



Hepatitis B Virus (Pregnancy) Investigation Guideline

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Revision History:

Date	Replaced	Comments
07/2016	03/2016	Updated background information with 2014 numbers. Updated Data Management and Reporting section. Updated attached files.
03/2016	11/2013	Updated post-vaccination testing recommendations for infants to "Between 9-12 months of age..." Reformatted document to add table of contents.

Hepatitis B Virus (Pregnancy)

Disease Management and Investigative Guidelines

CASE DEFINITION

Clinical Criteria:

A female, currently pregnant or who has recently given birth, with a documented positive hepatitis B lab result.

Laboratory Criteria for Case Classification:

- Positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative or genotype testing),

Case Classification (KDHE Definition Only):

- **Confirmed:** A case that is laboratory confirmed
 - **Suspect:** A case that has a birth certificate indicating positive hepatitis B status, but no documented lab result.
-

LABORATORY ANALYSIS

- The Kansas Health and Environmental Laboratories (KHEL) is equipped to test for hepatitis B virus (HBV) on a limited basis for diagnosis of acute and chronic disease among clients of local health departments and some state-operated facilities. Emphasis is placed on testing prenatal patients and household and sexual contacts of hepatitis B positive clients.
- For additional information and/or questions concerning specimen submission, collection/transport and laboratory kits call (785) 296-1620 or refer to online guidance at http://www.kdheks.gov/labs/lab_ref_guide.htm

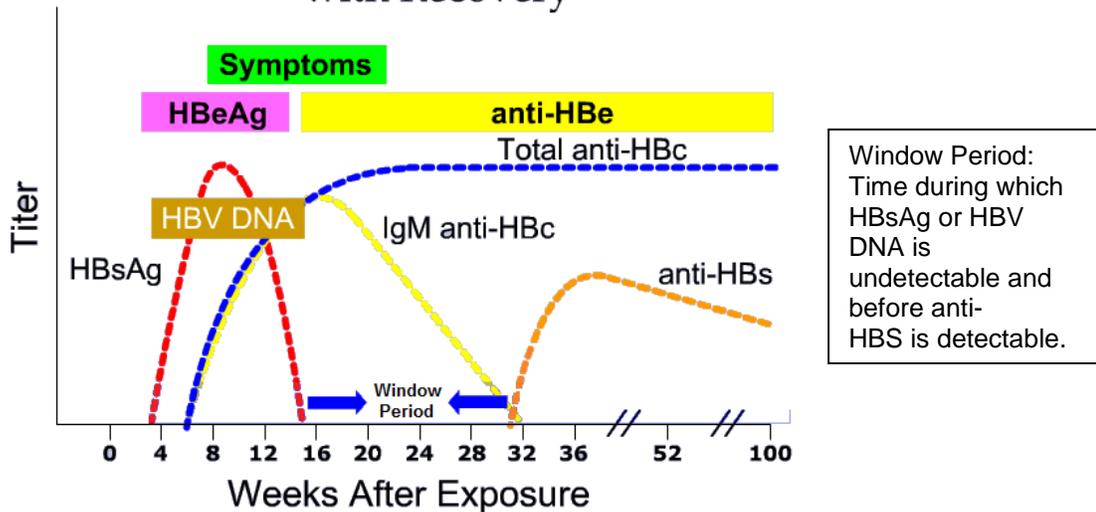
Description of Hepatitis B Laboratory Tests				
Tests		Marker Of	Indicates	Detection
HBsAg	<i>Hepatitis B surface antigen</i>	Infectivity	<u>Acute or chronic</u> natural infection	1 or 2 weeks to 11 or 12 weeks after exposure
Anti-HBs or HBsAB	<i>Antibody to hepatitis B surface antigen</i>	Immunity	Natural infection or vaccination or passively acquired antibody	During recovery (after HBsAg is no longer detected); lasts for life
Anti-HBc (total) or HBcAb	<i>Antibody to hepatitis B core antigen</i>	Nonspecific	Natural infection that could be acute, chronic or resolved [Need to determine <u>why testing was done</u> to ensure case is not acute or chronic.]	Time of illness onset (after HBsAg is detectable); lasts for life
IgM anti-HBc	<i>IgM antibody subclass of anti-HBc</i>	Recent infection within the past 6 months	<u>Acute</u> natural infection	Time of illness onset (after HBsAg is detectable) until 4-6 weeks after exposure
HBeAg	<i>Hepatitis B "e" antigen</i>	High degree of infectivity	High level of HBV replication (used for clinical management of chronic infection)	
Anti-HBe	<i>Antibody to hepatitis B "e" antigen</i>	Nonspecific (infected or immune person)	In chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity	
HBV-DNA	<i>HBV Deoxyribonucleic acid</i>	Viral replication	Correlates well with infectivity (used to monitor treatment of chronic HBV patient)	

