

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

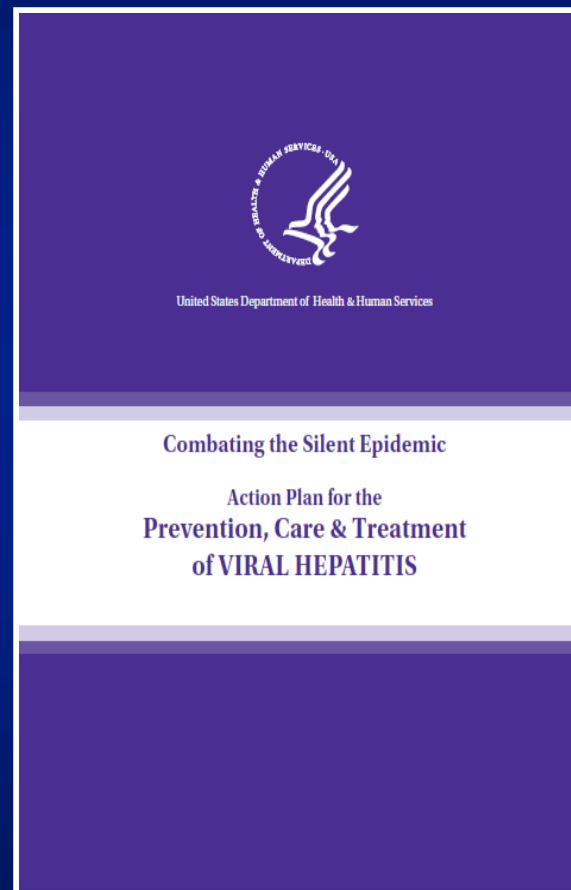
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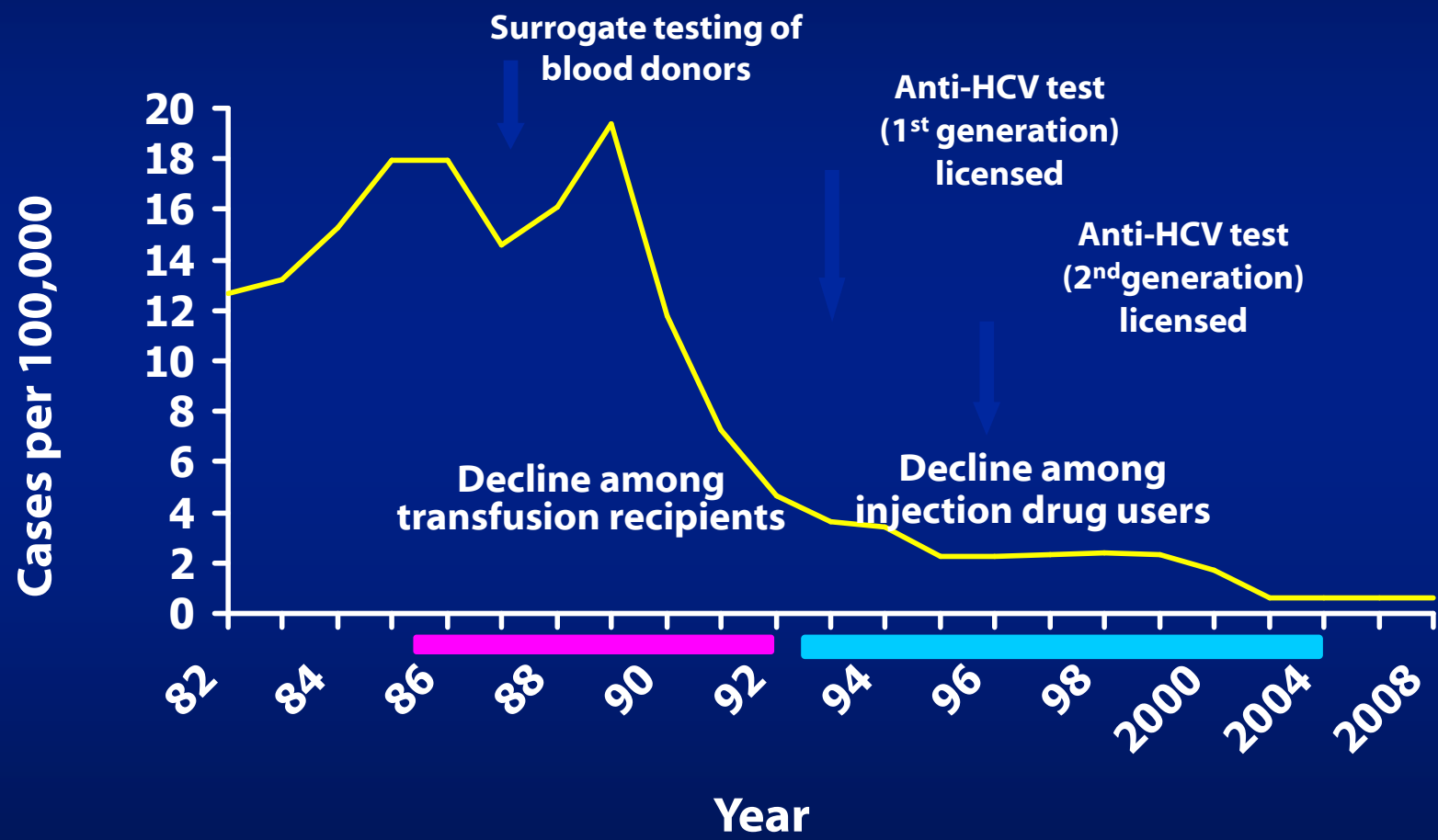


HHS Viral Hepatitis Action Plan

- EDUCATING PROVIDERS AND COMMUNITIES TO REDUCE HEALTH DISPARITIES
- IMPROVING TESTING, CARE, AND TREATMENT TO PREVENT LIVER DISEASE AND CANCER
- STRENGTHENING SURVEILLANCE TO DETECT VIRAL HEPATITIS TRANSMISSION AND DISEASE
- ELIMINATING TRANSMISSION OF VACCINE-PREVENTABLE VIRAL HEPATITIS
- REDUCING VIRAL HEPATITIS CASES CAUSED BY DRUG-USE BEHAVIORS
- PROTECTING PATIENTS AND WORKERS FROM HEALTH-CARE-ASSOCIATED VIRAL HEPATITIS



