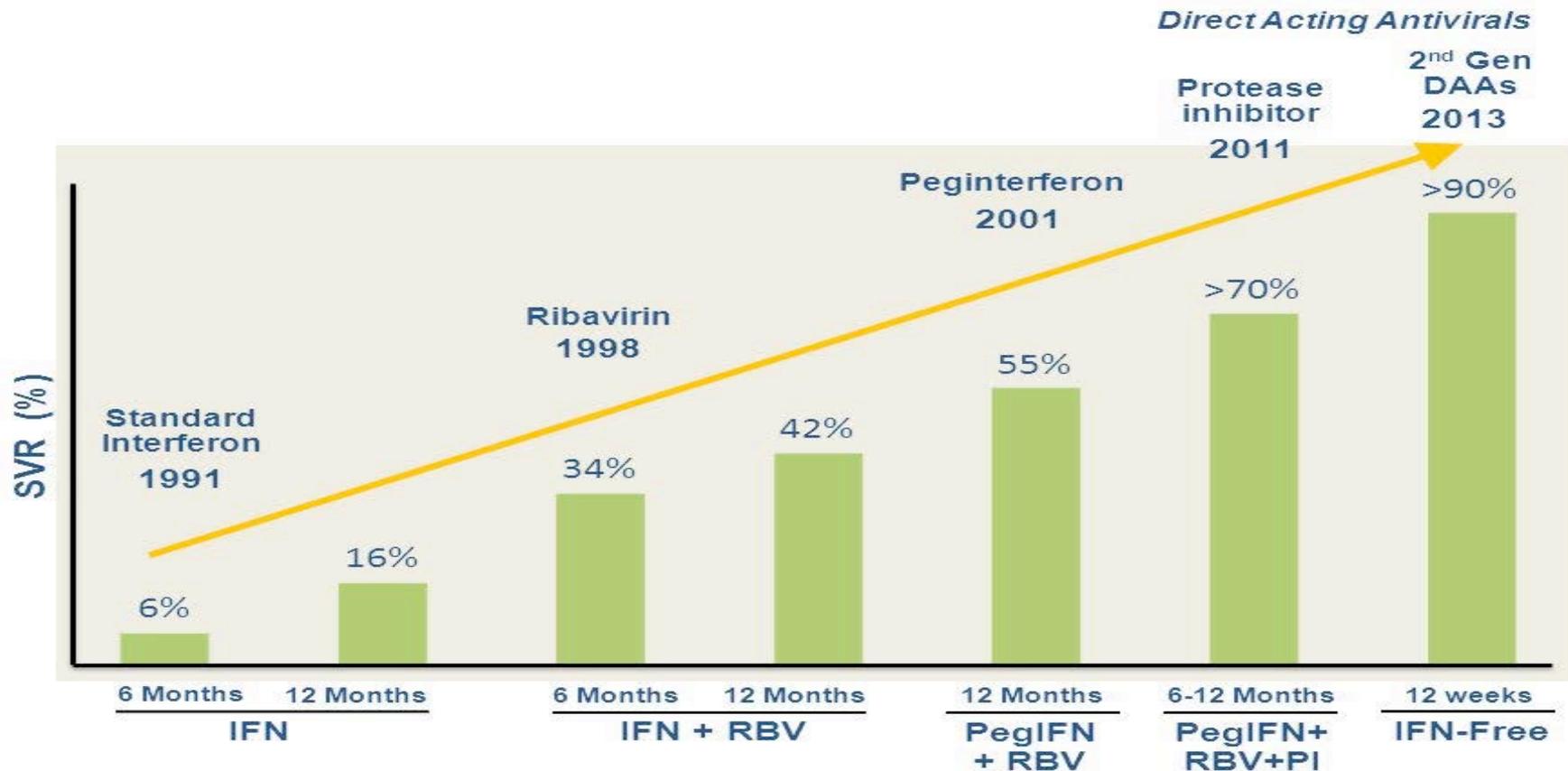
Annual number of hepatitis C-related deaths vs. other nationally notifiable infectious conditions in the US, 2003-2013



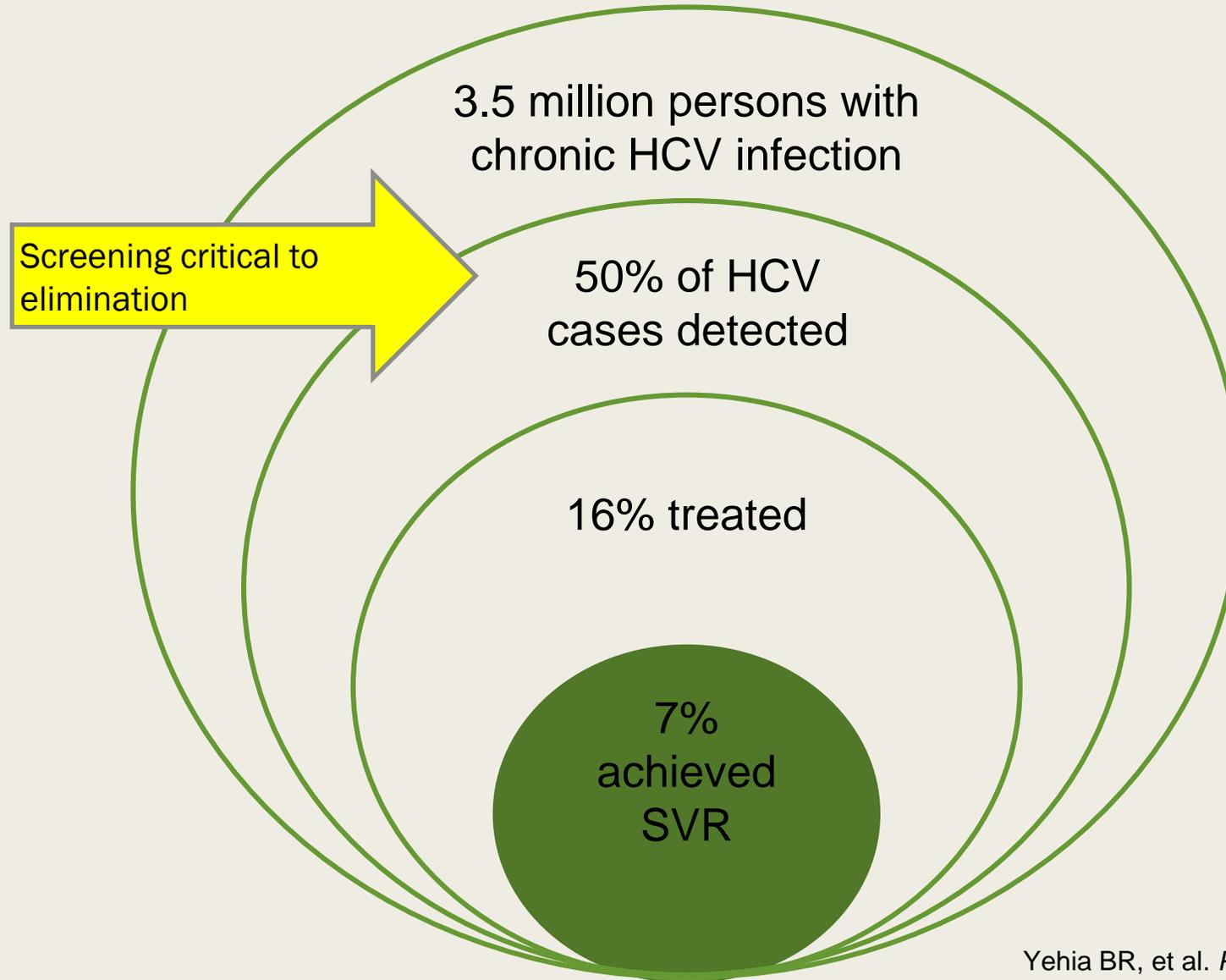
Source: Centers for Disease Control and Prevention

