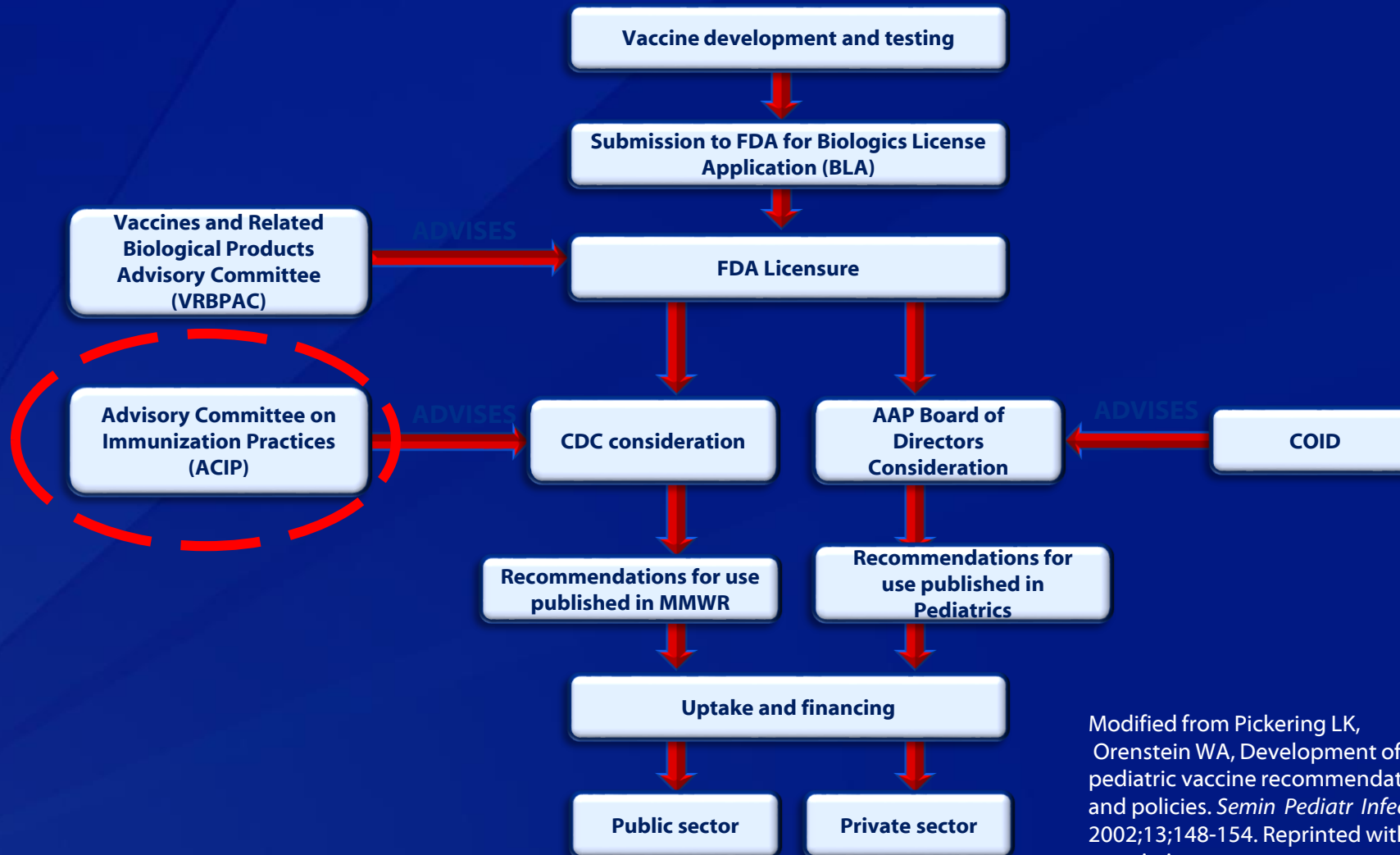


**Policy Development**  
**Prevention of Perinatal HBV and HCV Transmission**  
**United States**

# Agenda

- ACIP process
- ACIP recommendations
- Perinatal Hepatitis B Prevention Program
- Perinatal Hepatitis C Policy Development

# Development of Vaccine Recommendations – United States



Modified from Pickering LK, Orenstein WA, Development of pediatric vaccine recommendations and policies. *Semin Pediatr Infect Dis.* 2002;13:148-154. Reprinted with permission.