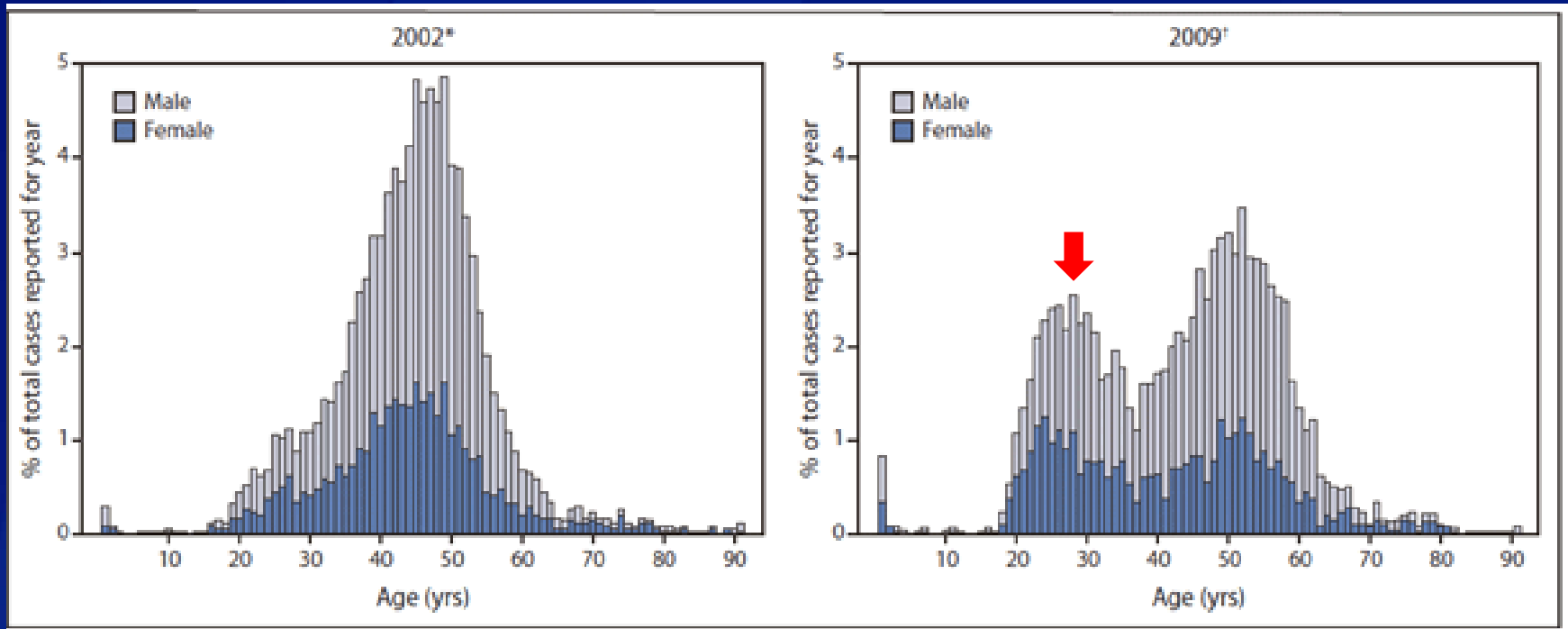
Estimated Incidence of Acute Hepatitis C United States, 1982 - 2009



Source: Sentinel Counties Study of Viral Hepatitis and State Disease Surveillance, CDC

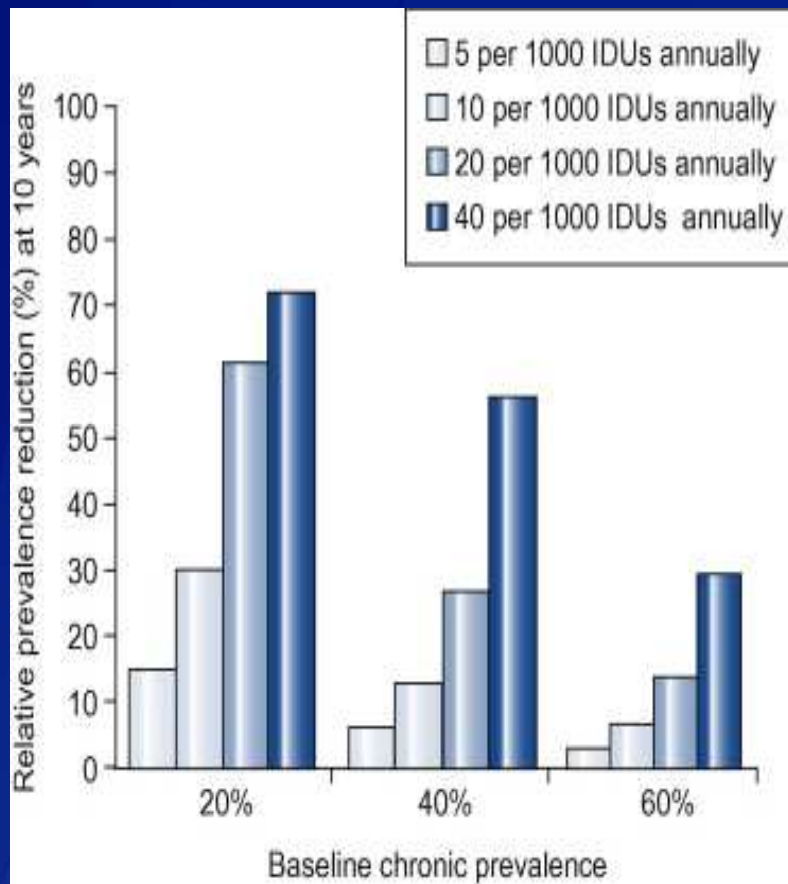


Age Distribution of Confirmed Hepatitis C Cases Massachusetts, 2002, 2009*



- 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

Can antiviral therapy reduce HCV prevalence among injecting drug users?



