

HEPATITIS WEB STUDY

Hepatitis C Testing Recommendations

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Disclosure Information

- Speaker's Bureau and Consultant: Gilead Sciences

Hepatitis C Testing Recommendations in the U.S.

- CDC HCV Testing Recommendation
- Rationale for Birth Cohort HCV Testing Recommendations
- Goals and Potential Impact of HCV Birth Cohort Testing

CDC HCV Testing Recommendations

1998 – CDC Risk-Based HCV Screening Recommendations

■ HCV screening based on risk for infection:

- Persons who ever injected illegal drugs
- Persons with selected medical conditions, including
 - receipt of clotting factor concentrates produced before 1987;
 - ever on chronic (long-term) hemodialysis; and
 - persistently abnormal alanine aminotransferase levels
- Prior recipients of transfusions or organ transplants (before July 1992)

■ HCV screening based on recognized exposure:

- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to HCV-positive women

Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



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

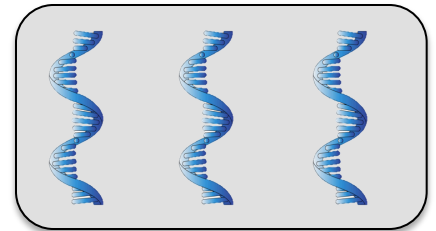
2012 CDC Birth Cohort HCV Testing Recommendations

In addition to testing adults of all ages at risk for hepatitis C virus:

- Adults born during **1945 to 1965** should receive 1-time testing for HCV without prior ascertainment of HCV risk.
- All persons identified with HCV infection should receive:
 - A brief alcohol screening and intervention as clinically indicated,
 - Referral to appropriate care and treatment services for HCV infection,
 - Post-test counseling

Hepatitis C Testing Methods

- **Screening: Hepatitis C Antibody Testing**
 - Highly sensitive and specific
 - Reactive test indicates current or resolved infection
- **Supplemental: Nucleic Acid Testing**
 - Quantitative and qualitative HCV RNA tests used
 - Positive test indicates active infection



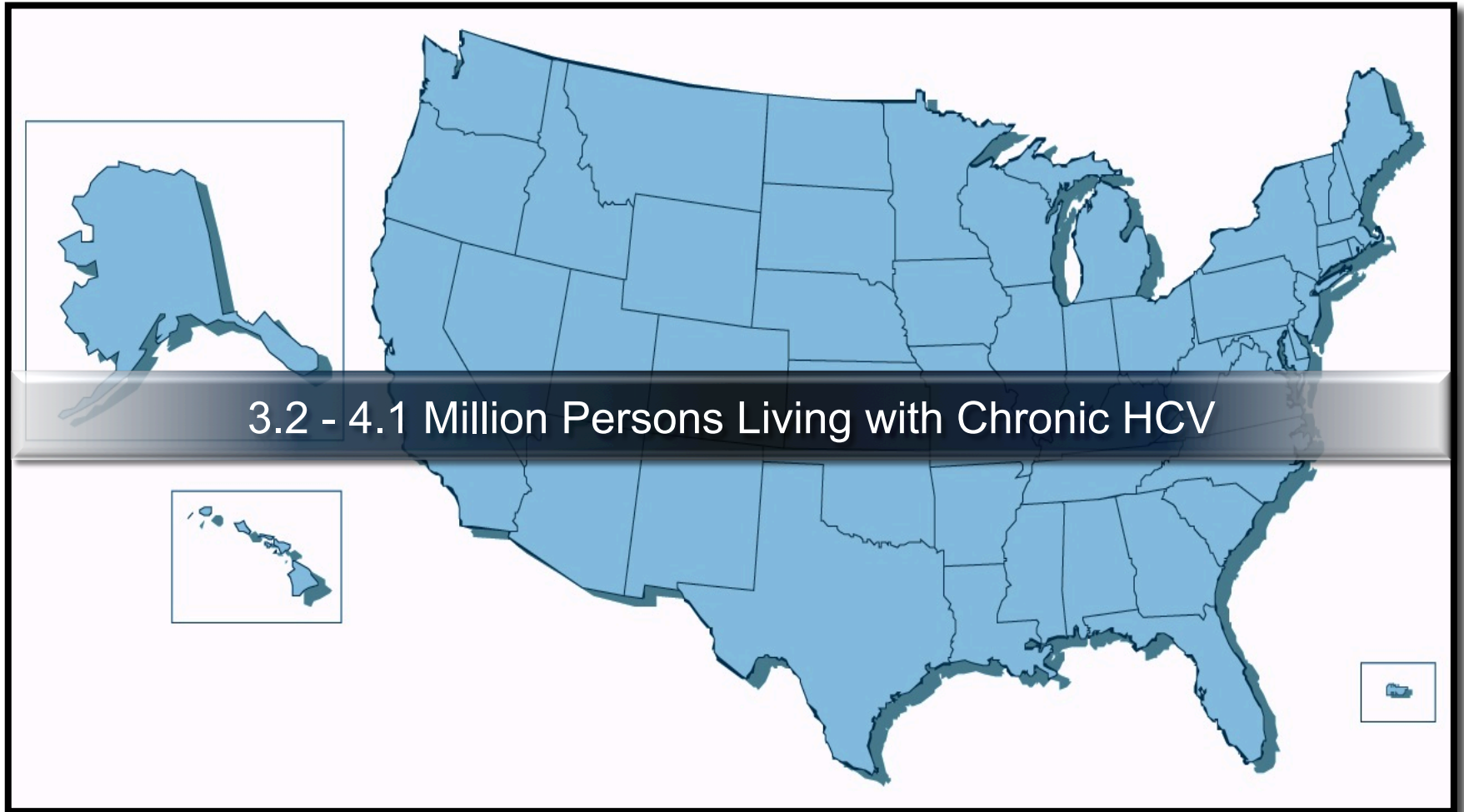
Rationale for Birth Cohort HCV Testing Recommendations

1968 World Health Organization Guidelines Criteria for New Screening Programs

When considering general public health screening programs, the following factors should be considered:

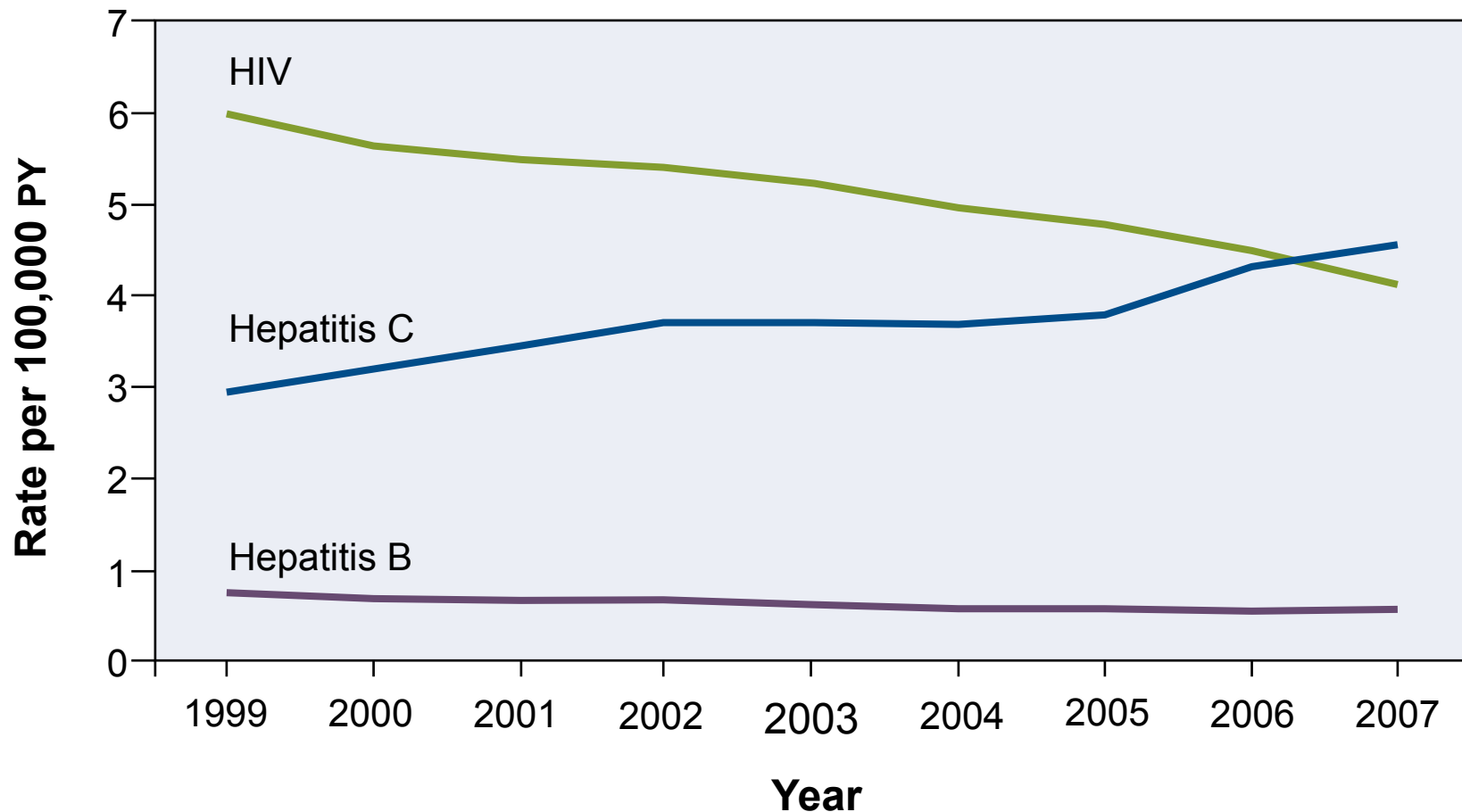
- **Relevance:** Is the condition an important public health problem with a well-understood natural history and a latent phase?
- **Feasibility:** Is there an effective intervention? Is a screening test available, easy to use, accurate, and acceptable to the population?
- **Effectiveness:** Does early diagnosis and treatment affect outcomes?
- **Cost Effectiveness:** Is the cost of the screening program worth the investment in terms of health benefit gained?

