

PERINATAL HEPATITIS B PREVENTION PROGRAM

Program Overview from a Case Management Perspective

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2015 Regional Training for Local Health Departments and
Regional Epidemiologists



By the end of this session, participants will be able to:

- Identify, report, and manage hepatitis B surface antigen (HBsAg) positive pregnant women and their infants to ensure appropriate newborn post exposure prophylaxis (PEP) is received.
- Describe completion of the hepatitis B virus (HBV) vaccination series for affected infant, as well as appropriate post vaccination serology testing (PVST).
- Understand the case management requirements of the state and local health department (LHD).

- Perinatal Hepatitis B Prevention Program (PHBPP) was established in 1990.
- It is funded by Section 317 of the federally funded immunization grant.
- 2013 – 2017 is the current funding cycle.
- Program works closely with the Centers for Disease Control and Prevention (CDC), Division of Viral Hepatitis (DVH).
- DVH worked on Advisory Committee of Immunization Practices (ACIP) recommendations that are used to frame the program today.


MMWR[™]
Morbidity and Mortality Weekly Report

Recommendations and Reports December 23, 2005 / Vol. 54 / No. RR-16

**A Comprehensive Immunization Strategy
to Eliminate Transmission of Hepatitis B Virus Infection
in the United States**

**Recommendations of the Advisory Committee
on Immunization Practices (ACIP)
Part 1: Immunization of Infants, Children, and Adolescents**



INSIDE: Continuing Education Examination

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

Program Objectives for Current Funding Cycle

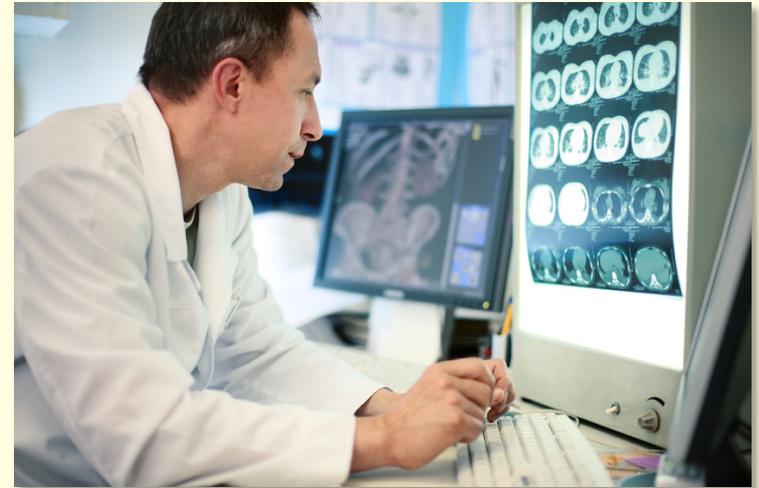
- Identify infected HBsAg positive pregnant women.
- Ensure PEP for infants by administering Hepatitis B Immune Globulin (HBIG) and birth dose of HBV vaccine within 12 hours of delivery.
- Ensure completion of HBV vaccine series, along with PVST.
- This approach shown to be 85% – 95% effective in preventing mother to child transmission (MTCT).

What is Hepatitis B?

- A contagious liver disease caused by an infection with hepatitis B virus.
- It can lead to chronic, lifelong illness capable of causing serious health problems.
- 15% – 25% of those with chronic infections develop serious liver problems:
 - Chronic hepatitis
 - Cirrhosis
 - Liver failure
 - Liver cancer



- HBV is spread through contact with blood and body fluids of an infected person.
- Various possibilities for exposure:
 - Of particular importance – BIRTH – spread from infected mothers.
 - Intrapartum most common route of MTCT via:
 - Micro-transfusion or hematologic leaks of the mother's blood to the fetus during contractions.
 - Inoculation of fetal mucus membranes or breaks in the skin (scalp electrodes).



Without PEP:

- Mother positive for HBsAg and hepatitis B e antigen (HBeAg):
 - Infant has 70% – 90% chance of becoming infected.
 - 90% of infected infants become chronically infected.

- Mother positive for HBsAg only:
 - Infant has 10% chance of becoming infected.
 - 90% of infected infants become chronically infected.

- Prevention is our focus.



Commission for Case Management Certification defines case management as:

- Case management is a collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet the client's health and human service needs. It is characterized by advocacy, communication, and resource management; and promotes quality and cost-effective interventions and outcomes.

Source: <http://ccmcertification.org>

Perinatal Hepatitis B Definition

- HBsAg positivity in an infant from birth through 24 months of age who was born in the United States (US) or US territories to an HBsAg positive mother.
- Definition helps us to better understand some of the program's requirements and reporting time frames.
- Identifies why the program and case management efforts focus on the infant's first 1 – 2 years of life.