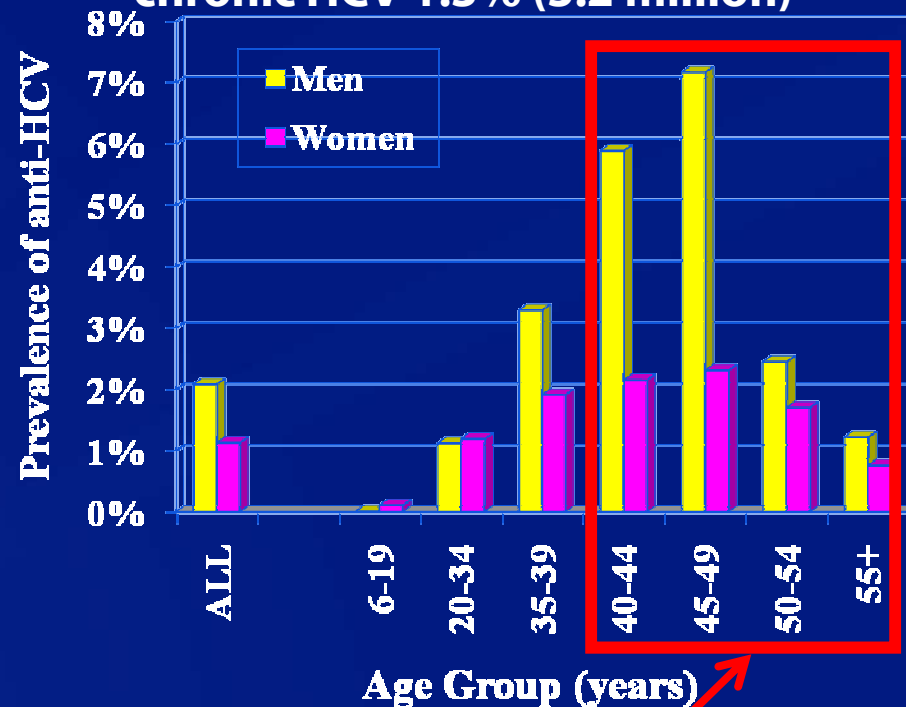
- Annually treating 10 HCV infections per 1000 IDU and achieve SVR of 62.5%
- Projected to result in a relative decrease in HCV prevalence over 10 years of 31%, 13%, or 7% for prevalences of 20%, 40%, or 60%, respectively

Prevalence of Anti-HCV by Risks and Demographic Characteristics

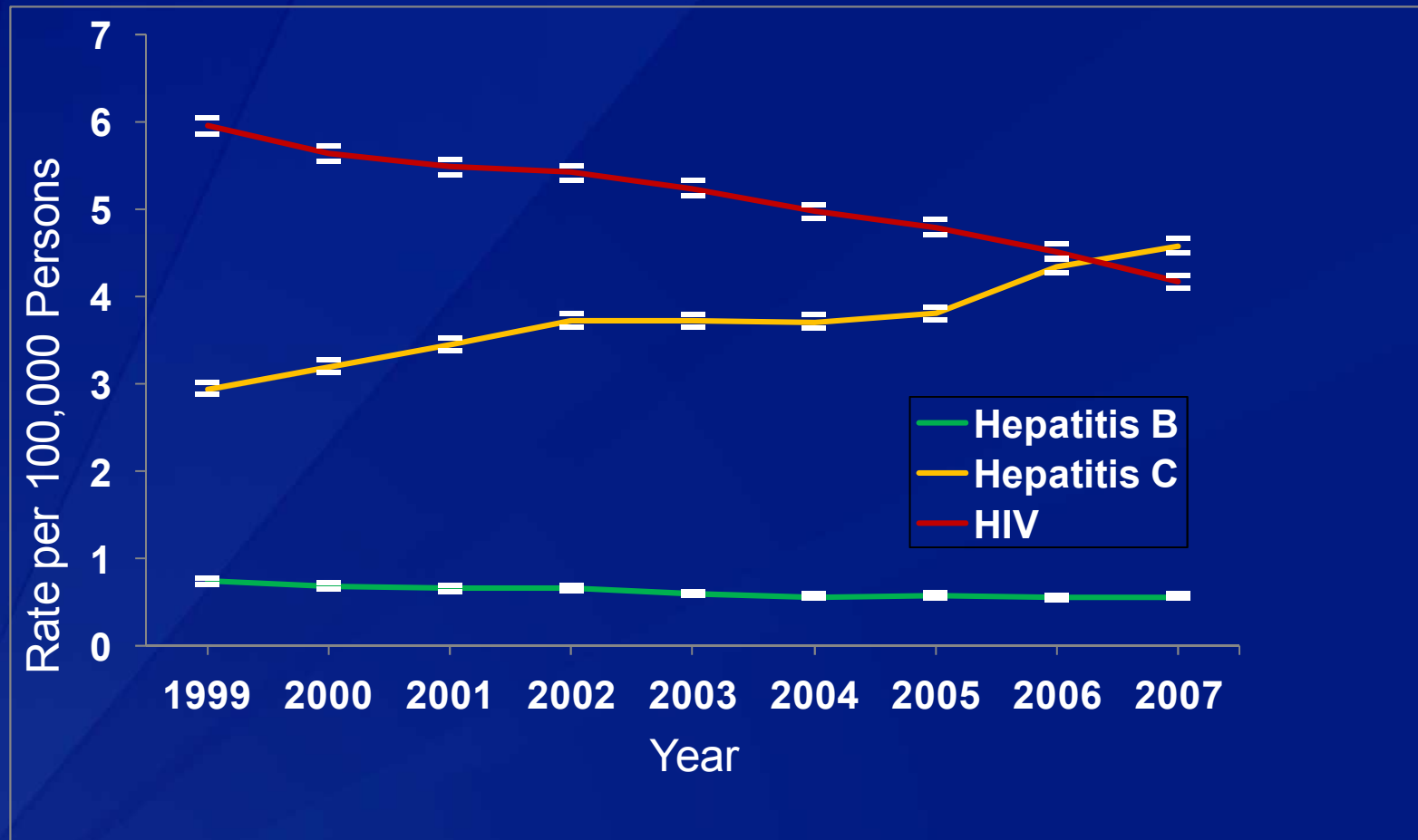
1999-2002 NHANES

- Elevated HCV prevalence
 - 57.5% IDU
 - only 17% reported injection in past year
 - 5.8% Transfusion history
 - 7.5% >20 lifetime sexual partners
- 3.0% Black
- Highest prevalence among persons born in 1945-1965

Overall prevalence:
anti-HCV 1.6% (4.1 million)
chronic HCV 1.3% (3.2 million)