Estimated Prevalence of Chronic Active Hepatitis C in U.S.

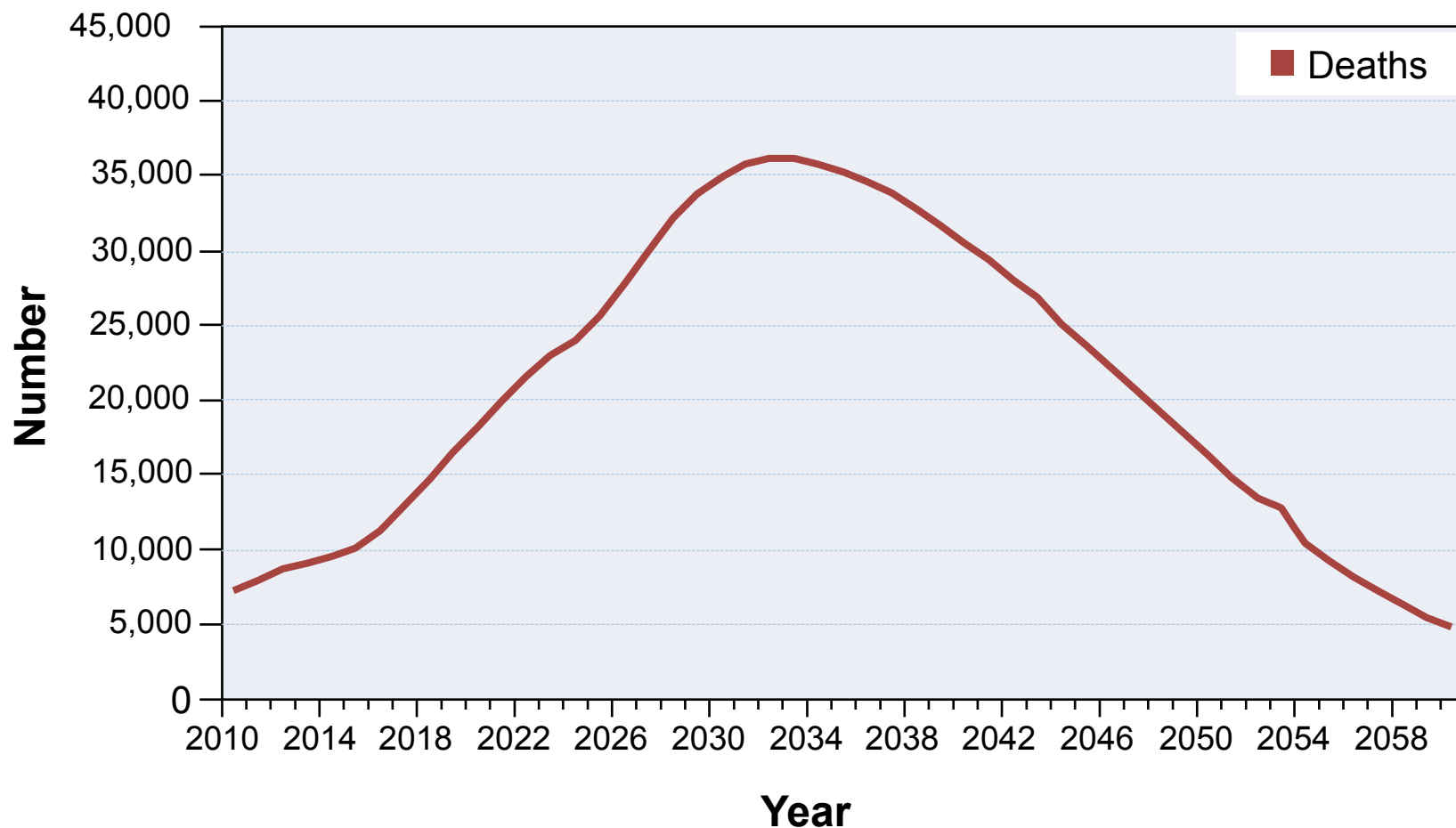


Sources: Armstrong GL, et al. *Ann Intern Med.* 2006;144:705-14.
Chak E, et al. *Liver Int.* 2011;31:1090-101.

