

# Hepatitis C Testing and Linkage to Care



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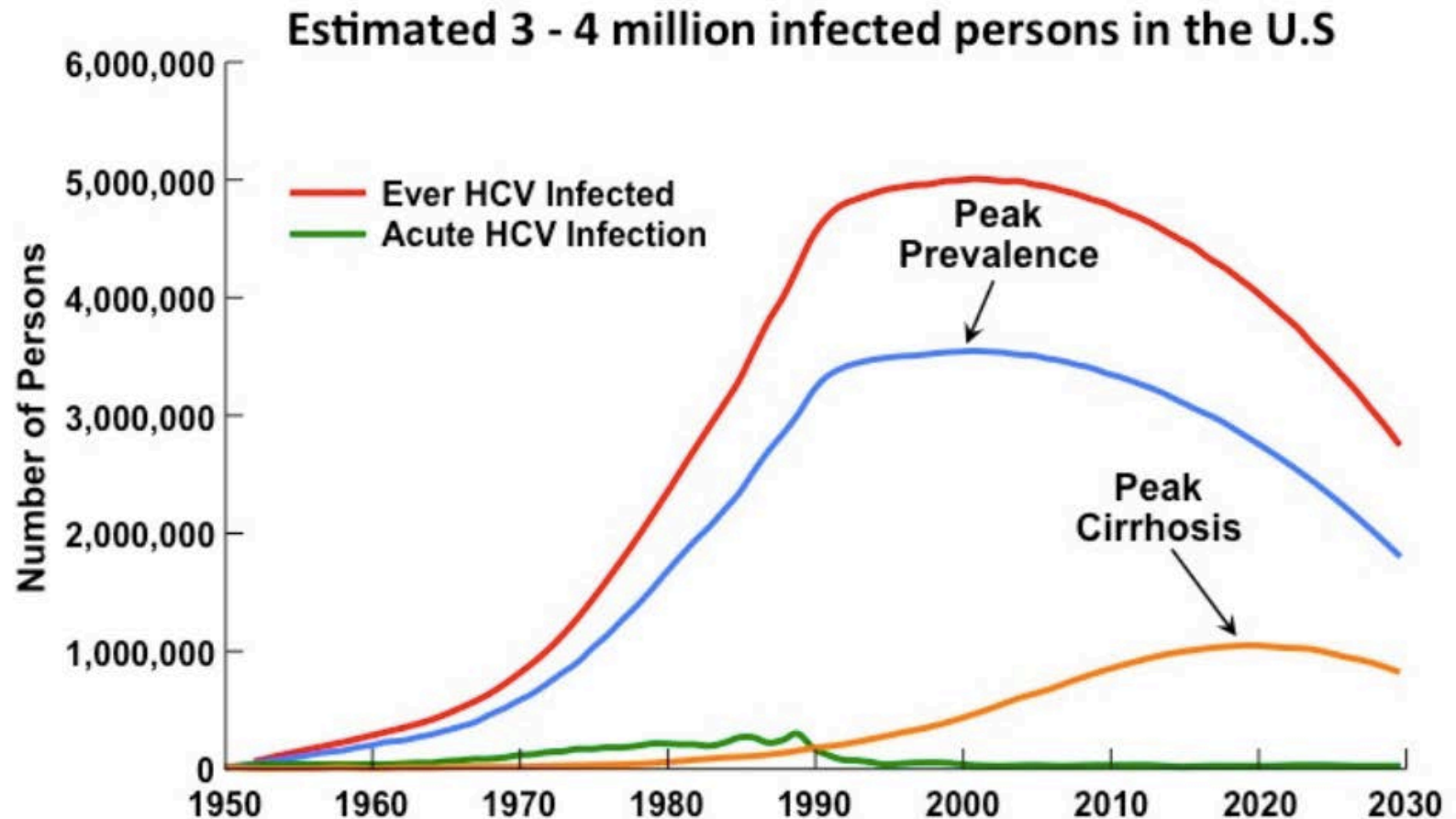
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January 21, 2016

# Overview

- Changing face of HCV in US
- Guidelines for HCV testing and treatment
- CDC HCV testing and linkage to care project
- HCV program at the Durham County Department of Public Health