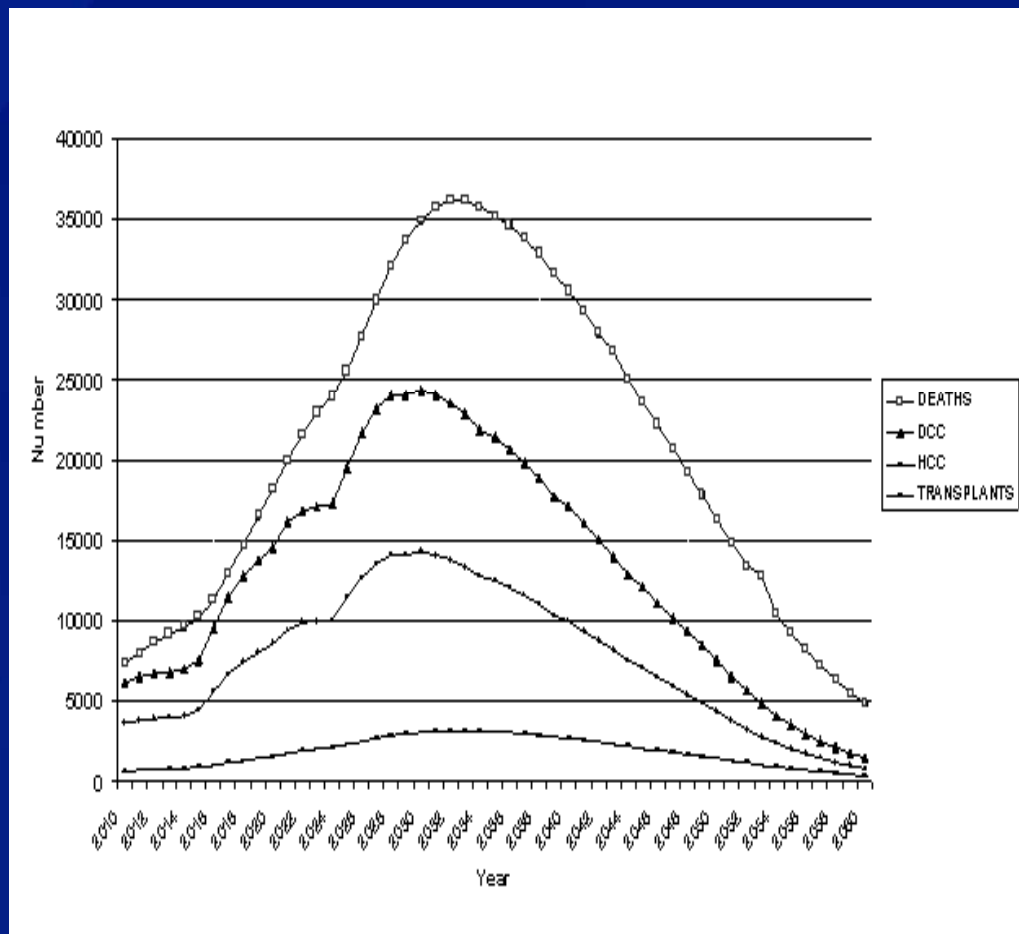
Age-Adjusted Rates of Mortality: Hepatitis B, Hepatitis C, and HIV, United States, 1999–2007



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



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*



MMWR 1998;47 (No. RR-19)

National Hepatitis C Prevention Strategy

2001



SAFER • HEALTHIER • PEOPLE™

Limitations of Risk- and Medical Condition-Based Testing

- **Physician knowledge and experience**
 - Prevalence and natural history
 - Screening and testing procedures
 - Treatment effectiveness
 - Reluctant to ask about sensitive risk behaviors
- **ALT screening misses more than 50% of chronic cases**
- **45%-85% of infected persons are unidentified**
 - Varies greatly by setting, risk level in population, and site-specific screening practices

CDC Proposal: One Time HCV Testing for Persons Born 1945-1965

- Rationale
 - 45%-85% of infected persons are unidentified
 - Higher HCV prevalence (3.29%) than others (0.55%)
 - 81% of HCV infections
 - Supplement current recommendations for HCV testing
 - Amenable to monitoring as a performance metric

Cost Effectiveness of HCV Testing and Care for Persons Born 1945-1965*

Birth Cohort (BC) Screening with Therapy

Outcome	PegIFN+Riba	PegIFN+Riba + TVR
Screening cost per new chronic case identified	\$2,874	\$2,874
Cost per QALY gained compared to risk-based screening with PegIFN+Riba treatment	\$15,700	\$35,700

BC+PR has same relative impact as colorectal screening
 BC+PR+PI has the same relative impact as cervical cancer and cholesterol screening
 Both have a higher relative impact than breast cancer screening



; PegIFN= Peglyated interferon Riba = Ribavirin; TVR =Telaprevir; PI =Protease inhibitor

* Rein D, et al. Ann Int Med 2011

Potential Impact of HCV Testing of Persons Born 1945-1965

- ❑ 2.1M chronic infections in the birth cohort (NHANES 1999-2008)
- ❑ 45%-85% of persons do not know their status
- ❑ 940,000-1.77m unidentified persons

Level of Implementation	Chronic Cases Identified
10%	94,000 – 177,000
25%	235,000 – 433,000
50%	470,000 – 885,000
75%	705,000 – 1,328,000
100%	940,000 – 1,770,000