- Interpretation of laboratory tests for HBV:

Tests Results and Interpretations				
HBsAg	anti-HBc	IgM anti-HBc	anti-HBs	Interpretation
-	-		-	Susceptible
-	+		+	Immune due to natural infection
-	-		+	Immune due to Hepatitis B vaccination
-	+		-	Interpretation unclear; four possibilities*
+	+	+	-	Acutely infected
+	+	-	-	Chronically infected

* 1) Resolved infection (most common) 2) False-positive anti-HBc, thus susceptible
 3) "Low level" chronic infection 4) Resolving acute infection

Acute Hepatitis B Virus Infection with Recovery



- Additional training for HBV serology: www.cdc.gov/hepatitis/Resources/Professionals/Training/Serology/training.htm

BACKGROUND

Hepatitis B virus (HBV) is a major cause of chronic liver disease and cancer worldwide. In the United States and other developed countries, the infection rate is low. The rate of new HBV infections has declined by approximately 82% since 1991, when a national strategy to eliminate HBV infection was implemented in the United States and routine vaccination of children was recommended. In 2014, 2,953 cases of acute Hepatitis B in the United States were reported to CDC; the overall incidence of reported acute Hepatitis B was 0.9 per 100,000 persons, the lowest ever recorded. However, because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be approximately tenfold higher. Rates are highest among adults; particularly males aged 25-44 years.

Perinatal transmission of HBV is highly efficient and usually occurs from blood exposures during labor and delivery. The risk that an infant born to an hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg) positive mother will acquire HBV from prenatal exposure is 70% - 90% if the appropriate immunoprophylaxis is not administered; the risk of acquiring HBV is 5% to 20% in infants born to HBsAg positive and HBeAg-negative mothers.

CDC predicts that without post-exposure immunoprophylaxis, approximately 40% of infants born to HBV-infected mothers in the United States will develop chronic HBV infection, approximately one-fourth of whom will eventually die from chronic liver disease.

The National Health and Examination Survey (NHANES) estimated that if post-exposure prophylaxis is not given to prevent perinatal HBV infection, 12,000 infants and children in the United States will be infected with HBV yearly.

Hepatitis B screening of pregnant women has been recommended since 1991 by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP).

NOTIFICATION TO PUBLIC HEALTH AUTHORITIES

Hepatitis B (acute, perinatal, and chronic) disease shall be designated as infectious or contagious in their nature, and cases or suspect cases shall be reported within seven days:

1. Health care providers and hospitals: report to the local public health jurisdiction.
2. Local public health jurisdiction: report to KDHE-BEPHI (see below).
3. Laboratories: report to KDHE-BEPHI (see below.)

**Kansas Department of Health and Environment (KDHE)
Bureau of Epidemiology and Public Health Informatics (BEPHI)
Phone: 1-877-427-7317 Fax: 1-877-427-7318**

(Local public health can report cases with New CMR creation in EpiTrax.)

Hepatitis B Pregnancy Surveillance and Reporting:

1. The HBsAg perinatal screening law (K.S.A. 153f) states that all women are to be tested for HBsAg within 14 days of pregnancy diagnosis.
2. Laboratories will report positive results to the KDHE-BEPHI, as described above.

INVESTIGATOR RESPONSIBILITIES

- 1) [Report](#) all cases to the KDHE-BEPHI.
- 2) Investigate cases to determine outcomes of pregnancy.
- 3) Contact medical provider to collect additional information and confirm diagnosis using current [case definition](#).
 - Collect all information requested in [Case Investigation](#).
 - Ensure that case is aware of her diagnosis.
 - If notified during pregnancy, conduct a [case investigation](#) to identify potential delivery hospitals/facilities and to ensure proper care will occur at time of delivery.
- 4) Initiate any needed control and prevention measures, as directed under [Case Management](#) and [Contact Management](#).
- 5) [Record](#) data, collected during the investigation, in the KS EpiTrax system.
- 6) As appropriate, provide educational material to patient and providers (see [References](#)).

STANDARD CASE INVESTIGATION

Case Investigation

The investigation process is dependent on when the local health department is notified of the diagnosis of hepatitis B in a pregnant or post-partum woman.