# The Changing Face of HCV in US



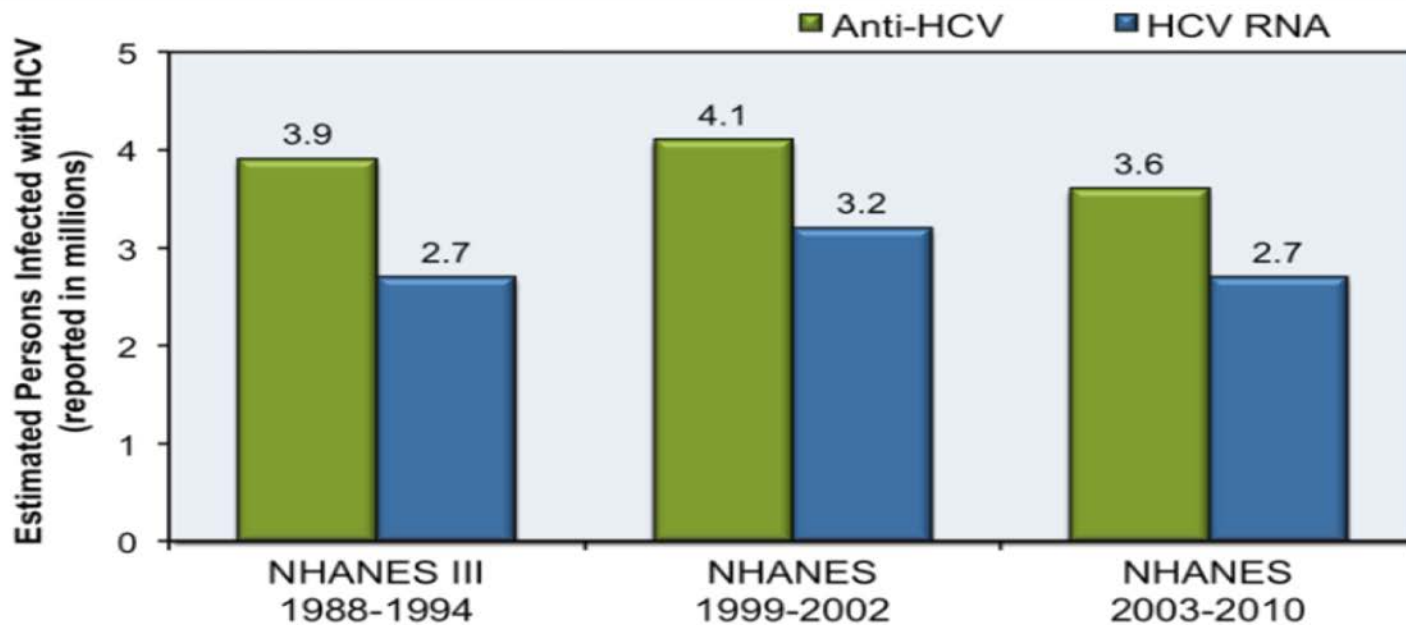
Adapted from Davis GL et al Gastroenterol 2010;138:513-521

# Estimated Number of Persons Infected with HCV in the US

**Figure 2 Estimated Number of Persons Infected with HCV in the United States.**

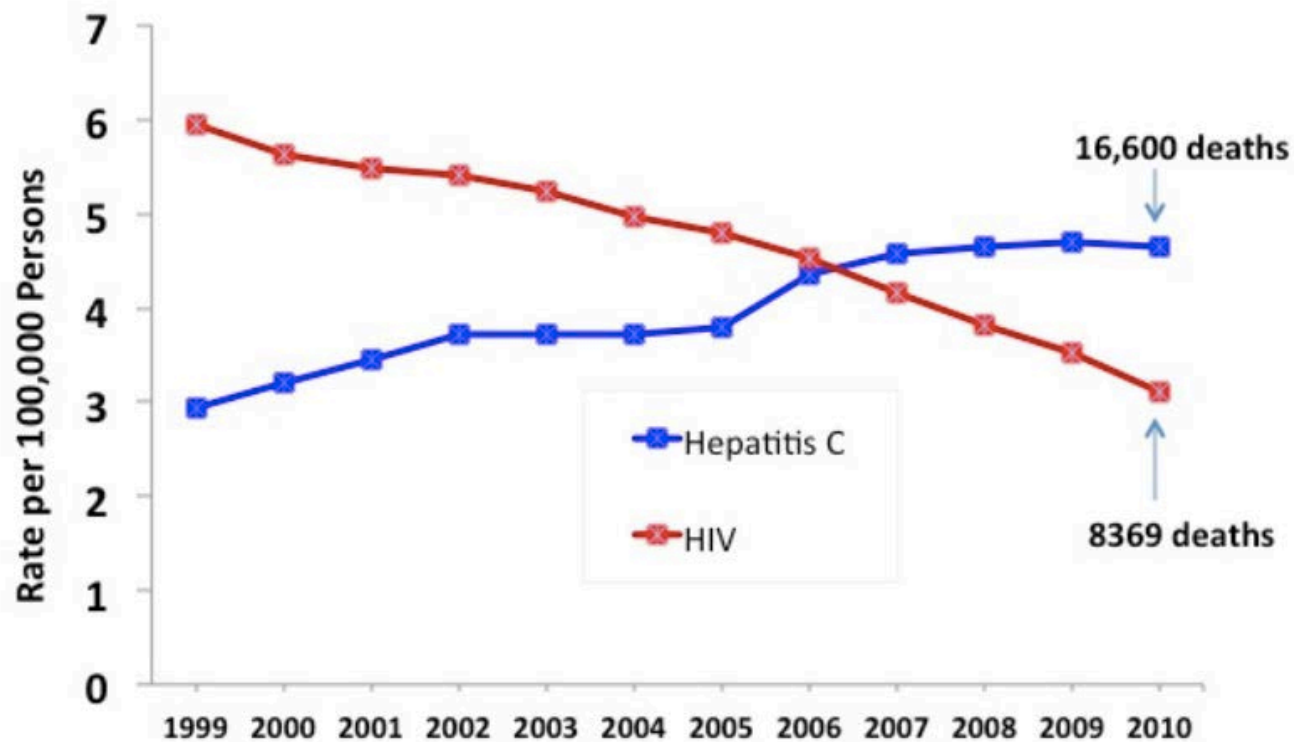
This graphic shows data representing seroprevalence (anti-HCV) and chronic infection (HCV RNA) from three distinct NHANES studies. The numbers on the bar graph represent millions of persons.