Implementation of CDC Policies for HCV Testing

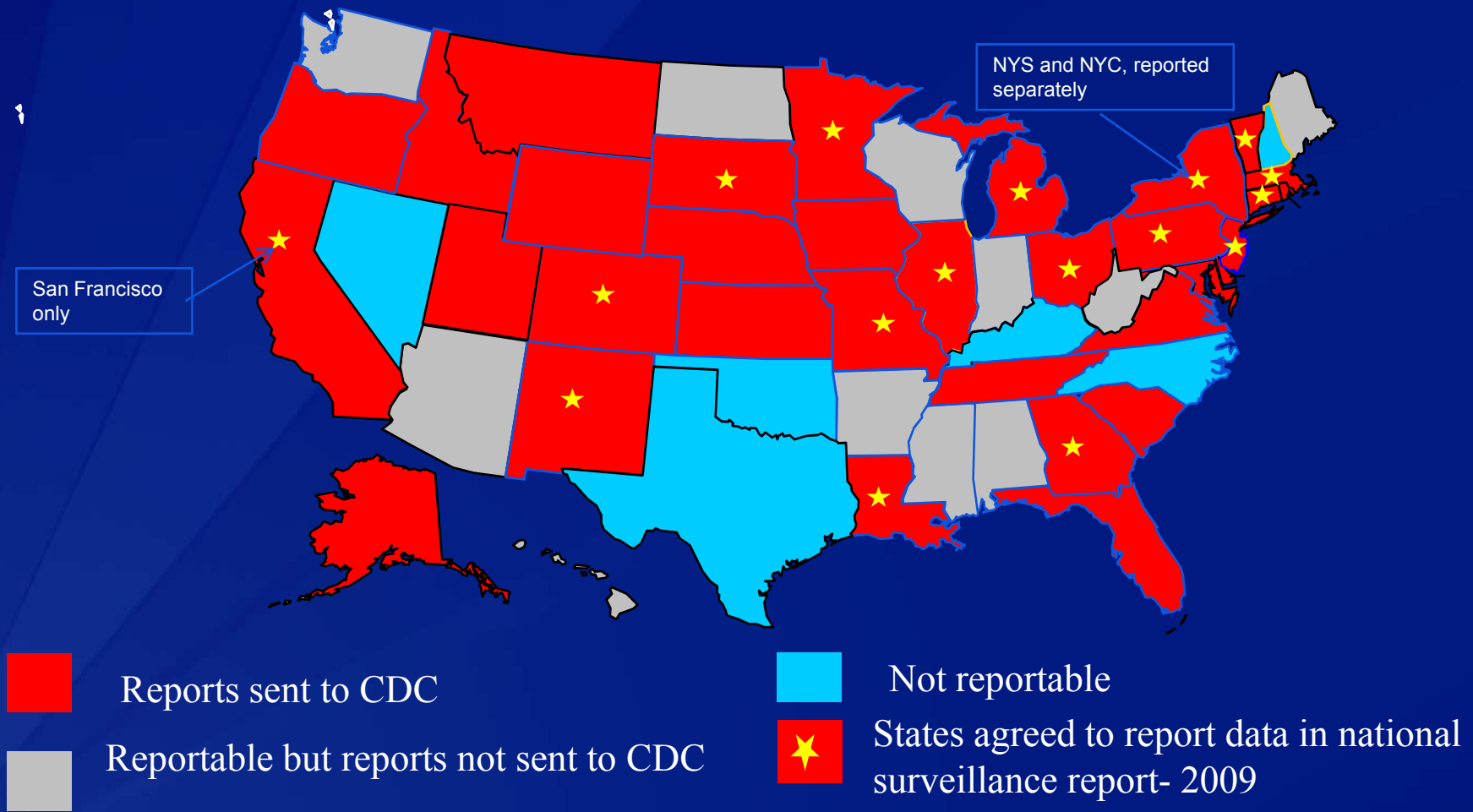
- Expand Education
 - Community- *KNOw* More Hepatitis campaign
 - Provider training
- Direct public health capacity to testing and care referral
- Revise health care policies
 - Add HCV as condition covered in health home provision
 - Add HCV testing as adult health quality measure.
 - Update USPSTF recommendation (in progress)
- Engage stakeholders
 - Government
 - NGO- (Professional societies, health care, civil society)
- Monitor progress and impact



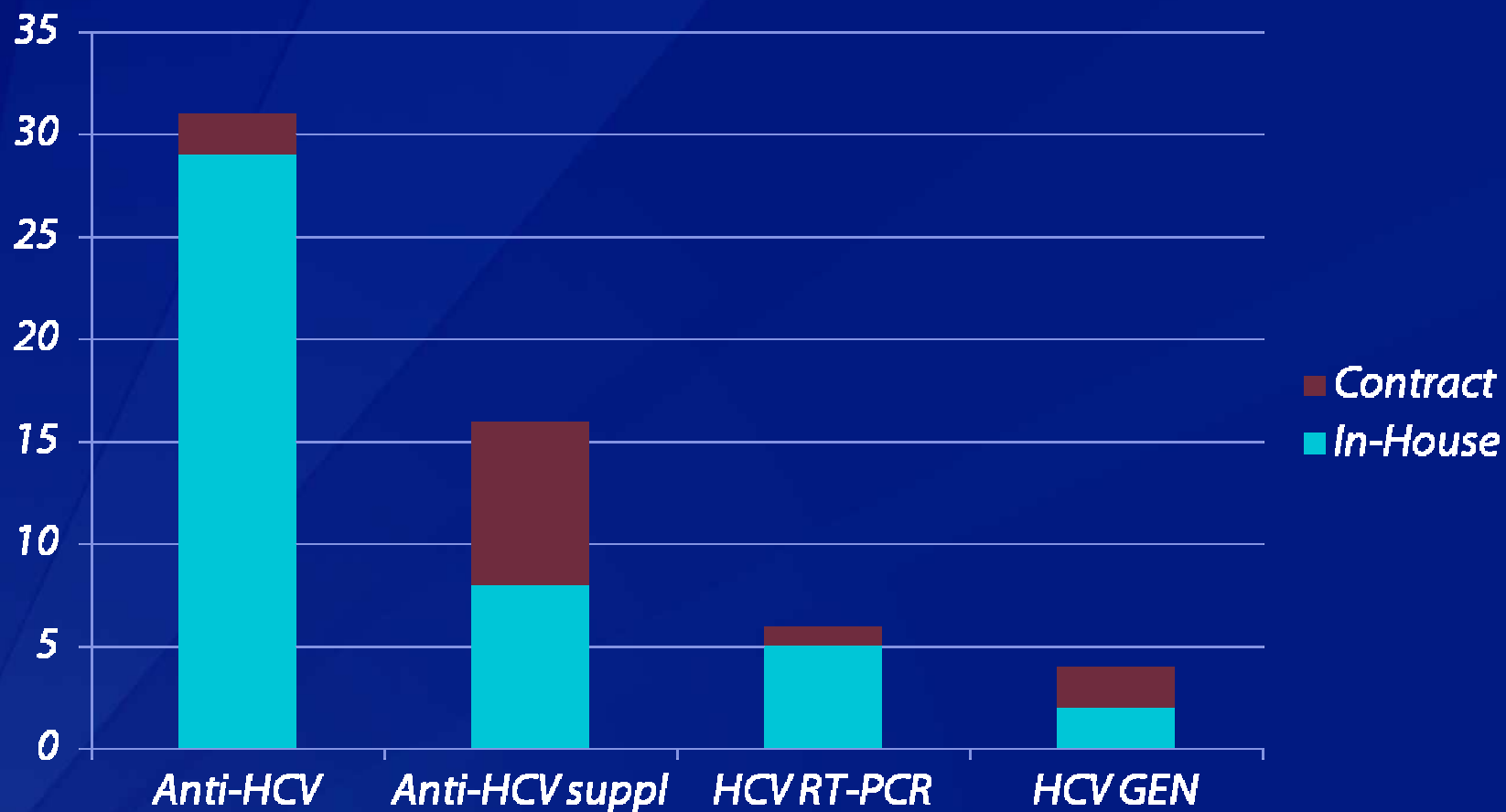
Monitoring to Assure Implementation of Policies for HCV Testing, Care, and Treatment

