Hepatitis C & African American Women

May 7, 2015

Hosted by the Department of Health and Human Services

Office on Women's Health,

Office of Minority Health, &

Office of HIV/AIDS and Infectious Disease Policy

HCV Prevention Webinar Logistics

- In case of technical difficulties, call:

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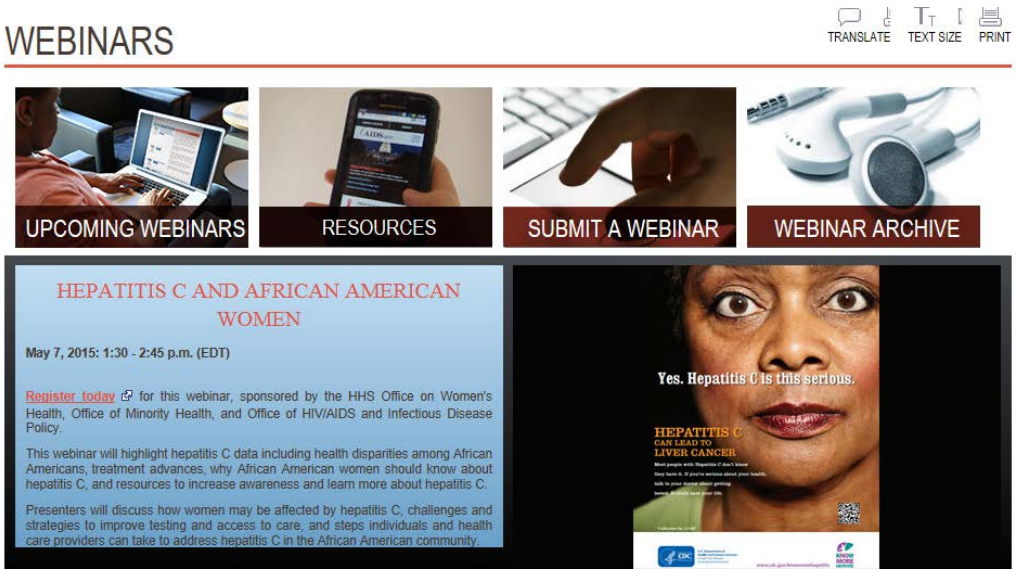
- The webinar is being recorded and will be archived on AIDS.gov



Introductory Remarks

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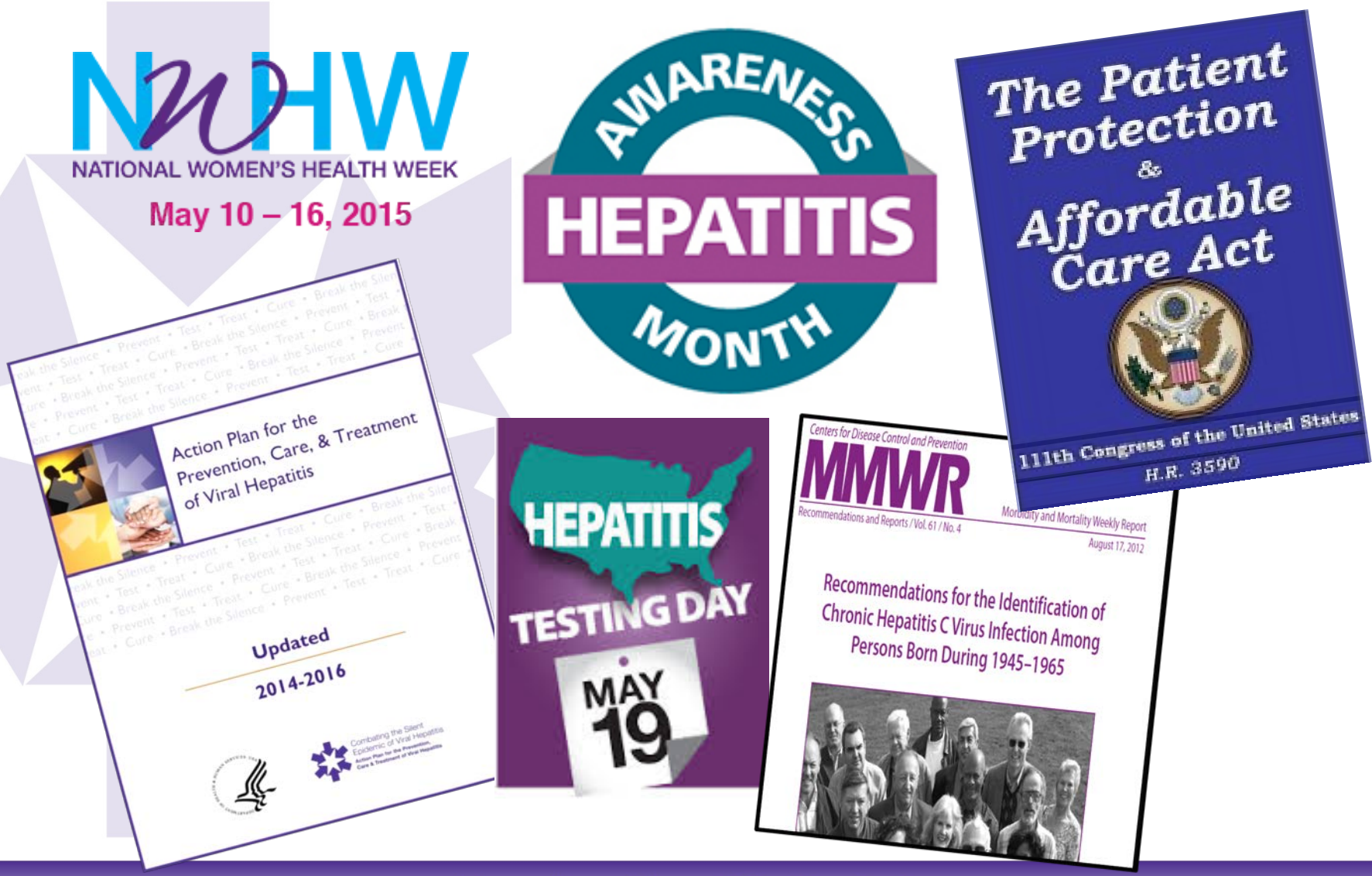
Director, Office of HIV/AIDS & Infectious Disease Policy