HCV is curable

Cure Rates for Chronic Hepatitis C Therapy



HCV Care Cascade



HCV Screening

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*



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

Case Study: Screening at Grady Health System

Setting

- Atlanta's 1,000 bed safety-net teaching hospital

Patient Population

- High prevalence HCV

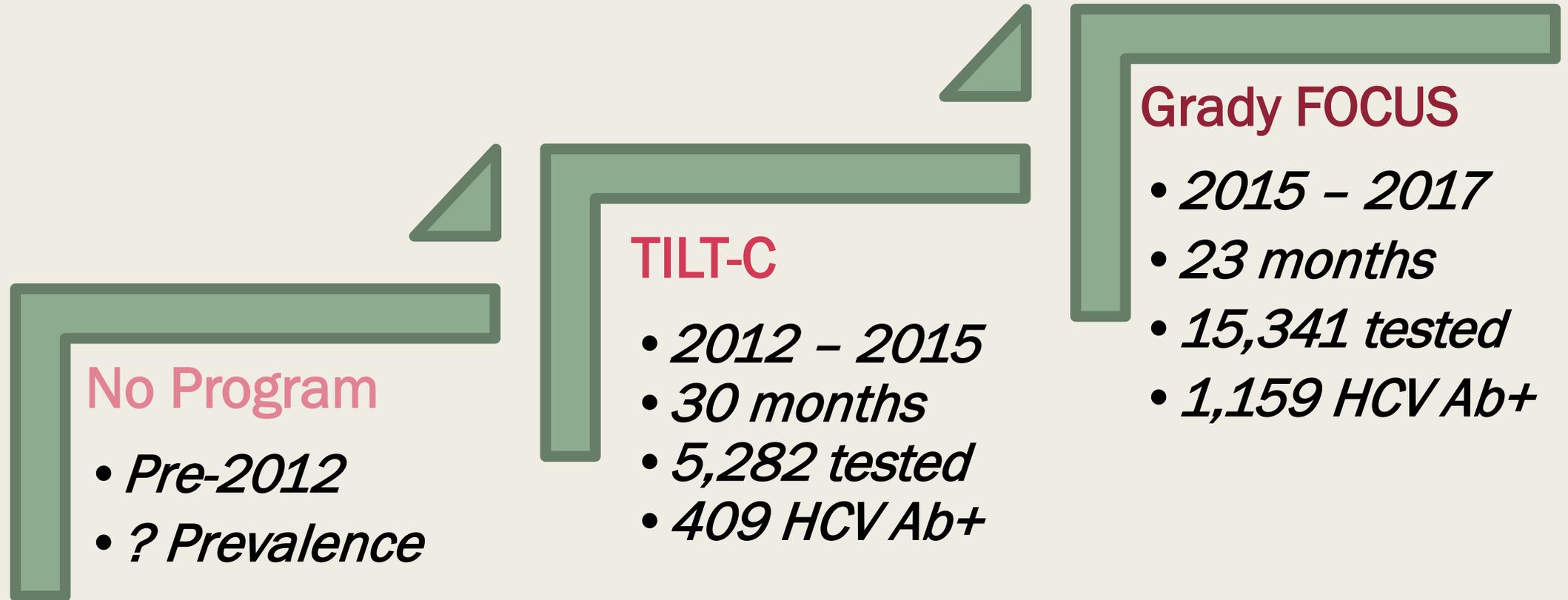
The Grady Liver Clinic

- Primary care-based HCV specialty clinic
- Access to care for uninsured
- Screening to cure onsite

Intervention

- Baby boomer screening in Primary Care Center 2012
- Expanded to community clinics 2015
- Expanded to inpatient 2017
- Relied on provider training and EMR prompts

Evolution of Routine HCV Screening at Grady



Creating an Epic Alert Boosted Screening Rates

The screenshot shows an Epic BestPractice Advisories alert titled "HCV FOCUS". The alert features a purple banner on the left that reads "BORN 1945-1965? CDC RECOMMENDS YOU GET A BLOOD TEST FOR HEPATITIS C". To the right of the banner is a yellow box with a red "STOP" sign icon and the following text:

- This patient has been flagged as needing hepatitis C screening
- An HCV antibody order has been automatically generated
- Please uncheck the box below if patient declines screening

Below the text is a section for "Acknowledge reason:" with three buttons: "Patient Refused", "Clinically not indicated", and "Already Completed Outside GHS". The "Patient Refused" button is highlighted with a red box. Below this is a checkbox labeled "Add to unsigned orders: HCV AB (2nd Generation)" which is checked, also highlighted with a red box. Below the checkbox is the text "(Last done by Stacie Schmidt, MD on 12/8/2015 at 10:18 AM)".