- Observational study of 10000 patients in care for hepatitis C
- Medical data sets
 - National Hospital Discharge Survey (NHDS) – non-Federal short-stay hospitals
 - National Ambulatory Medical Care Survey (NAMCS) -- non-federal office-based physician practices
 - Centers for Medicare & Medicaid Services (CMS)
- Electronic health records- performance metrics
 - AGA Hepatitis C physician performance measures
 - HHS measure (CMS, HRSA)

States Notifying CDC of Past or Present Hepatitis C Virus Infections, 2009



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

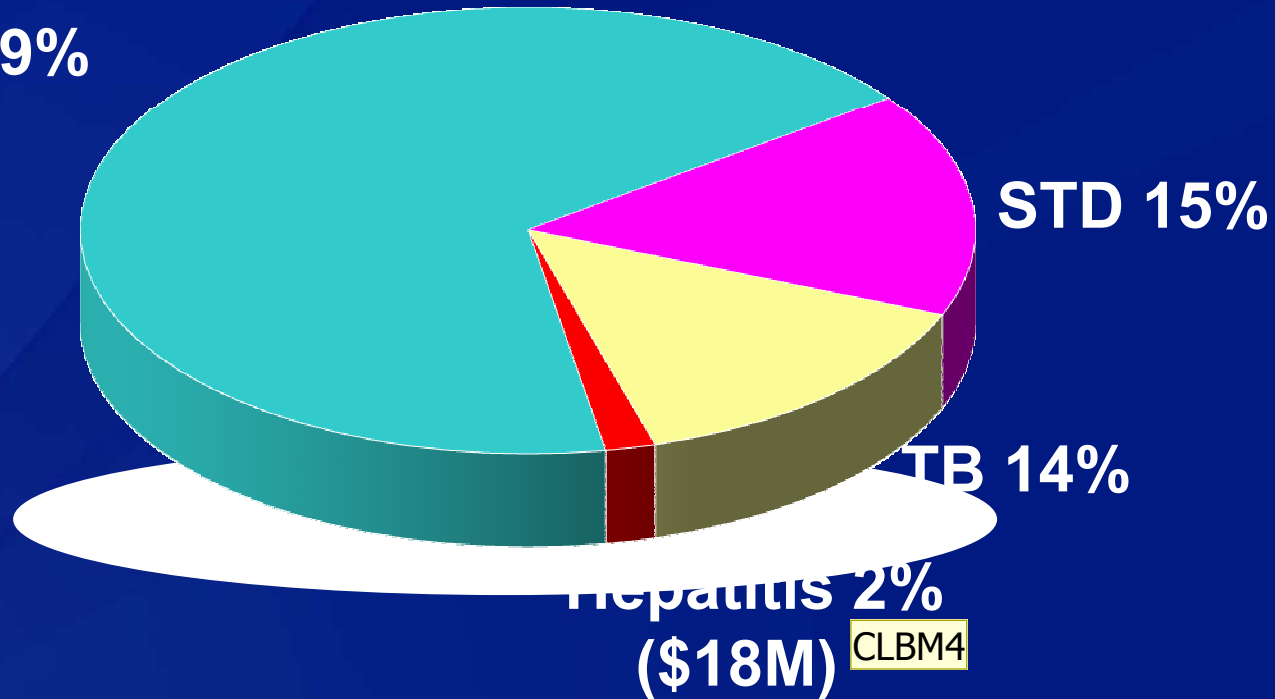


FY 2010 Enacted Funding Lines to CDC

CLBM2

Annual Total: ^{CLBM3} \$1 billion

Domestic HIV
69%



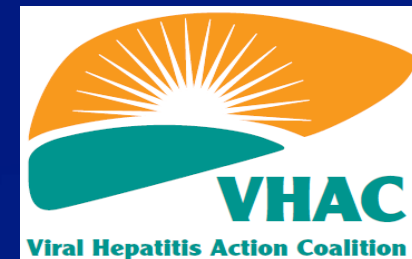
CLBM4

Slide 18

- CLBM2** again...not a CDC literate crowd... I'd spell out CDC National Center for HIV/AIDS, Hepatitis, STDs and TB Prevention (NCHHSTP)
Carol L. Brosgart, MD, 12/2/2011
- CLBM3** I'll add suggested revisions in red where they are easy one word items
Carol L. Brosgart, MD, 12/2/2011
- CLBM4** consider inserting a slide that shows what the focus of the Division has been in the past or constrained to due to funding. What type of total annual funding would it take to do what's called for in the IOM and the National Viral Hepatitis Action Plan. Let's make sure that the audience understands that the focus until now has been on acute disease surveillance and prevention, largely due to \$. Help them understand what it would take on national, state and local level to be able to have surveillance for chronic disease....so that we could speak to stage of disease at diagnosis, how many are diagnosed late, differentiate between states of localities that are doing a better job of testing, diagnosing, linkage to care, etc. Without adequate funding or a sea change, some of the creative ways that we will work to get at this information
Carol L. Brosgart, MD, 12/2/2011

Viral Hepatitis Action Coalition

- Public-private partnership with CDC Foundation
 - CHECS- observational cohort of >12,000 HCV+ patients
 - Best-C- evaluate new HCV testing strategies
 - “Know More Hepatitis” - national education campaign
 - Fellowships
 - Surveillance
 - Global



Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb,
Genentech, *A Member of the Roche Group*, Gilead Sciences,
GlaxoSmithKline, Janssen Therapeutics, Merck Sharp & Dohme, OraSure
Technologies, Vertex Pharmaceuticals

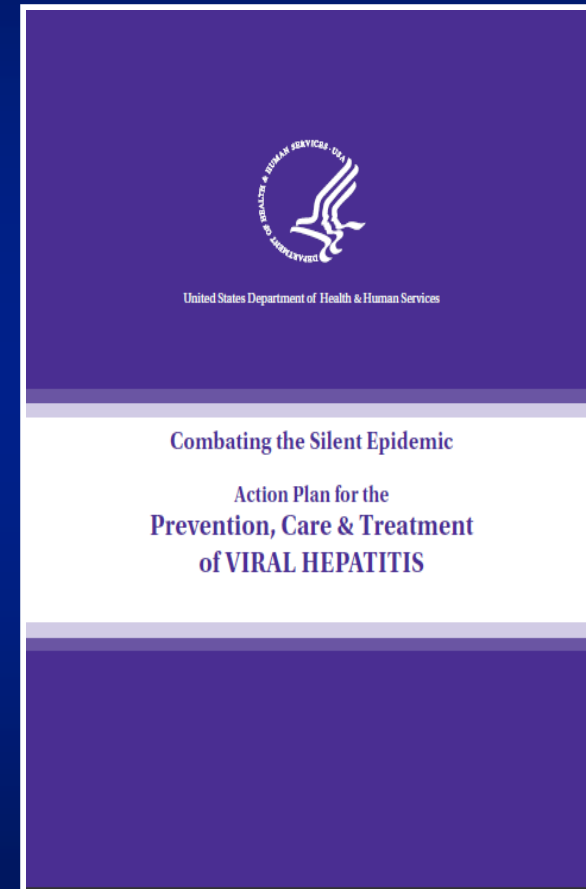


Summary

- HCV treatment can reduce HCV disease and in the future HCV transmission
- Access to HCV testing and care must improve to realize health gains from improvements in therapies
- Changes in testing policies and health care practice can expand access to HCV testing, and care, and treatment
- Innovative strategies are needed to build capacity for prevention, care, and treatment
- Surveillance must evolve to identify HCV infected persons and monitor the impact of clinical preventive and care services

