**Perinatal Hepatitis B Prevention Program and
Case Management Protocol**

Kentucky Administrative Regulation, 902 KAR 2:020, requires all licensed health professionals and facilities to report hepatitis B infection in pregnant women to the local or state health department. The Perinatal Hepatitis B Prevention Program consists of surveillance, tracking, and a reminder/recall program for infants born to hepatitis B surface antigen (HBsAg)-positive women.

Each local health department (LHD) must designate one person as the Perinatal Hepatitis B Prevention Coordinator for case management of these infants.

**Screening and Reporting**

* Kentucky Revised Statute 214.160, <http://www.lrc.ky.gov/statutes/statute.aspx?id=8792>, requires that all pregnant women shall be screened for hepatitis B surface antigen (HBsAg) during every pregnancy. This testing shall be completed regardless of past test results or hepatitis B immunization status.
* If a woman has a positive HBsAg screening, notification to the local or state health department “shall be considered a priority and shall be made within one (1) business day per 902 KAR 2.020”, <http://www.lrc.ky.gov/kar/902/002/020.htm>.
* If a woman has a positive HBsAg screening, that woman must have further serological testing completed for confirmation of infection, unless she is known to have chronic hepatitis B infection.
	+ CDC recommended additional tests shown in the “Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women” on page 2, to include: hepatitis B e antigen (HBeAg, associated with a higher risk of infectivity when positive), quantitative HBV DNA concentration, and alanine aminotransferase (ALT). Assure that medical providers are aware of CDC recommendations for immediate referral of a pregnant woman to a hepatitis specialist when results on those additional lab tests are reported as:
	+ HBeAg-positive
	+ HBV DNA concentration of 20,000 IU/mL or greater
	+ ALT of 19 IU/L or greater
* See Table 1 for correct interpretation of the results of the following serological markers that may also be ordered by medical providers: HBsAg, antibody to hepatitis B core antigen (total anti-HBc and IgM anti-HBc).
* The American Association for the Study of Liver Diseases (AASLD) suggests maternal antiviral therapy when the maternal HBV DNA is >200,000 IU/mL. All HBsAg positive pregnant women should receive information concerning HBV that discusses the potential us of antiviral therapy, and the importance of prophylaxis for their infant.
* Women who present to the delivering hospital with an unknown HBsAg status must have lab tests drawn at the time of delivery to determine their HBsAg status. The results must be recorded on the Perinatal Hepatitis B Prevention Form for Infants(EPID 399) form prior to discharge and sent to the health department in the county of residence of the mother, whether located in Kentucky or in another state.
* If it is not possible to determine the mother’s HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive post vaccination serologic testing (PVST) at age 9-12 months, and revaccination if necessary.
* Positive results must be reported in the National Electronic Disease Surveillance System (NEDSS) or on a Hepatitis B Infection in Pregnant Women or Child(EPID 394) form. Forward all HBsAg-positive results on pregnant women, reported on the EPID 394 form, to the Kentucky Perinatal Hepatitis B Prevention Coordinator by mail or fax, within one business day of results being reported:

Mail the results to:

Perinatal Hepatitis B Prevention Coordinator

275 East Main Street, HS2E-B

Frankfort, KY 40621

Fax the results to 502-564-4760



<https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf>

| **Table 1: Interpretation of Hepatitis B Serologic Tests** |
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| **Test** | **Results** | **Interpretation** |
| HBsAgAnti-HBcAnti-HBs | NegativeNegativeNegative | Susceptible to infection |
| HBsAgAnti-HBcAnti-HBs | NegativeNegativePositive with ≥10 mIU/mL+ | Immune due to vaccination |
| HBsAgAnti-HBcAnti-HBs | NegativePositivePositive | Immune and recovered from past hepatitis B virus (HBV) infection  |
| HBsAgAnti-HBcIgM anti-HBcAnti-HBs | PositivePositivePositiveNegative | Acutely infected |
| HBsAgAnti-HBcIgM anti-HBcAnti-HBs | PositivePositiveNegativeNegative | Chronically infected |
| HBsAgAnti-HBcAnti-HBs | NegativePositiveNegative | Four interpretations are possible\*\* |

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| **Table 1: Interpretation of Hepatitis B Serologic Tests** |
| + For infants born to hepatitis B-infected mothers, postvaccination serologic testing (PVST), consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w>. Postvaccination quantitative anti-HBs antibody testing, when it is recommended for other persons, should be performed 1 to 2 months following the last dose of the hepatitis B vaccine series. |
| \*\* 1. May be recovering from acute HBV infection.  2. May be distantly immune, and the test is not sensitive enough to detect a very low  level of anti-HBs in serum.  3. May be susceptible with a false positive anti-HBc.  4. May be chronically infected and have an undetectable level of HBsAg present in the serum.  |
| Taken from ***Epidemiology and Prevention of Vaccine Preventable Diseases***(Pink Book) 13th edition (2015), page 153. |