Age-Adjusted Mortality Rates from HBV, HCV, & HIV United States, 1999-2007

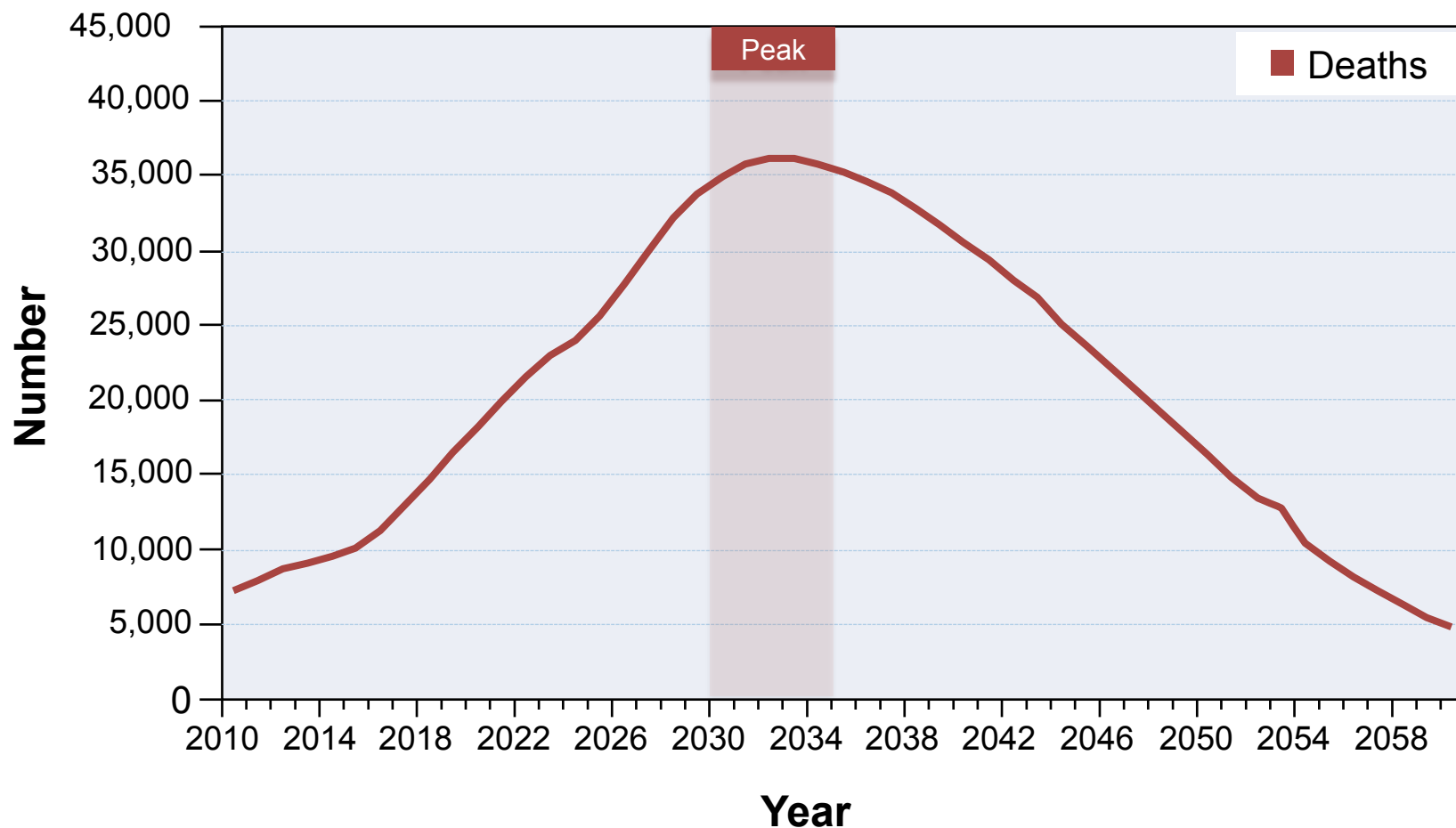


Forecasted 2010-2060 Annual HCV-Related Deaths in the United States Persons with Chronic Hepatitis C and no Cirrhosis in 2005



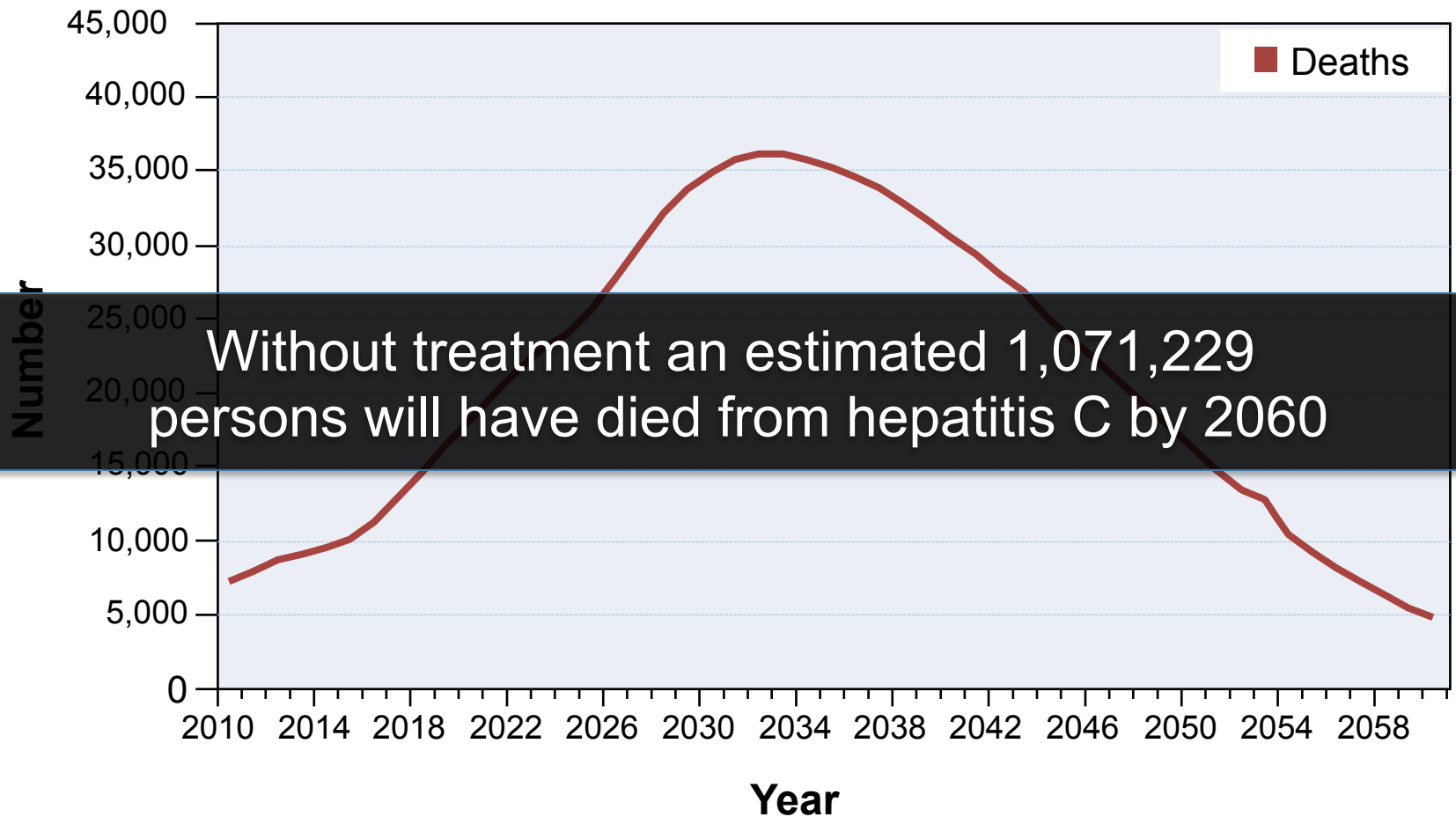
Source: Rein DR, et al. Dig Liver Dis. 2011;43:66-72.

Forecasted 2010-2060 Annual HCV-Related Deaths in the United States Persons with Chronic Hepatitis C and no Cirrhosis in 2005