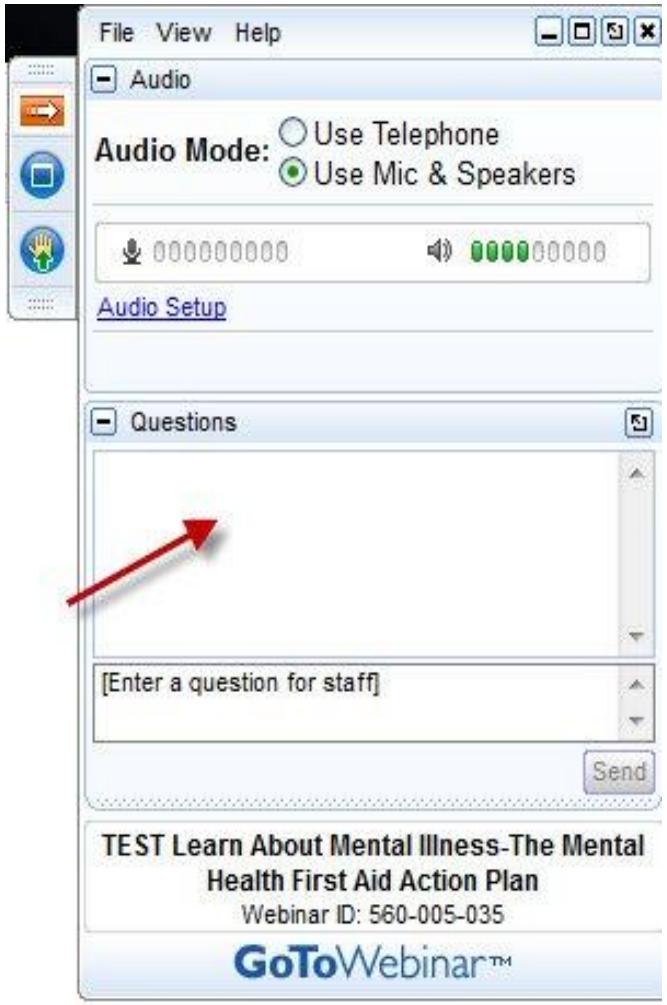
Addressing Hepatitis C Health Disparities



Hepatitis C & African American Women Q & A

Got Questions?

Please type your questions into the "Questions" box throughout the webinar and we will address them during the Q & A.



Epidemiology of Hepatitis C Virus Infection

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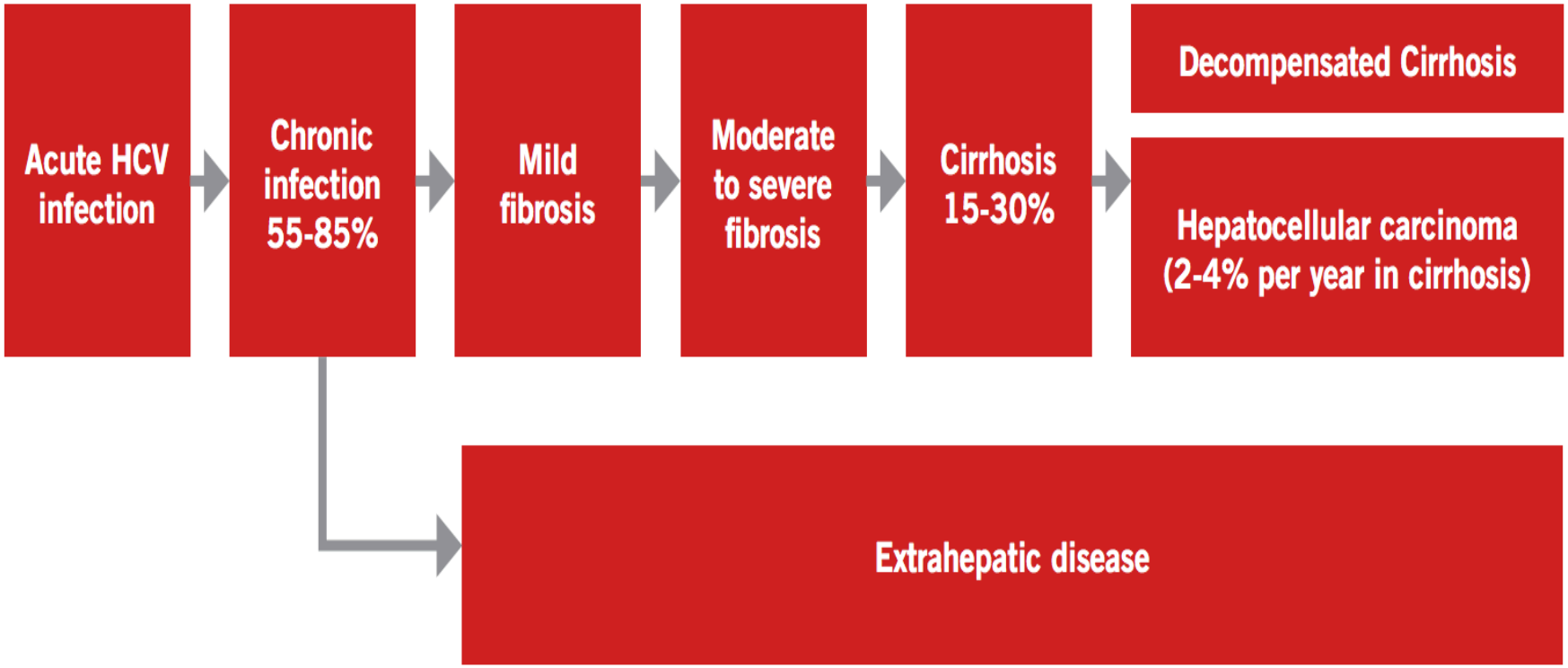
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

What is Hepatitis C?

- Hepatitis C is a liver disease that results from infection with the hepatitis C virus (HCV).

Natural History of HCV Infection



HIV, HBV, alcohol, and steatosis can accelerate disease progression

ESLD: End-stage liver disease. HCC: Hepatocellular cancer. HIV: Human immunodeficiency virus. HBV: Hepatitis B virus.