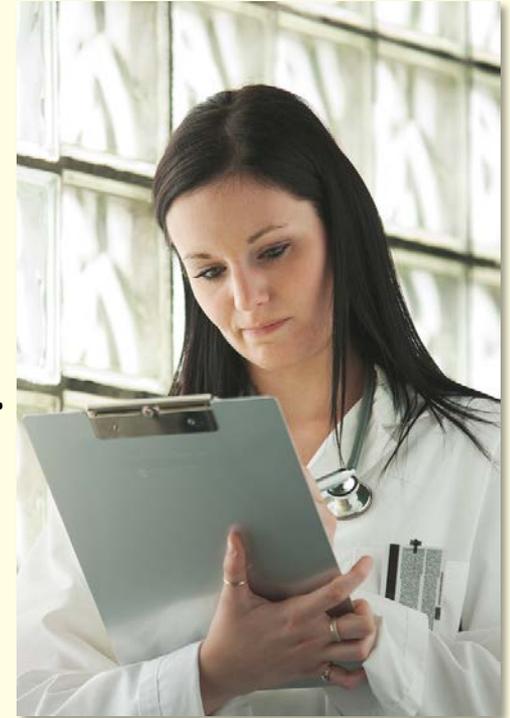
Connects with four program objectives:

- Identification of HBsAg positive pregnant women.
- Assuring infants born to HBsAg positive women obtain timely and appropriate PEP at birth and complete the HBV vaccine series.
- Infant receives PVST to identify if the infant is protected, infected, or still susceptible to the HBV.



Case Management Requirements - State

- Oversee and ensure grant requirements are met (PHBPP efforts are federally funded).
- Liaison between local and federal government.
- Available for consultation and case management assistance with LHD and providers.
- Track, monitor, and report local case management efforts to CDC via mid-year and annual report.



Grant Requirements

- Establish a mechanism to identify all HBsAg positive pregnant women.
- Conduct case management of all identified infants at risk of acquiring perinatal HBV infection, which includes:
 - administration of appropriate immunoprophylaxis to all infants born to HBsAg positive women (including HBIG, HBV vaccine birth dose, and complete vaccine series); and
 - completion of PVST of all infants born to HBsAg positive women and reporting all HBsAg positive infants to CDC.



Grant Requirements (Continued)

- Evaluate completeness of identification of HBsAg positive pregnant women, case management, reporting of HBsAg positive infants, and appropriate care of infants born to mothers of unknown HBsAg status, based on methodology provided by CDC.
- Develop and examine feasibility to implement a state plan to put into practice a universal reporting mechanism with documentation of maternal HBsAg results for all births.
- Work with hospitals to achieve universal birth dose coverage and documentation of the birth dose in an immunization information system (IIS).

Case Management Requirements - Local

- Conduct case management of infants at risk of acquiring perinatal HBV.
- Track, monitor, report HBIG, HBV vaccine series, and PVST to State PHBPP Coordinator.
- Protection of at risk infant program goal – team effort, cannot do it alone.
- LHD has better connection to the local providers as well as the mothers of these infants.



When Does Case Management Begin?

- Receipt of HBsAg positive lab.

- Follow hepatitis B surveillance protocol in West Virginia Division of Infectious Disease Epidemiology (DIDE) manual including:
 - Contact client's physician.

 - Determine pregnancy status.

 - Determine educational needs of client.



When Does Case Management Begin? (Continued)

- Inform physician of case management requirements, reinforce joint effort, protection of baby a priority.
- Report to Perinatal Hepatitis B Prevention Coordinator and Division of Infectious Disease Epidemiology.



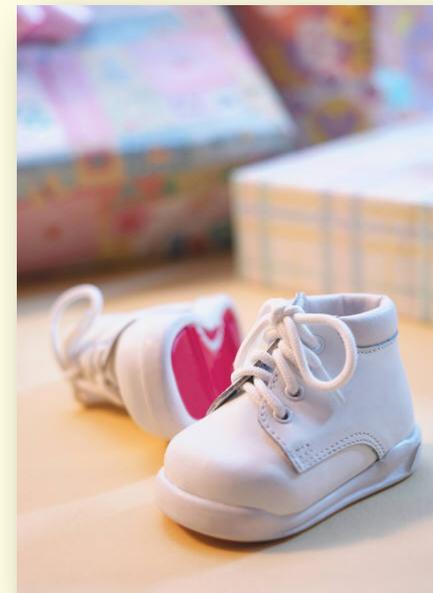
All hepatitis B acute, chronic, and perinatal cases must be reported by health care providers and facilities ***within 24 hours*** to your LHD. (WV CODE 16-3-1; 64CSR7)