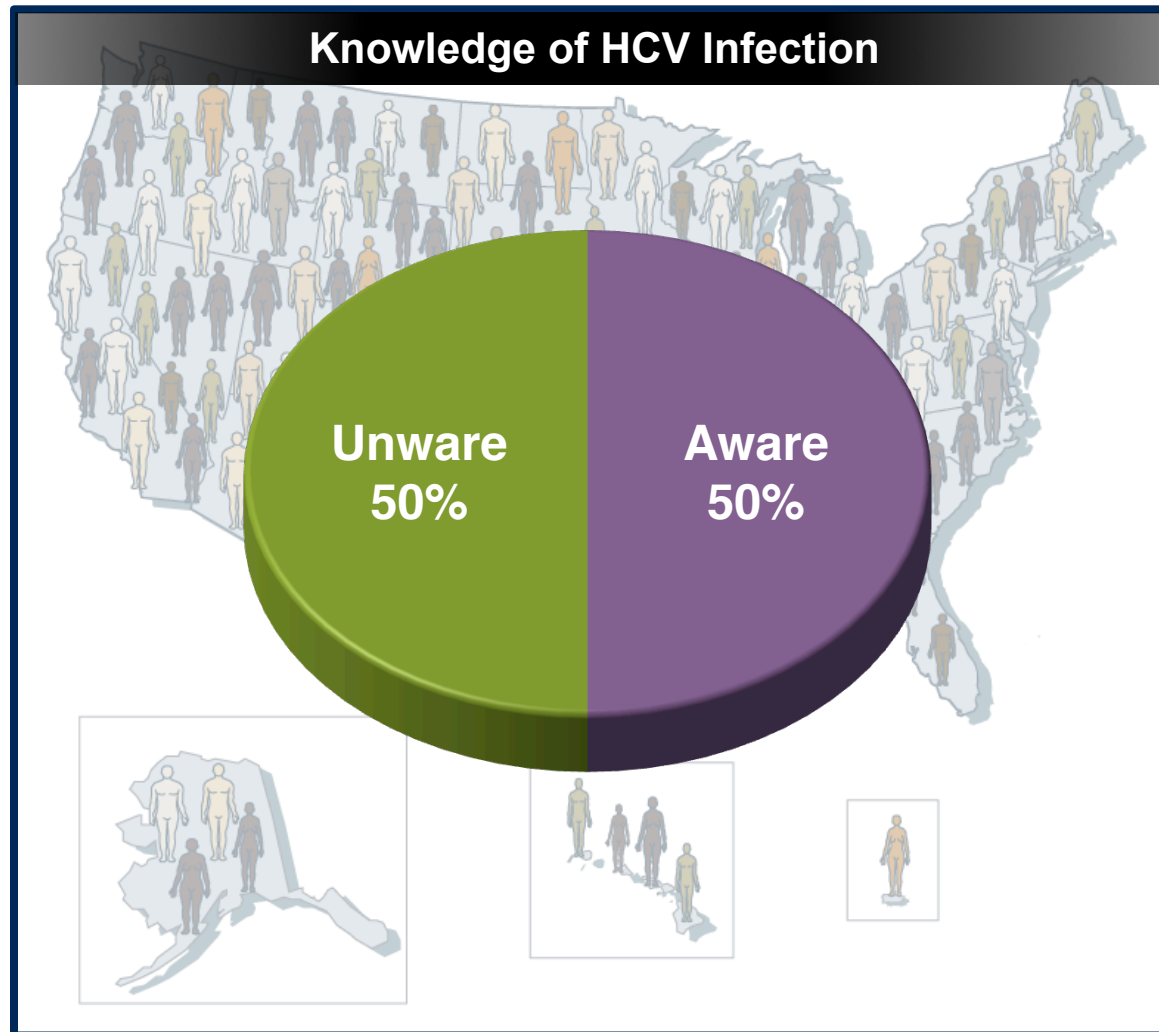


Source: Rein DR, et al. Dig Liver Dis. 2011;43:66-72.

Forecasted 2010-2060 Annual HCV-Related Deaths in the United States Persons with Chronic Hepatitis C and no Cirrhosis in 2005



NHANES Survey, United States, 2001-2008 Awareness of HCV Infection Status



Source: Denniston M, et al. *Hepatology*. 2012;55:1652-61.

Burden of disease related to HCV

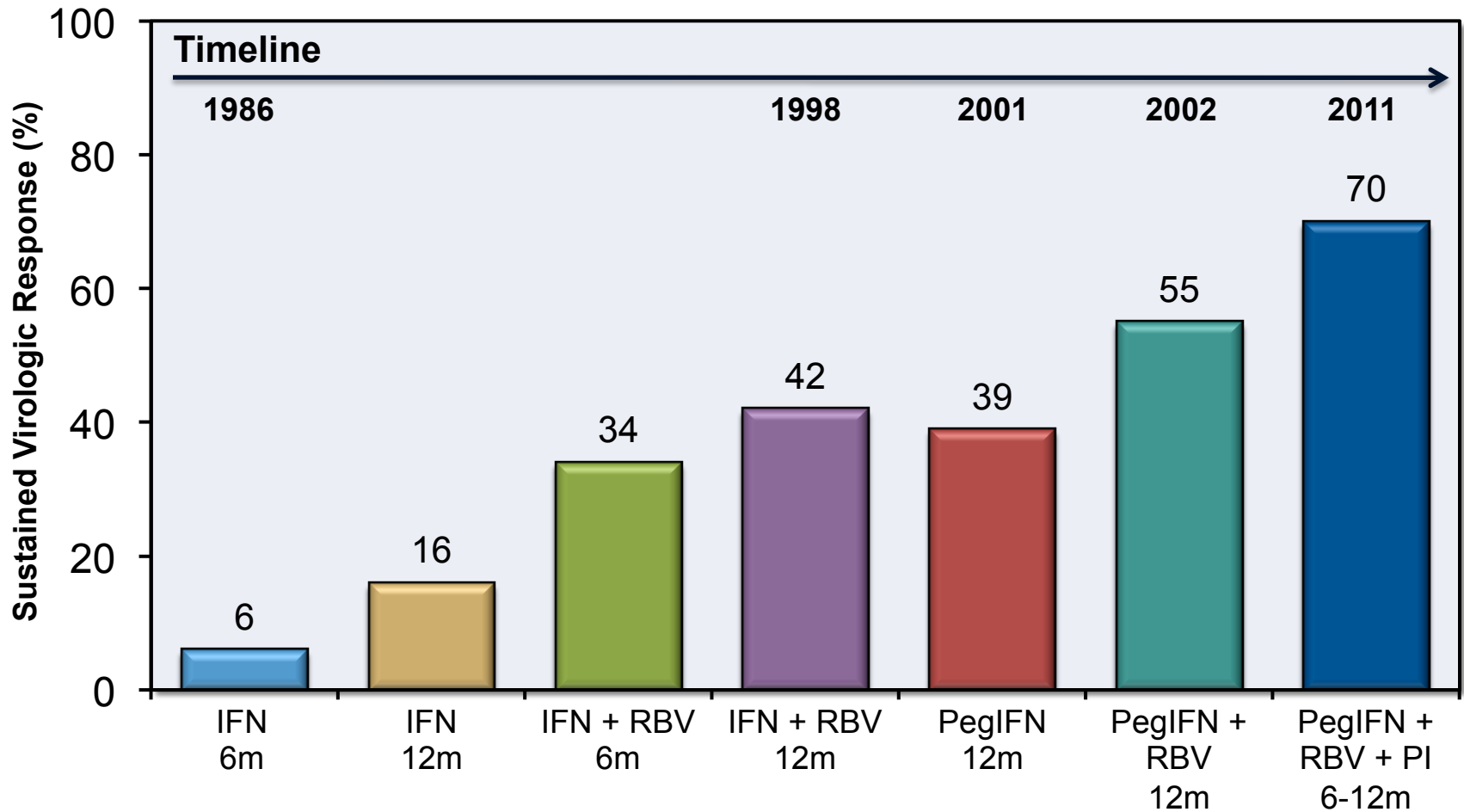
Outcome	Key Facts
Cirrhosis	<ul style="list-style-type: none">• Develops in 20% of those who are chronically infected with HCV over 20-30 years
Decompensated Cirrhosis	<ul style="list-style-type: none">• High risk of mortality from ruptured esophageal varices, bacterial peritonitis, hepatorenal syndrome/renal failure, encephalopathy
Hepatocellular Carcinoma	<ul style="list-style-type: none">• Fastest growing Cancer in the US• 76% associated with chronic HCV infection• 4% annual incidence in those with cirrhosis
Liver Transplantation	<ul style="list-style-type: none">• HCV responsible for 65% of liver transplants worldwide
HCV Mortality	<ul style="list-style-type: none">• Estimated at 16,000/year• Likely to peak ~2030