If Notified During Pregnancy:

- 1) Contact the medical provider who ordered testing of the case and obtain the following information:
 - Case's demographic data (birth date, county, sex, race/ethnicity) and contact information (address, phone number(s))
 - Estimated date of delivery (EDD),
 - Expected delivery facility
 - Insurance status (Private/Medicaid/Uninsured)
 - Provide provider with OB/GYN letter or Pediatric letter
- 2) Contact the delivery facility:
 - Ensure they are aware of the patient's positive HBsAg status and EDD
 - Provide them with Hospital letter and Hospital Perinatal Hepatitis B Prevention Reporting Form to report the birth.
- 3) Continue with the contact investigation.

If Notified Post-Partum:

- 1) Contact the attending medical provider or the delivery facility and obtain a copy of the most recent hepatitis B laboratory results.
- 2) Forward the laboratory results to KDHE.
- 3) If the laboratory result is HBsAg negative, no further follow up is needed.
 - Complete as "Not a Case" and approve the investigation in EpiTrax.
- 4) If laboratory result is positive, continue with the investigation.
 - Manage the case as in [Case Management](#).
 - Investigate contacts as instructed in [Contact Investigation](#).

Contact Investigation

Contacts include: only the infant. Other contacts such as household members, sexual partners, and needle sharing contacts would be listed in the hepatitis B CMR and not the hepatitis B pregnancy event.

Identify the infant’s medical provider(s) to allow for follow up with infant’s immunizations and post-vaccination serological testing (PVST) as described in Contact Management.

Case Management

- 1) Council the case on measures to avoid disease transmission, including risks to newborn, and measures to take to protect the liver.
- 2) Educate case on immunizations and testing that is needed for infant following birth, as described in Contact Management
 - Educational material are available in multiple languages from KDHE
 - Patient information brochure with state specific information specific from KDHE

Contact Management

For infants born to hepatitis B positive women:

- 1) Notify the infant’s physician of the mother’s hepatitis B status, and the steps that need to be taken to prevent the infant from contracting hepatitis B.
 - Within 12 hours of birth: Both HBIG (0.5 ml for newborns) and hepatitis B vaccine should be given to infants born to HBsAg-positive mothers.
 - At 1-2 months: Administer 2nd dose of hepatitis B vaccine.
 - At ~6 months: Administer 3rd dose to complete the hepatitis B series.
 - Between 9-12 months of age, at least 1-2 months following last hepatitis B immunization (i.e. at next well child visit): perform post-vaccination serological testing (PVST) for HBsAg and anti-HBs
 - Provide testing codes to physician to ensure appropriate tests are ordered
 - PVST testing codes by laboratory

Laboratory	Hepatitis B Surface Antigen (HBsAg)	Hepatitis B surface antibody (anti-HBs, HBsAb)
AMS	5196-1	10900-9
KDHE	Perinatal – PVST (call 877-427-7317 for Approval)	
LabCorp	006510	006530
Mayo Medical Labs	9013	8254
Quest	498	8475
Via Christi and Wesley	HBSAG	HBSAB

- 2) Obtain these immunization dates and laboratory results of PVST from the provider.

Environment

None.

Education

- 1) Pregnant women should be told about the risk of hepatitis B infection to their newborn and of the importance of prophylaxis for her infant, especially PVST. Educational materials are available from the CDC and can be found at: www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm
- 2) Educational material is also available from KDHE
 - Available in multiple languages
 - Kansas specific public services is attached
- 3) Advise all cases who are HBsAg-positive:
 - To notify household, sex, and needle-sharing contacts that they should be tested for markers of HBV infection, vaccinated against hepatitis B, and, if susceptible, complete the vaccine series.
 - That the virus may be transmitted through sexual contact and should be instructed to practice abstinence, use condoms, or otherwise practice safe sex until the sex partners are vaccinated and immunity documented
 - Refrain from donating blood, plasma, tissue, or semen. (Organs may be donated to HBV-immune or chronically infected persons needing a transplant.);
 - Cover cuts or skin lesions to prevent contact with secretions and blood;
 - Refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could be contaminated with blood.
 - Surfaces contaminated with saliva and blood should be cleaned and properly disinfected, but objects potentially contaminated with blood (e.g., razors, toothbrushes) should not be shared with other people.
 - Do not share needles with other people.
 - When seeking medical or dental care, HBsAg-positive persons should be advised to inform those responsible for their care of their HBsAg status so they can be evaluated and their care managed appropriately.
- 4) Advise cases on measures to prevent future liver damage.
 - Avoid or limit alcohol consumption;
 - Refrain from beginning to take any new medicines, including over-the-counter and herbal medicines, without consulting their health-care provider; and
 - Obtain vaccination against hepatitis A.