. Fattovich G, Gastroenterology 1997; NIH Consensus Statement. June 2002. http://www.who.int/hiv/pub/hepatitis/

How is HCV Transmitted

- Hepatitis C is usually spread when blood from a person infected with the Hepatitis C virus enters the body of someone who is not infected.

- Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs. Before 1992, when widespread screening of the blood supply began in the United States, Hepatitis C was also commonly spread through blood transfusions and organ transplants.

- Although uncommon, outbreaks of hepatitis C have occurred in medical settings, most often from lapses in infection control.

How is HCV Transmitted

- Hepatitis C can be transmitted through sex although experts believe this does not occur often. However, there is some research showing that men who have sex with men , who are HIV positive and have multiple sex partners have an increased risk for hepatitis C.

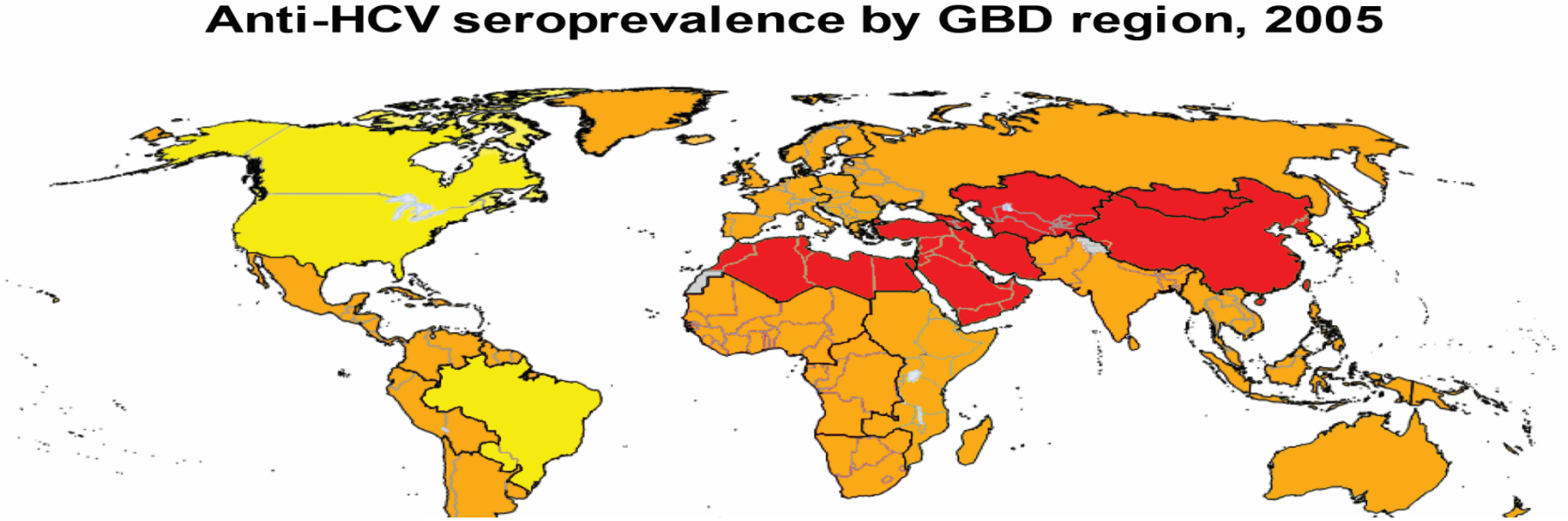
- There is little evidence that hepatitis C is transmitted by getting tattoos in licensed, commercial facilities, but whenever tattoos or body piercings are given in informal settings (such as prisons) or with non-sterile equipment, transmission of hepatitis C is possible.

Public Health Issue

- Hepatitis C virus (HCV) is the most common blood-borne infection in the USA and worldwide.

- However, most of those infected don't know they have it, thereby increasing the risk of developing severe liver disease and transmitting the virus to others.

Global Burden of Hepatitis C



- An estimated 3–4 million people are infected with HCV each year
- Approximately 3% (about 130 to 170 million) of the world's population is chronically infected with HCV
- More than 350,000 people die from HCV-related liver diseases each year

GBD: Global burden of disease.
Hanafiah K, *Hepatology* 2012. Lozano R, *Lancet* 2012.
Anti-HCV
Anti-HCV Seroprevalence is defined as the number of persons in a population who test positive for a hepatitis C based on blood specimens

Division of Viral Hepatitis

Prevalence of Current HCV Infection Among Persons in the United States

Population	Number	%
Non-Institutionalized Civilian Population (data source: NHANES)	2.7 Million (2.2–3.2 million)	1.0% (0.8%–1.2%)
Among Homeless and Incarcerated Persons (Not Included in NHANES)	360,000–840,000	22%–52%

Denniston M, *Ann Int Med* 2014.
Chak E, *Liver Int* 2011.
Berg CL, Am J. Transplant, 2009.
Ly, KN, Ann Intern Med, 2012

Burden of Hepatitis C Virus Among Persons Born 1945–1965

- For persons born during 1945 to 1965
  - Prevalence of Hepatitis C virus (HCV) is 5.3 times higher than other ages (3.25% vs. 0.55%);
  - Of all HCV infected in U.S. Adults, 81% were born in this cohort;
  - Of all HCV related deaths in U.S. 73% were born in this cohort;
  - HCV infection prevalence was highest among non-Hispanic black males (8.12%), followed by non-Hispanic white males (4.05%) and Mexican-American males (3.41%); and
  - Up to 75% do not know they are infected

Smith, *AASLD Liver Meeting* 2011. Armstrong, *Ann Int Med* 2006. Kramer, *Hepatology* 2011. Ly, *Ann Int Med* 2012.

Burden of Hepatitis C Virus Among African Americans

- HCV prevalence among African Americans (3.2%) was more than two times that of non-Hispanic whites (1.5%).
- African Americas accounted for 11% of the population, yet represented 25% of participants living with HCV.
- Hepatocellular Carcinoma (Liver Cancer) is significantly higher in African Americans compared to non-Hispanic whites.