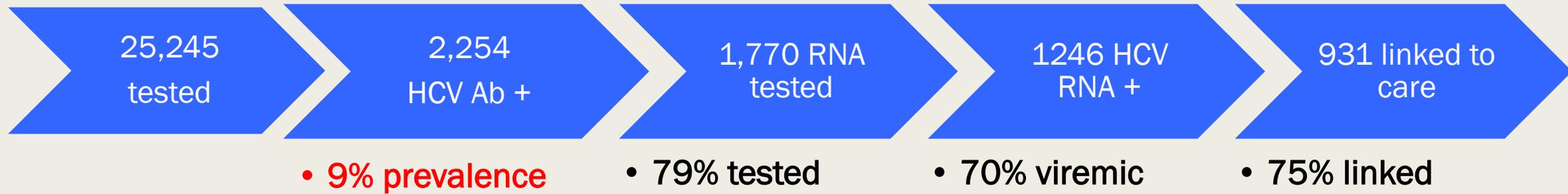
At the bottom of the alert, there is a "Refresh" button and the text "Last refreshed on 12/9/2015 at 2:15 PM". On the far right, there is an "Accept" button with a green checkmark, highlighted with a red box. Below the alert is a "SmartSets" section with a search bar and a "+ Add" button.

On the left side of the screen, there is a navigation menu with the following items:

- Encounter Provider
- Enc Provider
- Outside Records
- Charting
- Chief Complaint
- Vital Signs
- SBIRT
- Fall Risk Assessm...
- PHQ-2/9
- HIV Results
- HIV Screening
- Allergies
- Travel Screen
- Verify Rx Benefits
- Reconcile Dispens...
- Medications
- Add Med Details
- History
- Progress Notes
- Problem List
- Goals
- Minor Time Out
- Major Time Out
- MyChart Sign-up
- Consents
- BestPractice
- SmartSets
- Visit Diagnoses

Grady HCV Care Cascade

2012-2018



HCV Treatment

Access to Care: Grady Liver Clinic



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

Grady Liver Clinic

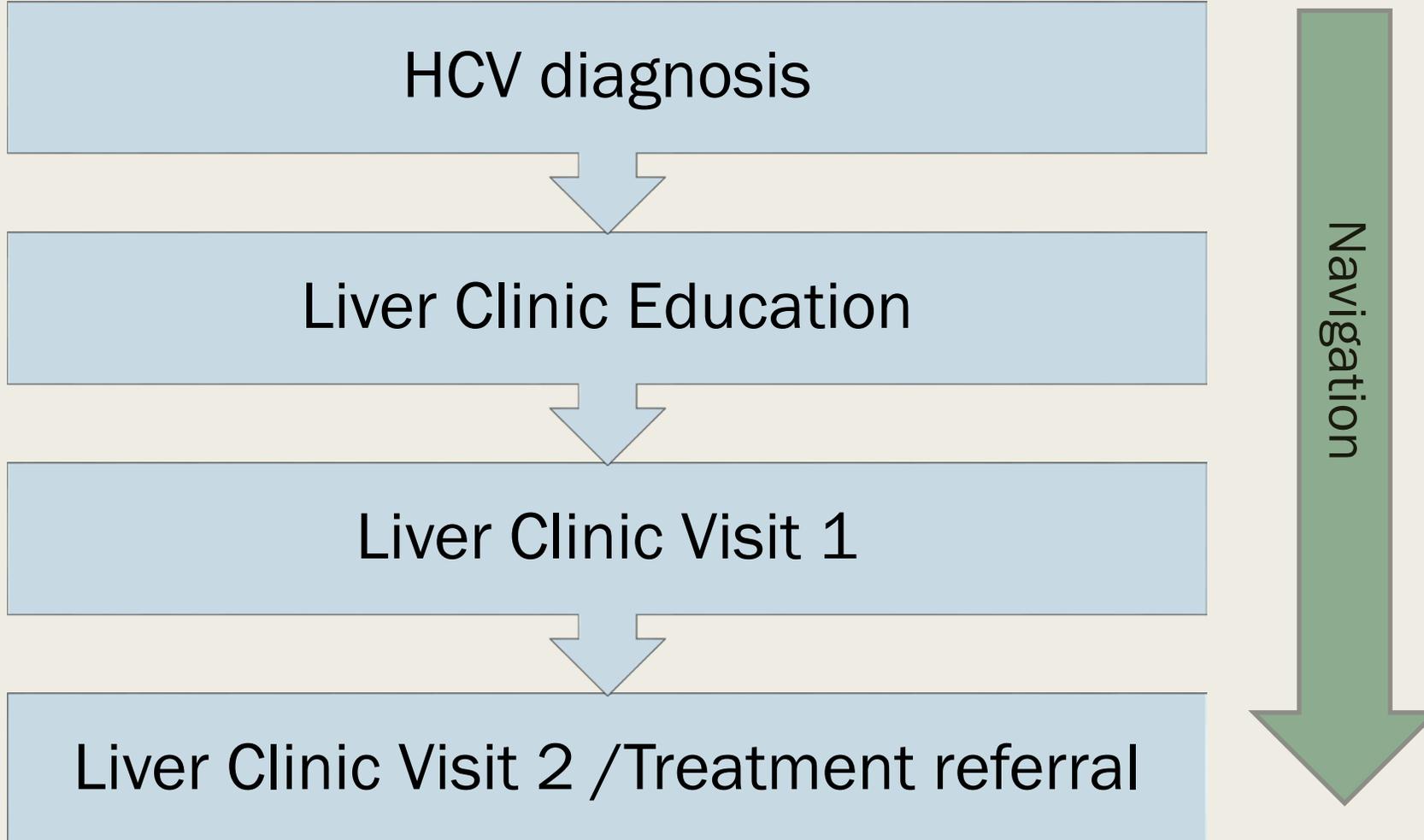
Structure:

- Main site at Grady treating hepatitis C
- Primary Care Center
- 80 new referrals per month
- 2,500 patient visits annually
- Start with group education session

Staffing :

- 6 Gen Med faculty
- Residents and fellows
- CDC volunteers
- 2 Clinical Pharmacists
- Patient Assistance Analyst
- Patient Navigators
- Program Coordinator
- Nurse Practitioner