DATA MANAGEMENT AND REPORTING TO KDHE

1. On the hepatitis B virus infection, chronic CMR (the mom’s original case), under the **[Clinical]** tab, change pregnant status to “Yes” and enter the expected delivery date. Then “Save & Continue”.



Pregnancy Status

Pregnant: **Yes** Expected delivery date:

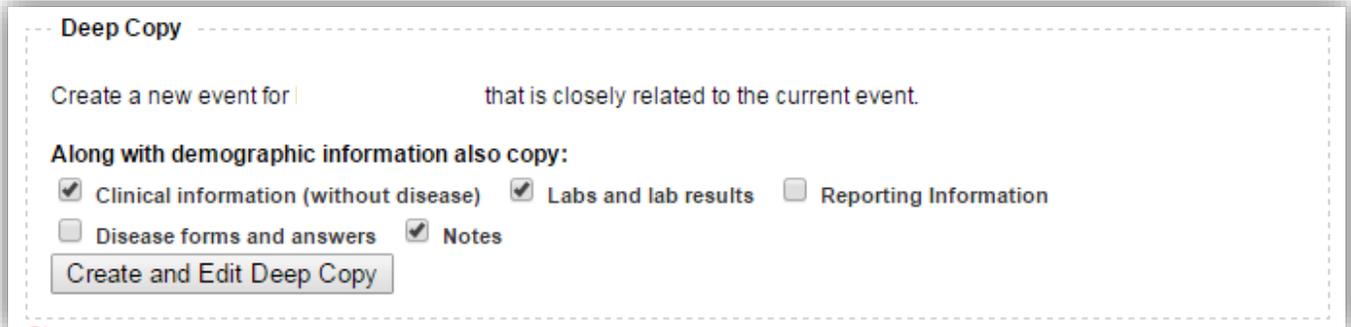
2. Then, click “Create a new event from this one”.



Morbidity Event

[Edit](#) | [Print](#) | [Delete](#) | [Add Task](#) | [Add Attachment](#) | [Export to CSV](#) | **Create a new event from this one** | [Events](#)

3. When the options come up, under “Deep Copy”, select “Clinical information”, “Labs and lab results”, and “Notes”. Then “Create and Edit Deep Copy”.



Deep Copy

Create a new event for _____ that is closely related to the current event.

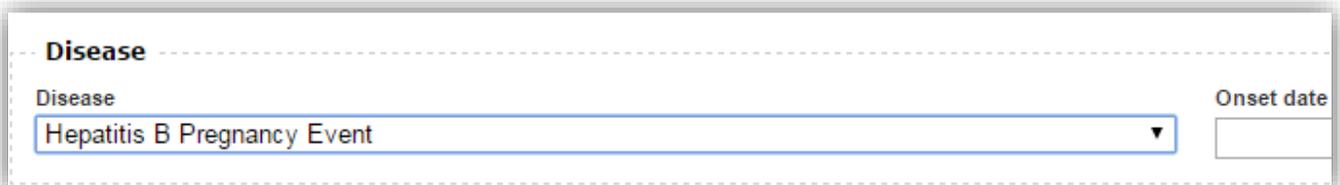
Along with demographic information also copy:

Clinical information (without disease) Labs and lab results Reporting Information

Disease forms and answers Notes

Create and Edit Deep Copy

4. **In the new CMR:** under **[Demographic]** tab have today’s date as “Date first reported to public health”. Then, under **[Clinical]** tab, select “Hepatitis B Pregnancy Event” from the disease list. Then select “Save and Continue”.



Disease

Disease: **Hepatitis B Pregnancy Event** Onset date:

- Fill out [Demographic] tab regarding mom and pregnancy, paying special attention to filling out “insurance type”

Insurance [Hide]

Insurance type
 Private ▼

- Under [Clinical] tab, enter information about expected delivery date and expected delivery facility. Once the delivery facility has been notified, select “Yes” under “Hospital notified”.

Pregnancy Status

Pregnant	Expected delivery date	Hospital notified?	Area code	Phone number	Extension
Yes	2016-12-19	Yes	(316)	962-2000	

Expected delivery facility Place type

Wesley Medical Center Hospital / ICP, Laboratory, and Clinic / Doctor's Office

Actual delivery date

Actual delivery facility Place type Area code Phone number Extension

Health Care Provider

- Once the child is born:** Under [Clinical] tab, enter information about actual delivery date and actual delivery facility.