## Advisory Committee for Immunization Practices ACIP

- ACIP was established in **1964** by the Surgeon General of US Public Health Service
- Advises CDC on recommendations for vaccine-preventable diseases (i.e. vaccines)
- 15 members; 4 year terms; screened for conflicts of interest
- Three meetings per year; open to public ( live webcast); materials posted < 90 days
- ACIP work groups draft policies for ACIP discussion/vote- e.g., hepatitis vaccines
- Recommendations become **official US policy** with acceptance by Director, CDC, publication in *MMWR*
- Recommendations are not mandates

## Vaccines for Children Program

- ❑ Vaccines for Children (VFC) Program – established in August 1993
- ❑ ACIP determines vaccines included in the VFC Program
- ❑ VFC is a federal entitlement program - current cost is ~\$4 billion annually  
<http://www.cdc.gov/vaccines/programs/vfc/index.html>
- ❑ Eligible children- 0 through 18 years of age
- ❑ Medicaid eligible; uninsured; American Indian/Alaska native; underinsured
- ❑ Currently, approximately 48% of young children in the US are entitled to VFC

## **Objectives of the U.S. Perinatal Hepatitis B Prevention Programs**

- ❑ Funds to 64 public health jurisdictions**
- ❑ Identify HBsAg-positive pregnant women through reports to perinatal coordinators**
- ❑ Ensure timely initiation and completion of infant post-exposure prophylaxis *and* post-vaccination testing**
- ❑ Encourage universal hepatitis B vaccination starting at birth (“birth dose”) as a safety net**

<http://www.cdc.gov/hepatitis/HBV/PerinatalXmtn.htm>

## **Program Status**

- ❑ 1994-2009, case-managed >167,000 HBsAg\*-positive pregnant women and their infants (~½ estimated number)**
- ❑ >95% infants received hepatitis B vaccine and HBIG by <24 hours of life**
- ❑ Post-vaccination testing increased from ~24% to >58%**
- ❑ Perinatal chronic hepatitis B infections decreased from ~2.5% to <1%**
- ❑ ~ 800 HBV infected newborns per year**

\*HBsAg, hepatitis B surface antigen; Smith E et al. Pediatrics 2012;129:609-16; CDC. Unpublished data from the Perinatal Hepatitis B Prevention Program