Source: Denniston MM, Jiles RB, Drobeniuc J, Klevens RM, Ward JW, McQuillan GM, Holmberg SD. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med.* 2014;160:293-300.

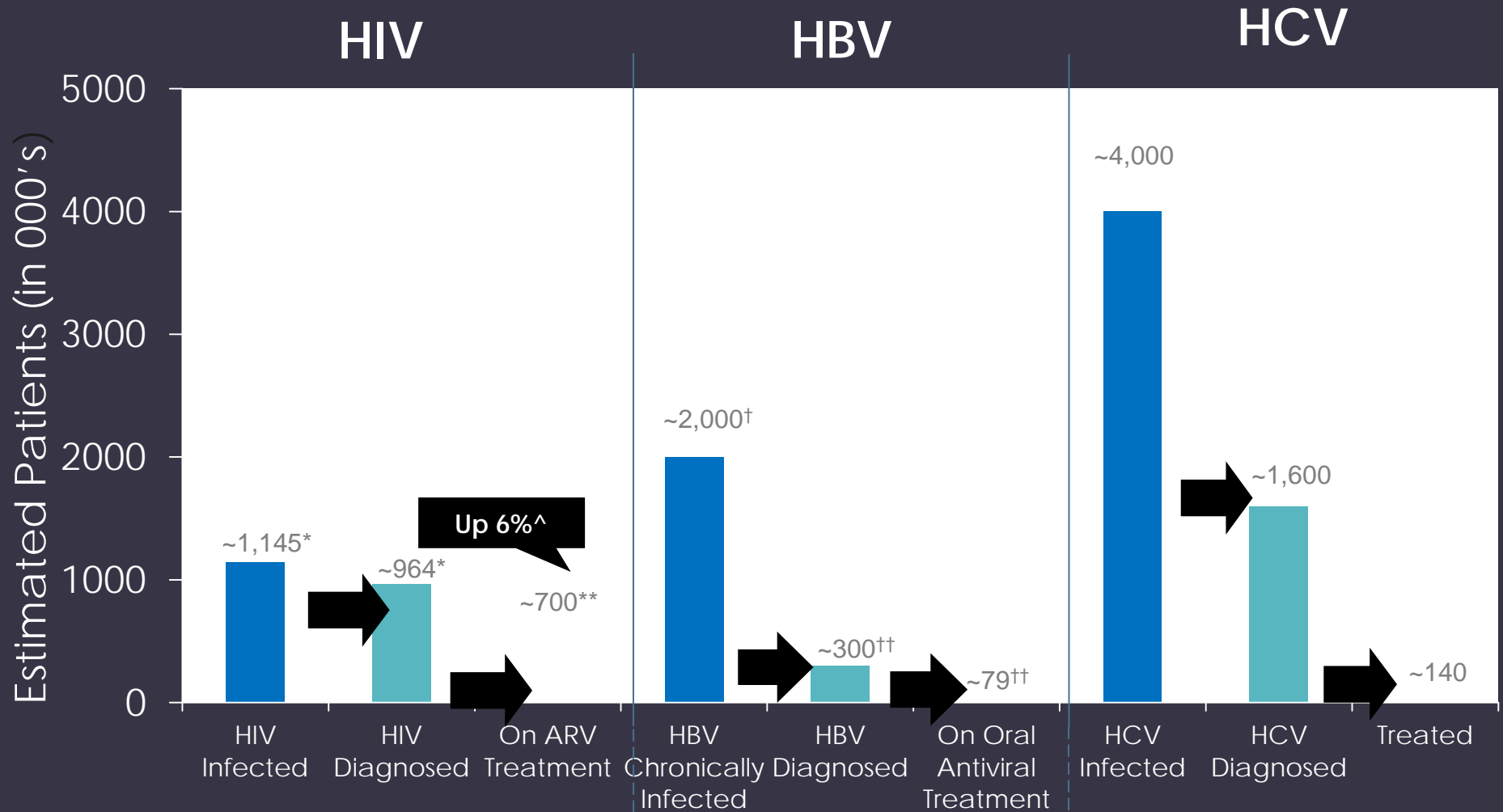


# Deaths From Hepatitis C Have Surpassed Deaths From HIV Infection

Age-adjusted Mortality Rates of HIV and Hepatitis C: United States, 1999-2010