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

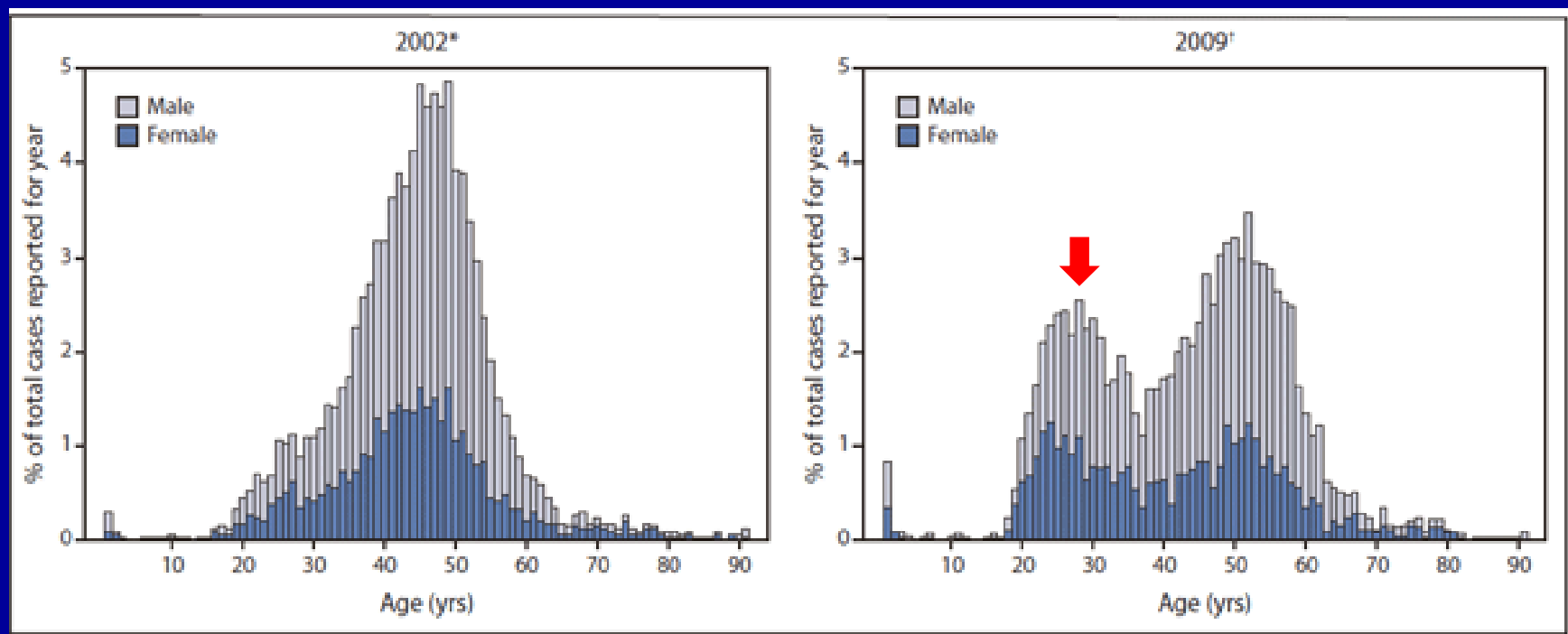


HCV Transmission

- In 2009, an est. 16,000 new cases
 - Level incidence since 2004 ; large decline since peak in mid 1980s
 - 50% cases reported as IDU
- IDU incidence among new injectors¹
18-27 HCV infections/100 p.yrs. within 2 yrs^{2,3}
HCV prevalence has declined but remains high ; 32% in Seattle⁴
- Sexual transmission
Large number (>50) of sex partners associated with HCV +
0.5%-1% incidence among HIV+ MSM in US⁵
- Health-care associated
Inadequate infection control
Eight outbreaks reported to CDC in 2010

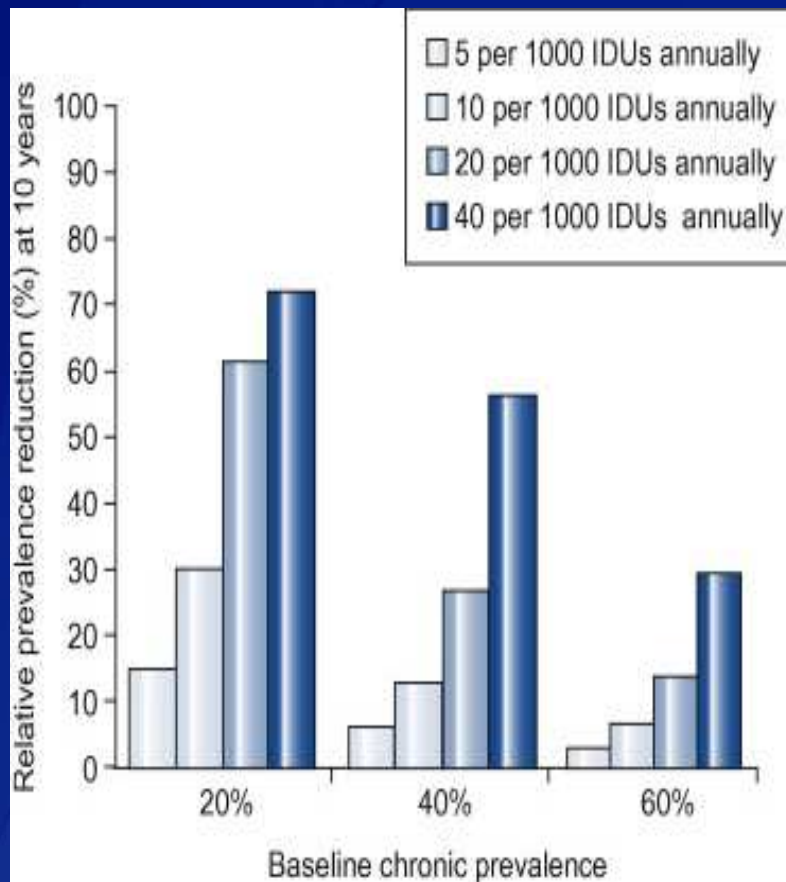
¹ Hagan, et al, Int J Drug Policy 2007; ² Hagan et al, Amer J Public Health 2001.; ³ Lucidarme, et al, Epid and Infect 2004; ⁴ Burt et al, J Urban Health 2007. ⁵ Burt, et al Drug Alcohol Dependence 2009.); ⁵ Clin Infect Dis. 2011 Mar 15;52(6):812-8. Epub 2011 Jan 31