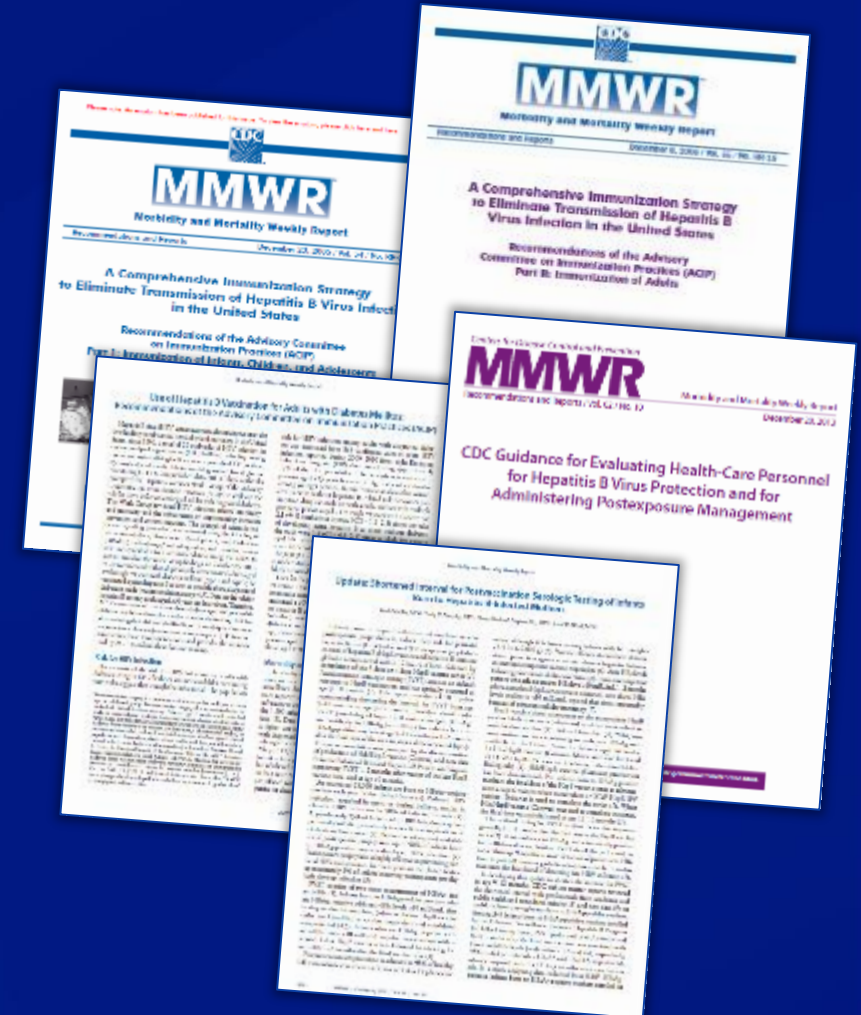
# Updates to ACIP Statement

- Hepatitis B vaccine birth dose administered **within 24 hours of birth** for medically stable infants weighing  $\geq 2,000$  grams and born to HBsAg-negative mothers
- **Testing HBsAg-positive pregnant women for hepatitis B virus (HBV) DNA to guide the use of maternal antiviral therapy during pregnancy for prevention of perinatal HBV transmission**
- Refer to AASLD recommendation for the use of antiviral therapy among mothers with HBV DNA  $>200,000$  IU/mL for preventing perinatal transmission
- Post-vaccination serologic testing for infants whose mother's HBsAg status remains unknown indefinitely
- Recommend hepatitis B vaccination for persons with HCV and for those with chronic liver disease