# Treatment Cascades



\* CDC estimates at the end of 2010 taken from the HIV Surveillance Supplemental Report vol. 18 no. 5.

\*\* Ipsos Healthcare U.S. HIV Monitor Q2 2014.

^ Growth rate calculated as MAT (moving annual total).

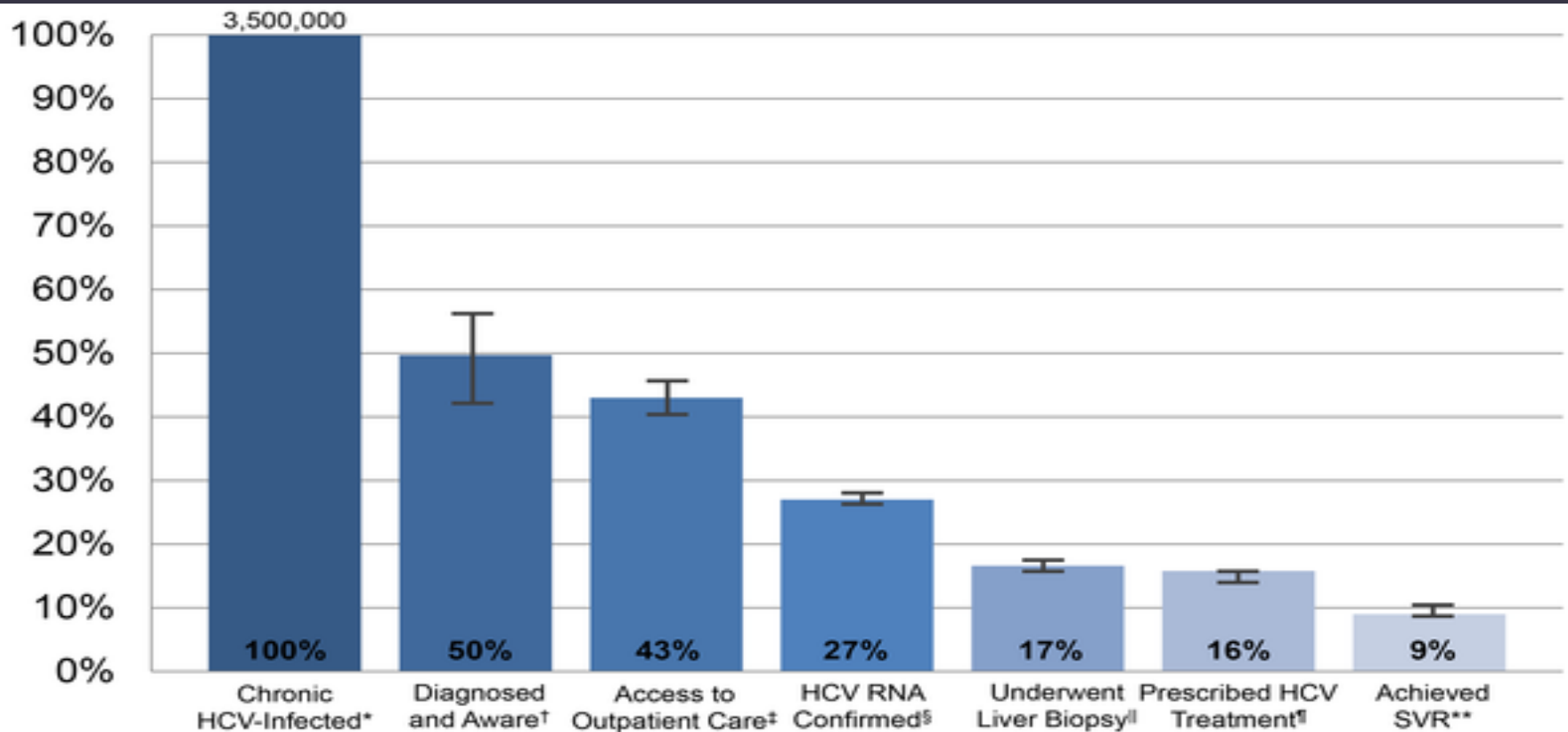
† CDC 12/4/08 Institute of Medicine presentation.