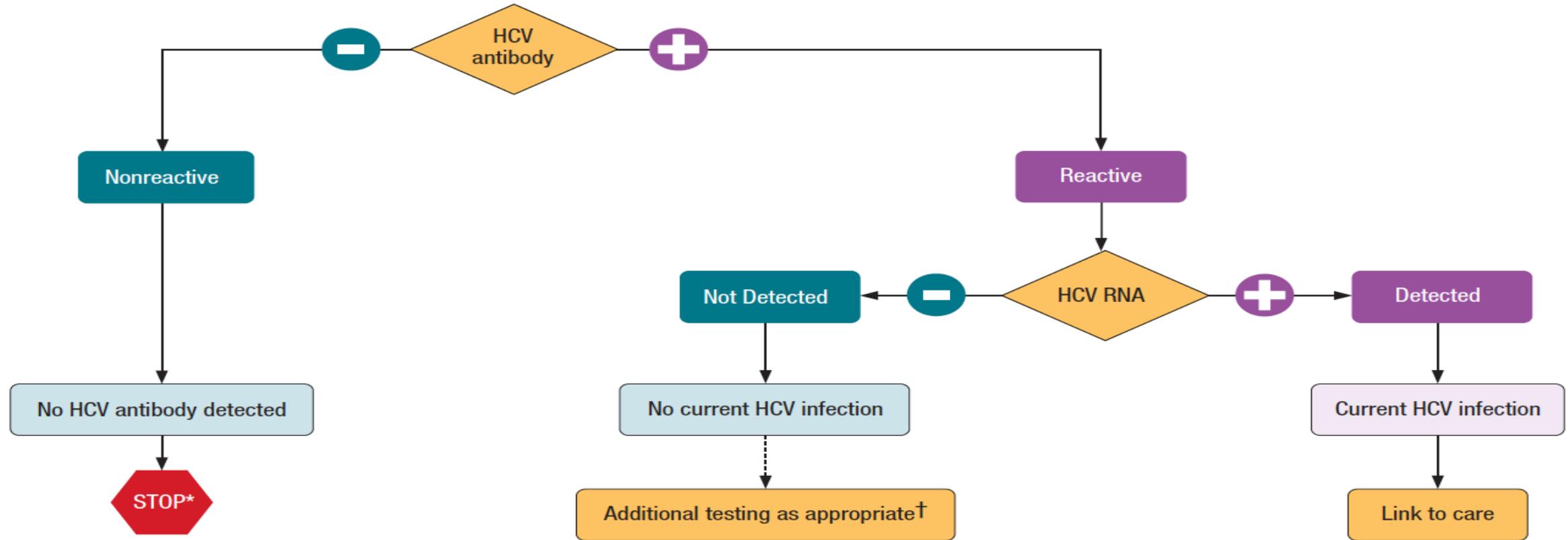
Liver Clinic Sequence



Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention



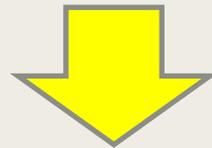
* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

HCV Work-up

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



Medication Choice

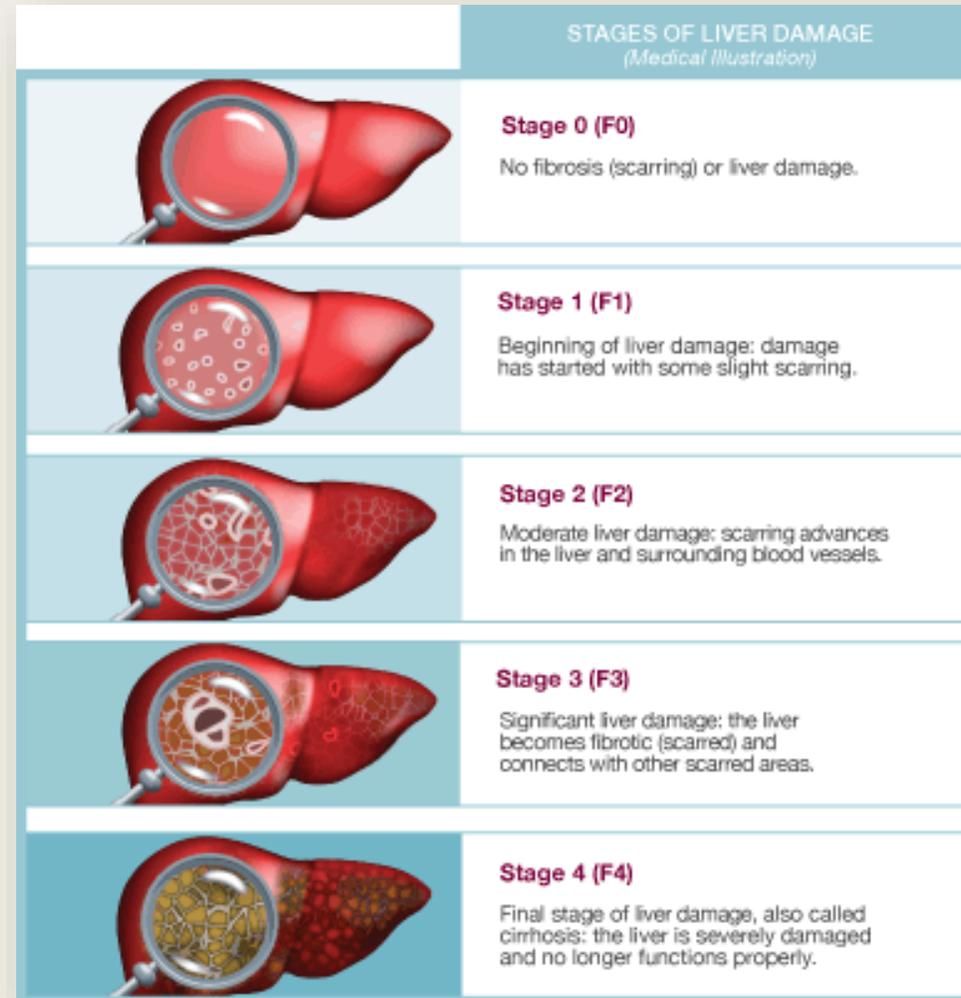
Quiz time

Which of the following is NOT commonly used to assess liver fibrosis (scarring)?

- A. Laboratory studies
- B. Liver imaging
- C. Fibroscan
- D. Liver biopsy

Staging Liver Fibrosis

- Labs
 - *APRI, FIB-4*
 - *FibroSure*
- Imaging
 - *Ultrasound*
 - *CT/MRI*
- Other
 - *Fibroscan*
- Gold standard
 - *Liver biopsy*



FIB-4 Score

Hepatitis C Online Sign In Create an Account

HCV Medications > Course Modules > **Clinical Calculators** > Slide Lectures > Core Concepts > Master Bibliography Search

Clinical Calculators

- APRI Calculator
- AUDIT-C Questionnaire
- BMI Calculator
- CrCl Calculator
- CAGE Questionnaire
- CTP Calculator
- FIB-4 Calculator**
- Glasgow Coma Scale
- GFR Calculator
- MELD Calculator
- SAAG Calculator

Fibrosis-4 (FIB-4) Calculator

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count (10}^9\text{/L)} \times \sqrt{\text{ALT (U/L)}}} = \text{[Yellow Oval]}$$

Interpretation:
Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

Source: Sterling RK, Lissen E, Clumeck N, et. al. Development of a simple noninvasive index to predict significant fibrosis patients with HIV/HCV co-infection. Hepatology 2006;43:1317-1325.