Armstrong GL et al., *Ann Intern Med* 2006;
Denniston et al. Ann Intern Med. 2014
Sarathchandra I. Reddy and Chinweike Ukomadu, *Cancer Epidemiol Biomarkers Prev March 2003*

Division of Viral Hepatitis

African Americans and HCV Mortality

- In 2010, among patients with HCV, the highest death rates have been observed among ethnic minorities including African Americans.
- In 2011, the death rate with HCV listed as a cause of death was 7.89 per 100,000 for African Americans, compared to 4.19 per 100,000 for whites
- African Americans have the highest mortality rates of liver and bile duct cancer.

Ly K. et al, 2010. Clin. Infect. Dis.

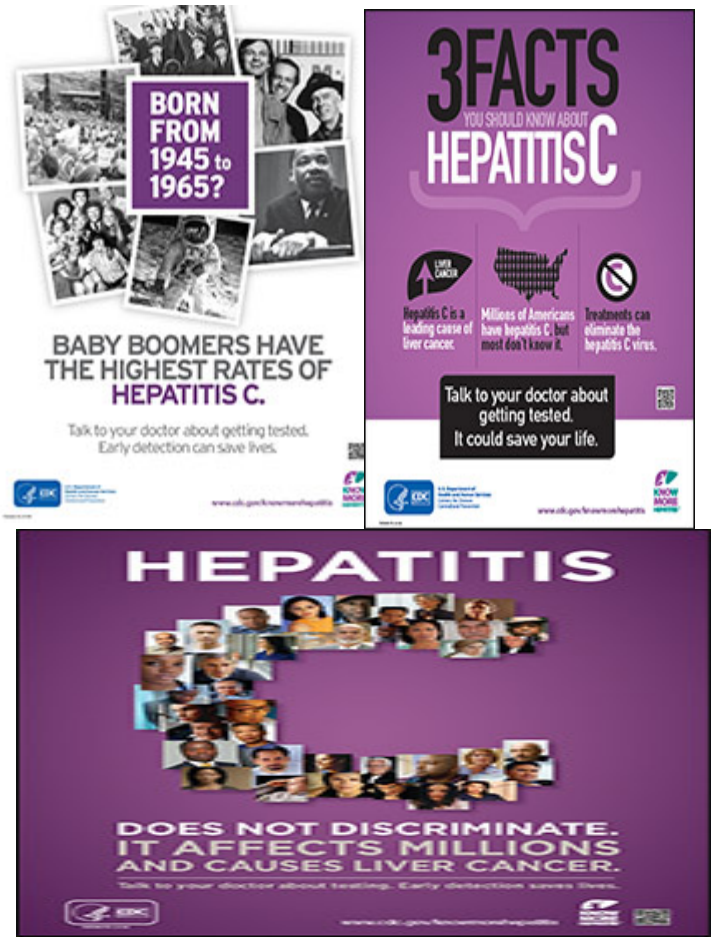
Viral Hepatitis Surveillance United States 2012. CDC. (p. 51)

NCI 2013. Seer Cancer Statistics Review, 1975-2010. Table 1.21. http://seer.cancer.gov/csr/1975_2010/sections.html

Mortality rate: is a measure of the number of deaths (in general, or due to a specific cause) in a particular population, scaled to the size of that population, per unit of time.

African Americans and HCV Screening/Testing

- Testing is critical to reducing death and disease from Hepatitis C.
- To help increase testing, CDC and USPSTF recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965.
- CDC and U.S. Preventive Services Task Force (USPSTF) recommends testing screening for hepatitis C virus (HCV) infection in persons at high risk for infection.



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CDC Recommendations for Testing for Hepatitis C

- **Persons born from Adults born during 1945-1965**
- **High Risk Persons who should be tested for hepatitis C virus infection include those who:**
  - Currently inject drugs
  - Ever injected drugs (including those who injected only once many years ago)
  - Who received blood products made prior to 1987
  - Who were ever on long-term hemodialysis
  - With persistent abnormal alanine aminotransferase levels (ALT)
  - Who have HIV infection
  - Who were recipients of blood transfusions, blood components or an organ transplants before July 1992
  - Persons with known exposures to HCV (i.e., needle sticks exposures) to infected blood.
  - Children born to women with hepatitis C

MMWR Aug 2012. Moyer VA, *Ann Int Med* 2013.

In Summary

- The burden of HCV-related disease is large and growing
- African Americans have twice the HCV prevalence and mortality as White Americans
- CDC & USPSTF recommends HCV testing for persons
  - Born during 1945 to 1965
  - Persons at high risk for infection
- Early diagnosis of hepatitis C infection can lead to HCV treatment.
- New HCV treatments have cure rates as high as 90% to 100%.

Citation for Cure Rates: M Manns, S Pol, IM Jacobson, et al. All-oral daclatasvir plus asunaprevir for hepatitis C virus genotype 1b: a multinational, phase 3, multicohort study. Lancet, 384 (2014), pp. 1597–1605

Resources

CDC website for viral hepatitis:

- http://www.cdc.gov/hepatitis

Know More Hepatitis Information:

- http://www.cdc.gov/knowmorehepatitis/

Online Risk Assessment for Hepatitis Testing:

- http://www.cdc.gov/hepatitis/RiskAssessment/

African American Targeted Material:

- http://www.cdc.gov/hepatitis/Populations/AAC-HepC.htm

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Thank you!!