State Contacts

Acute/Chronic: Division of Infectious Disease Epidemiology
(800) 423-1271 or (304) 558-5358, Extension 1

Perinatal: Division of Immunization Services
(800) 642-3634 or (304) 558-2188

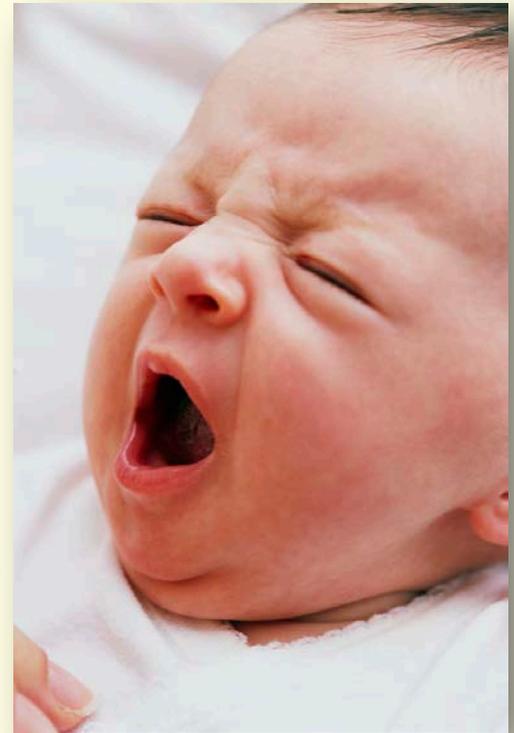
- Contact client, educate or reinforce physician's educational efforts.
- Pregnant – stress HBIG, HBV vaccine series – timing and completion, and PVST.
- Possible Right From The Start (RFTS) referral via alternate entry – RFTS can assist with case management, discuss benefits of program with client.



- Notify birthing facility – infectious disease personnel.
- Touch base with woman 1 - 2 time(s) during pregnancy – reinforce HBIG, vaccine series, and PVST.
- Contact birthing facility 1 - 1 ½ months prior to expected delivery date as a reminder of upcoming birth (keep in mind, may deliver early).
- Send Initial Report Delivery Form to delivery hospital.

- Upon delivery, birthing facility should provide the LHD with Initial Report Delivery Form detailing:
 - Infant's date and time of birth, and birth weight
 - Date and time of HBIG
 - Date and time of HBV vaccine
 - Pediatrician's name and phone number

- Notification of birth within 3 days of delivery.
(LHD to State Perinatal Hepatitis B Prevention Coordinator)



PHBP: Initial Report & Delivery Form

Sample Form

	
STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES Bureau for Public Health Office of Epidemiology and Prevention Services DIVISION OF IMMUNIZATION SERVICES 350 Capitol Street, Room 125 Charleston, West Virginia 25301 (304) 558-2188 or 1-800-642-3634	
Earl Ray Tomblin Governor	Karen L. Bowling Cabinet Secretary
Perinatal Hepatitis B Prevention: Initial Report & Delivery Form	
Date of Report:	County:
Name of Person Completing Report:	
Mother's Name:	Mother's Date of Birth:
Mother's Address: City, State:	
Zip Code:	Insurance: <input type="checkbox"/> Private <input type="checkbox"/> Public (Medicaid) <input type="checkbox"/> Uninsured <input type="checkbox"/> Unknown
Mother's Race: <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Hispanic <input type="checkbox"/> White <input type="checkbox"/> African American <input type="checkbox"/> Other: _____	Mother's Birth Country: EDD:
Mother's Hepatitis B Surface Antigen Test Results	
Date: _____	HBsAg Positive: Yes _____ No _____
Name of Conducting Lab: _____	
Was testing completed/repeated at time of delivery: Yes _____ No _____	
Please fax a copy of the original lab results with this form	
OB Provider:	Phone:
Date of Birth:	Time of Birth:
Sex: Male _____ Female _____	
Infant's Name:	Infant's Birth Weight:
Delivery Hospital:	Phone:
Prophylaxis	
HBIG Given: Yes _____ No: _____	Date Given: _____ Time: _____
Hepatitis B Given: Yes _____ No: _____	Date Given: _____ Time: _____
If no, please state reason: _____	
HBIG and Hepatitis B #1 should be given within 12 hours of birth	
Pediatrician:	Phone:
PLEASE COMPLETE AND FAX THIS FORM TO: (304) 558-6335 ATTN: Perinatal Hepatitis B Prevention Coordinator Division of Immunization Services	
This form provides the means for us to initiate the tracking of an infant born to an <u>HBsAg positive</u> mother through the completion of the Hepatitis B series and post vaccination serological testing. Local Health Department, please fax a copy of this form to the birthing facility's infection control nurse and/or obstetrics floor to be completed.	
August 2014	

Contact pediatrician:

- Ensure pediatrician is aware of birth mother's hepatitis B positive status.
- Discuss LHD case management efforts.
- Review PHBPP efforts to ensure HBV vaccine doses are completed on schedule, reported to the West Virginia Statewide Immunization Information System (SIIS), and followed by PVST.



