

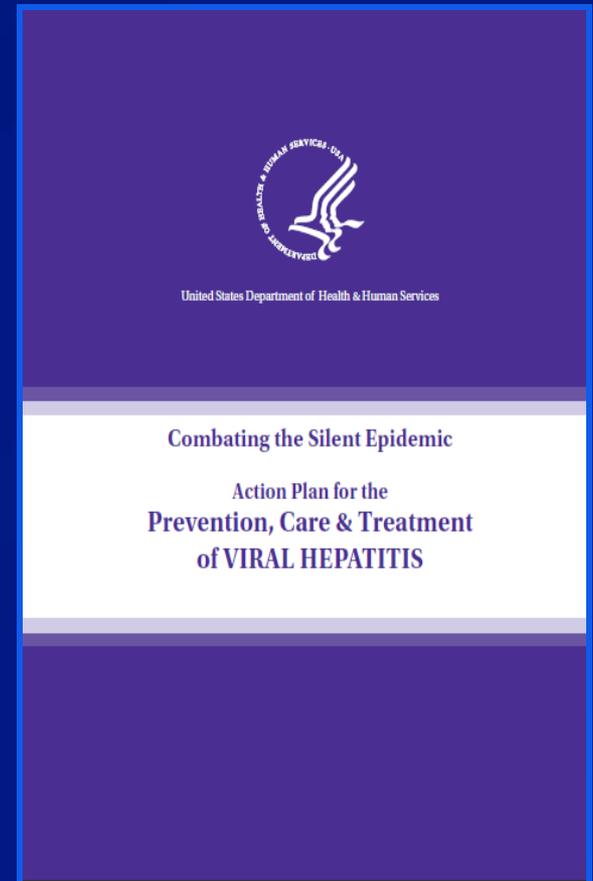
Identification, Screening, and Surveillance in Era of Improving Therapy for Hepatitis C

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HHS Viral Hepatitis Action Plan

- *Identify persons infected with viral hepatitis early in the course of their disease*
- *Assess new laboratory tests to accurately identify persons infected with viral hepatitis*
- *Develop and implement new technologies to improve viral hepatitis surveillance*
- *Develop approaches to detect and treat acute HCV in IDUs.*