†† Based on Gilead estimates as of Q1 2013.

Chak et al 2008, Armstrong et al 2005, Volk et al 2011, Culver et al 2000

Decision resources: CDA AASLD 2012, NHANES 2012, Ipsos Monitor Q1 2014 and Gilead estimates. Data is applicable to the 12 month period beginning January 2014 through December 2014.

# HCV Treatment Cascade



\* Chronic HCV-Infected; N=3,500,000.

† Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.

‡ Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage with access to outpatient care (86.9%); n=1,514,667.

§ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.

|| Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.

¶ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=555,883.

\*\* Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.

Note: Only non-VA studies are included in the above HCV treatment cascade.



**One-time HCV testing is recommended for persons born between 1945 and 1965\*, without prior ascertainment of risk.**

**Rating:** Class I, Level B

**Other persons should be screened for risk factors for HCV infection, and 1-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.**

1. *Risk behaviors*

- Injection-drug use (current or ever, including those who injected once)
- Intranasal illicit drug use

2. *Risk exposures*

- Long-term hemodialysis (ever)
- Getting a tattoo in an unregulated setting
- Healthcare, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-infected blood
- Children born to HCV-infected women
- Prior recipients of transfusions or organ transplants, including:
  - were notified that they received
  - tested positive

**Annual HCV testing is recommended for persons who inject drugs and for HIV-seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV.**

**Rating:** Class IIA, Level C

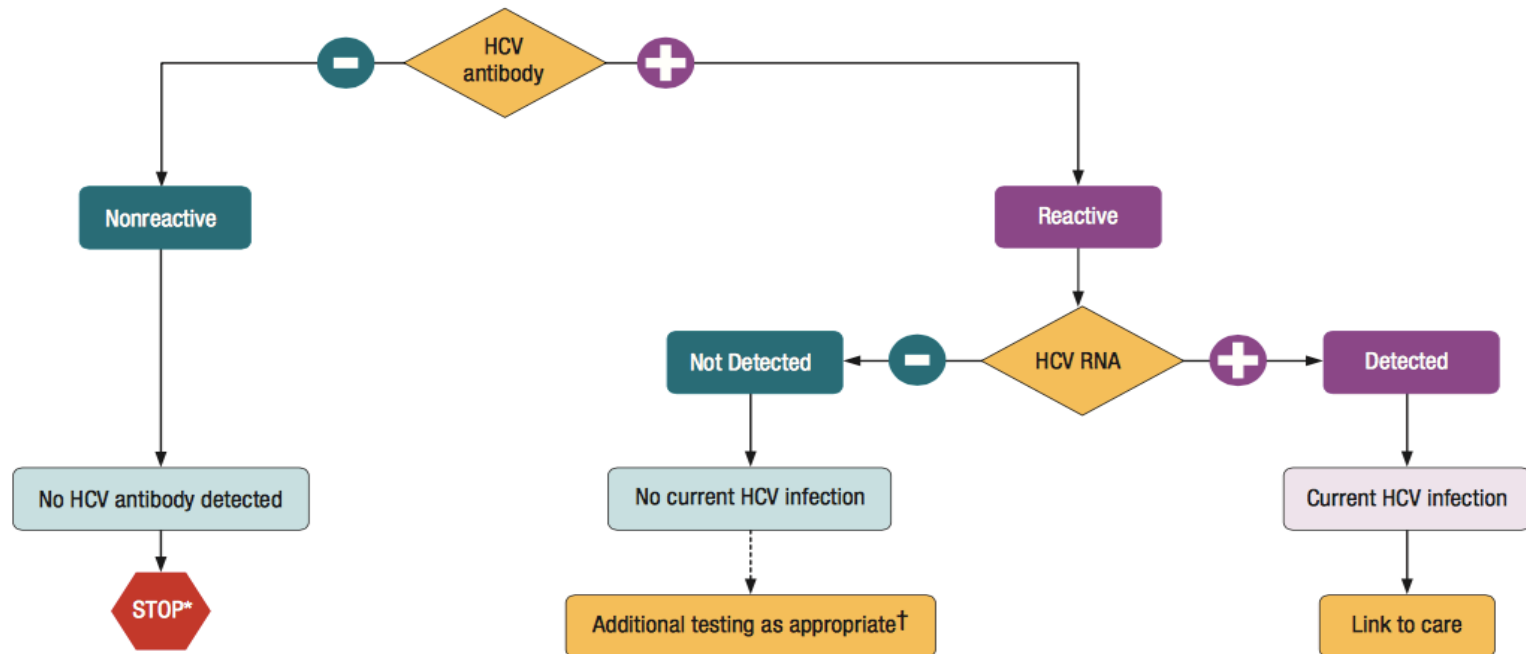
... chronic hepatitis including elevated  
... use levels  
... organ donors (deceased and living)