Burden of Liver disease expected to triple in next 10-20 yrs

Source: WHO Hepatitis C Fact Sheet

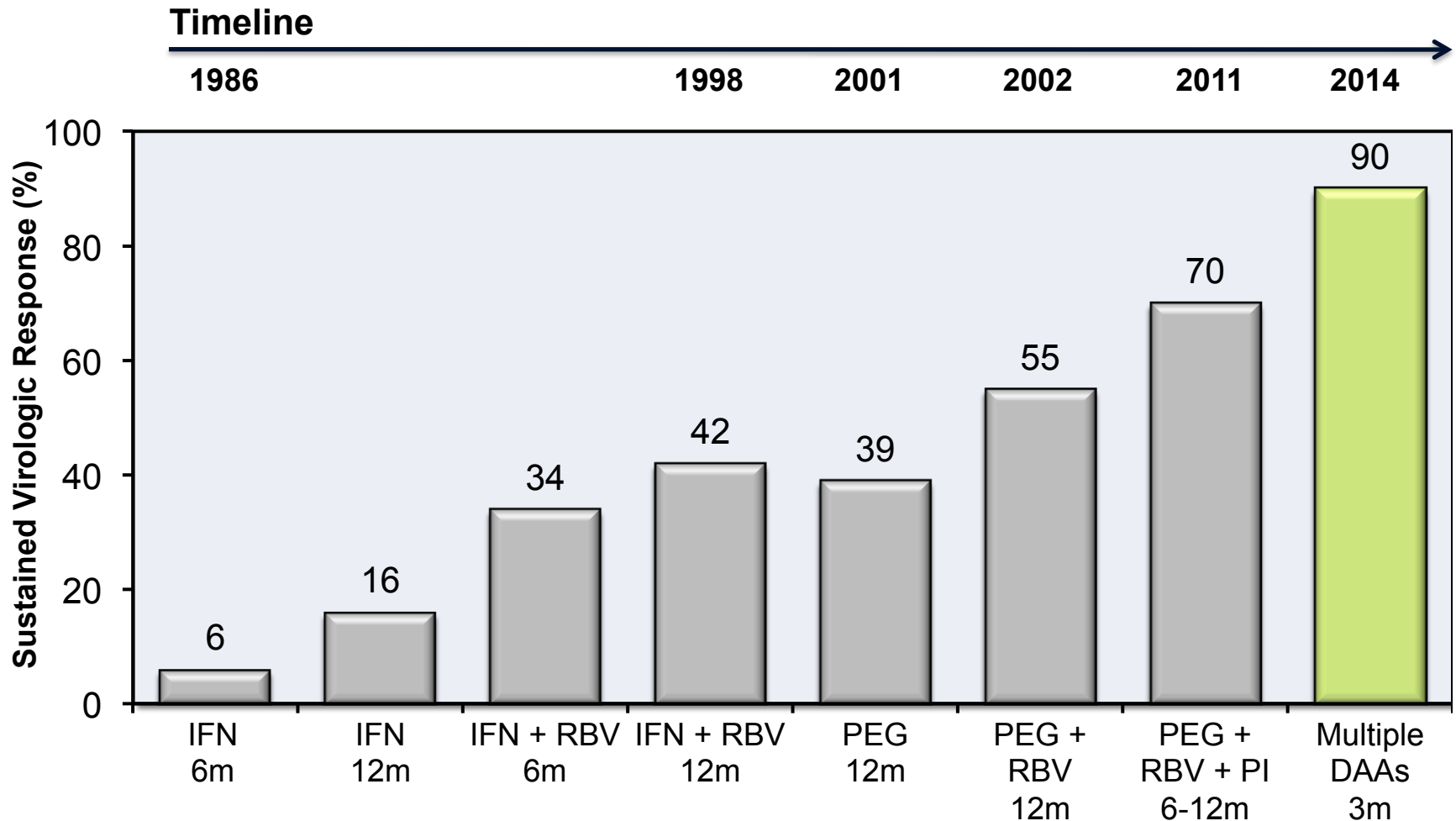
http://www.who.int/immunization/topics/hepatitis_c/en/index.html