Funded by a grant from the Centers for Disease Control and Prevention

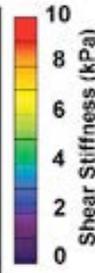
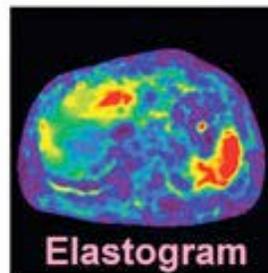
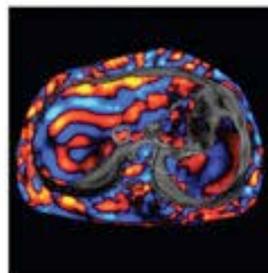
UNIVERSITY of WASHINGTON

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

IAS-USA
International Antiviral Society-USA



Acoustic Driver System for MRE



Passive Driver

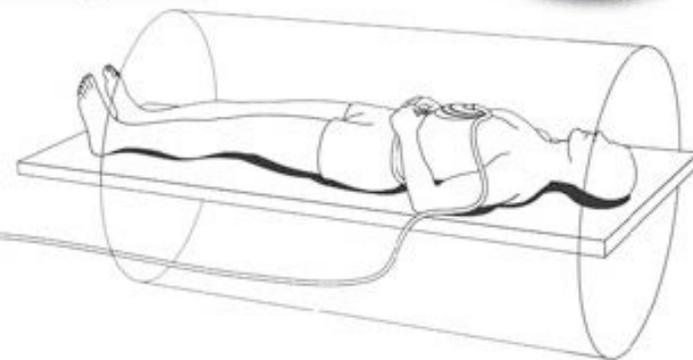


Acoustic waves at 60Hz

Imaging time: 15 sec



Active Driver



Recommended HCV Medications

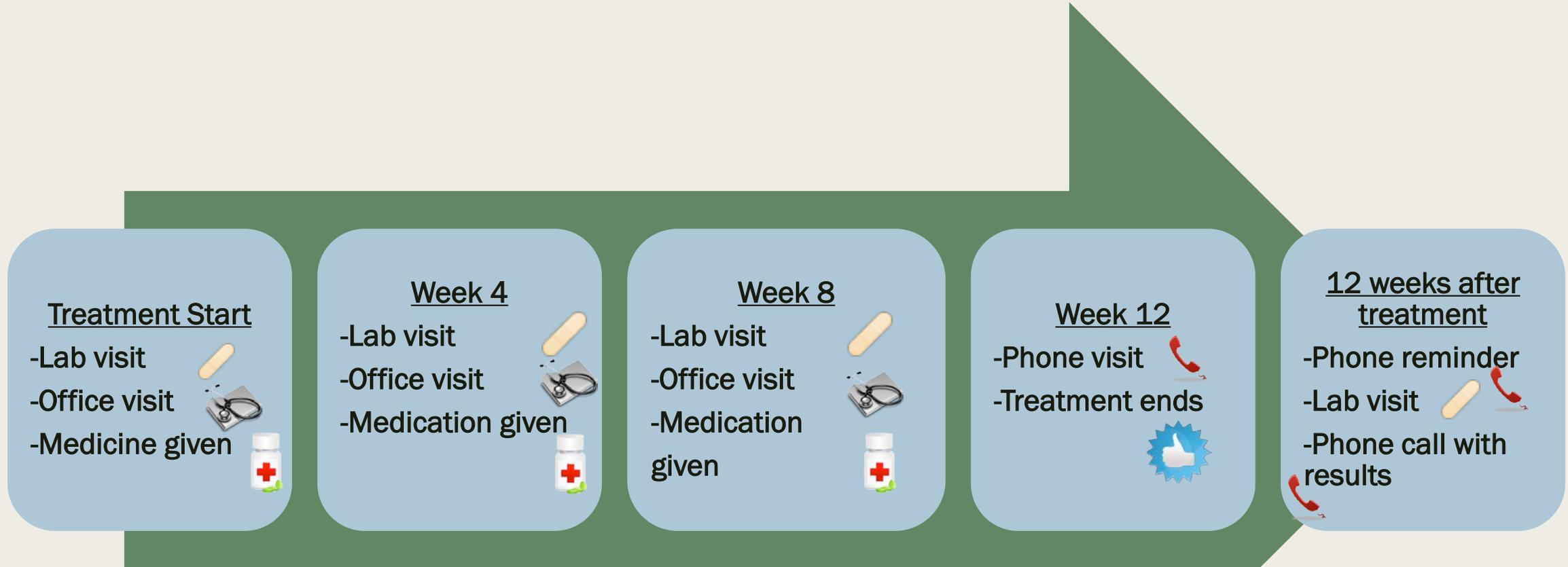
Ledipasvir/ sofosbuvir		SVR >90%
Elbasvir/ grazoprevir		SVR >90%
Velapatasvir/ sofosbuvir		SVR >90%
Sofosbuvir/ Velpatasvir/ Voxilaprevir		SVR >90%
Glecaprevir/ Pibrentasvir		SVR >90%

