

**Back to Basics:**  
**The Challenge of Reinstating  
Hepatitis B Vaccination at Birth**

This material was developed by the  
August A. Fink Memorial Education Division, LLC  
(AAF-MED)

# Faculty

**Philip Rosenthal, MD**

**Program Chair**

Director, Pediatric Hepatology  
Medical Director, Pediatric Liver Transplant Program  
University of California, San Francisco Medical Center  
San Francisco, CA

**Arnon G. Humiston, MD, MPH**  
Assistant Professor of Emergency Medicine  
University of Rochester Medical Center  
Strong Memorial Hospital  
Rochester, NY

**Thomas N. Saari, MD, FAAP**  
Professor of Pediatrics  
Department of Pediatrics  
Division of Pediatric Infectious Disease  
University of Wisconsin School of Medicine  
Madison, WI

**Deborah L. Wexler, MD**  
Executive Director/Medical Director  
Immunization Action Coalition  
Saint Paul, MN

# Objectives

- To ensure that physicians and hospital personnel are aware of the widespread availability of hepatitis B vaccines that do not contain thimerosal as a preservative
- To underscore the rationale and importance of resuming the routine birth dose of hepatitis B vaccine for all infants
- To stress the importance of screening pregnant women for hepatitis B surface antigen (HBsAg)

# Case Report

- **A woman tested HBsAg-positive during pregnancy**
- **Test results were inaccurately reported as “negative” to the hospital where the infant was born, and not reported to the health department as required by laws**

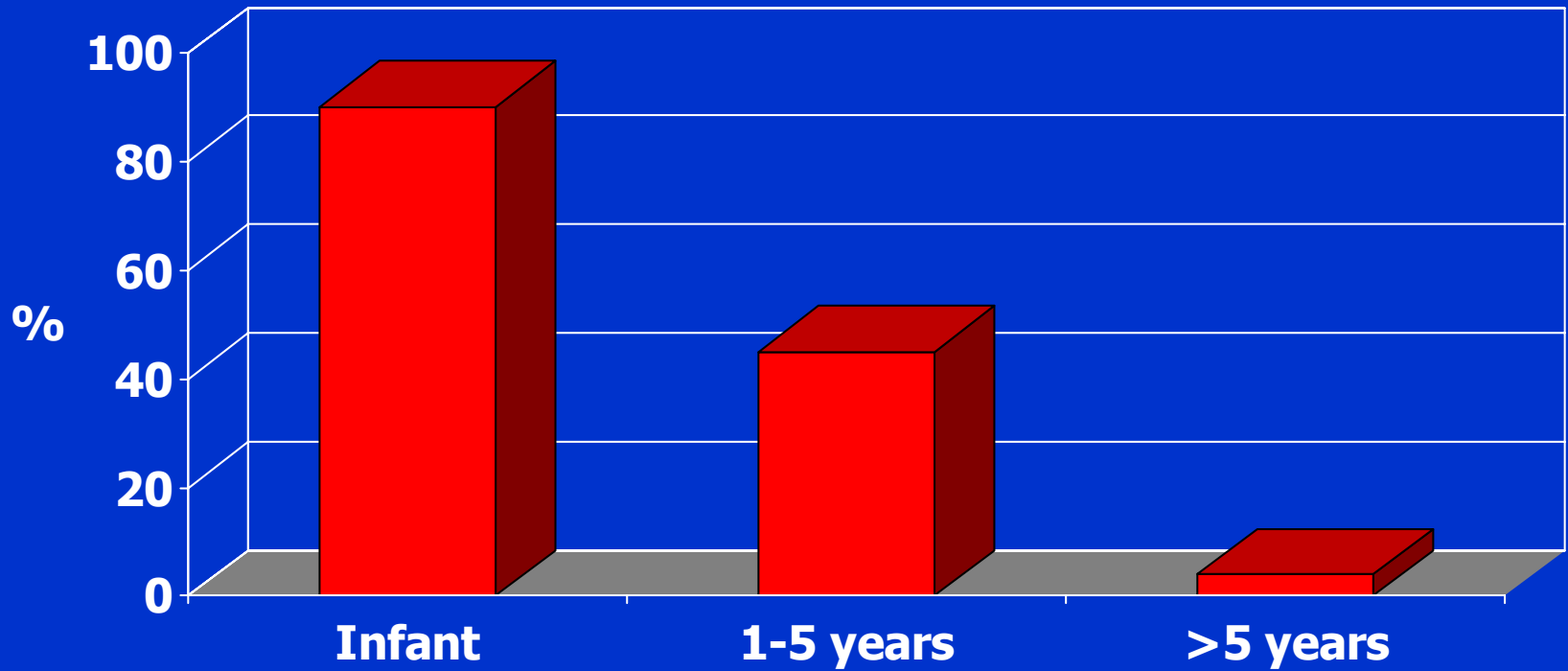
# Case Report – continued

- **July 1999: The hospital stopped giving newborns the 1<sup>st</sup> dose of hepatitis B vaccine because of thimerosal concerns**
- **September 1999: Hepatitis B vaccine without thimerosal as a preservative became available, but hospital elected not to resume routine neonatal hepatitis B immunization**