Therapy for Hepatitis C: Historical Milestones

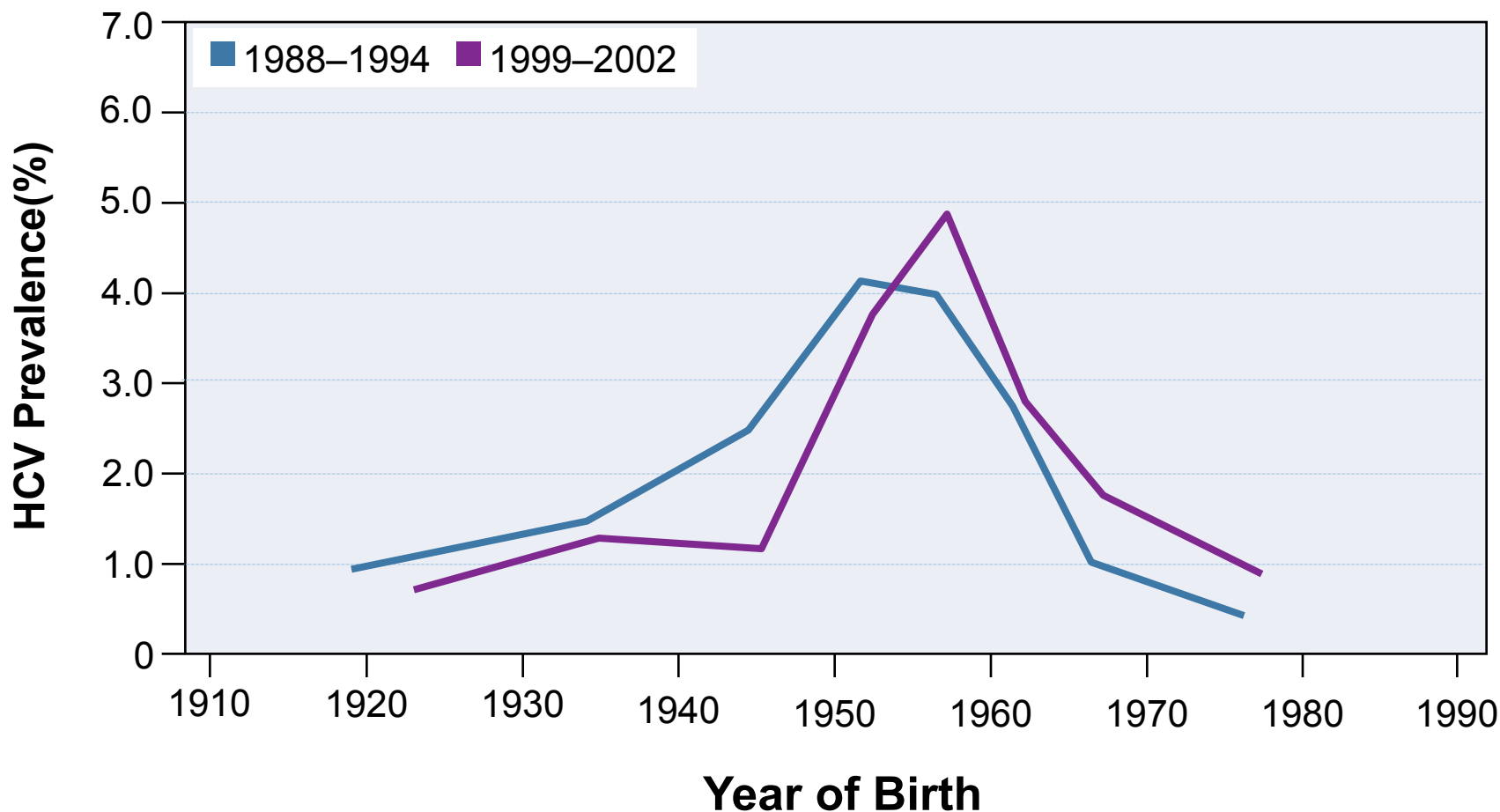


Therapy for Hepatitis C

Projected SVR Rates with Multiple DAAs

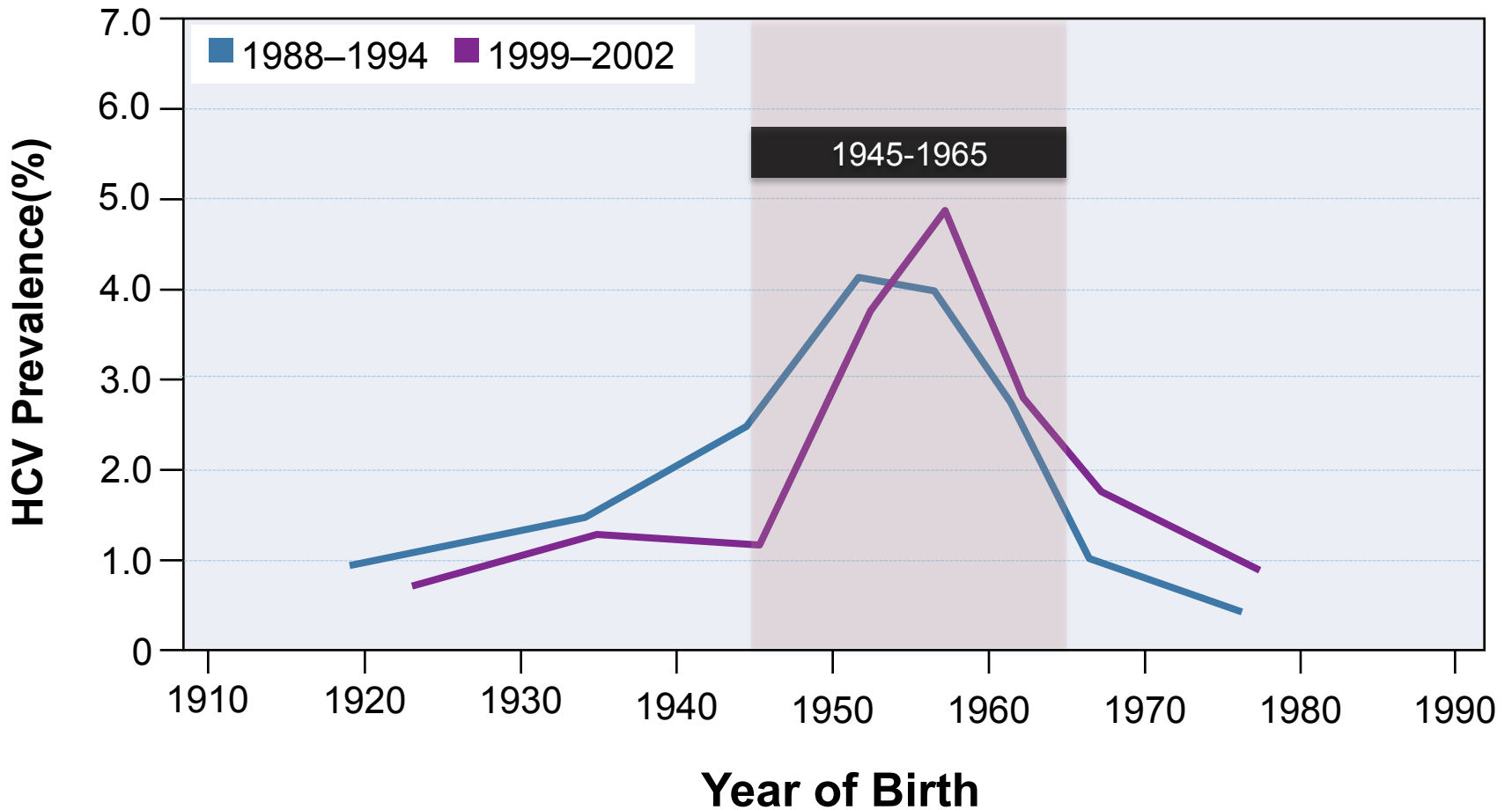


NHANES Survey: United States, 1988-1994 and 1999-2002 Prevalence of HCV Antibody, by Year of Birth



Source: Armstrong GL, et al. *Ann Intern Med.* 2006;144:705-14.

NHANES Survey: United States, 1988-1994 and 1999-2002 Prevalence of HCV Antibody, by Year of Birth



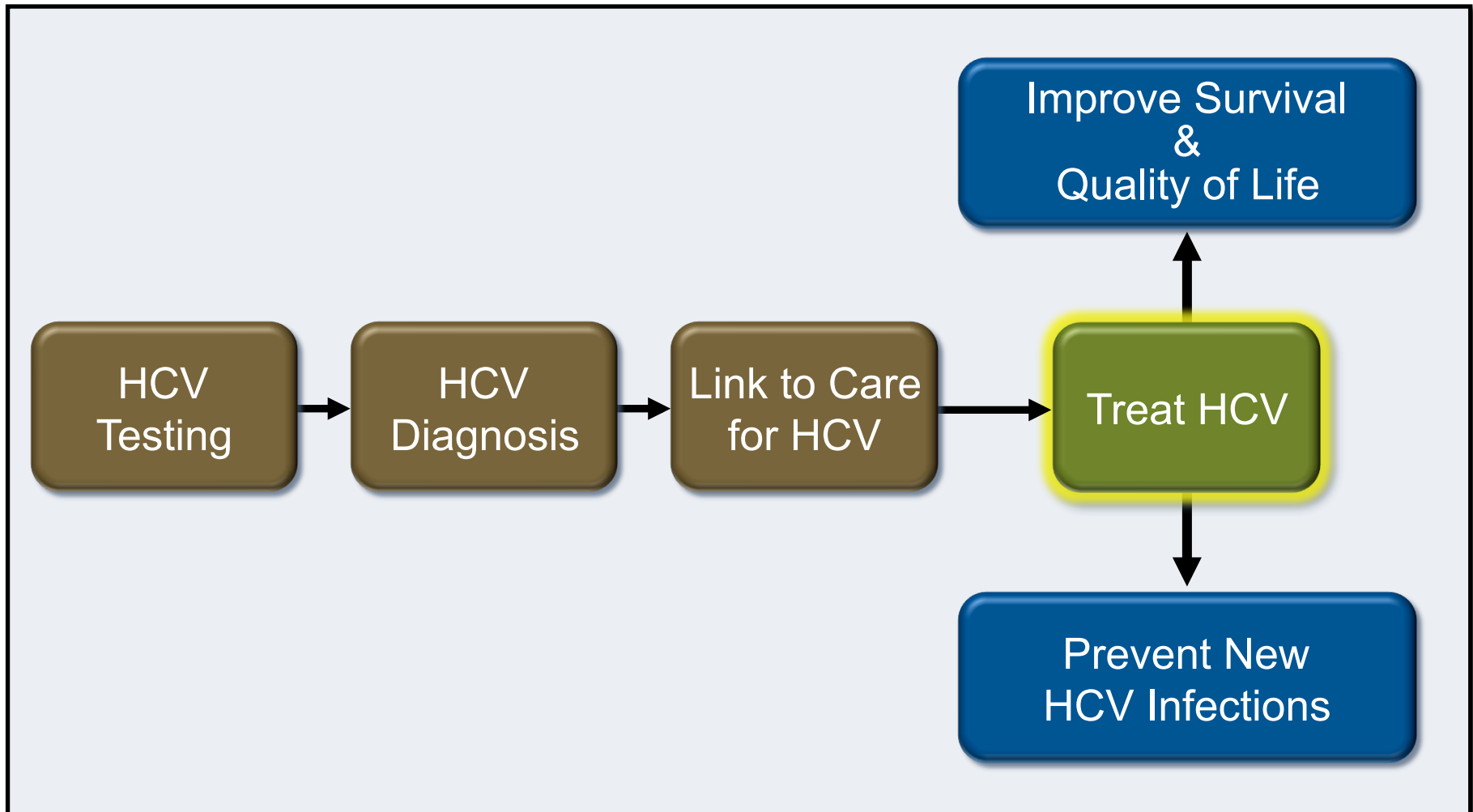
Source: Armstrong GL, et al. Ann Intern Med. 2006;144:705-14.

Rationale for One-Time HCV Testing of All Persons Born in United States during 1945 to 1965