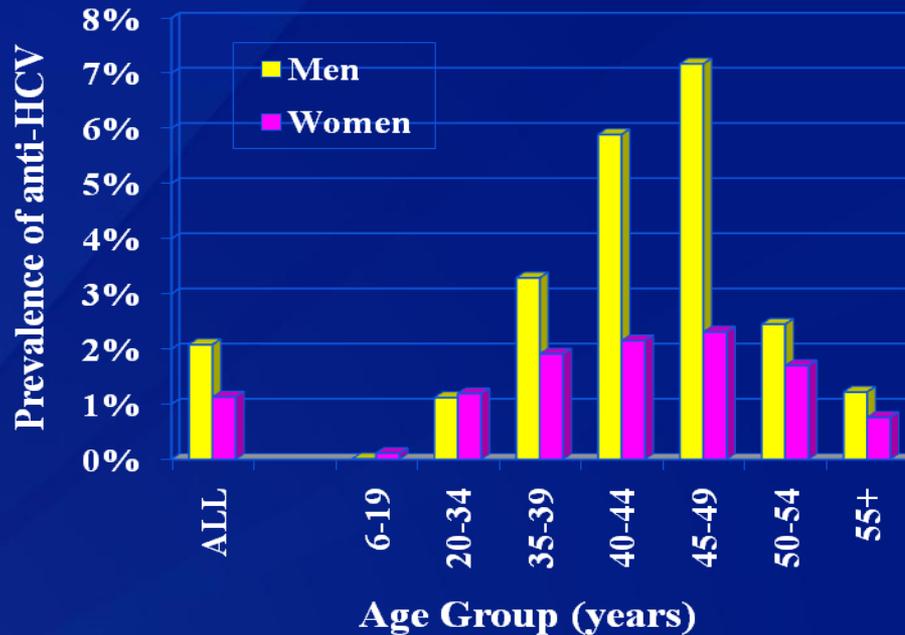


High Prevalence of HCV infection

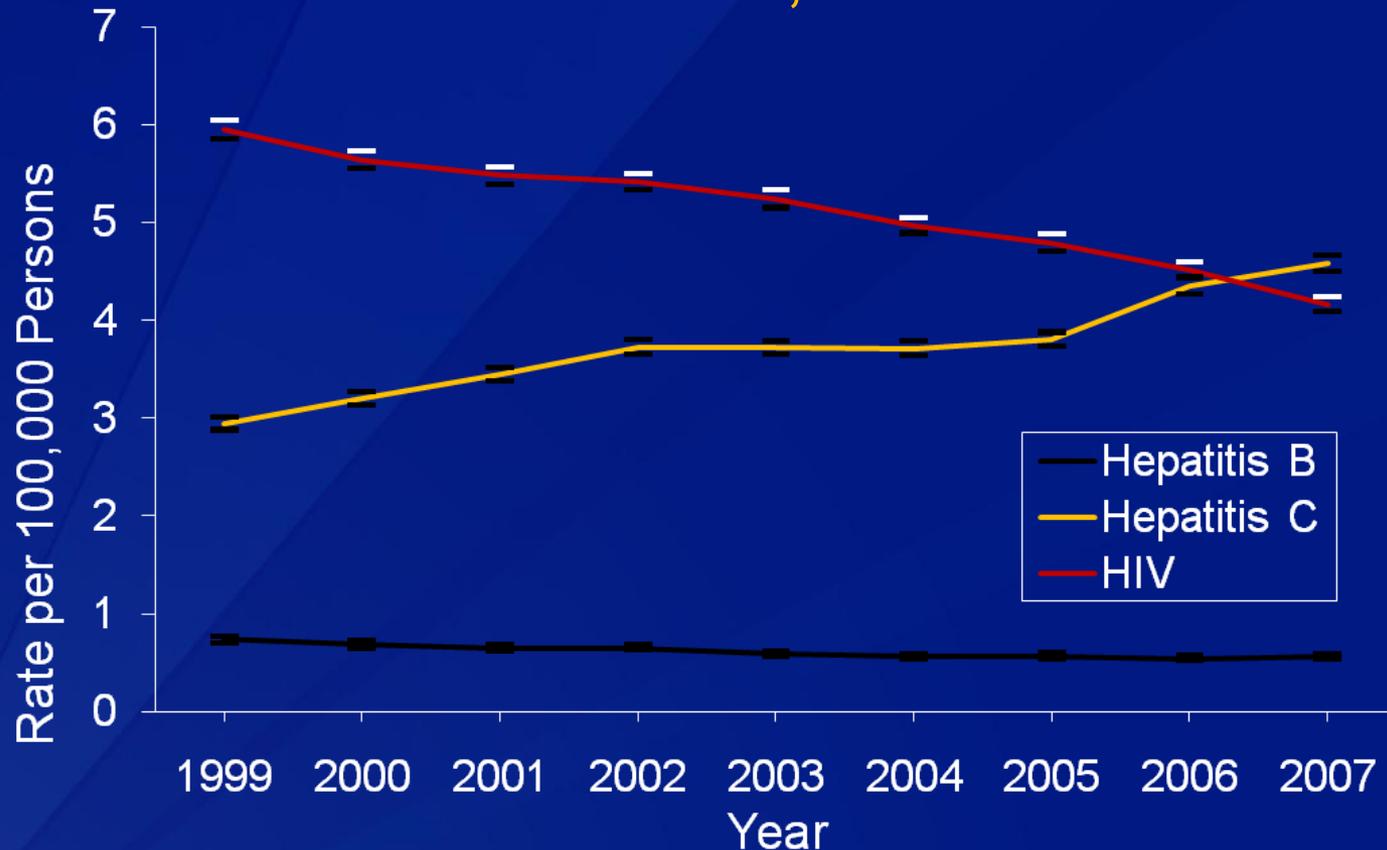
Overall prevalence:

anti-HCV 1.6% (4.1 million)

chronic HCV 1.3% (3.2 million)