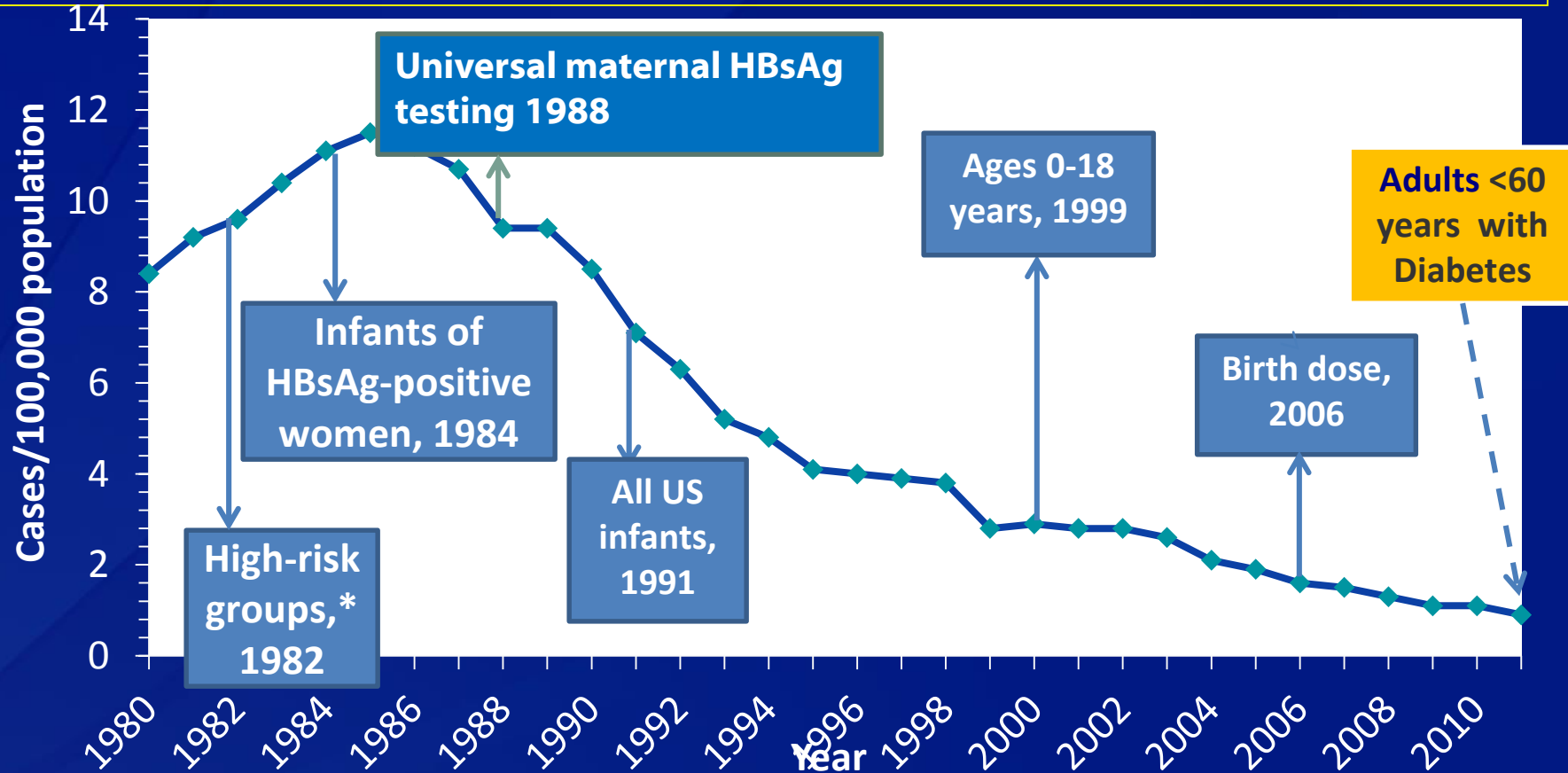


# The U.S. Immunization Strategy to Eliminate HBV Transmission

- **Screen all pregnant women**
  - Prophylaxis (HepB vaccine and HBIG) within 12 hours of birth for all infants born to infected women
- **Universal vaccination of all infants beginning at birth (before hospital discharge) as a safety net**
- **Routine vaccination of previously unvaccinated children and adolescents aged <19 years**
- **Vaccination of adults at risk**



# Hepatitis B Vaccine Policy and Rates of Acute Hepatitis B, U.S., 1980-2011



\*Health care providers, MSM, IDU, hemodialysis patients, household & sexual partners of persons with chronic HBV, persons in certain institutional settings, e.g, inmates of long-term correctional facilities.

Source: National Notifiable Disease Surveillance System (NNDSS)

# Revised ACIP Statement Hepatitis B Vaccination

- ❑ **Updates ACIP recommendations for HepB vaccination of children and adults**
- ❑ **Incorporates previously-published recommendations from:**
  - ACIP
  - CDC
- ❑ **Augmented with AASLD recommendation<sup>1</sup>**
  - *Recommendation 8A: The AASLD suggests antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg-positive pregnant women with an HBV DNA level >200,000 IU/mL*

<sup>1</sup>Terrault et al. American Association for the Study of Liver Diseases (AASLD) Guidelines for Treatment of Chronic Hepatitis B. Hepatology 2016. Vol. 63.

# **Revised ACIP Statement Hepatitis B Vaccination Updates**

- ❑ **Testing HBsAg-positive pregnant women for HBV DNA**
- ❑ **Perinatal post-exposure prophylaxis in the absence of maternal HBsAg-positivity but when other evidence suggests maternal HBV infection**
- ❑ **Postvaccination serologic testing for infants whose mother's HBsAg status remains unknown indefinitely (e.g., when an infant is surrendered confidentially shortly after birth)**

# Revised ACIP Statement Hepatitis B Vaccination Updates

- ❑ **Strengthening birth dose recommendation (for infants born to HBsAg-negative mothers)**
  - Removal of permissive language to delay birth dose until after hospital discharge (no WG consensus)
  - Preference for birth dose within 12 or 24 hours of birth
- ❑ **WHO recommends “All infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours.”**