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Hepatitis C Management and Update on Treatment

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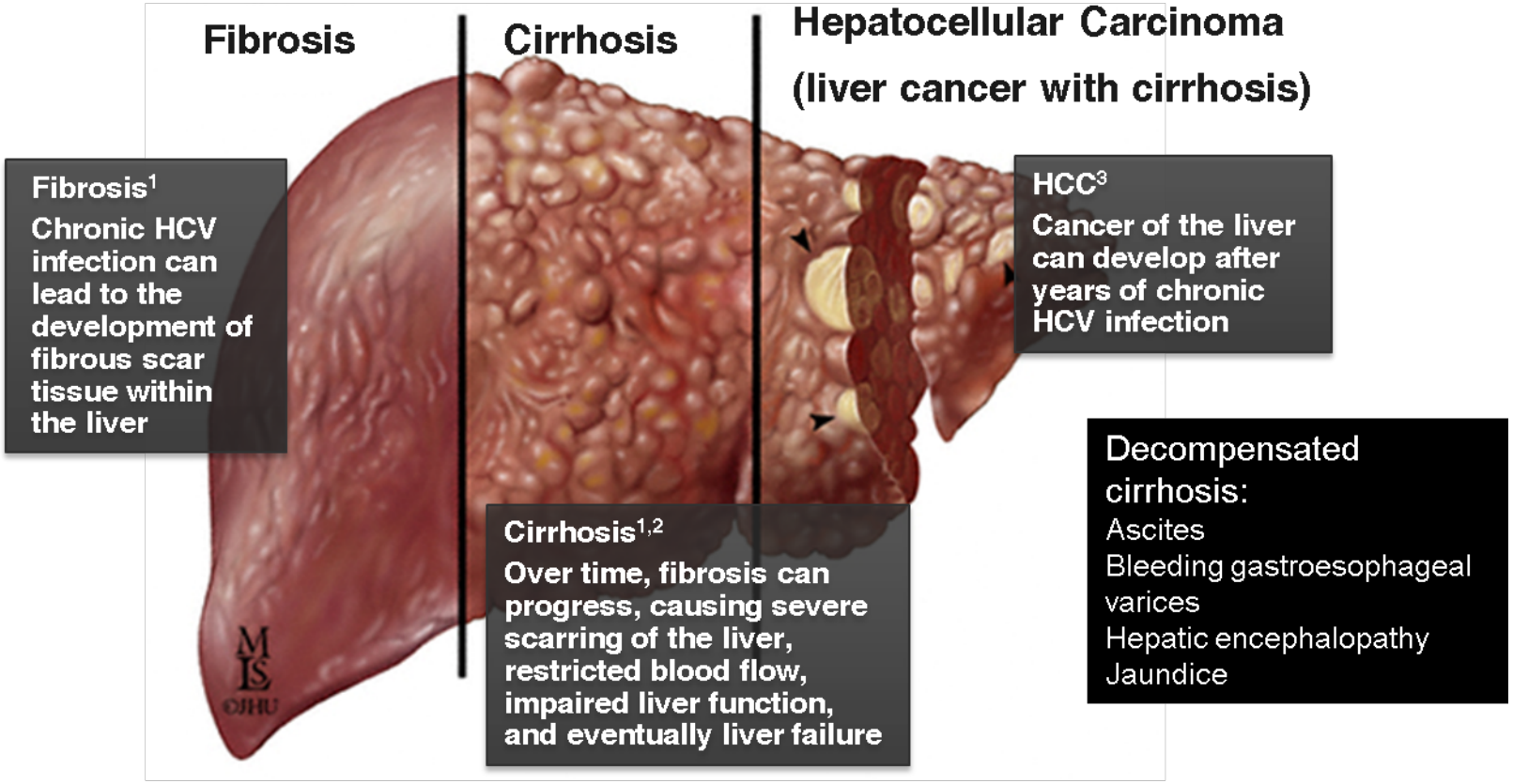
Chronic HCV Infection May Lead to Chronic Liver Disease and Liver Cancer



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

1. Highleyman L. Hepatitis C Support Project. http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Fibrosis.pdf. Accessed August 18, 2011; 2. Bataller R et al. *J Clin Invest*. 2005;115:209-218;
3. Medline Plus. http://www.nlm.nih.gov/medlineplus/enxy.article/000280.htm. Accessed August 28, 2012; 4. Centers for Disease Control and Prevention. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm. Accessed May 8, 2012.

Complications of Hepatitis C

- Most baby boomers were infected with hepatitis C 20 to 40 years ago and are now developing severe complications
  - 25% of people born 1945-1965 already have cirrhosis
  - 75% of people with cirrhosis are men
- The peak of cirrhosis and liver failure will be in 2020 if more people are not diagnosed and treated
- African Americans have similar or possibly slower rates of liver scarring than Caucasians, but higher rates of liver cancer
  - Age-adjusted, all-cause mortality rates for African Americans infected with HCV among highest for all racial/ethnic groups

Saab, Am J Gastro 2014; 109:1576

HCV Counseling for Newly Diagnosed

- Do not donate blood.
- Do not share personal items that might have small amounts of blood
  - Toothbrushes, razors, nail-grooming equipment
- HCV is not spread by hugging, kissing, food or water, sharing utensils, or casual contact
- Limit Tylenol to 2 gm a day and discuss all other medications (including OTC and herbal) with a provider
- Check exposure status for hepatitis A and B and vaccinate if needed

Adapted from Winston et al. Management of hepatitis C by the primary care provider: Monitoring guidelines; 2010
http://www.hcvadvocate.org/hepatitis/factsheets_pdf/PCP_web_10.pdf

Additional Counseling Based on Risk Behaviors

- If using illicit drugs, stop using. If continued, get into a treatment program and do not share needles, syringes or works
  - Concern among payers about poor adherence and reinfection after antiviral Rx
- If in short term, multiple, or MSM relationships, use latex condoms. No condom use is recommended for long-term monogamous heterosexual couples
  - Maximum incidence rate of HCV sexual transmission estimated about 1 new infection per 190,000 sexual contacts per year (Terrault, Hepatology. 2013; 57(3):881)

Address Alcohol Use in HCV

- The CDC recommends brief alcohol intervention for all patients with HCV
- There is no “safe” amount of alcohol consumption
- Absolute abstinence is important if there is liver disease
- Risky alcohol use
  - Men: >2 drinks/day (>14/week) or more that 4 in one day
  - Women: >1 drink/day (>7/week) or more than 3 in one day
- Alcohol misuse
  - How many times in the past year have you had X or more drinks in a day?”, where X is 5 for men and 4 for women, and a response of >1 is considered positive

http://www.integration.samhsa.gov/images/res/tool_auditc.pdf

Moyer et al. Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse: USPSTF Recommendation Statement. Annals Int Med; 14 May 2013 online

Determine Who Has Cirrhosis: Liver Biopsy Rarely Needed

- Noninvasive blood tests that indicate liver scarring can show the likelihood of cirrhosis
- Enlarged spleen on exam or ultrasound
- Any signs of liver failure

