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

Vaccine development and testing

Submission to FDA for Biologics License Application (BLA)

FDA Licensure

Advisory Committee on Immunization Practices (ACIP)

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

CDC consideration

AAP Board of Directors Consideration

Recommendations for use published in MMWR

Recommendations for use published in Pediatrics

Uptake and financing

Public sector

Private sector

COID

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

- 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 (~1/2 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 ≥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

- Infants of HBsAg-positive women, 1984
- High-risk groups, * 1982
- Universal maternal HBsAg testing 1988
- All US infants, 1991
- Ages 0-18 years, 1999
- Birth dose, 2006
- Adults <60 years with Diabetes

*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\(^1\)
  - **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

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)
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

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<tr>
<th>Target</th>
<th>2030 Targets</th>
<th>Performance Measures</th>
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<td>HBV mortality</td>
<td>50% reduction (2015 baseline)</td>
<td>Diagnose and link to care:</td>
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<td>– 90% of chronic hepatitis B cases diagnosed</td>
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<td>– 90% of those diagnosed brought to care</td>
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<td>Treat: 80% for whom treatment is indicated</td>
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<td>HBV incidence in children less than 5 years old</td>
<td>Reduce toward zero (baseline: 800 children in 2015)</td>
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<td>HCV mortality</td>
<td>65% reduction (2015 baseline)</td>
<td>Diagnose and cure: 260,000/year 2015-2030</td>
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<td>HCV incidence</td>
<td>90% reduction (2015 baseline)</td>
<td>Annual new infections</td>
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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