# HBV Transmission Among People Who Inject Drugs

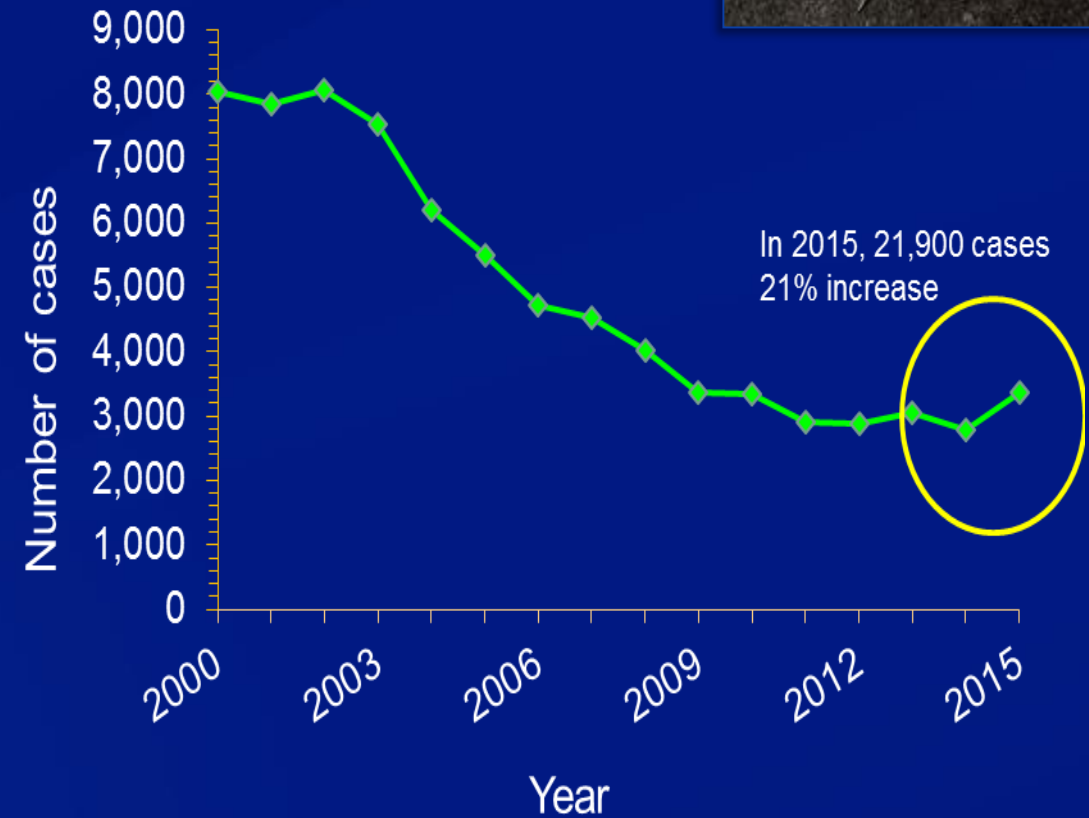


12 states reported increases in Hepatitis B (2015)

Injection drug use is most common reported behavioral risk

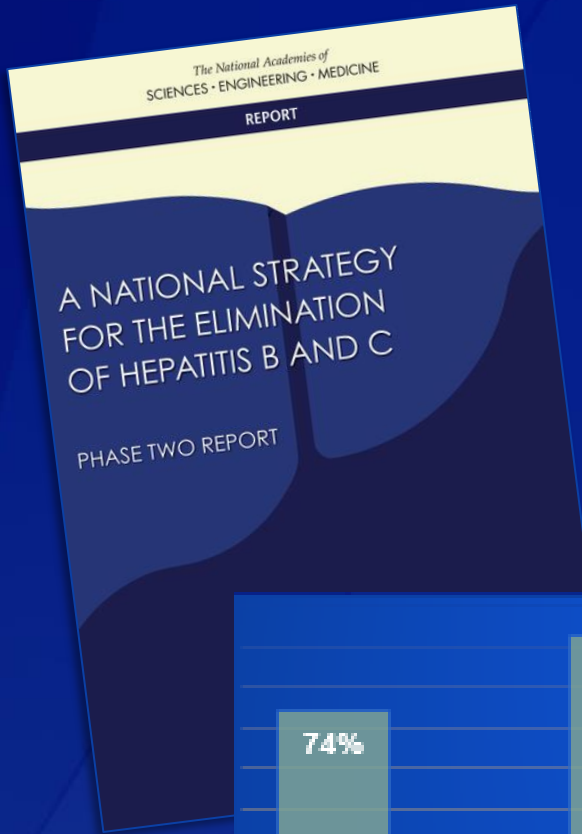
Hepatitis B vaccination of persons who inject drugs is cost saving

Incidence declines following successful hepatitis B vaccination in appropriate settings (e.g., drug treatment, corrections)