- Review Perinatal Hepatitis B Prevention: Pediatrician Form with provider and send copy.
- Stress importance of completion and reporting to LHD following each step.
- Offer to send provider Perinatal Hepatitis B Prevention flyer outlining vaccine, PVST, tests to order, and interpretation values.



- Case management efforts can continue through 18 months; rare occasion may last until infant is 24 months of age.
- Ongoing contact keeps needs of infant in the forefront:
 - Ideal to contact mother and pediatrician approximately 2 weeks prior to next vaccine due date.
 - Review updating pediatrician form with provider, stressing importance of faxing form to the LHD after each additional update.
 - LHD to fax updated form to Perinatal Hepatitis B Prevention Coordinator.
 - Continue to follow through PVST.

PHBP: Pediatrician Form

Sample Form

		
STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES Bureau for Public Health Office of Epidemiology and Prevention Services DIVISION OF IMMUNIZATION SERVICES 350 Capitol Street, Room 125 Charleston, West Virginia 25301 (304) 558-2188 or 1-800-642-3634		
Earl Ray Tomblin Governor	Karen L. Bowling Cabinet Secretary	
<u>Perinatal Hepatitis B Prevention: Pediatrician Form</u>		
Date of Report:	County:	
Name of Person Completing Report:	Phone:	
Pediatrician:	Phone:	
Infant's Name:	Infant's Birth Weight:	
Date of Birth:	Time of Birth:	Sex: Male ___ Female ___
Address:		
City, State:	Zip Code:	
Mother's Name:	Mother's Date of Birth:	
Prophylaxis	Infant's Insurance: ___ private ___ Medicaid ___ uninsured ___ other	
HBIG Given: ___ Date/Time: _____	Hepatitis B #1 Given: ___ Date/Time: _____	
<small>HBIG and Hepatitis B #1 should be given within 12 hours of birth</small>		
Delivery Hospital:	Phone:	
Hepatitis B #2:	Signature of Person Administering:	
<small>Hepatitis B #2 should be given at 1-2 months of age and at least 4 weeks after dose #1</small>		
Hepatitis B #3:	Signature of Person Administering:	
Hepatitis B #4:	Signature of Person Administering:	
<small>The final (3rd or 4th) Hepatitis B dose should be given no earlier than 24 weeks of age; and at least 8 weeks after dose #2; and at least 16 weeks after dose #1</small>		
Infant Serology		
Infant Serology Completed: Yes ___ No ___ Unknown ___ If Yes, Date: _____ <small>Serology should be completed between 9-12 months of age (minimum age for testing is 9 months), and 1-2 months after completion of the vaccine series.</small>		
HBsAg: Positive ___ Negative ___ Incomplete ___ Anti-HBs: Positive ___ Negative ___ Incomplete ___ <small>Please fax a copy of the original lab results with this form</small>		
PLEASE COMPLETE AND FAX THIS FORM TO: (304) 558-6335 ATTN: Perinatal Hepatitis B Prevention Coordinator Please complete and fax this document at the patient's first appointment and when new vaccines are administered. The same form may be used throughout the completion of serology. If at any time the patient moves from your practice, please contact the Immunization Services and forward this form to the new provider. October 20, 2015		

HBV Vaccine and PVST Timeframe

Age	Intervention
Birth	Hepatitis B Immune Globulin (HBIG) AND Hepatitis B Vaccine # 1 (Within 12 hours of delivery)
1-2 Months	Hepatitis B Vaccine # 2 *
6 Months	Hepatitis B Vaccine # 3
9-12 Months Should be performed 1 to 2 months after completion of the vaccine series, minimum age for testing is 9 months.	Post Vaccination Serological Testing Hepatitis B Surface Antigen (HBsAg) AND Antibody to Hepatitis B Surface Antigen (Anti-HBs)

* Preterm infants weighing less than 2,000 grams (4.4 lbs.) at birth should receive HBIG and HBV within 12 hours of delivery **and** an additional 3 doses of hepatitis B vaccine, as the birth dose is not counted as part of the vaccine series.