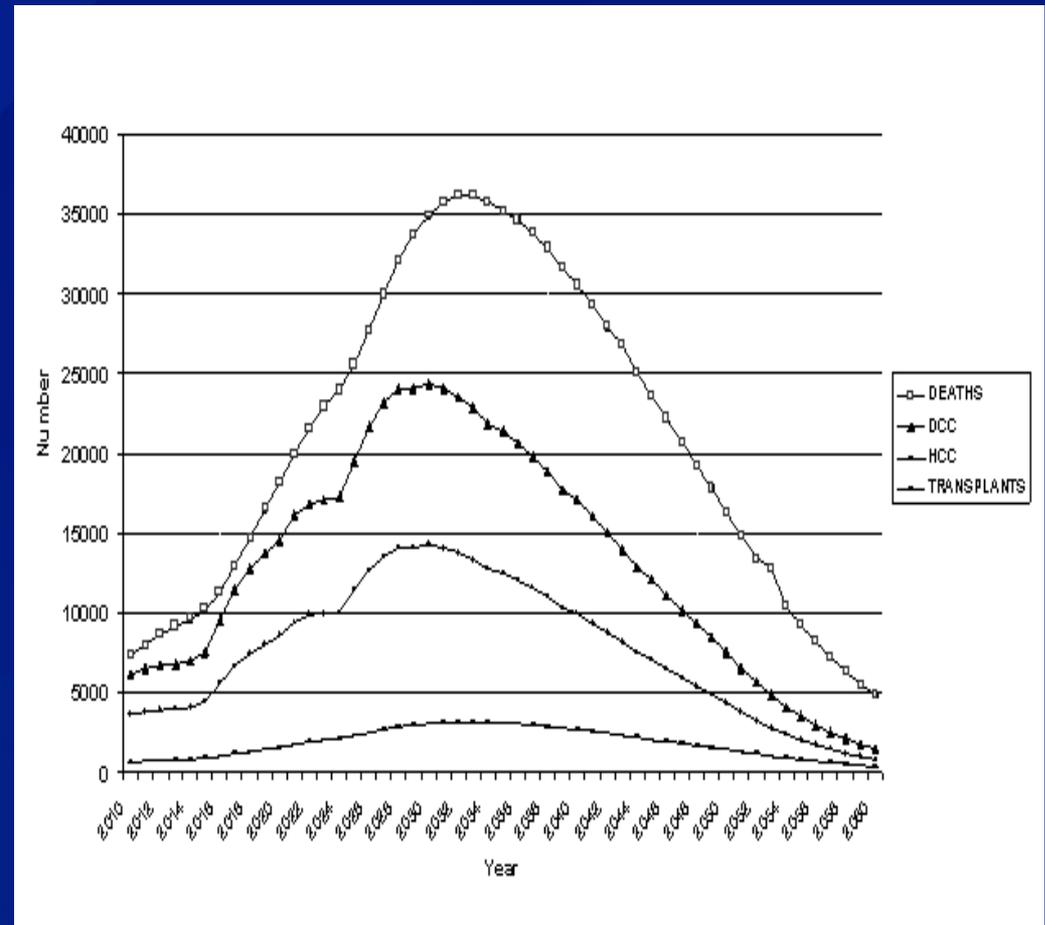
Age-Adjusted Rates of Mortality Associated with Hepatitis B, Hepatitis C, and HIV United States, 1999 – 2007