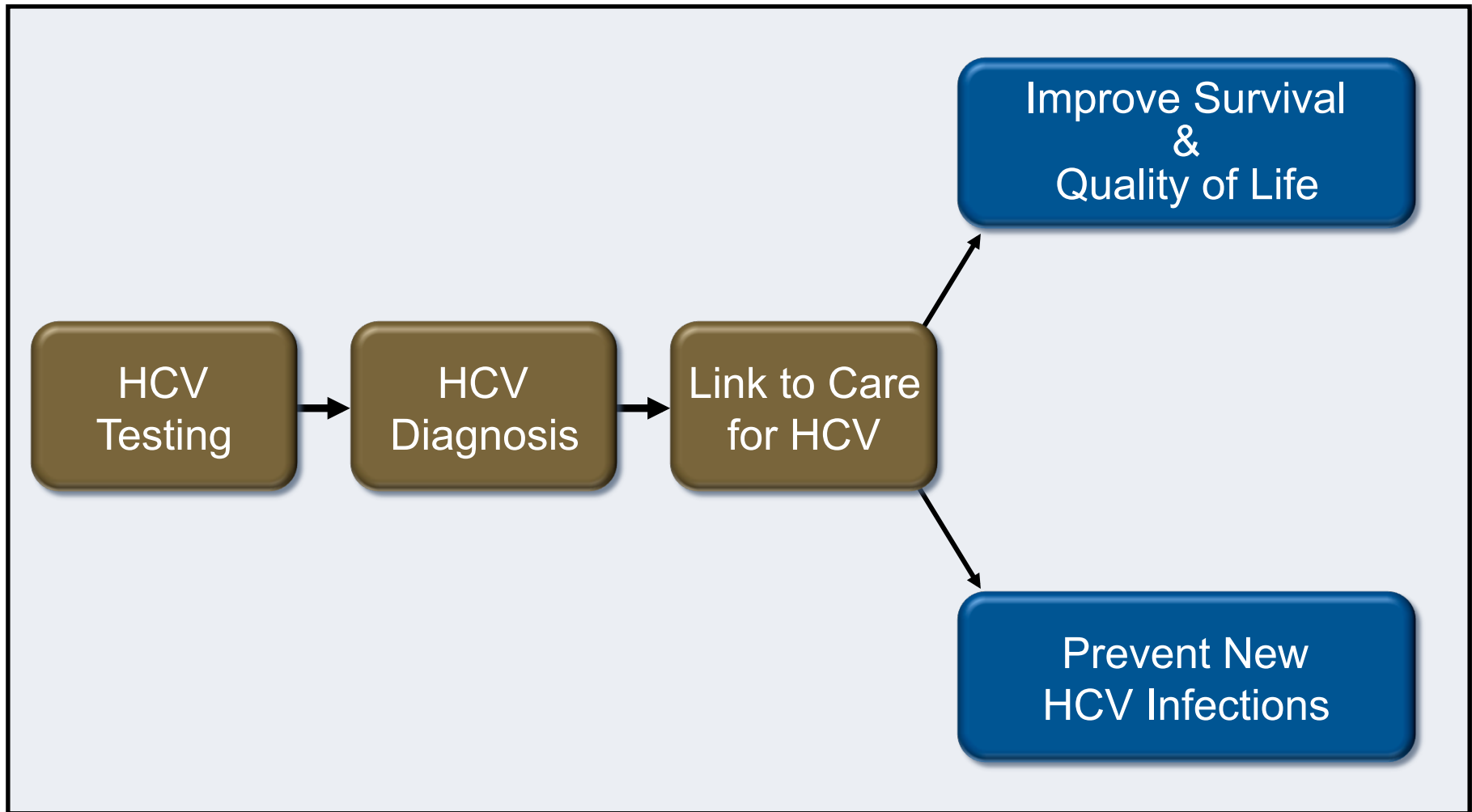
- Hepatitis C is a major current & future health problem in United States
- Testing can identify persons before onset of severe HCV-related disease
- Hepatitis C infection can be cured with treatment
- Bulk of HCV problem in United States involves persons born 1945-1965
- Approximately 50% of persons with HCV remain unaware of HCV status

Goals and Projected Impact of Birth-Cohort Screening

Goals for Birth Cohort Hepatitis C Testing in U.S.



Goals for Birth Cohort Hepatitis C Testing in U.S.



HCV Testing of Persons in 1945-1965 Birth Cohort

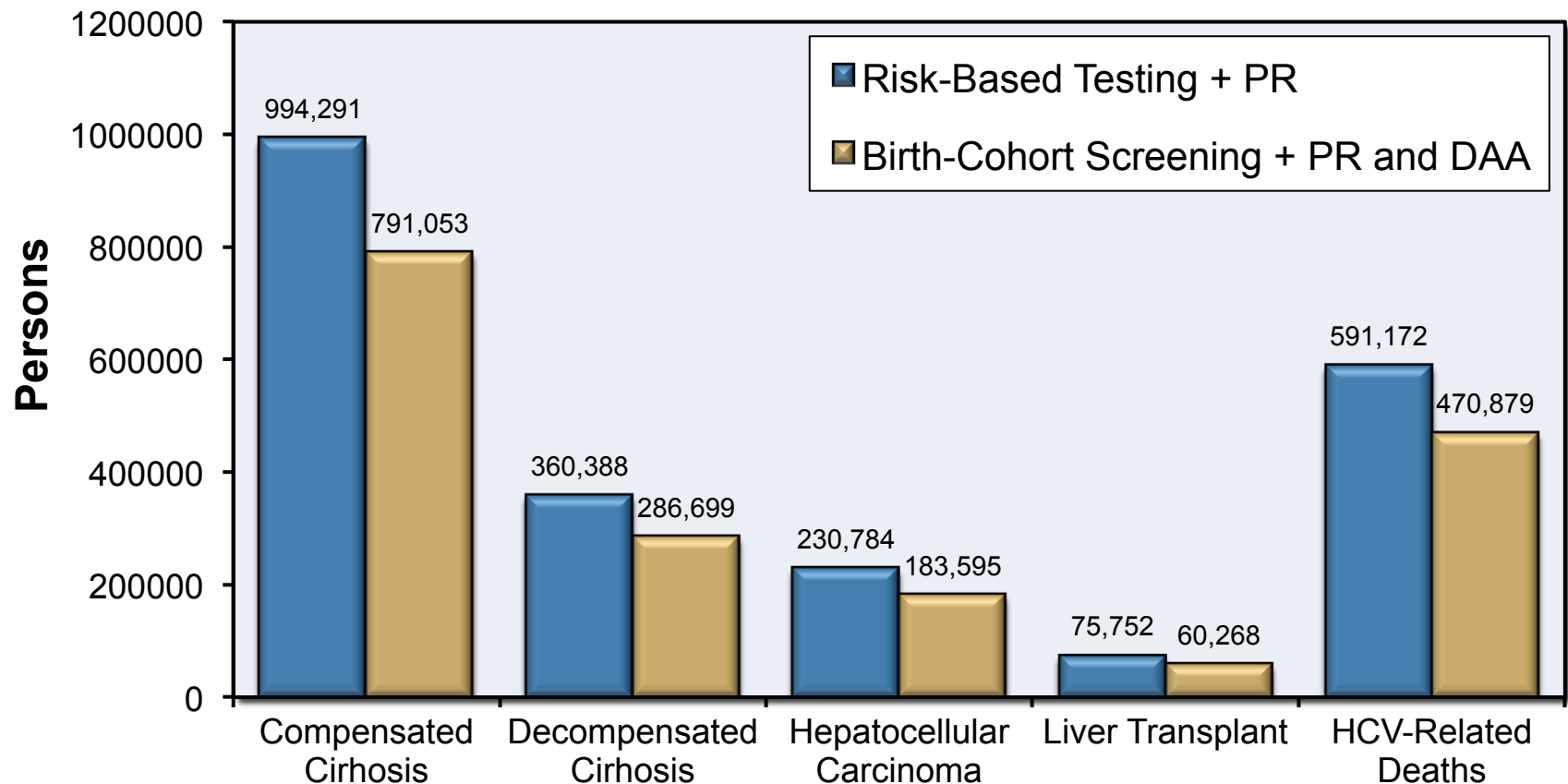
CDC Recommendations for Post Test Counseling

- **Refer or obtain advice for care of HCV**
 - experienced primary care provider or specialist
- **Educate patient on how to protect liver from further harm**
 - Immunization against Hepatitis A and B
 - Brief alcohol screening and intervention
 - Limit exposure to hepatotoxic drugs (e.g. acetaminophen)
- **Counsel obese patients on diet & weight Loss**
 - Especially BMI $\geq 25\text{kg/m}^2$
- **Advise on decreasing risk of transmission to others**
 - Donation of blood, tissue, semen
 - Use of razors, toothbrushes, nail clippers