Understanding the Vaccine and PVST Timeframe

- Recommended age for interventions follow the recommended timeframe of the ACIP immunization schedule which parallels the routine well-child exam.
- Two pronged approach – similar to Vaccines for Children (VFC) Program (age and insurance). This is age and intervention. PVST is spaced from last dose of vaccine AND age of child.
- Understanding perinatal hepatitis B definition helps us understand why the work of the PHBPP focuses its efforts during an infant's first 1 – 2 years of life.
- Age of diagnosis is one of the criteria for an infant with HBsAg positivity being reported and counted as a perinatal hepatitis B case.



Post Vaccination Serological Testing Interpretation

Immunity

HBsAg: Negative

Anti-HBs: Positive

**Infants who are protected
will need no further
medical management.**

Susceptible

HBsAg: Negative

Anti-HBs: Negative

**Infants who remain
susceptible should be
revaccinated with a
second 3-dose series and
retested 1 – 2 months
after the final dose.**

Infected

HBsAg: Positive

Anti-HBs: Negative

**Infants who are positive
should be referred for
medical evaluation and
management of chronic
Hepatitis B.**

Case Study

An infant is born in the United States to a HBsAg positive mother. The post vaccine serological testing was performed when the infant was 35 months of age. The results show:

- HBsAg: Positive
- Anti-HBs: Negative

QUESTION:

Is this child infected with hepatitis B?

YES.

QUESTION:

Would this child meet the case definition for perinatal hepatitis B?

NO, because of the timing of the test. HBsAg positivity for perinatal hepatitis B diagnosis is > 1 – 24 months of age.

Challenges – Local Health

- Despite best efforts – some will be lost to follow-up.
- Don't give up quickly.
- Work with other agencies in your community (RFTS).
- Conduct a home visit.
- Offer services at LHD:
 - If no show with pediatrician, offer vaccines at LHD.
 - Possible PVST at LHD (contact us prior to this to ensure State Lab is aware of specimen; prevents LHD from being charged).



Challenges – Local Health (Continued)

- A non-compliant parent (missing appointments, infant missing HBV vaccine, PVST not obtained) could show aspects of neglect or abuse.
- If so, as a mandatory reporter, a referral to CPS may be warranted:

WEST VIRGINIA CODE (excerpt)

WVC 49 - 6 A- 2 49-6A-2. Persons mandated to report suspected abuse and neglect.(a) Any medical, dental or mental health professional, Christian Science practitioner, religious healer, school teacher or other school personnel, social service worker, child care or foster care worker, emergency medical services personnel, peace officer or law-enforcement official, humane officer, member of the clergy, circuit court judge, family court judge, employee of the Division of Juvenile Services, magistrate, youth camp administrator or counselor, employee, coach or volunteer of an entity that provides organized activities for children, or commercial film or photographic print processor who has reasonable cause to suspect that a child is neglected or abused or observes the child being subjected to conditions that are likely to result in abuse or neglect shall immediately, and not more than forty-eight hours after suspecting this abuse or neglect, report the circumstances or cause a report to be made to the Department of Health and Human Resources: Provided, That in any case where the reporter believes that the child suffered serious physical abuse or sexual abuse or sexual assault, the reporter shall also immediately report, or cause a report to be made, to the State Police and any law-enforcement agency having jurisdiction to investigate the complaint: Provided, however, That any person required to report under this article who is a member of the staff or volunteer of a public or private institution, school, entity that provides organized activities for children, facility or agency shall also immediately notify the person in charge of the institution, school, entity that provides organized activities for children, facility or agency, or a designated agent thereof, who may supplement the report or cause an additional report to be made.

Challenges – State

- Pediatrician unaware of mother's HBsAg positive status
- Delay of vaccines or PVST
- PVST performed too soon
- Wrong test ordered

Optimal Timing for PVST Antibody Detection

Why wait until the infant is 9 months or older?

- Earlier testing may detect anti-HBs from HBIG and not the vaccine. HBIG protection can from 3 – 6 months.

2014 May						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Why is it necessary to wait 1 – 2 months after the last dose of vaccine before testing?

- Testing performed before 1 month (4 weeks) may result in a false positive HBsAg.
- Optimal time for detecting protective antibodies is 1 – 2 months after the final dose of HBV – at 9 months of age.

Can testing wait until the infant is older?

- 9 – 12 months follows the established schedule associated with well-child exams and the immunization schedule.
- Timeframe is after the recommended completion date of the HBV vaccine series.
- Anti-HBs levels decline rapidly in the first year of life.
- Delays in testing can miss the peak anti-HBs level as well as the level defined as protection ($\geq 10\text{mIU/ml}$).