In 2007, > 70% of registered deaths in HCV-infected were aged 45-64 yo

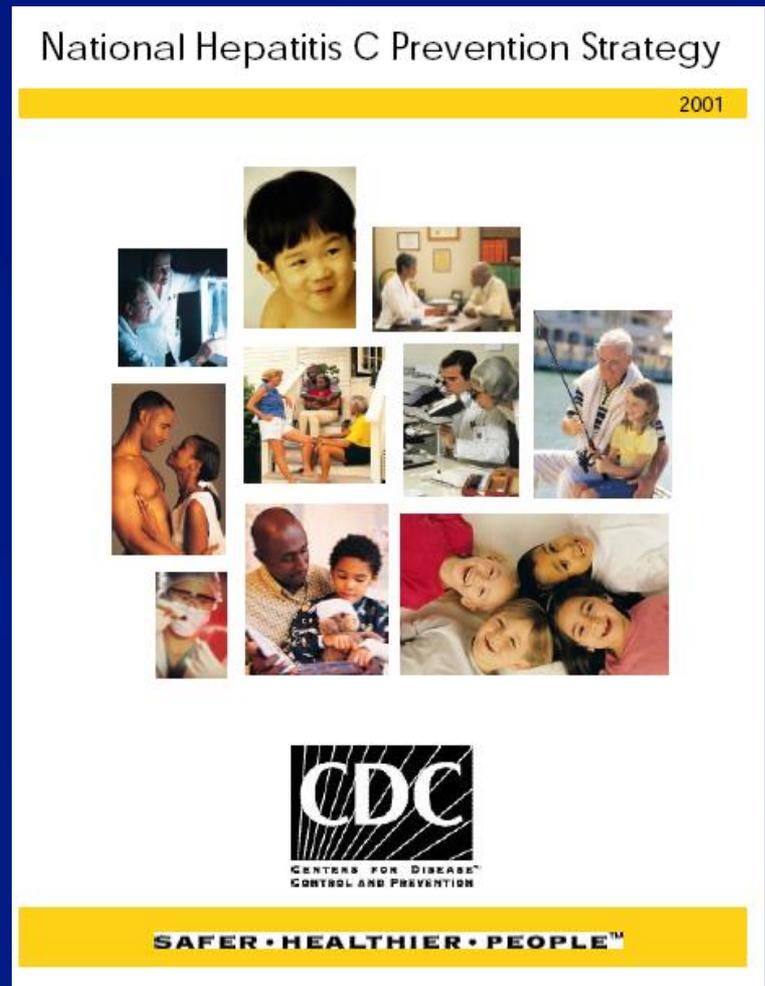
Future Burden of Hepatitis C Related Morbidity and Mortality in the US

- **Markov model of health outcomes -**
- **Of 2.7 M HCV infected persons in primary care**
 - 1.47 M will develop cirrhosis
 - 350,000 will develop liver cancer
 - 897,000 will die from HCV-related complications
- **Incur expenses**
 - \$24.7 productivity losses
 - \$179.53 per person in primary care
 - \$33.3 billion medical costs