~One pill daily

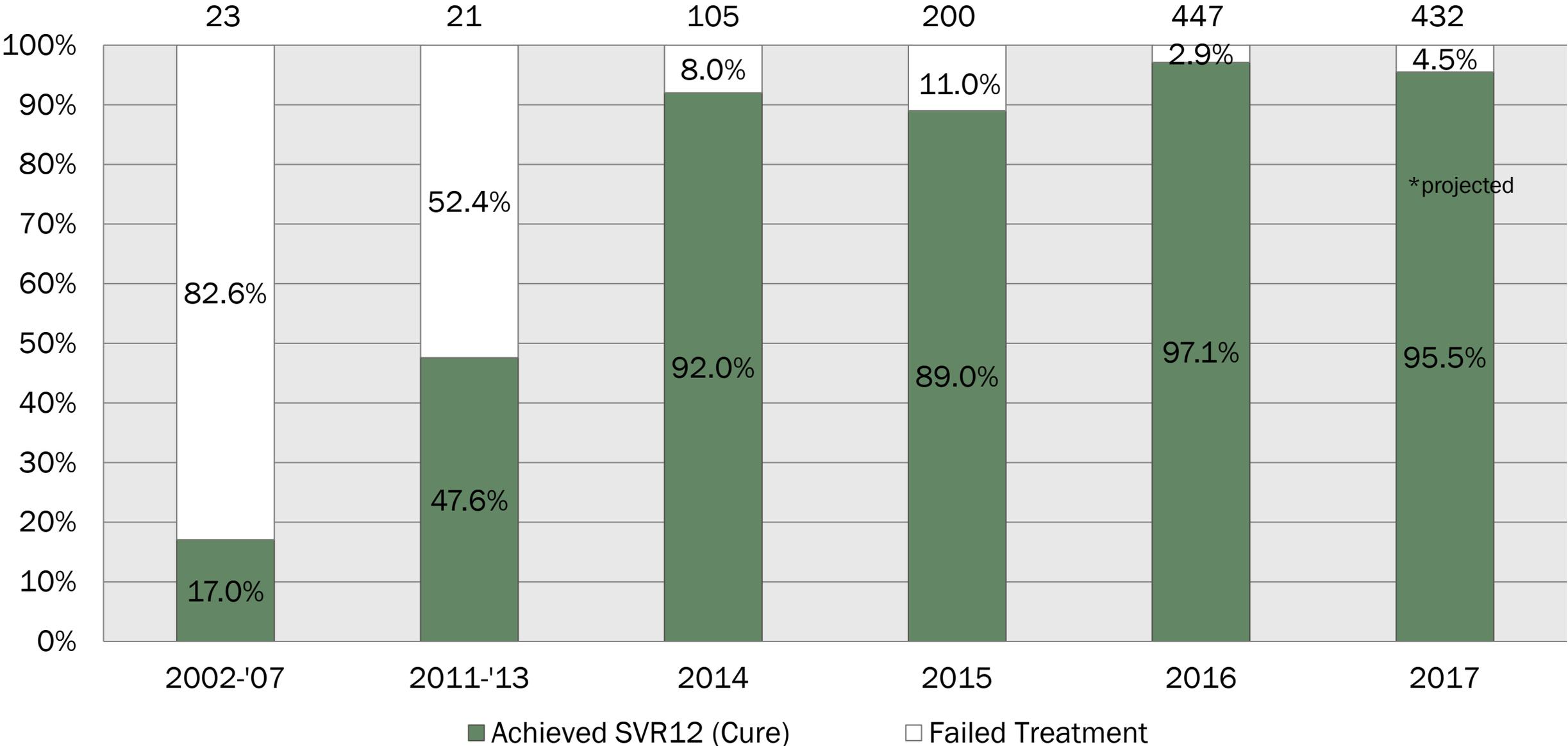
~8-12 week course

Well-tolerated

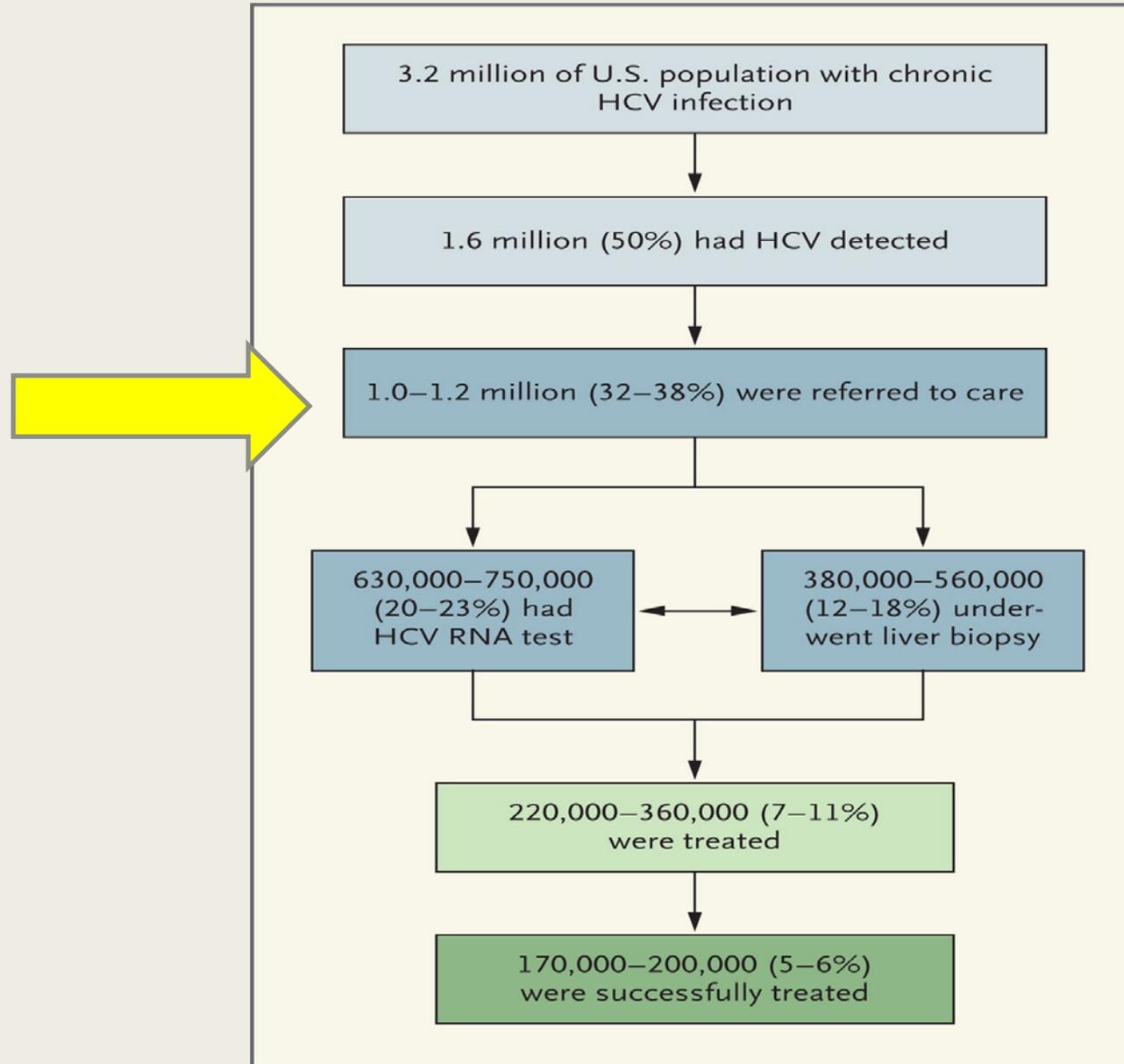
Grady Liver Clinic Treatment Timeline



Grady Liver Clinic Cure Rates



HCV Linkage to Care



Excellent HCV Treatment Outcomes by PCPS

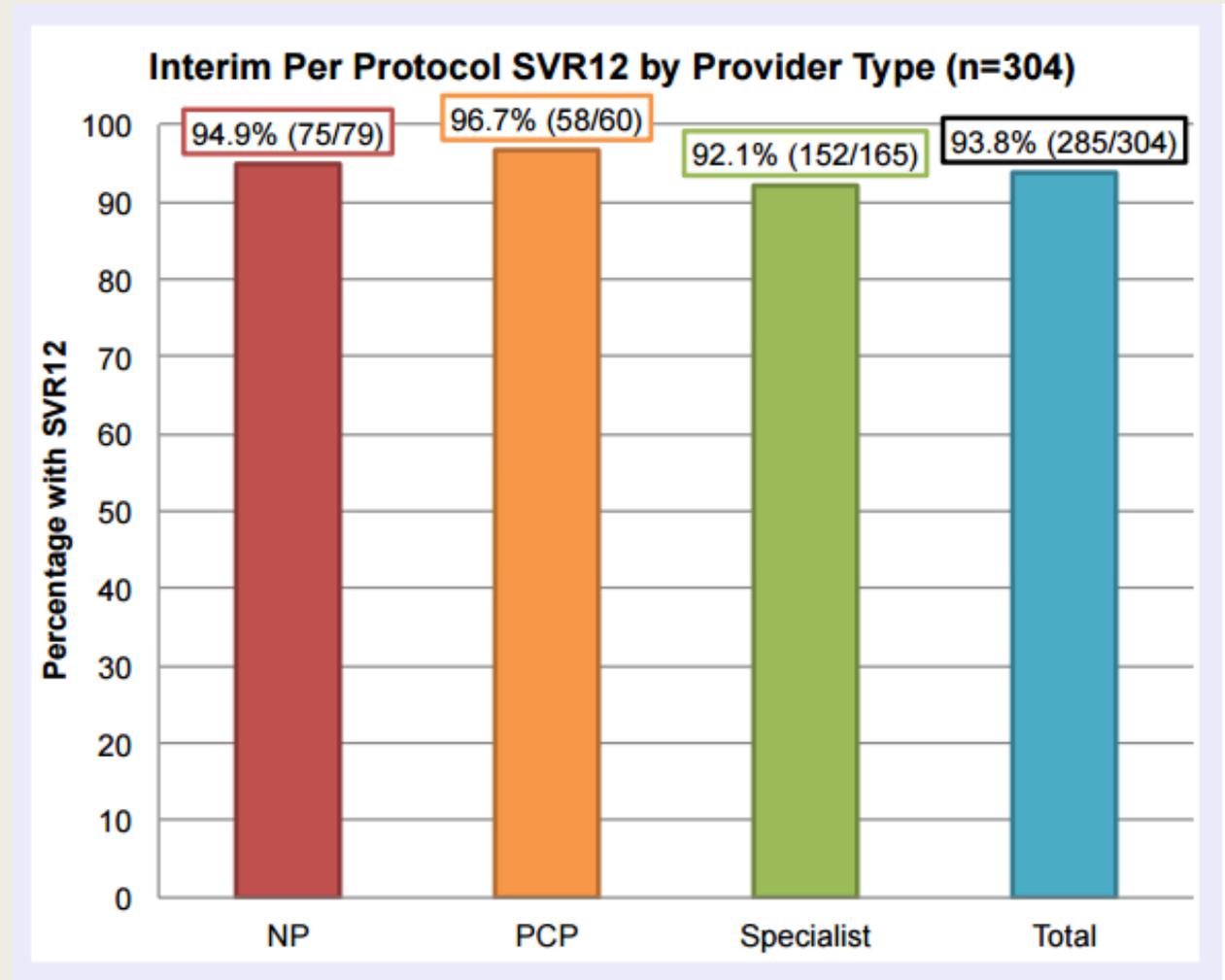