Chou, Annals Int Med 2013; 158:807; Bonder, Curr Gastro Rep 2014; 16:372; Berenguer #640 and Lo Re #650 CROI 2014

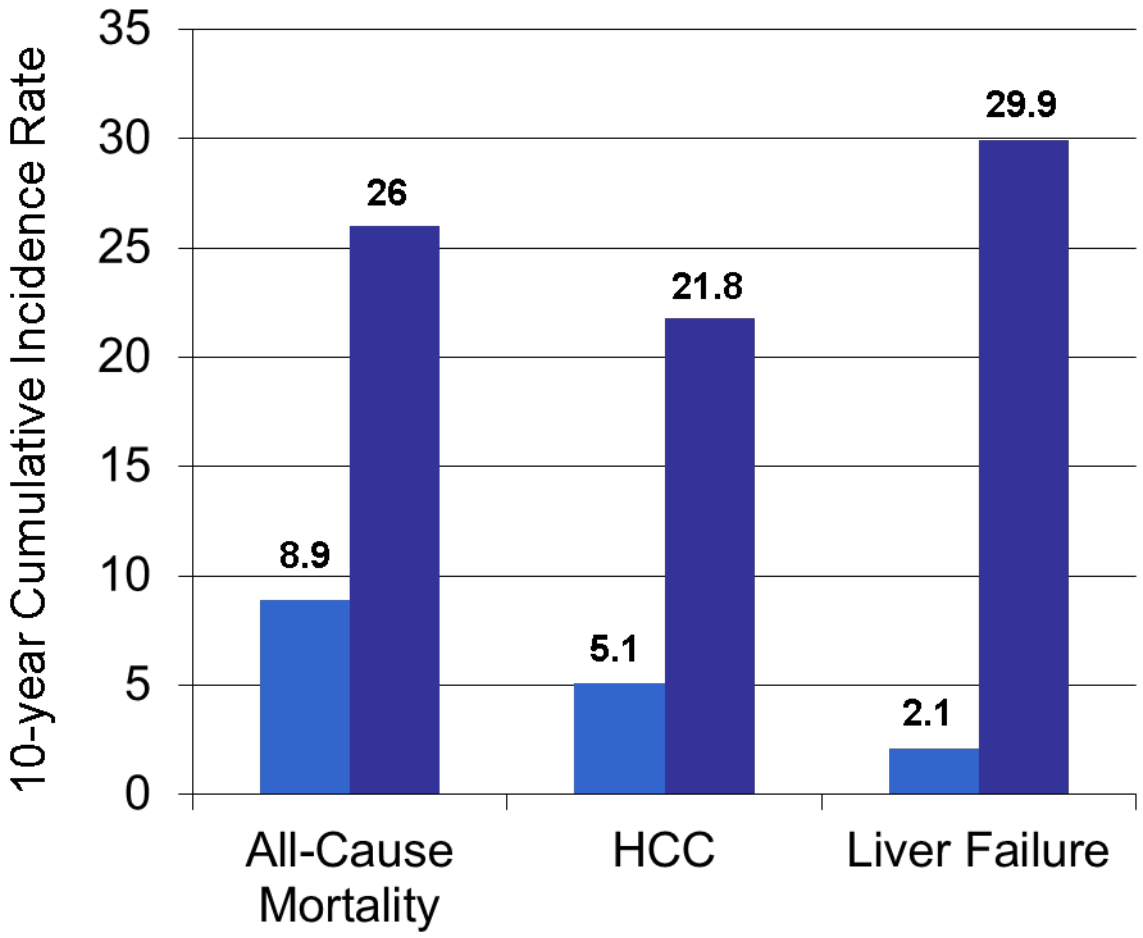
FibroScan - Transient Elastography

Alternative to liver biopsy

- Ultrasound technology measures liver stiffness
- Entire process requires 15 to 20 minutes, provides immediate results

Bonder, Curr Gastro Rep 2014; 16:372

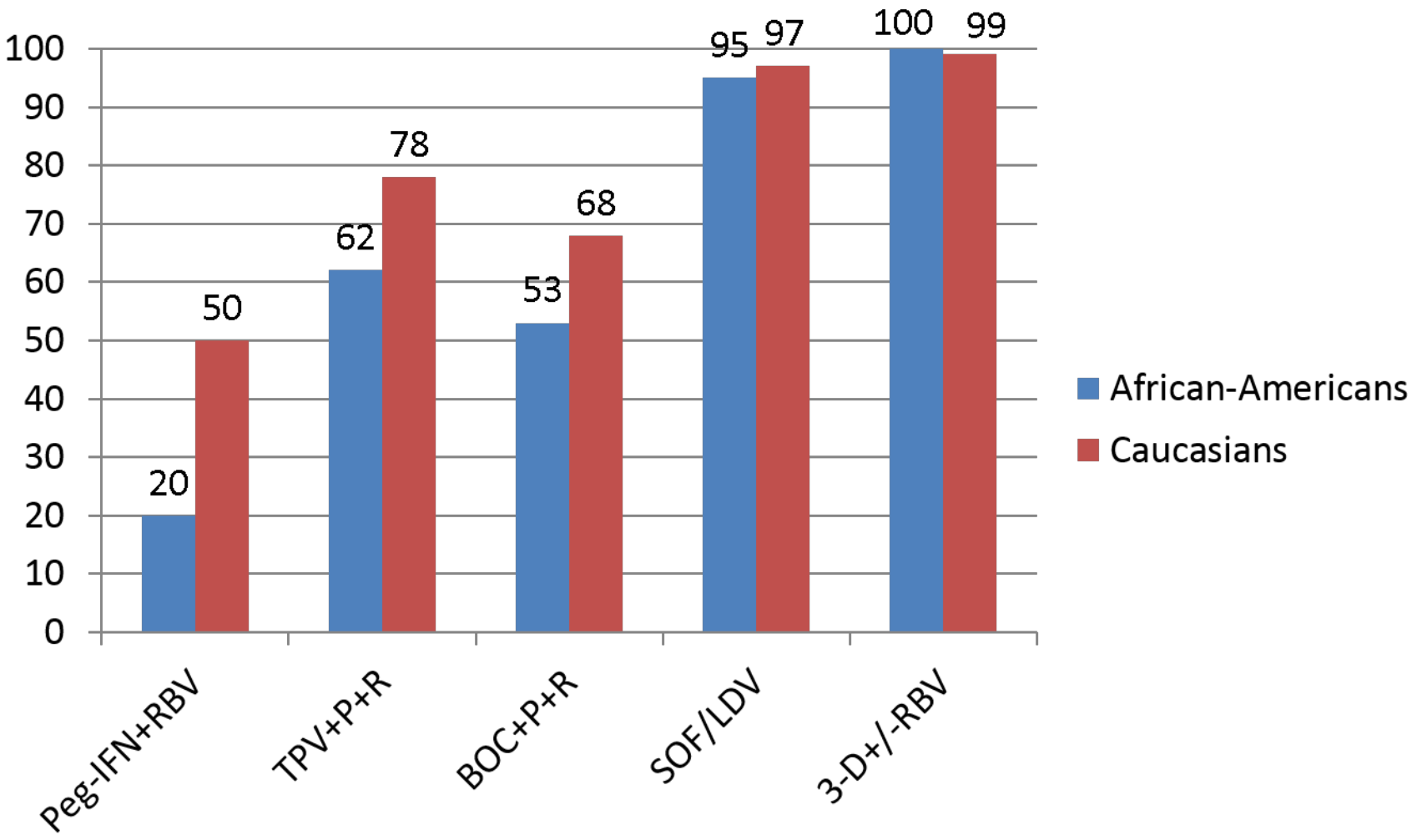
Hepatitis C Cure (SVR) is Associated with Decreased All-Cause Mortality