# Case Report – continued

- **The infant received neither hepatitis B vaccine nor hepatitis B immune globulin (HBIG)**
- **The infant developed hepatitis B at 3 months of age and died from fulminant hepatitis less than 2 weeks after the onset of symptoms**
- **This tragedy is preventable and should never happen again !!**

# Risk of Developing Chronic Hepatitis B by Age at Infection



# Hepatitis B Mortality

- **About 1/3 of chronic HBV infections in the United States start in perinatal and early childhood**
- **Except flu and pneumococcal infections, HBV kills more people/year than any other vaccine-preventable disease (VPD) (>5,000 HBV deaths/year)**
- **HBV causes hepatocellular carcinoma that kills about 1,000 Americans annually**



# **Estimated HBV Infections among US Born Children (aged <10 years) of HBsAg-Negative Mothers, 1990**

<b>Race/Ethnicity</b>	<b>Births/ year</b>	<b>Annual Incidence/ 100,000</b>	<b># of Annual Infections</b>
<b>White/Black/ Hispanic</b>	<b>3,656,618</b>	<b>23.7</b>	<b>8677</b>
<b>Asian/ Pacific Islander</b>	<b>120,298</b>	<b>605</b>	<b>7280</b>



**Hepatocellular Carcinoma Secondary to Childhood-acquired HBV Infection**

# **Pediatric Deaths Due to Vaccine Preventable Diseases (VPD) (aged < 12 years)**

## **Estimated Annual VPD Deaths in Wisconsin\***

<b>Varicella</b>	<b>1</b>
<b>Pneumococcal Disease</b>	<b>3</b>
<b>H. Influenza Disease</b>	<b>6</b>
<b>Measles</b>	<b>10</b>
<b>Hepatitis B</b>	<b>25**</b>

\* Pre-vaccine era

\*\* Most HBV deaths are deferred until 15-30 years from time of perinatal/childhood exposure

# Thimerosal Alert

**July 1999: American Academy of Pediatrics (AAP) and the United States (U.S.) Public Health Service state:**

- The first dose of hepatitis B vaccine given to infants born of HBsAg-negative women may be postponed until 2-6 months of age**
- Women who are HBsAg-positive or who have unknown HBsAg status should receive thimerosal-containing hepatitis B vaccine, due to the substantial risk of infection to their infants**

# **Thimerosal Alert - continued**

- **Hepatitis B vaccine without thimerosal as a preservative were quickly developed and subsequently received Food and Drug Administration (FDA) approval**
- **The supply of these vaccines are now sufficient for U.S. recommendations!!!**

# Back to Basics

- **Based on the availability of hepatitis B vaccines without thimerosal as a preservative, the AAP and the U.S. Public Health Service have recommended that routine hepatitis B immunization for all newborn infants should be reintroduced *immediately* in hospitals in which this policy and practice had been discontinued**  
***MMWR*. September 10, 1999;48:780-2.**

# Back to Basics

- **Unfortunately, resumption of the birth dose has not occurred in many hospitals throughout the U.S.**
- **Centers for Disease Control and Prevention (CDC) studies indicate that, soon after the AAP-U.S. Public Health Service statement was issued, most hospitals discontinued routine immunization of newborn infants of HBsAg-negative mothers**
- **An alarming number of hospitals suspended hepatitis B immunization to newborns regardless of the mother's HBsAg status**

# Hepatitis B Vaccine Recommendation

## Who:

- **Advisory Committee on Immunization Practices (ACIP)**
- **AAP**
- **American Academy of Family Physicians (AAFP)**

## What:

- **Hepatitis B vaccine for all  $\leq 18$  years of age**



# How is Hepatitis B Vaccine Given?

- Hepatitis B vaccine is given as a series of three intramuscular doses
- There is flexibility of the dosing schedule for hepatitis B immunization series, regardless of how long the intervals might be stretched
- More than 95% of children and adolescents develop adequate antibody to the recommended series of three doses