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| **Table 2:** **Hepatitis B Post Exposure Management of Infants with Birth Weight of 2,000 Grams or More**  |
| **HEPATITIS B (HepB) VACCINE SCHEDULES FOR NEWBORNS INFANTS BY MATERNAL HEPATITIS B SURFACE ANTIGEN (HBsAg) STATUS\*** |
| Maternal HBsAg Status | Monovalent (Single-antigen)HepB vaccine | Monovalent (Single-antigen) HepB and Combination Vaccine |
| Dose | Age | Dose | Age |
| Positive | 1† | Birth (12 hours or less) | 1† | Birth (12 hours or less) |
| HBIG§ | Birth (12 hours or less) | HBIG§ | Birth (12 hours or less) |
| 2 | 1 through 2 months | 2 | 2 months |
| 3¶ | 6 months | 3 | 4 months |
|  |  | 4¶ | 6 months (PEDIARIX®)  |
| Unknown\*\* | 1† | Birth (12 hours or less) | 1† | Birth (12 hours or less) |
| 2 | 1 through 2 months | 2 | 2 months |
| 3¶ | 6 months | 3 | 4 months |
|  |  | 4 | 6 months (PEDIARIX®) |
| Negative | 1†,++ | Birth (24 hours or less) | 1† | Birth (24 hours or less) |
| 2 | 1 through 2 months | 2 | 2 months |
| 3¶ | 6 through 18 months | 3 | 4 months |
|  |  | 4¶ | 6 months (PEDIARIX®) |
| \*See Table 3 for hepatitis B vaccine schedules for preterm infants weighing less than 2,000 grams |
| †Either RECOMBIVAX HB® or ENGERIX-B® should be used for the birth dose. PEDIARIX® cannot be administered at birth or before age 6 weeks. |
| § Hepatitis B immune globulin (HBIG) (0.5 mL) should be administered intramuscularly in a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb.  |
| ¶ The final dose in the vaccine series should not be administered before age 24 weeks (164) days. For infants born to hepatitis B-infected mothers, postvaccination serologic testing (PVST), consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed). |
| \*\* When the maternal HBsAg status is unknown, the mother should have blood drawn and tested for HBsAg after admission for delivery. If the mother is found to be HBsAg-positive, the infant should receive HBIG as soon as possible but no later than 7 days after birth. |
| For medically stable infants weighing ≥ 2000 grams at birth and born to HBsAg-negative mothers, the first dose of vaccine should be administered within 24 hours of birth (new recommendation in 2018). Only single-antigen HepB vaccine should be used for the birth dose. |
| Adapted from the 2015 Red Book (Hepatitis B chapter), the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017”: <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>, and ACIP VFC Resolution 10/16-1 |

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| **Table 3. Hepatitis B Post Exposure Management of Preterm Infants, Birth Weight Less Than 2,000 grams, by Maternal Hepatitis B Surface Antigen (HBsAg) Status** |
| **Maternal HBsAg Status** | **Recommendations** |
| Positive | * Administer HBIG\* and monovalent (single-antigen) hepatitis B vaccine within 12 hours of birth.
* Do not count the birth dose as part of the vaccine series
* Administer 3 additional hepatitis B vaccine doses with either monovalent HepB vaccine at 1, 2 through 3, and 6 months of age, or a hepatitis B containing combination vaccine at 2, 4, and 6 months of age (PEDIARIX®)
* For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed)
 |
| Unknown | * Administer HBIG and monovalent (single-antigen) hepatitis B vaccine within 12 hours of birth.
* Test mother for HBsAg status
* Do not count the birth dose as part of the vaccine series.
* Administer 3 additional hepatitis B vaccine doses with either monovalent HepB vaccine at 1, 2 through 3, and 6 months of age, or a hepatitis B containing combination vaccine at 2, 4, and 6 months of age (PEDIARIX®)
* For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed).
 |
| Negative | * Delay first dose of hepatitis B vaccine until age 1 month if medically stable or at hospital discharge.
* Complete the hepatitis B vaccine series with either monovalent HepB vaccine at 1, 2 through 3, and 6 months, or a hepatitis B containing combination vaccine at 2, 4 and 6 months (PEDIARIX®)
 |
| \* Hepatitis B immune globulin (HBIG) (0.5 mL) should be administered intramuscularly in a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb.  |
| The final dose in the vaccine series should not be administered before age 24 weeks (164) days. For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed). |
| Adapted from ***MMWR*** 2015, Vol 64, and (No. RR-39), ***Epidemiology and Prevention of Vaccine Preventable Diseases*** (Pink Book) 13th edition, and the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017”: 2015 CDC Update for PVST, and ACIP VFC Resolution 10/16-1 |

**RESPONSIBILITIES**

**Kentucky Perinatal Hepatitis B Prevention Coordinator**

* Maintains the Kentucky Perinatal Hepatitis B prevention database.
* Serves as a resource for the local health departments.
* Develops templates and educational materials for the local health departments to use in case management for the parent and providers.