**Rating:** Class I, Level B

\*Regardless of country of birth



# HCV Testing Algorithm

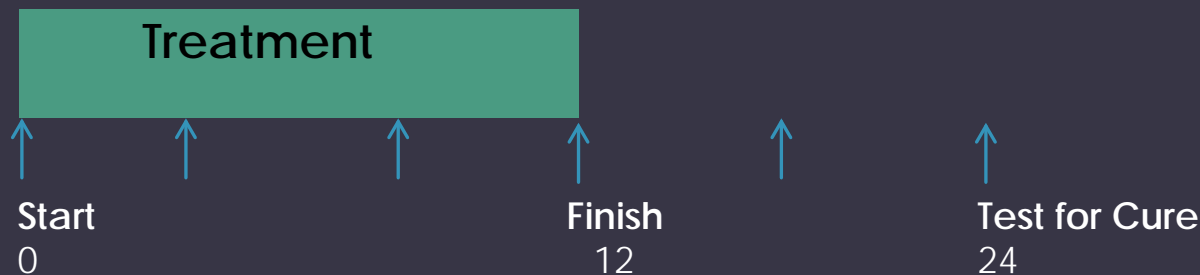


\* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† 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.

# HCV Therapy

- 8-12 week regimen
- Can be a single pill (with or without ribavirin)
- Well tolerated but costly
- 80-90% cure rates



# Evolving HCV Treatment

- Prior to 2011: Pegylated interferon; ribavirin
- May 2011: Protease inhibitors – boceprevir; telaprevir
- November 2013: Simepravarir
- December 2013: Polymerase inhibitor – Sofosbuvir
- October 2014: Ledipasvir/sofosbuvir
- November 2014: Simeprevir/sofosbuvir
- December 2014: Ombitasvir/partaprevir/ritonavir/dasabuvir
- July 2015: Ombitasvir/paritaprevir/ritonavir; daclatasvir

# CDC RFA PS12- 1209 PPHF12

## Project Objectives and Strategies, Durham NC

- To conduct 2000 HCV tests to identify chronic HCV-infected persons not previously aware of their infection in Durham County
  - Targeted screening - STD clinic, homeless clinic, community sites including residential substance abuse recovery program
  - Universal screening – Detection center
- To link a minimum 75% of persons who test positive for HCV RNA to care, treatment, and preventive services.
  - HCV Bridge Counselor (patient navigator)
  - Collaborations with HCV care providers
  - On-site HCV assessment clinics