# Is Hepatitis B Vaccine Safe?

- **Hepatitis B vaccines have been available since 1982**
- **Hepatitis B vaccines currently available in the U.S. are made using recombinant DNA technology, and contain only a portion of the outer protein of the virus**
- **The vaccine does not contain any live components**

# Is Hepatitis B Vaccine Safe?

- **Hepatitis B vaccines have been shown to be very safe when given to infants, children or adults**
  - **More than 40 million persons have received the vaccine in the U.S.**
  - **More than 750 million persons have received the vaccine worldwide**
  - **Most common side effects are pain at the injection site and mild to moderate fever that is not more common than among children receiving other vaccines**

# Is There an Association Between Hepatitis B Vaccine and Serious Side Effects?

There is no confirmed scientific evidence that hepatitis B vaccine causes:

- chronic illness
- multiple sclerosis
- Guillain-Barre syndrome
- transverse myelitis
- optic neuritis
- seizures
- sudden infant death syndrome
- chronic fatigue syndrome
- rheumatoid arthritis
- autoimmune disorders

# **Routine Newborn Hepatitis B Vaccination**

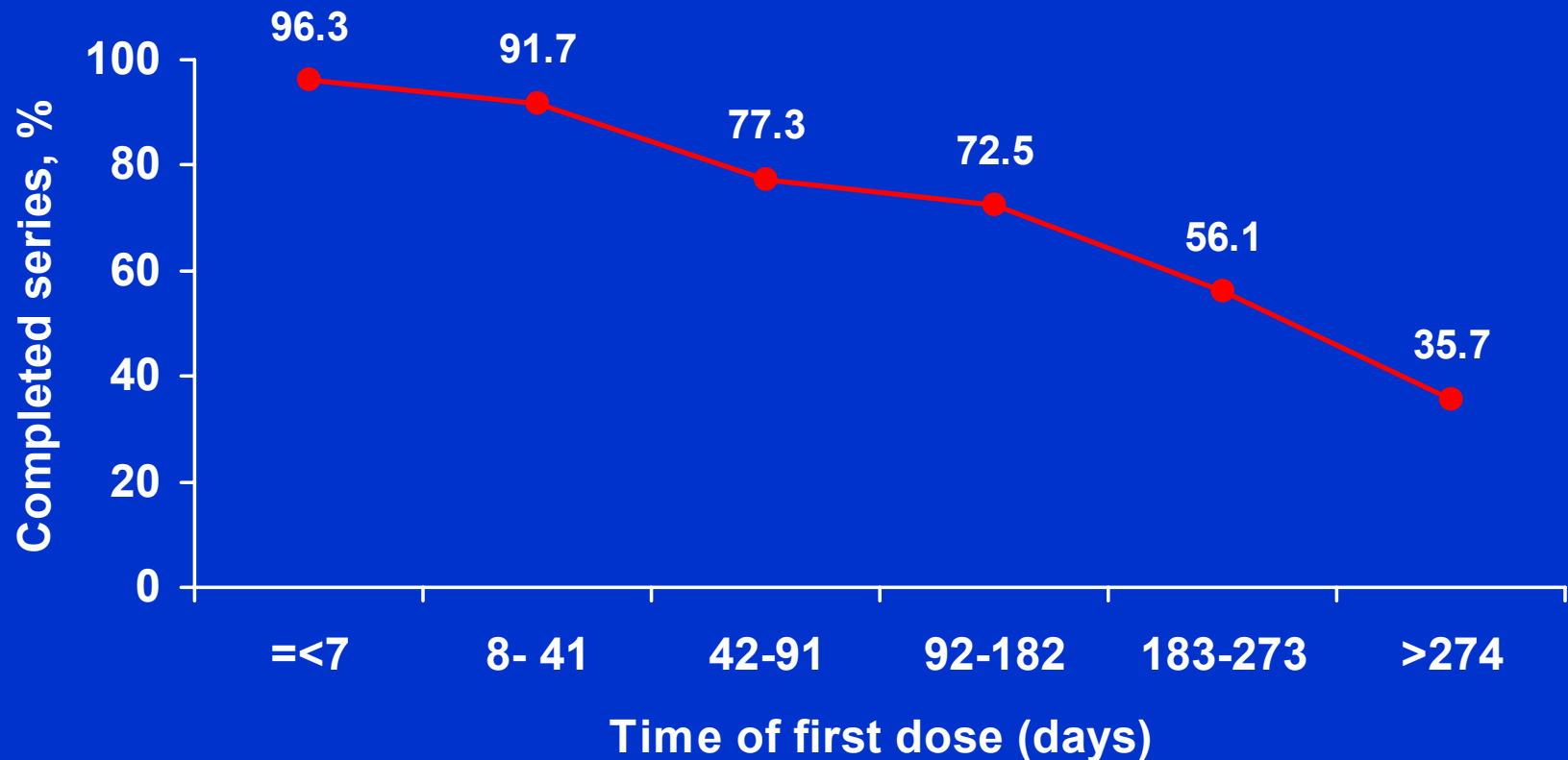
- **Benefits**
  - **Only vaccine that prevents cancer**
  - **Only vaccine that is reliably immunogenic in the newborn period**
  - **An opportunity to immunize during one of the few dependable medical encounters (at delivery in a hospital)**