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

Van der Meer et al. JAMA 2012; 308:2584

African American Patients Have Similar Cure Rates as Caucasians with All-Oral Treatment



HCV Treatment Evolution

Previous HCV Treatment

(before 2011)

- 20-60% cure rate in African Americans
- 48 weeks long
- Injections and oral medications
- Multiple side effects
- Many contraindications

Current HCV Treatment

(2014 to present)

- 90-100% cure rate
- 8-24 weeks long
- All oral medications
- Few side effects
  (approximately 2% of people discontinue)
- Few contraindications

Compare Key Attributes of Harvoni vs. Viekira Pak

Harvoni	Viekira Pak
SVR ≥95% with correct duration	SVR ≥92% with correct duration
Very well tolerated	Needs monitoring for anemia, may need dose reduction
Pts with decompensation and post-Tx need RBV	85% of patients need RBV
One pill once a day	10 pills a day (if require RBV)
8 to 12 week duration	12 to 24 week duration
Can use with very severe liver disease	Cannot use with very severe liver disease
Common Drug Interactions: HIV meds, acid blockers	Common Drug Interactions: HIV meds, Estradiol, fluticasone, salmeterol, some statins

Package inserts for Harvoni and Viekira Pak

Current Negative Environment Created By High Price of HCV Drugs

- Confusion and doubt among HCV providers about whom to treat
- Hesitation to encourage hepatitis C testing from Primary Care Providers, health departments, community health centers, drug rehabilitation centers, prisons
- Concern among payers (public and private) about budget impact
- Rationing of treatment (ie F3-F4; substance use) and conflict between provider, patient and payer over rationing
  - Justification for overt discriminatory practices like mandating clean urine samples
- Very limited discussion of cure-as-prevention
- Patients may feel that they are not “worth” treatment
- Loss of opportunity to use transformative, curative therapies

"Standard of Care" Regimens for Hepatitis C Have Been Expensive for Years: Examples of Treatment Cost

Regimen	SVR rates	WAC Price	Cost per SVR
Pegasys + Ribavirin x 48 weeks[1]	41%	$41,758	$101,849
Telaprevir + PegIFN + Ribavirin x 24 weeks[2]	75%	$86,843	$115,791
Sofosbuvir + PegIFN + Ribavirin x 12 weeks	90%	$94,421	$104,912
Harvoni x 12 weeks	99%	$94,500	$95,454 ($51,545?)*

Package inserts for products; *http://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/

The Problems with Not Allowing Treatment until Advanced Fibrosis

- Since no test can perfectly distinguish moderate from advanced liver fibrosis or cirrhosis, limiting access to advanced fibrosis (F3/F4) really means directing treatment to cirrhotic patients
- If we wait until advanced fibrosis, need to do life-long screening for HCC every six months even if cured (expense, logistics, patient anxiety)
  - If a liver has moderate scarring or less when cured, patients are managed the same as people who never had hepatitis C

Compare: Department of Veterans Affairs (VA) Guidelines for PWID

"There are no published data supporting a minimum length of abstinence as an inclusion criterion for HCV antiviral treatment. Patients with active substance- or alcohol-use disorders should be considered for therapy on a case-by-case basis and care should be coordinated with substance-use treatment specialists."

- http://www.hepatitis.va.gov/provider/guidelines/2014hcv/special-groups.asp

Resources

- IDSA/AASLD/IAS–USA HCV Guidance
- CDC Know More Hepatitis Campaign
- Federal guidelines (VA, prison system)
- National Viral Hepatitis Roundtable
  - Collects templates, sample slide presentations, analyses of state and federal policies
  - Program assistance with 1945-1965 birth cohort testing
  - www.NVHR.org

Hepatitis C and African American Women

Gloria Searson, ACSW
COPE
Coalition On Positive Health Empowerment
New York, NY
May 7, 2015

Current State of HCV Research & Treatment

There are amazing breakthroughs in treatment resulting in a "Cure."

- I am a living testament. The new meds cleared my viral infection without side effects.
- 80-90% are cured regardless of race or sex & these numbers will continue to increase

However, fewer people are being treated than anticipated, especially among African American women. Why is that?

Who are African American Women Living with HCV Today?