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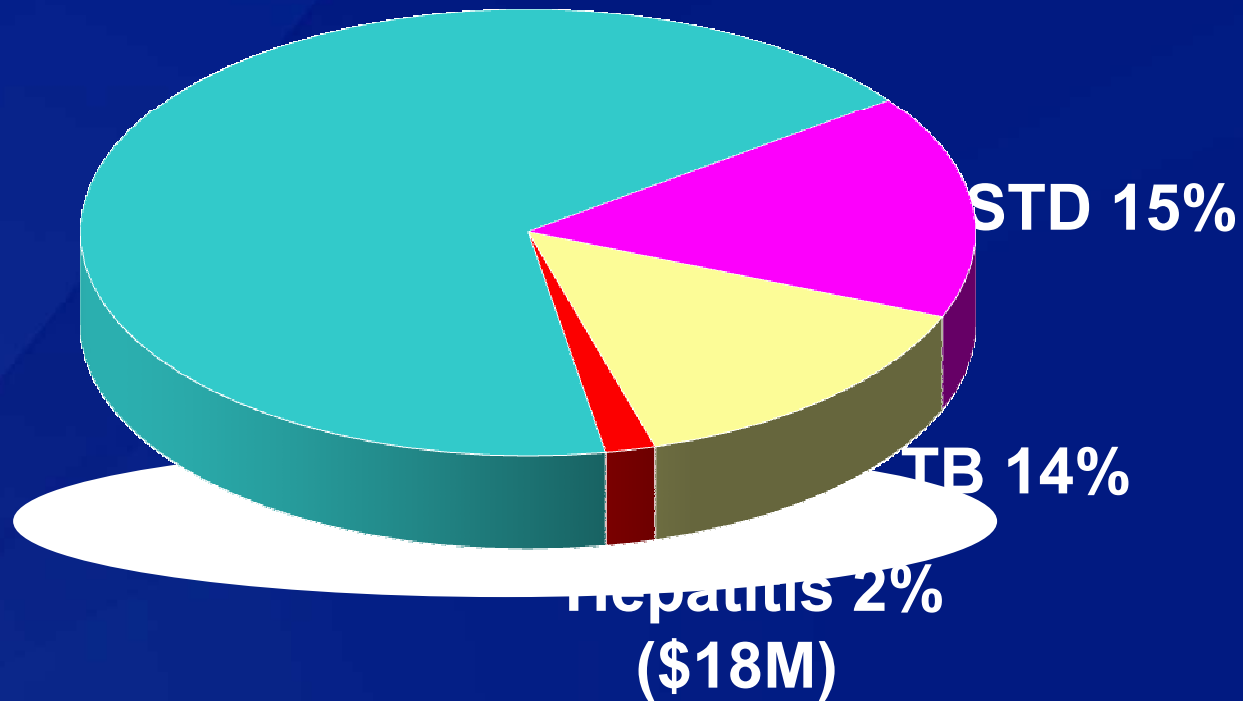
Monitoring Implementation and Impact of CDC Policies for HCV Testing

- National Hospital Discharge Survey (NHDS) – non-Federal short-stay hospitals
- National Ambulatory Medical Care Survey (NAMCS) -- ambulatory care services in non-federal office-based physician practices
- National Hospital Ambulatory Medical Care Survey (NHAMCS)- ambulatory care services in hospital emergency/ outpatient departments
- Healthcare Cost and Utilization Project (HCUP) – state estimates comparable to the national data for NHDS, NAMCS, NHAMCS.
- Centers for Medicare & Medicaid Services (CMS) – characteristics, conditions, treatments, etc. for recipients of Medicare/Medicaid

FY 2010 Enacted Funding Lines NCHHSTP

Total: ~\$1 billion

**Domestic HIV
69%**



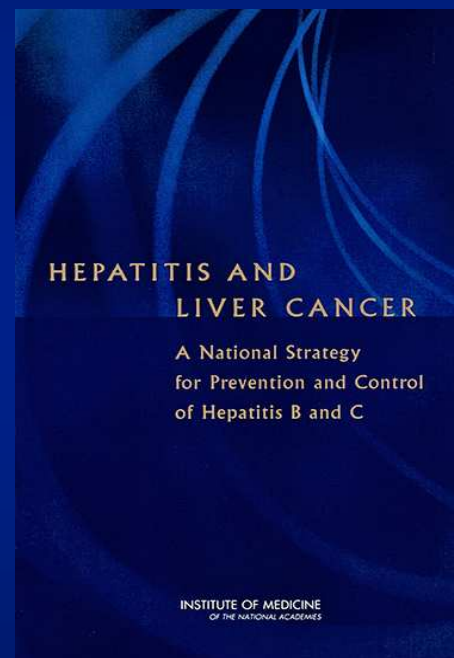
Implementing New Technologies: HCV rapid point of care tests

- *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*



Viral Hepatitis Prevention Policy Development

- Public education and provider training
- Public health surveillance
- Immunization
 - Perinatal
 - Adult
- Care services
 - Community outreach and awareness
 - Harm reduction
 - Identification of infected people
 - Medical management



Coordination at national



Examples of Clinical Settings with High Rates of HCV Screening: Primary Care

- **Three primary care clinics in the Bronx**
- **Review records of 9579 patients in Jan/Feb 2008**
 - 40% of 3803 patients had record of HCV testing
 - High testing rates for patients with risks for HCV
 - 78% of 436 substance abusers; 191 (44%) HCV+
 - 67% of 555 patients with elevated ALT/ (31%) HCV+
 - ~ 49% of HCV infected patients remain untested
 - Screening persons born 1945-1964 would have identified 78% of positives
 - “A Birth cohort approach is a useful adjunct to risk based testing”