# HCV Testing Results, Durham County, 2012-2014

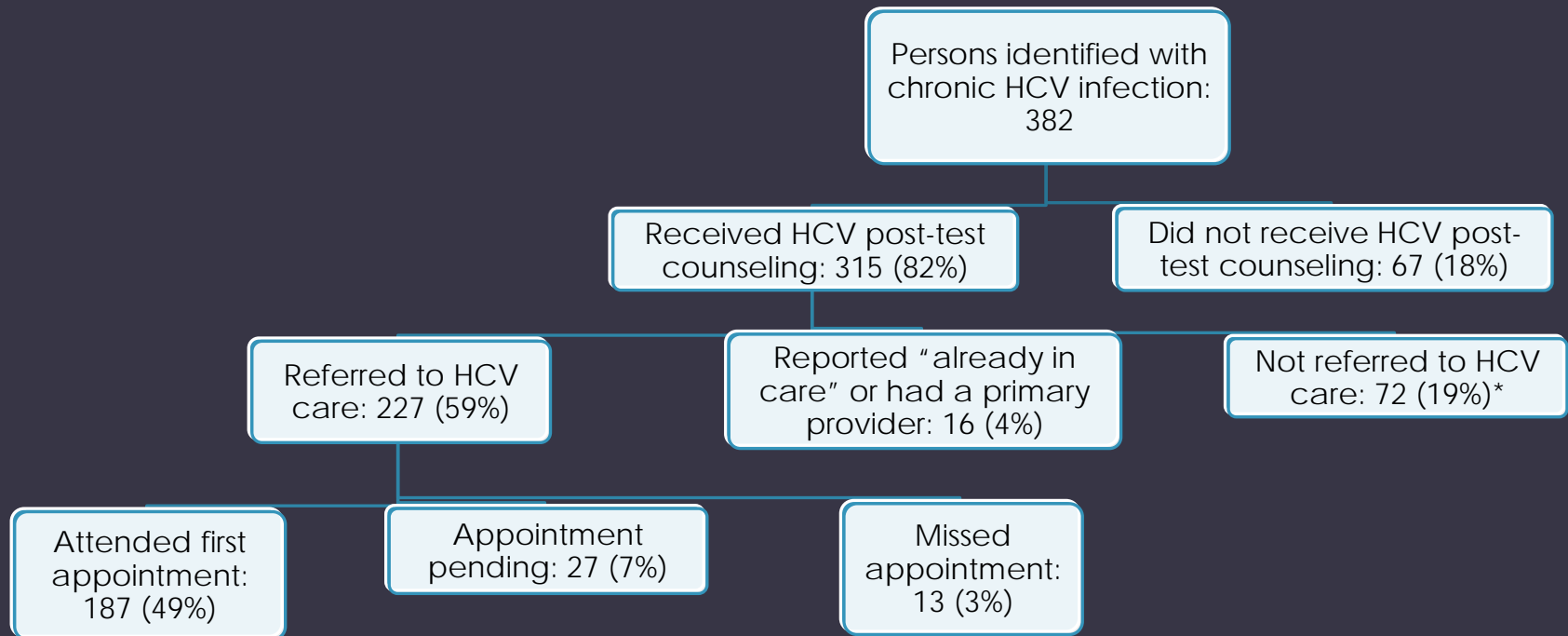
Testing Facility	Total Tests	HCV Antibody Positive	HCV Antibody Positive/RNA Positive	HCV Antibody Negative
County Jail	699	87 (12%)	71 (10%)	612 (88%)
STD Clinic	773	110 (14%)	82 (10%)	662 (86%)
Community Testing Sites	1418	272 (19%)	210 (15%)	1146 (81%)
Homeless Clinic	113	32 (28%)	27 (24%)	81 (72%)
Total	3003	501 (17%)	390 (13%)	2501 (83%)

# HCV Bridge Counselor Role

- Made first contact with HCV-infected clients
  - Assisted with post-test counseling and control measures
- Provided education to newly diagnosed persons
  - Alcohol prevention
  - Benefits of treatment
- Collected drug history, medical history, and contact information
- Served as the middle person to help facilitate the first doctor's visit



# HCV Linkage to Care, Durham County, 2012-2014



- Reasons for not being referred for HCV care: incarceration (n=16), relocation (n=16), refusal of linkage services (n=6), loss to follow-up/could not be located (n=25), or other (n=9).

# Lessons Learned

- HCV testing and linkage to care can be facilitated at the local public health level and integrated with HIV/STI programs.
- HCV bridge counseling is important to assist patients with barriers to care, including transportation, insurance status, stigma and other concerns about diagnosis.
- Getting HCV-infected patients to treatment remains problematic due to limited access (e.g. small number of prescribing providers, treatment costs).

# FOCUS PROGRAM

*"HIV and Hepatitis C Testing and  
Linkage to Care in Durham,  
North Carolina"*

Gilead Sciences, Inc.

# The FOCUS Model

## TEST: FOUR PILLARS OF ROUTINE SCREENING

### TESTING INTEGRATED INTO NORMAL CLINICAL FLOW

To promote the normalization and sustainability of testing.

### ELECTRONIC MEDICAL RECORD MODIFICATION

To prompt testing, automate processes, populate lab orders and track performance.

### SYSTEMIC POLICY CHANGE

A multi-level, organization-wide commitment to implement routine testing and linkage to care.