- African American women, especially baby-boomers, are a population with specific risk activities/behaviors that differ from other populations impacted by HCV.
  - These are not addressed by current public health and policy efforts in terms of testing and community education
  - This community does not receive the necessary support to access and remain in treatment
- Lack of knowledge and cultural competency from providers compounds the disconnect for African American women.
- Other major structural components leading to lack of response from the African American community to the "Cure" are:
  - Lack of funding;
  - Treatment infrastructure; and
  - Comprehensive wraparound services

COPE's Work Towards a Cure

COPE was founded in 2010 to educate people living with HCV or HIV/HCV and to advocate for their voices to be heard in all aspects of treatment & policy .

- COPE's mission statement includes:
  - Education
  - Advocacy
  - Prevention
  - Support
  - Research
- In the past 2 ½ years, we have tested more than 3,000 people. Our data provokes thought around the roles of gender and race in HCV infection.

Who Were Tested

- From March 21, 2012 to August 5, 2014, **3,044** people were tested
- The majority of those tested were African American women.
  - The mean age was 48 years old.
- COPE tested throughout NYC and surrounding areas
  - The ten most common zip codes (8 in Harlem and 2 in Brooklyn & Queens) accounted for 41% of the total tests.

Gender	Number	%
Female	1,729	56.8
Male	1,312	43.1
Transgender	3	0.1

Race	Number	%
African-American	2,091	68.7
Hispanic	738	24.2
Caucasian	151	5.0
Other/mixed, not reported	63	2.1

Results

- Overall, 8.2% of the participants were seropositive for HCV
- Higher prevalence in men
  - 3.8% of the women
  - 14.0% of the men
- High prevalence in all races*
  - 6.5% of African American
  - 13.6% of Hispanic
  - 10.0% of Caucasian
  - 4.3% of other/mixed/unreported

Group	Number Tested	% positive
AA male	867	10.7
AA female	1,224	3.8
Hispanic male	352	22.4
Hispanic female	381	3.6
Caucasian male	69	13
Caucasian female	80	5

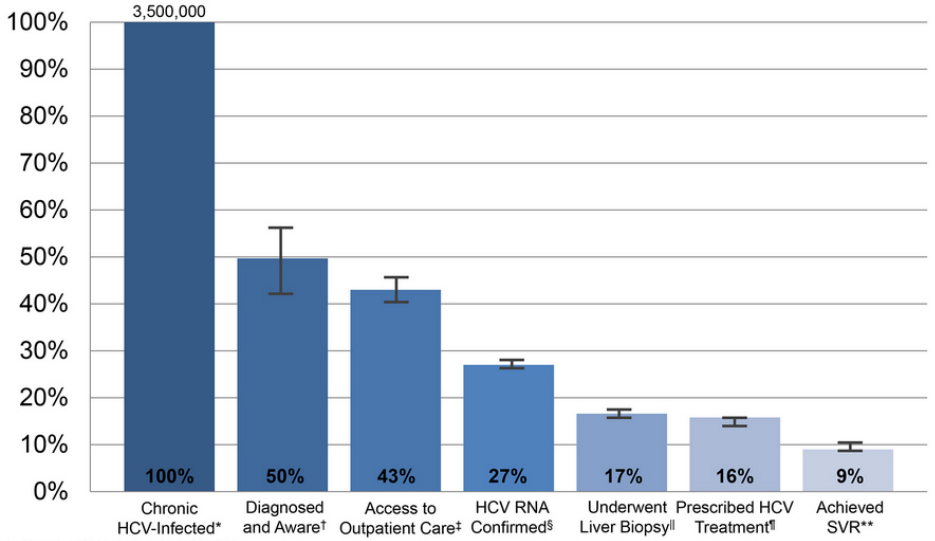
* Compared to NHANES

Reaching African American Women

Our data suggest that African American women are more likely to be tested for HCV in a non-traditional setting.

COPE has worked to reach them and succeeded in finding and supporting women as they work towards a cure.

However, this hasn't been the outcome in many other settings. What makes the difference?



* 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.

Yehia B, et al. PLoS ONE 9(7), July 2014.

Barriers to Treatment

There are a wide array of systemic barriers to care provider biases, and cultural beliefs that impact African American women's access and success in treatment for HCV, such as:

- Lack of priority in family system regarding health values
- Other medical/psychosocial issues they deem more worrisome or are affecting their quality of life
- Prioritization of time: Treatment will impact family system
- Mistrust and privacy concerns with the current health system
- Persistent alcohol/substance abuse: not ready to change behaviors

If previous treatment failed, they may harbor bad feelings or distrust data on the benefits of new medications.

Individual Barriers to Treatment for African American Women

In addition to the systemic challenges, there are personal barriers to address such as:

- Open communication with providers: understand side effects and tradeoffs. Need time to contemplate
- Restricted access to new meds, including denials with adequate insurance coverage
- May need extra assistance regarding personal challenges
  - Children or other dependents
  - Other medical or social problems
- Address stigma and treat as partners in the treatment of the disease. Create a community response.
  - Someone to say *"We are going to ride it out with you" YJ*

Importance of African American Women as Treatment Advocates

- African American women can be a huge political force in their communities. They may choose to speak out about the feelings of exclusion, racism, stigma, and other issues surrounding HCV.
  - Their voice is essential to ensure that their needs are addressed and their barriers are understood.
- The Federal government, payers, states, and localities can help advocates and organizations like COPE be productive on many levels in education, testing, treatment and wraparound services.
- Training and support for these advocates are essential!

Current Limitations in Implementing Best Practices

- Access (Pharma and payers)
  - Prior authorization
  - Medicaid, **payers**, treatment restrictions, HCV policy, lack of providers
- Government response
  - Federal –inactive and in need of solutions, States expressing overwhelming problems vs. solutions, cities & service providers looking for support, infrastructure and resources
- Treatment Issues
  - Real challenges around cost, access and response rates by genotype
- Diverse patient populations
  - Advocacy and access are not equal for all population groups

What Do We Need to Implement these Best Practices?

- Federal funding, leadership
- Large-scale national screening program
- Educated clinicians
  - Evidence-based treatment
  - Culturally competent for diverse patient populations
- Patients prepared for treatment
- Unrestricted access to treatment
- Individualized treatment plans & availability of support services

Thank you

COPE

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Hepatitis C & African American Women

Q & A

Enter questions into the GotoWebinar Question box

Hepatitis C & African American Women

Thank You!