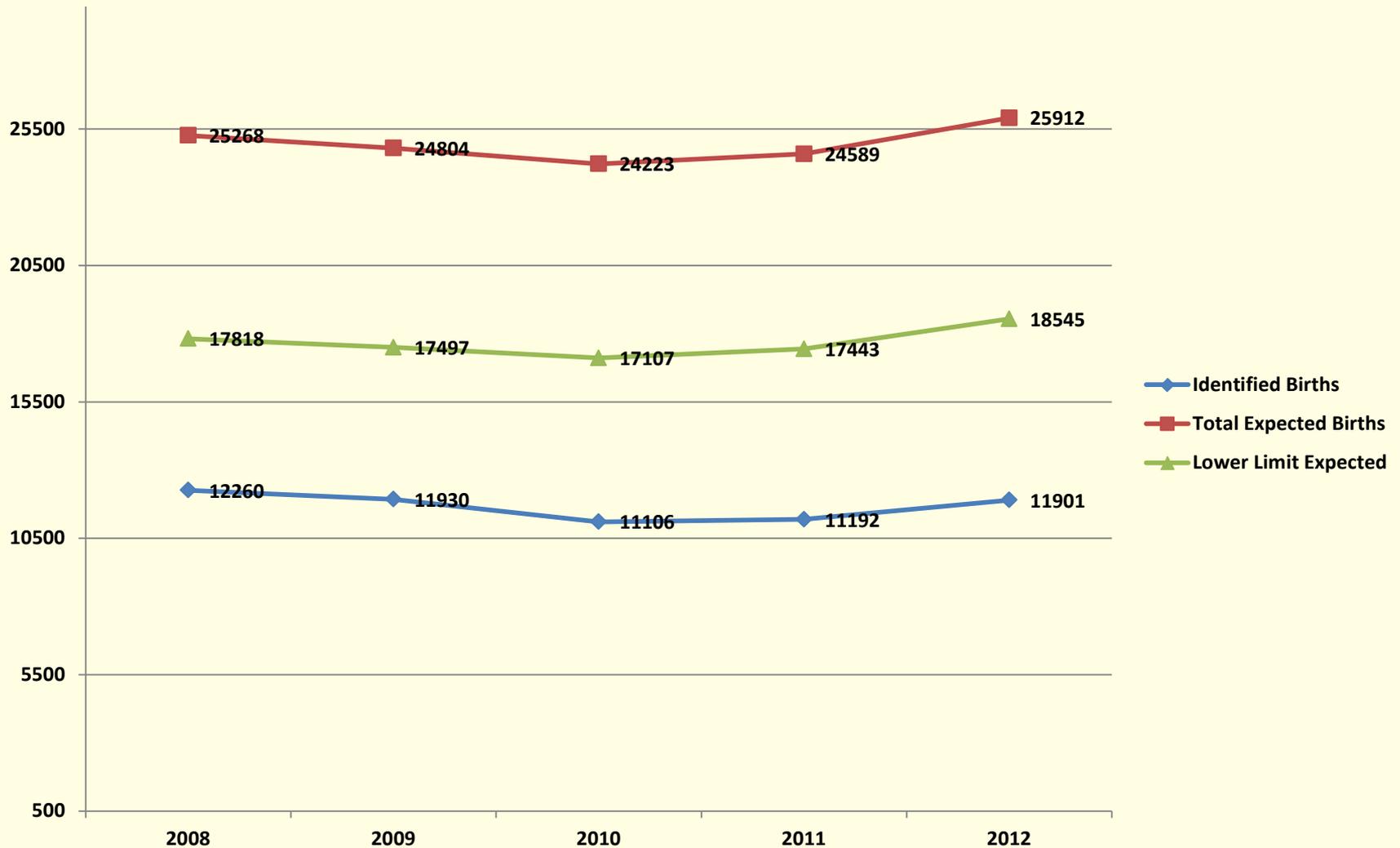
Additional Challenges – State

- Confusion over when and where to report – LHD or directly to State PHBPP Coordinator.
 - Forms are prepared for LHD to fax to State.
 - Sometimes physician sends forms to State.
 - If so, we will contact the LHD with updated information.
- Incomplete forms – often insurance status missing. Insurance information is needed for mom and baby.

Bottom line: We need you!