HCV Testing Recommendations in US

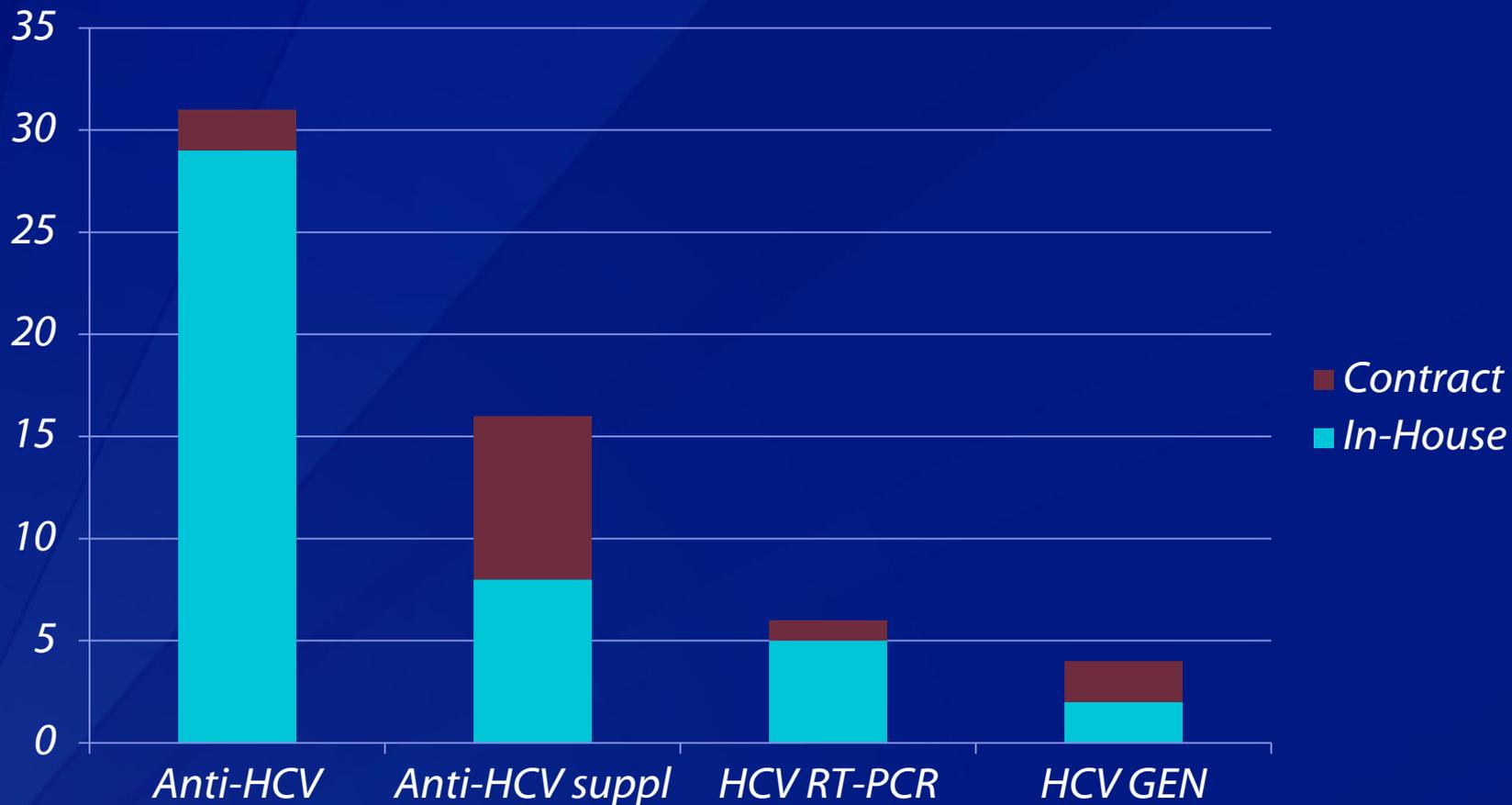
- **CDC recommendations (1998)**
 - *Ever injected illegal drugs*
 - *Received clotting factors <1987*
 - *Received blood/organs < July 1992*
 - *Ever on chronic hemodialysis*
 - *Evidence of liver disease (elevated ALT)*
 - *Infants born to HCV infected mothers*
 - *HIV infection*
- **45%-85% of HCV infected persons not tested and identified**
 - *940,000-1.77m persons*



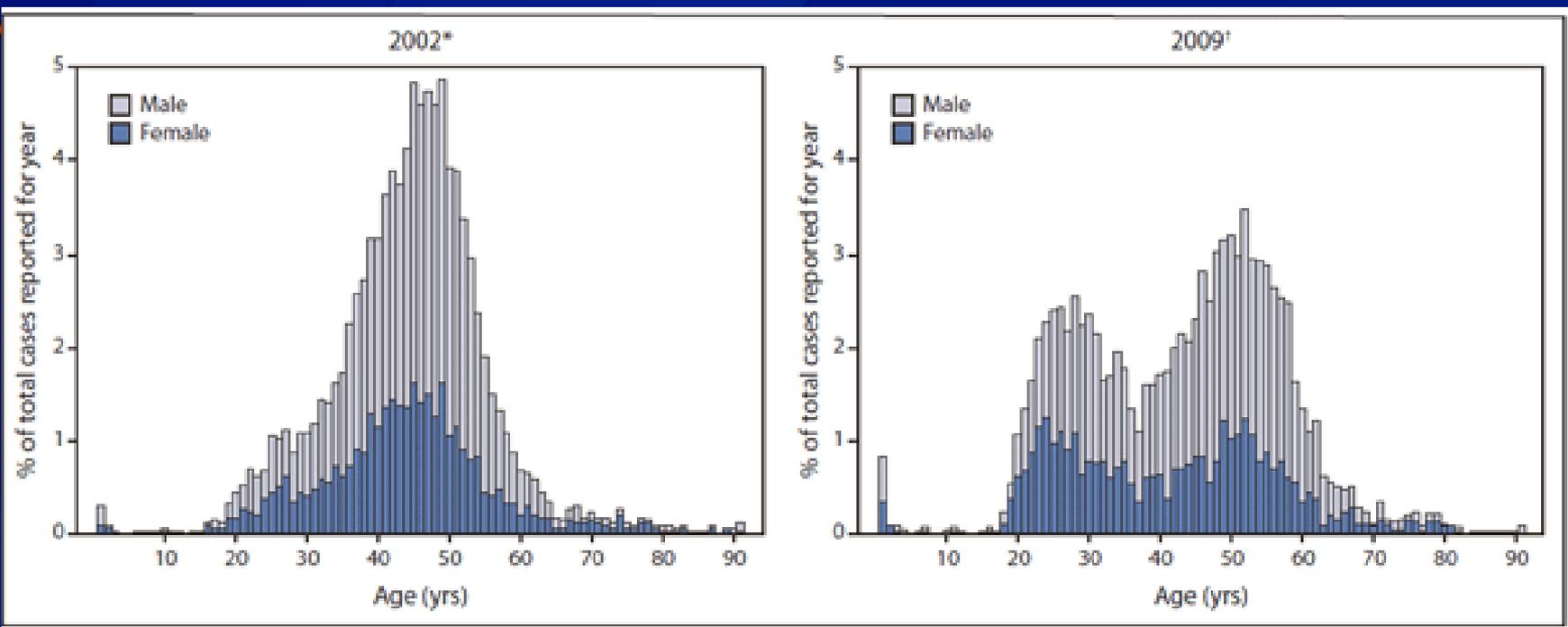
HCV Infection Among Persons Born 1945-1965