**Local Health Department Perinatal Hepatitis B Prevention Coordinator**

* Determine pregnancy status on all reports of HBsAg-positive women aged 11 through 46 years.
* Follow-up with the reporting provider of an HBsAg-positive pregnant woman to obtain more information needed for case management. The Coordinator should ensure that the provider is aware of the pregnant woman’s HBsAg-positive status and of the additional CDC recommended tests in the “Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women”.
* Complete an EPID 394 form or enter the case information into NEDSS on all
HBsAg-positive pregnant women.
* Initiate a case management form (EPID 395 form).
* Forward a copy of the EPID 394 form to the Kentucky Perinatal Hepatitis B Prevention Coordinator at the Kentucky Department for Public Health in Frankfort.
* Contact the HBsAg-positive woman as soon as a case is identified. Provide education and counseling about protecting the liver, the prevention of perinatal hepatitis B infection for the infant, and protecting others from exposure to the hepatitis B virus. For educational materials, visit <http://www.cdc.gov/hepatitis>. A letter may be sent
(PHBPP-1 form).
* Determine sexual and household contacts of the HBsAg-positive woman and offer them education, testing and/or hepatitis B immunizations. Testing should not unduly delay or impede immunization efforts. Document contacts and outcomes in NEDSS or on the EPID 395 form. Refer all HBsAg-positive patients to a medical provider to monitor outcomes or progress of HBV infection. Document if referral was completed.
* Send a reminder letter or call mother one month prior to delivery. (PHBPP-2 form)
* Notify the delivering hospital of the mother’s HBsAg status. (PHBPP-3 form)
* Once an infant is born to an HBsAg-positive mother, verify that the infant received HBIG and hepatitis B vaccine after delivery per the EPID 399 form from the delivering hospital.
* Review all EPID 399 forms for missing information. All sections of the EPID 399 form must be completed. The EPID 399 form should be sent to the local health department in the mother’s county of residence for case management, whether located in Kentucky or in another state.
* Contact the hospital if the due date is two weeks past for follow-up.
* Notify the infant’s provider for follow-up care, and refer them to the American Academy of Pediatrics recommendations in the 2015 ***Red Book*** for Post Exposure Management of Infants born to HBsAg-positive mothers and to the 2015 “Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers**,”** <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w> from CDC.A case management form can be sent to this provider. (PHBPP 4, and
PHBPP-5 forms).
* Ensure the infant, born to an HBsAg-positive mother, receives three or more doses of the hepatitis B vaccine series and postvaccination serological testing (PVST). Send reminder letters and/ or make phone calls to the mother and the provider two to four weeks prior to each vaccination dose and for serology testing due dates (PHBPP-6, PHBPP-7, and PHBPP-8 forms).
* HBsAg negative infants with anti-HBs less than 10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive PVST one to two months later. Infants whose
anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST one to two months after the final dose.
	+ Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs less than 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by PVST performed one to two months after the final dose of vaccine.
* Send a final letter to mother with dates immunizations were received and results of PVST for the infant’s immunization record. (PHBPP-9 form)
* Case is closed if the results of PVST indicate that the infant is HBsAg-negative and
anti-HBs-positive. The results must be attached to the final printout.
* If infant is HBsAg-positive, results must be reported to the local health department or KDPH within one business day of the report of a positive result in accordance with 902 KAR 2:020.
* Send updates by the 15th of each month to the Kentucky Perinatal Hepatitis B Prevention Coordinator by mail or fax.
	+ Mail the updates and lab results to:

Perinatal Hepatitis B Prevention Coordinator

275 East Main Street, HS2E-B

Frankfort, KY 40621

* + Fax the updates and lab results to 502-564-4760

**HBsAg-positive women identified at or after delivery**

Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to a HBsAg-positive mother. The infant should receive both HepB and HBIG within 12 hours of birth

If it is not possible to determine the mother’s HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive postvaccination serologic testing at age 9-12 months, and revaccination of necessary.