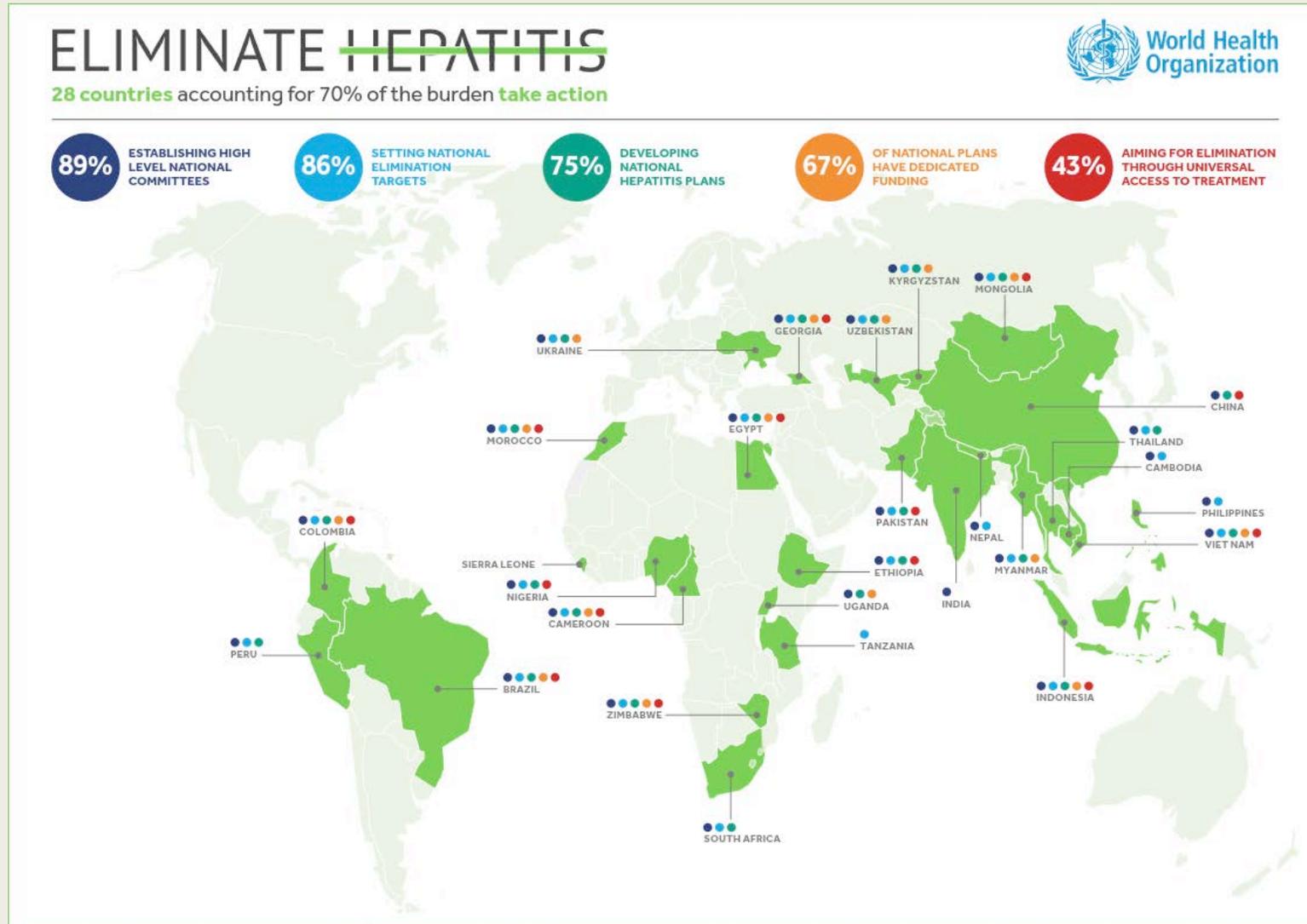
Figure 1. Interim Per Protocol SVR12 by Provider Type. Of 304 patients with available SVR12 results, 93.8% achieved SVR12. There was no significant difference in SVR12 between patients treated by NPs, PCPs, and specialist physicians