### TRAINING, FEEDBACK & QUALITY IMPROVEMENT

To identify best practices and motivate staff.

FOCUS FOUR PILLARS, GILEAD SCIENCES, 2014

## HIV

Centers for Disease Control and Prevention  
**MMWR**  
Weekly / Vol. 63 / No. 25

Morbidity and Mortality Weekly Report  
June 27, 2014

National HIV Testing Day and  
New Testing Recommendations

Routine HIV Screening in Two Health-Care Settings — New York City and New Orleans, 2011–2013

## HCV

Centers for Disease Control and Prevention  
**MMWR**  
Weekly / Vol. 64 / No. 17

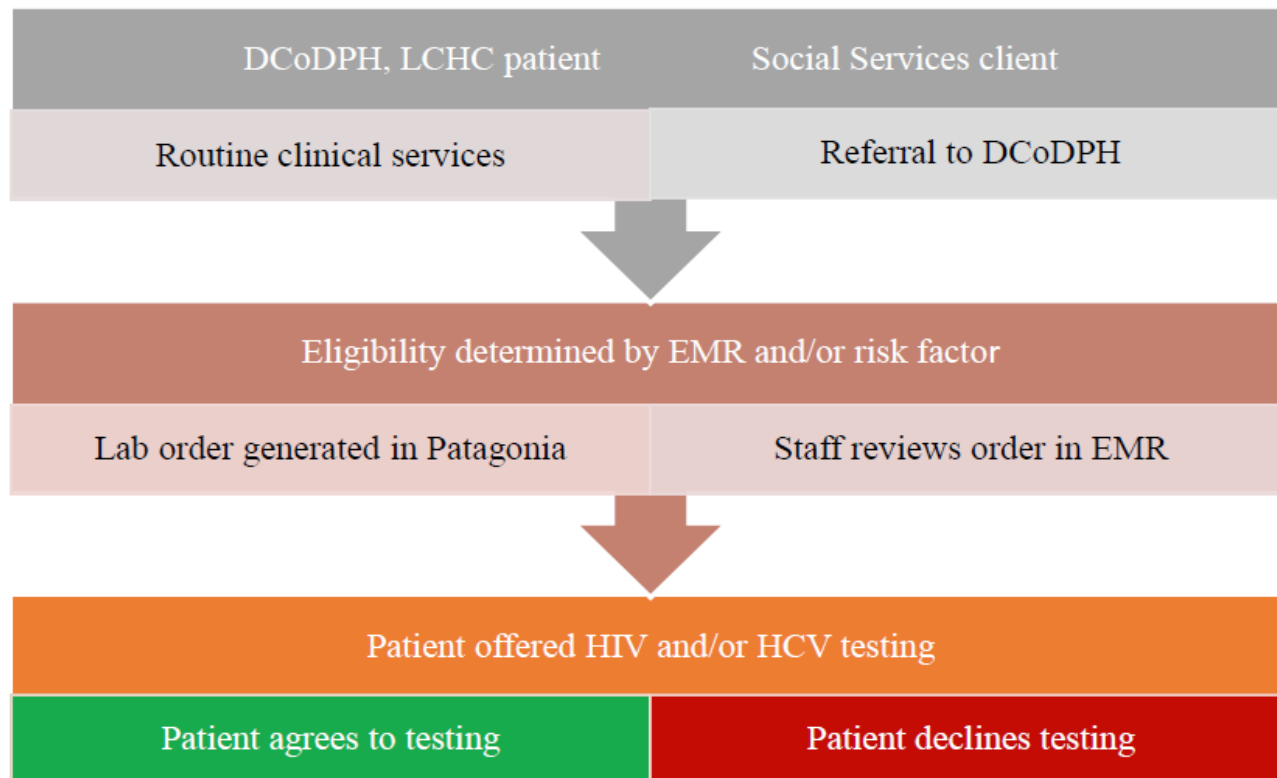
Morbidity and Mortality Weekly Report  
May 8, 2015

Hepatitis Awareness Month and  
National Hepatitis Testing Day  
— May 2015

Identification and Linkage to Care of  
HCV-Infected Persons in Five Health  
Centers — Philadelphia, Pennsylvania,  
2012–2014

# Integrated Testing

## APPENDIX A: Testing Integration Flow Chart



# Innovative Strategies

- Maximizing opportunities to provide routine HIV/HCV testing within a human services facility;
- Offering HIV/HCV screening to clients seeking social services;
- Co-location of services (primary care clinic within health department) under one roof to assist linkage to care;
- Creation of an HIV/HCV testing and coordination resource center for the community within the health department.



# Questions