- *Rationale*
 - *Higher HCV prevalence (3.29%) than others (0.55%)*
 - *Represents 81% of HCV infections*
- *Costs*
 - *Per case identified -\$2874*
 - *Per QALY \$15,700-\$35,700*
- *Impact –Comparable with other interventions*
 - *Colorectal screening*
 - *Cervical and breast cancer screening*

Types of Hepatitis C tests Offered by State Public Health Laboratories -2008



Age Distribution of Confirmed Hepatitis C Cases- Massachusetts, 2002, 2009*



- 1,925 reports of HCV among 15-24 yrs., 2007-2009
- Cases from all areas of state; equally male: female, mostly white
- 72% past or current IDU, 84% injectors in past 12 mos.
- Other states are reporting similar increases

Implementing New Technologies: HCV rapid point of care tests

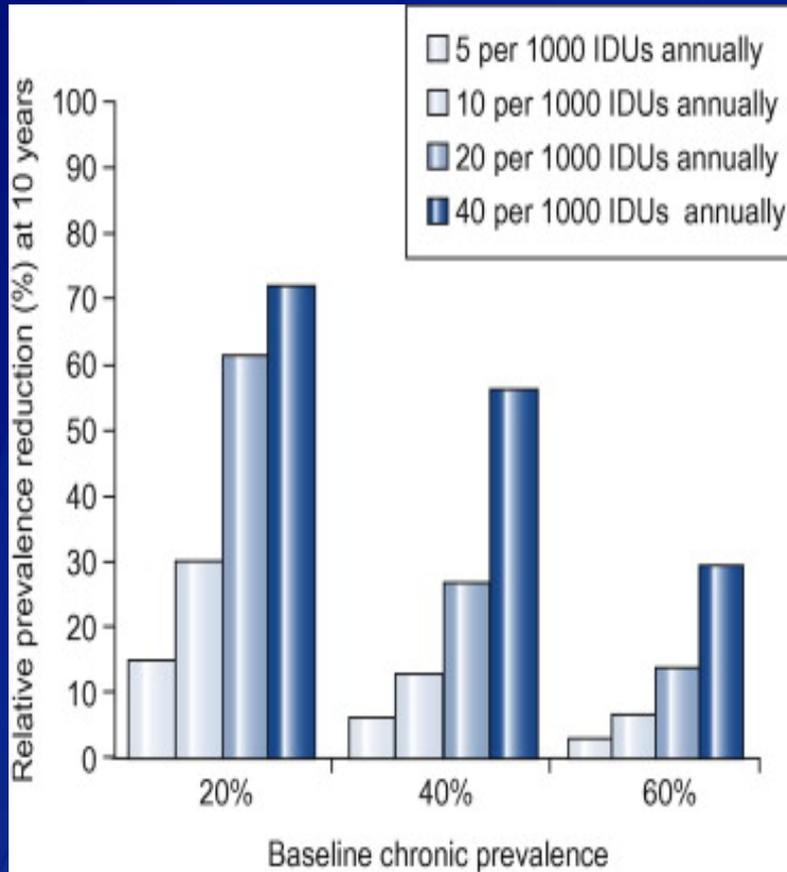
- *FDA licensed: Venous blood*
- *Recently received CLIA waiver*
- *Expands access to testing*
 - *Primary care*
 - *Marginalized populations*
- *CDC evaluating ways to integrate point-of-care tests in various screening settings*



What are the ways to improve detection of incident HCV infection?