HCV Testing of Persons Born 1945-1965

Projected Benefit of One Time Birth Cohort Testing

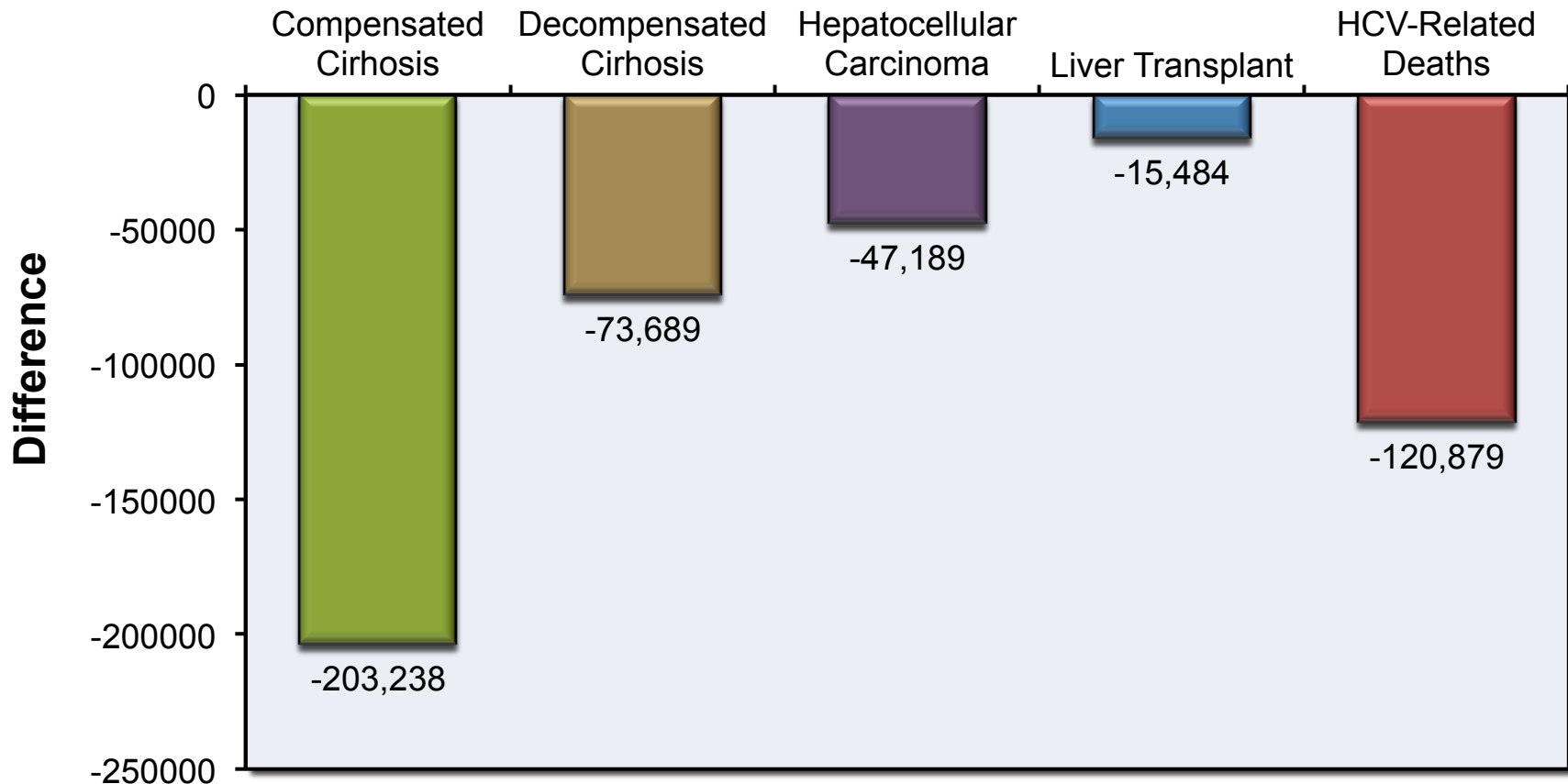
Clinical Outcomes Associated with Risk Based versus Birth Cohort HCV Testing



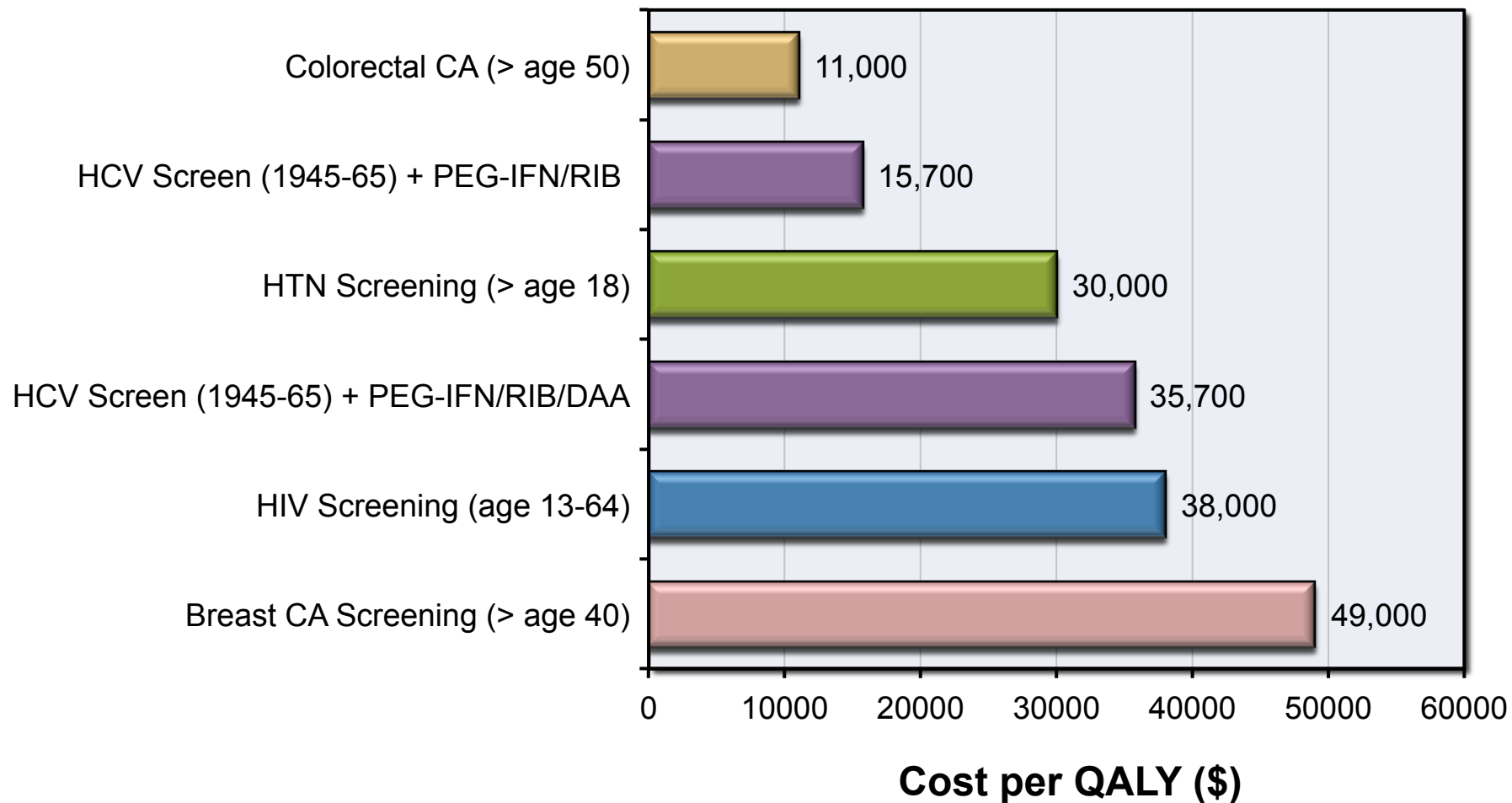
HCV Testing of Persons Born 1945-1965

Projected Benefit of One Time Birth Cohort Testing

Cases Averted with Birth Cohort HCV Testing versus Risk Based HCV Testing



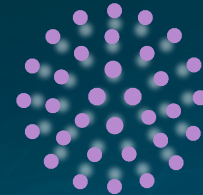
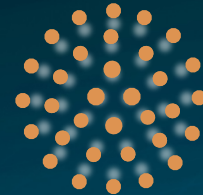
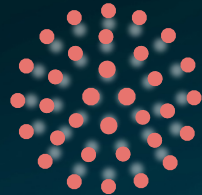
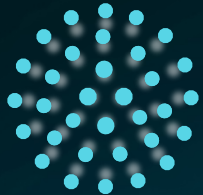
HCV Testing of Persons Born 1945-1965 Cost Effectiveness Compared with other Screening Tests



CDC Birth Cohort HCV Testing Recommendations in U.S. : Summary

- Perform one-time HCV testing of all persons born 1945-1965
- Continue risk-based HCV screening
- Sound rationale exists for birth-cohort screening
- Potential for large impact of birth-cohort testing

End



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