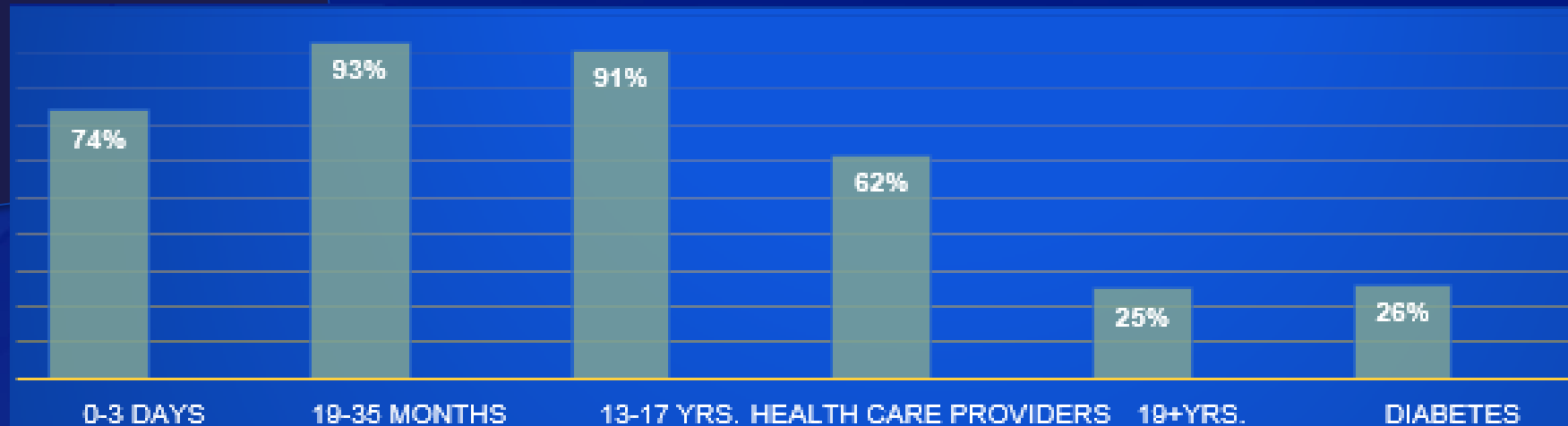


# Prevention of Hepatitis B Transmission



***“States should expand access to adult hepatitis B vaccination, removing barriers to free immunization in pharmacies and other easily accessible settings.”***

- **Low adult vaccination coverage**
- **ACIP has requested CDC develop new vaccination strategies (in progress)**



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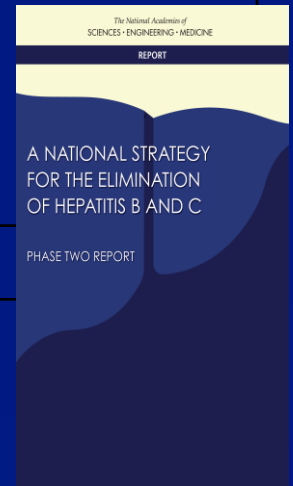
REPORT

# A NATIONAL STRATEGY FOR THE ELIMINATION OF HEPATITIS B AND C

PHASE TWO REPORT



# Eliminating the Public Health Threat of Viral Hepatitis in the United States - 2030 Targets



Target	2030 Targets	Performance Measures
HBV mortality	50% reduction (2015 baseline)	<b>Diagnose and link to care:</b> <ul style="list-style-type: none"> <li>– 90% of chronic hepatitis B cases diagnosed</li> <li>– 90% of those diagnosed brought to care</li> </ul> <b>Treat: 80% for whom treatment is indicated</b>
HBV incidence in children less than 5 years old	Reduce toward zero (baseline: 800 children in 2015)	
HCV mortality	65% reduction (2015 baseline)	<b>Diagnose and cure: 260,000/year 2015-2030</b> <b>Annual new infections</b> <b>30,240 2015-2016;</b> <b>22,620 2017-2019</b> <b>11,150 2020-2024</b> <b>2,730 2025-2030</b>
HCV incidence	90% reduction (2015 baseline)	

# **Development of Guidance for Perinatal HCV Testing and Prevention**

**CDC/HRSA Advisory Committee on HIV, Viral Hepatitis  
and STD Prevention and Treatment**

**CHAC**

# **CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment CHAC**

- Meets twice per year, open to public
- Technical experts and community representatives
- Increased viral hepatitis representation in recent years
- Hepatitis work group, expanded for perinatal HCV discussion

## Provisional Action Steps Recommended by CHAC Viral Hepatitis WG

- Convene a larger CHAC working group including appropriate subject matter experts- first meeting – Summer 2017
- Advise on recommendations for HCV testing
  - Women of childbearing age
  - Pregnant women and women planning to become pregnant
  - HCV exposed and at-risk infants
  - Align with IDSA/AASLD recommendations for HCV care and treatment of those populations..
- CDC publish interim guidance
- CDC consider epidemiologic and cost/effectiveness data and other information to target interventions