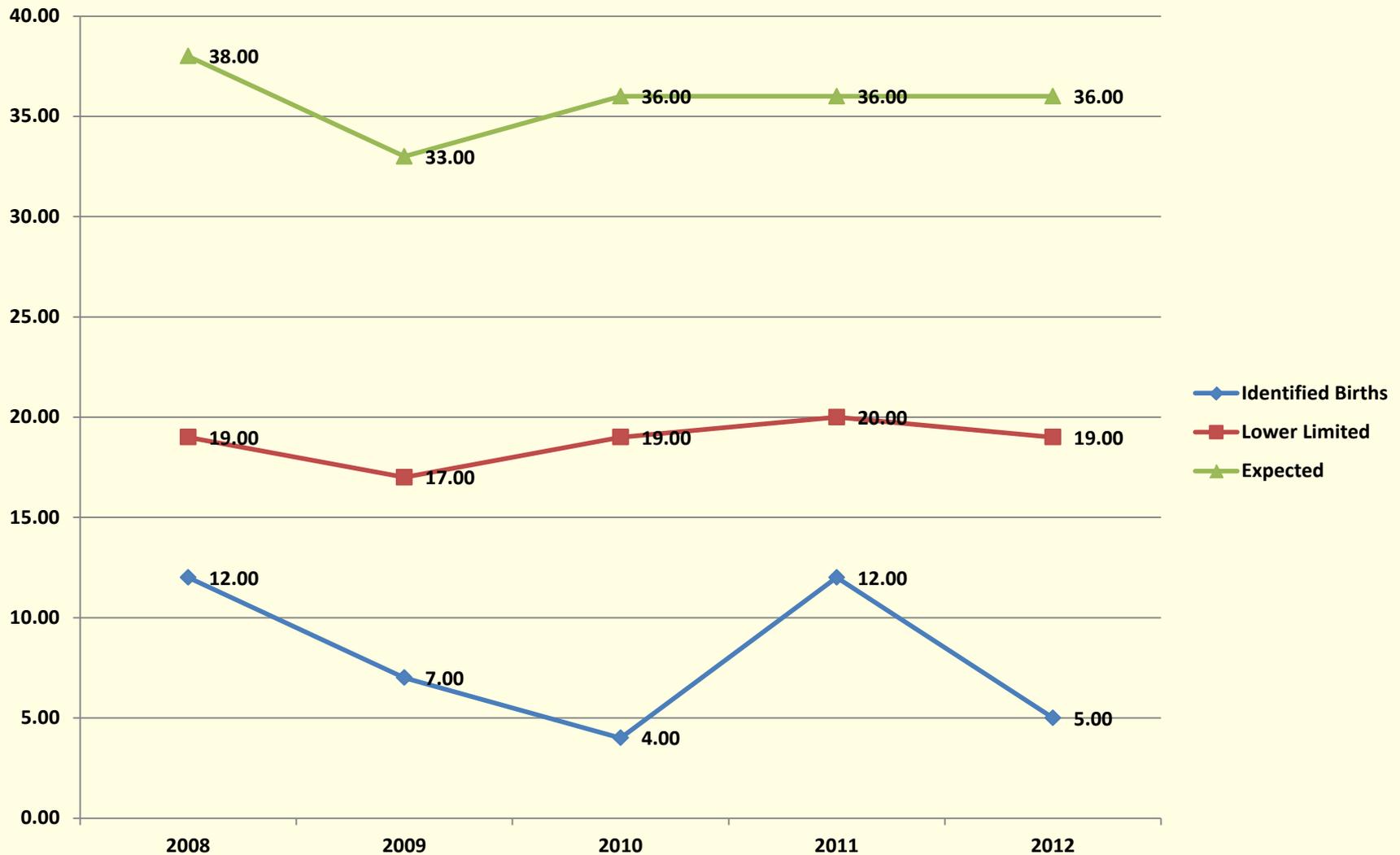
You are the direct link between mom, baby, physicians and State.