In some cases, HBV infection is detected at the time of delivery of the infant. In this case, the delivery hospital should contact the LHD of the county of residence for the infant and complete the EPID 399 form.

The LHD Perinatal Hepatitis B Prevention Coordinator shall confirm that the infant has received Hepatitis B vaccine and HBIG. HBIG should be given as soon as possible ideally within 12 hours of birth, but within seven days of birth, at a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb. The LHD Perinatal Hepatitis B Prevention Coordinator then begins case management for infants born to an HBsAg-positive woman.

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| **Table 4: Postvaccination Serological Test Results and Follow-Up** |
| **Serology Test Results** | **Follow-up** |
| HBsAg-negative and anti-HBs-positive (10 mIU/mL or greater)  | NoneInfant is immune |
| HBsAg-negative and anti-HBs-negative (less than 10 mIU/mL) | Infant did not develop immunity.HBsAg negative infants with anti-HBs less than 10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive post vaccination serologic testing 1-2 months later. Infants whose anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose.* Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs less than 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by post vaccination serologic testing (PVST) performed 1-2 months after the final dose of vaccine.
 |
| HBsAg-positive and anti-HBs-negative | Infant is infected with Hepatitis B virus and will need medical follow up. Send a report to Kentucky Perinatal Hepatitis B Prevention Coordinator in accordance with 902 KAR 2:020 and CCSG protocol titled “Reportable Diseases Deadlines for Health Professionals and for Local Health Departments”. |

Information from MMWR 2005, Vol. 54 and ACIP VFC Resolution 2/17-1

**Managing Missed Vaccination/ Serology Appointment**

* Send a reminder card for missed appointments.
* Send a letter, conduct home visit and/or make a telephone call to the parent or guardian.
* Send a certified letter for continued non-compliance. If there is no response to that letter, the infant is considered lost to follow-up.
* Send updates to the Kentucky Perinatal Hepatitis B Coordinator by the 15th of each month.

**Lost to Follow-up**

In the nine to 18 months that it takes to complete the newborn case management, some patients will move without providing the LHD with new contact information. To find patients, LHDs may use Women Infants and Children (WIC) and Medicaid databases to locate updated demographics. Additional tips for locating these patients can include:

* Call telephone information (411)
* Internet search engines (e.g., Google or white pages)
* Directories that list occupants of each household; most STD programs have directories like this.
* Old phone numbers listed in patient paperwork. Sometimes relatives or friends may still be at that number.
* Transpose the digits of telephone numbers and addresses.
* Search older health department records.

A patient can be classified as “lost to follow-up” and the file closed once the following conditions are met and the Kentucky Perinatal Hepatitis B Coordinator believes further investigation would be fruitless. Examples include:

* Failed phone contact after three calls.
* Failed home visit.
* Failed mail deliveries including returned certified letters.
* Parent refuses to participate in case management with the Perinatal Hepatitis B Prevention Program.

Document all attempts to find infants and their parents. If an infant is lost to follow-up and the infant is later located, the case should be reopened and follow-up continued from that point. Consult the Kentucky Perinatal Hepatitis B Prevention Coordinator for assistance.

**Optional Forms and Templates for Perinatal Hepatitis B Prevention Program (PHBPP)**

See CCSG Forms Section,<https://chfs.ky.gov/agencies/dph/dpqi/hcab/Documents/FormsListing.doc> , for the following forms:

EPID-395: EPID 395: Kentucky PHBPP Case Management Worksheet

PHBPP-1: PHBPP Introduction Letter (for the Mother)

PHBPP-2: Reminder Letter Prior to Delivery

PHBPP-3: Notification Letter to Hospital about an HBsAg + Pregnant Woman

PHBPP-4: Letter to the Infant’s Primary Care Physician

PHBPP-5: PHBPP for Infants Follow-up Form

PHBPP-6: Vaccination Reminder Letter to the Mother

PHBPP-7: PVST Reminder Letter to the Mother

PHBPP-8: PVST Reminder Letter to the Primary Care Provider

PHBPP-9: Notification Letter to the Mother that Infant is Immune

**References and Additional Resources**

Perinatal Transmission Guidelines and Recommendations at the CDC’s Website at

<https://www.cdc.gov/hepatitis/hbv/index.htm>

Educational materials at <http://www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm>

ACIP VFC Resolution 2/17-1, “Vaccines to Prevent Hepatitis B”
[http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2017-02-01-hepb.pdf](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2016-10-01-hepb.pdf)

Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to
Hepatitis B-Infected Mothers, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w>

CDC Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR, 2018, Vol. 67/No.1

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf>.

Footnotes to the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2018”:

<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

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