- *Detect emerging transmission patterns*
- *Increase accuracy of surveillance*
- *Prompt referral for care and treatment*

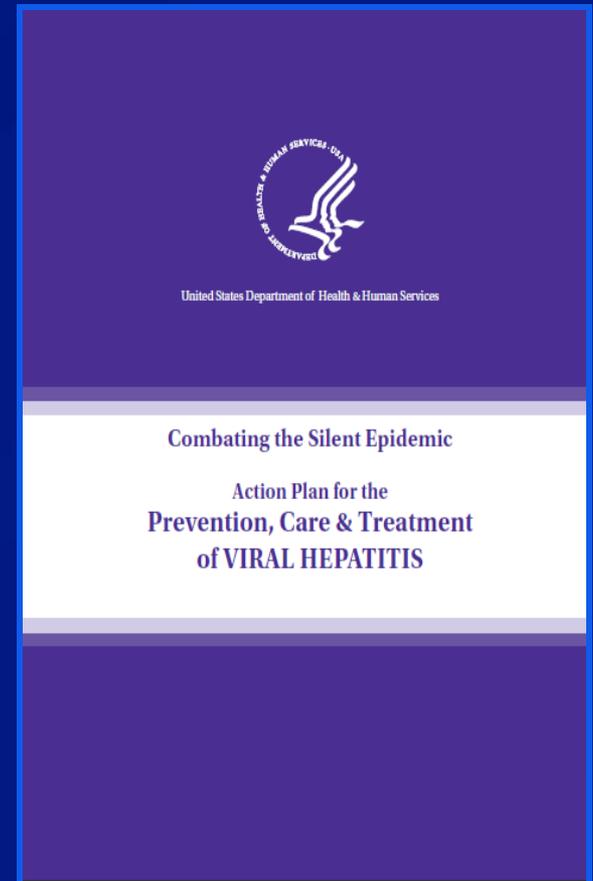
Antiviral Therapy Can Reduce HCV Prevalence Among Injecting Drug Users



- *Annually treating 10 HCV infections per 1000 IDU and achieve SVR of 62.5%*
- *Projected to result in a relative decrease in HCV prevalence over 10 years of 31%, 13%, or 7% for prevalences of 20%, 40%, or 60%, respectively*

HHS Viral Hepatitis Action Plan

- *Increase the proportion of persons who are aware of their HCV infection, from 45% to 66%;***
- *Reduce by 25% the number of new cases of HCV infection*



New Era of Direct Acting Agents Against HCV

Direct Acting Class	Select compounds	Phase
NS3/4A protease inhibitors		
	<i>Telaprevir</i>	<i>Approved</i>
	<i>Boceprevir</i>	<i>Approved</i>
	<i>BI 201335</i>	<i>II</i>
	<i>MK-7009</i>	<i>II</i>
	<i>TMC435</i>	<i>II</i>
	<i>R7227 (ITMN-191)</i>	<i>II</i>
NS5B polymerase (RdRp) inhibitors		
<i>Nucleos(t)ide analogue</i>	<i>IDX184</i>	<i>II</i>
	<i>PSI-7851</i>	<i>II</i>
	<i>INX189</i>	<i>I</i>
<i>Non-nucleos(t)ide</i>	<i>ABT-333</i>	<i>II</i>
	<i>ANA598</i>	<i>II</i>
	<i>MK-3281</i>	<i>II</i>
NS5A inhibitors		
	<i>BMS-790052</i>	<i>II</i>
Combinations		
	<i>RG7128 plus RG7227</i>	<i>II</i>
	<i>BI207127 plus BI201335 (+RBV)</i>	<i>1b/II</i>