National - Identified births to Total Expected Births 2008-2012



Source: CDC Perinatal Hepatitis B Prevention Program – Expected Birth Tables

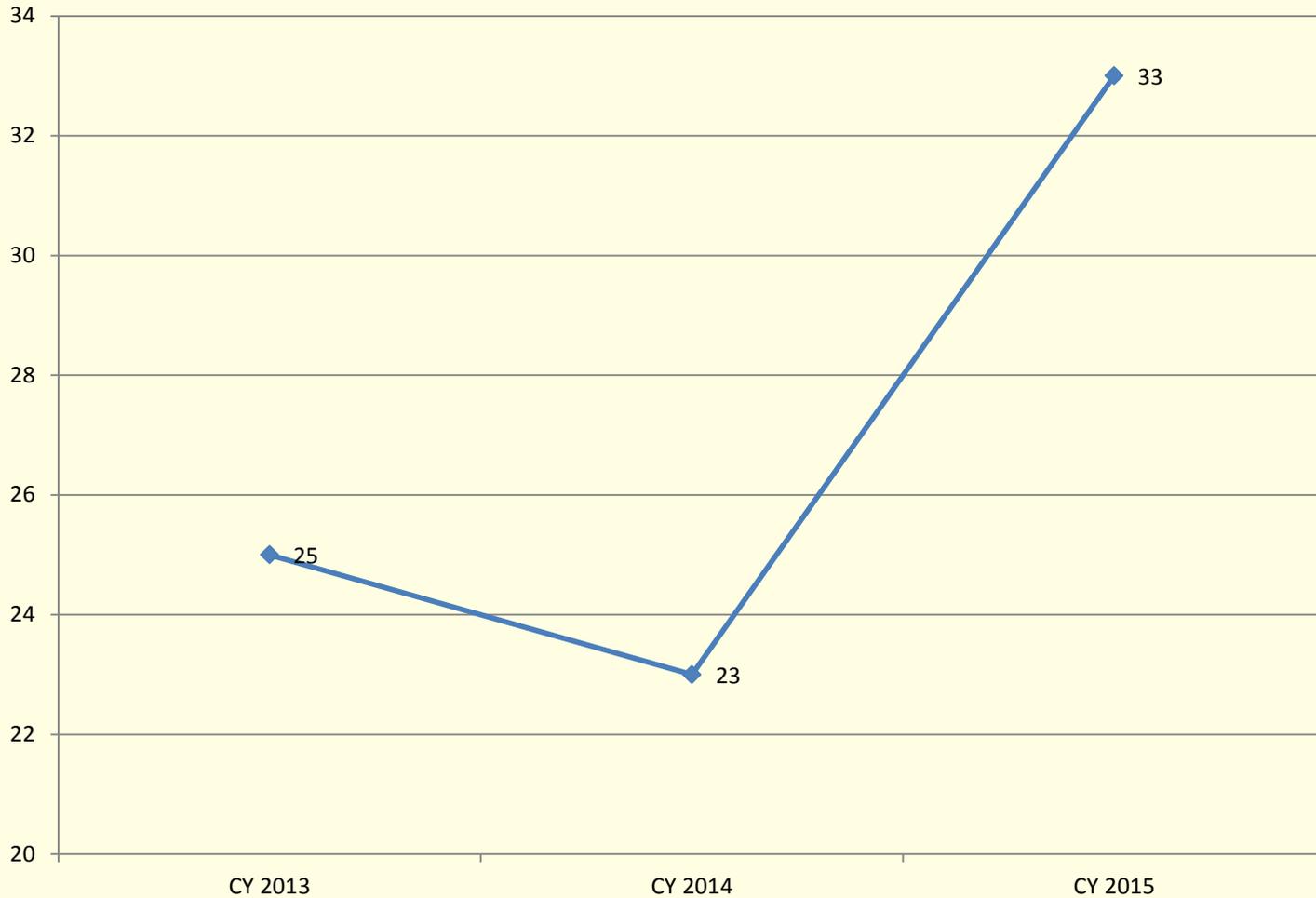
Identified Births to Total Expected Births for WV 2008-2012



Source: CDC Perinatal Hepatitis B Prevention Program Peritables

PHBP Case Management Efforts 2013 - 2015

West Virginia Identified and Enrolled per CY



PHBP Current Case Load

33 Open Cases*

Status of cases

Ready to Deliver	Ready for HBV #2	Ready for HBV #3	Ready for HBV # 4	Ready for PVST
5	4	9	3	10

* Infected infants (2)

Count per county

Counties with 1 case	Counties with 2 cases	Counties with 3 cases	Counties with 4 cases	Counties with 5 cases
12	4	0	2	1

Resource and Reference List

- Department of Health & Human Services, Centers for Disease Control and Prevention, Division of Viral Hepatitis (June 2010). Hepatitis B General Information [On-line], Available: www.cdc.gov/hepatitis
- Department of Health & Human Services, Centers for Disease Control and Prevention (April 2007). Managing a Perinatal Hepatitis B Prevention Program, A Guide to Life as a Program Coordinator [On-line], Available: www.cdc.gov/hepatitis/Partners/PeriHepBCoord
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- Epidemiology and Prevention of Vaccine-Preventable Diseases (12th ed., Second Printing) (2012). Hepatitis B (pp. 115 – 138).
- West Virginia Department of Health & Human Resources, Bureau for Public Health, Office of Epidemiology & Prevention Services, West Virginia Reportable Disease Manual. WVDIDE Protocol, Hepatitis B Surveillance Protocol [on-line], Available: <http://www.dhhr.wv.gov/OEPS/DISEASE/ATOZ/Pages/HepB.aspx>

Contact Information

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