CDC Recommendations for the Identification of Chronic Hepatitis C Virus Infection among Persons Born During 1945-1965

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# **HCV Background**

### Anti-HCV 1.6% 4.1 M (3.4-4.9)

- Chronic HCV 1.3% 3.2M (2.7-3.9)
- Leading cause of liver transplants and liver cancer (hepatocellular carcinoma)
  - HCC fasting rising cause of cancer-related death
- HCV-related deaths doubled from 1999-2007 to over 15,000/year
  - Expected to increase to over 35,000/year without intervention

## **HCV in the Context of HIV in the US**

## Age-Adjusted Rates of Mortality: Hepatitis B, Hepatitis C, and HIV, United States, 1999–2007



In 2007, > 70% of registered deaths in HCVinfected were aged 45-64 years old

## **HCV Therapy Can Eliminate HCV Infection**

- Therapy goal is HCV clearance known as sustained virologic response (SVR)<sup>1</sup>
- HCV therapy is effective but with risk for serious adverse events (SAE) of 5-10%
- Recent FDA approval of new medications has improved treatment effectiveness from 40% to 75% SVR while shortening length of treatment
- At least 20 drugs are in phase II/III trials some of which have 90% effectiveness with improved safety and tolerability profiles

## CDC Recommendations Based on Risk and Medical Indications (1998)

- Past or present injection drug use
  Signs of liver disease (persistently)
- Signs of liver disease (persistentl elevated ALT)
- Received blood/organs prior to June 1992
- Received blood products made prior to 1987
- Ever on chronic hemodialysis
  Infants of HCV-infected mothers
  HIV infection

#### National Hepatitis C Prevention Strategy





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### Limitations of Risk- and Medical Indication-based Testing

#### Barriers to HCV testing <sup>1-4</sup>

- Physician knowledge and experience
- Patient recall of long-past risk behavior and concerns of stigma

ALT screening misses more than 50% of chronic cases <sup>5</sup>

□ 45%-85% of infected persons are unidentified <sup>6-8</sup>

1. Shehab TM. J Viral Hepat, 2001. 2. Shehab TM, et al. Am J Gastroenterol, 2002. 3. Serrante JM, et al. Fam Med, 2008. 4. Shehab TM, et al. Hepatology, 1999. 5. Smith, et al. AASLD, San Francisco, CA. 2011. 6. Roblin, et al. Am J Man Care 2011. 7. Spradling, et al., Hepatology, 2012. 8. Southern, et al., J Viral Hepat 2010

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## CONSIDERATION OF A PREVALENCE-BASED BIRTH COHORT HCV TESTING STRATEGY

## Consideration of a Prevalence-based Strategy To Focus Testing on Persons Born 1945-1965

□ Persons in the 1945-1965 birth cohort are 4 times more likely to be anti-HCV+ than other adults
 □ Anti-HCV prevalence in the birth cohort = 3.25% <sup>1</sup>
 □ Represents 76.5% of all chronic HCV infections
 □ 68% have medical insurance
 □ Infected population has modifiable disease co-factors
 □ 58% consume ≥ 2 alcoholic drinks/day
 □ 80% lack Hep A/B vaccination
 □ Represents 73% of all HCV-associated mortality

**GRADING THE EVIDENCE FOR HCV TESTING OF PERSONS BORN 1945-**1965

## **Key Outcomes of Evidence Review**

## Harms

Effect of protease inhibitors on Serious Adverse Events

 There are serious adverse events associated with Boceprevir- and Telaprevir-based regiments that lead to discontinuation of treatment (RR 1.34, 95% CI 0.95, 1.87).

Insurability, HCV transmission, false positives, false negatives

 No studies evaluated these potential harms related to HCV testing and the birth cohort

## **Key Outcomes of Evidence Review**

## **Benefits**

Effect of Telaprevir- and Boceprevir-based therapies on sustained viral response (SVR)

 Protease inhibitor-based treatment regimens increase the possibility of achieving SVR by 50% (RR 0.53, 95% CI 0.47, 0.6)

### SVR and HCC

 Treatment-related SVR associated with a reduced risk of HCC of 75% (0.24; 95% CI=0.18, 0.31)

#### SVR and all-cause mortality

 Treatment-related SVR associated with reduced risk of all-cause mortality among persons diagnosed with HCV infection of 50% (RR=0.46; 95% CI=0.41, 0.51)

# Effect of clinician-directed intervention on alcohol use

 Meta-analysis found decline of alcohol use >38% for >1 year follow-up; indirect evidence for HCV-infected populations



Morbidity and Mortality Weekly Report

August 17, 2012

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### **Draft CDC Recommendations**

In addition to testing adults at risk for HCV infection, CDC recommends that:

- Adults born during 1945 through 1965 should receive onetime testing for HCV without prior ascertainment of HCV risk factor. (strong recommendation, moderate quality of evidence)
- All persons with identified HCV infection should receive a brief alcohol screening and intervention as appropriate, followed by referral to appropriate care and treatment services for HCV infection and related conditions as indicated. (strong recommendation, moderate quality of evidence)

## **Thank you!**

#### For more information please contact Centers for Disease Control and Prevention

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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## Health and Cost Impact of HCV Testing of Persons Born 1945-1965

**Birth Cohort Testing** 

with DAA Therapy

Outcome	PegIFN-Riba + TVR
Additional Identified Cases	809,000
Cirrhosis cases averted	203,000
Decompensated cirrhosis cases	74,000
averted	
Hepatocellular carcinoma cases	47,000
averted	
Transplants averted	15,000
Deaths from hepatitis C virus averted	121,000
Medical costs averted	\$2.5b
Cost/QALY gained (Societal)	\$35,700

•Rein DB, Smith BD, et al. The cost-effectiveness of birth year-based and universal hepatitis C screening and indicated treatment in the United States. *Annals of Internal Medicine*, 2011.

## Comparison of HCV Cost Effectiveness with other Routine Preventive Services

\$/QALY



## Groundwork for Implementing CDC Recommendation for HCV Testing of Persons Born 1945-1965

- Launch Know More Hepatitis campaign for public and providers
- Expand capacity for HCV testing and care referral (e.g., FY 12 PPHF)
  - □ \$5.0M available; > 100 applications
- Enhance surveillance to monitor implementation and impact
- Collaborate with other federal agencies to support testing (e.g., AHRQ, HRSA, CMS)
- Engage stakeholders
  - Professional societies (e.g., IDSA, ACP, AASLD, CSTE, AMA leadership)
  - Providers (Heath systems, insurers, laboratories)

#### MILLIONS OF AMERICANS HAVE HEPATITIS C. MOST DON'T KNOW IT.

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TALK TO YOUR DOCTOR ABOUT GETTING TESTED. EARLY DETECTION CAN SAVE LIVES.



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**JCDecaux** 

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## Train providers in implementing HCV testing, providing care and making decisions regarding HCV therapy

Target providers- primary care, ID, hepatology, GI

- Primary care organizations (ACP, AAFP, ACOG, AMA, NACHC) physicians/staff
- Clinical Specialists (IDSA, AASLD, AGA)
- Publically funded health programs (CHC, Medicaid/Medicare, military)
- Public health ( preventive health services, HIV/STI)
- Actions
  - Distance learning
  - Presentations at state/local and national professional society meetings - VH specific or in integrated format
  - Model curriculum