# **Routine Newborn Hepatitis B Vaccination**

- **Benefits**

- **The best opportunity to prevent unrecognized perinatal transmission and to prevent transmission within families due to unrecognized chronic HBV infection in the household**
- **Places the importance of immunization as an early and visible priority for parents**
- **Added insurance that an overall immunization series will be completed on time**
- **The foundation of the overall strategy to eliminate HBV infection in the U.S.**

# Completion of Hepatitis B Vaccine Series by Time of First Dose



Source: Yusuf H, et al, unpublished data, National Immunization Survey, 1998

# Implementing Protocols for HBV Prevention

- **Screen all pregnant women for HBsAg**
  - **Identifies infants requiring immunoprophylaxis soon after birth to prevent perinatal HBV infection**
  - **Identifies household contacts needing vaccination**
  - **Allows medical follow-up of women and other contacts with chronic HBV infection**



# **Pregnant Women and State HBsAg Requirements**

- **Currently, only 19 states require HBsAg screening of pregnant women in the US**
- **It is recommended that obstetricians and family doctors routinely screen all pregnant women for HBsAg during each pregnancy, regardless of the presence or absence of risk factors and regardless of history of vaccination**

# Hepatitis B Immunization at Birth

- **Eliminates the possibility of missed immunoprophylaxis in infants born to mothers who are HBsAg-positive**
- **Ensures that infants born of mothers whose HBsAg status is unknown at delivery receive timely immunoprophylaxis**
- **Reduces the risk of early childhood infection**

# Hepatitis B Immunization at Birth

- **Avoids a missed opportunity for immunization by initiating immunization at birth**
- **Helps convey the importance of immunization to the parents and hospital staff**
- **Reduces the number of doses needed to be administered simultaneously with other vaccines during subsequent well-child visits**
- **May increase the likelihood of completing the hepatitis B vaccine series as well as other childhood immunizations**

# How to Implement Routine Hepatitis B Vaccination at Birth

- Give all infants a birth dose of hepatitis B vaccine in the hospital
- Treat infants born to *HBsAg-positive* mothers within 12 hours of birth
  - HBIG
  - Hepatitis B vaccine (dosage for babies born to infected mothers)
  - Give first dose of vaccine with HBIG, but at a different site
  - Give the preferred vaccination schedule at aged 0, 1-2, 6 months with testing for HBsAg and antibody to HBsAg (anti-HBs) at aged 9-15 months

# **How to Implement Routine Hepatitis B Vaccination at Birth**

## **Transmit screening and vaccination records**

- **Follow-up of HBsAg-positive mothers and treatment of infants must be ensured**
- **Transfer of HBsAg screening information between prenatal care provider and delivery services**
- **Transfer of infant vaccination record between hospital nursery and pediatric services**

# How to Implement Routine Hepatitis B Vaccination at Birth

- **Management of infants born to women *without* prenatal HBsAg screening**
  - **Draw mother's blood for HBsAg testing on admission**
  - **Give hepatitis B vaccine to infant within 12 hours of birth**
  - **Give HBIG within 7 days of birth if maternal test results are positive**
  - **Complete infant hepatitis B vaccination series at 0, 1-2, 6 months**
  - **Assure following HBsAg and anti-HBs testing of infant at aged 9-15 months**

# Summary Points

- **The risk of HBV infection in children is not only from perinatal transmission from HBV-infected mothers, but from close contact with household members and caregivers who have acute or chronic HBV infection**

# Summary Points

- **Screen all pregnant women during each pregnancy for HBsAg - repeat during pregnancy if woman practices high risk behaviors**
- **Ensure that all infants born to HBsAg-positive mothers receive timely and appropriate immunoprophylaxis with HBIG and hepatitis B vaccine**