HCV Elimination

World Health Organization 2016 HBV and HCV Elimination Goals

Target areas		Baseline 2015	2020 target	2030 target
Impact leading to elimination	Incidence of chronic HBV and HCV infections	6–10 million	30% reduction	90% reduction
	Mortality from chronic HBV and HCV infections	1.46 million	10% reduction	65% reduction

Many countries are taking action

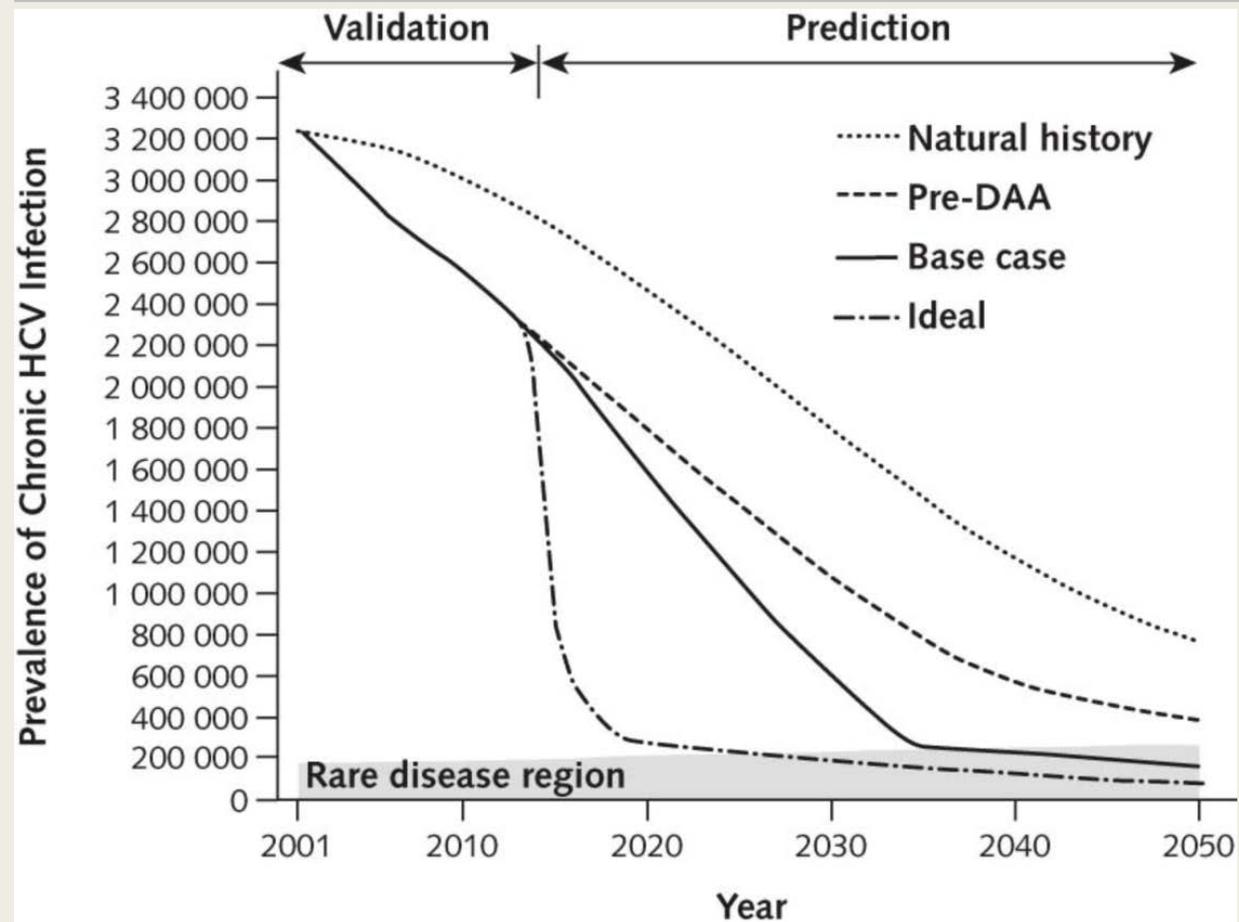


National Academies HCV Elimination Targets by 2030

- 90% reduction in HCV incidence (relative to 2015)
 - *Requires treatment without restriction on disease severity*
 - *Requires consistent ability to diagnose new cases*
 - *Depends on diagnosing 70-110k cases annually*
- Reduces mortality by 65%, averts 29k deaths

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



Conclusions

- HCV is common, deadly and curable, and incidence is rising
- Only 50% diagnosed, so screening is key to controlling the epidemic
- Alternate care models and patient navigation can improve linkage to care
- HCV treatment is now easy to tolerate, short duration and 95% successful
- Elimination can be achieved in a short time frame by leveraging existing screening, linkage and treatment strategies