Pregnancy Status

Pregnant	Expected delivery date	Hospital notified?	Area code	Phone number	Extension
Yes	2014-09-03		(316)	962-2000	

Expected delivery facility Place type

Wesley Medical Center Hospital / ICP, Laboratory, and Clinic / Doctor's Office

Actual delivery date

2014-09-03

Actual delivery facility Place type

Wesley Medical Center Hospital / ICP, Laboratory, and Clinic / Doctor's Office

(316) 962-2000 Extension

- Under the [Contacts] tab, enter the basic information for the infant. Be sure Contact type is “Infant”. When you are finished adding all of the information on this tab, click “Save & Continue”. Once you have saved and continued, you will then “edit contact”.

Disposition Disposition date Contact type Remove

PenHepB - Delivery March 07, 2013 Infant Show Contact | Edit Contact

9. In the infant's contact CMR: Fill out [Demographic] tab, paying particular attention to "Birth weight" in grams and "Insurance type"

Age

Date of birth: July 14, 2016

Age: []

Age at onset: []

Time of birth: 14:35

Birth weight: 3560

Insurance type: Private

10. Fill out [Clinical] tab, paying particular attention to the "Treatments", adding treatment for each dose of vaccine and HBIG (if given). Record time 1st dose of vaccine and HBIG were administered.

Treatments

Treatment given	Treatment	Date of treatment	Remove
Yes	HBIG	March 25, 2015	<input type="checkbox"/>
Yes	Hepatitis B Dose 1	March 25, 2015	<input type="checkbox"/>
Yes	Hepatitis B - Pediarix Dose 2	June 29, 2015	<input type="checkbox"/>

Add a Treatment

Time HBIG Given: 2145

Time HepB1 Given: 2146

11. Attach PVST results to contact CMR; then enter results under **[Laboratory]** tab for each HBsAg and anti-HBs and radio buttons under labs, if patient was screened.

The screenshot displays the 'Labs' section of a medical software interface. It features two lab entry forms. The first form is for 'Hepatitis B surface antigen' with a 'Positive' radio button selected. The second form is for 'Hepatitis B Surface Antibody Total (anti-HBs)' with a 'Positive' radio button selected. Both forms are associated with the 'Affiliated Medical Services Laboratory'. The first lab entry has a 'Test type' of 'Surface Antigen (HBsAg)', 'Organism' of 'Hepatitis B virus', and a 'Test result' of 'Negative / Non-reactive'. The second lab entry has a 'Test type' of 'Surface Antibody (HBsAb)', 'Organism' of 'Hepatitis B virus', and a 'Test result' of 'Positive / Reactive'. Both entries include fields for 'Accession number', 'Reference range', 'Test status' (set to 'Final'), 'Specimen source' (set to 'Blood'), 'Collection date' (March 26, 2015), and 'Lab test date' (March 26, 2015). There are also 'Remove' buttons for each lab entry.

12. Record all attempts to contact individuals in **[Encounters]** tab in pregnancy event; be sure to complete “Encounter date” and “Description” for each encounter with patient, provider, etc.

The screenshot shows the 'Encounters' tab in a medical software interface. The 'Encounter Information' section is expanded. The 'Encounters' section contains an entry for 'DANTE CORIMANYA' with an 'Encounter date' of 'June 07, 2016' and a 'Location' of 'Other'. The 'Description' field contains the text: 'Anti-HBs lab result received and attached to case. HBsAg was attached previously. PVST has been completed.' Blue arrows point to the 'Encounter date' and 'Description' fields. There is also a 'Remove' button and a 'Show Encounter | Ed' link.

13. If after 6 unsuccessful attempts to contact patient by phone AND mail, the case is lost to follow-up:

- Contact KDHE to examine public records to determine if there is indication patient has moved
- Change contact disposition to ‘Lost to Follow Up’ on the **[Contact]** tab of pregnancy event
- Record a reason for ‘lost to follow-up’ in **[Notes]**.

14. Once child completes PVST and change the disposition on the **[Contact]** tab to “Complete”
OR if the child becomes >24 months of age, leave the disposition on the **[Contact]** tab as it is. Leave a note in the **[Notes]** tab as to why investigation was not completed by 24 months.

- The LHD investigator will click the “Complete” button. This will trigger an alert to the LHD Administrator so they can review the case before sending to the state for review.
- The LHD Administrator will then “Approve” or “Reject” the CMR.
- Once a case is “Approved” by the LHD Administrator, BEPHI staff will review the case to ensure completion before closing the case.

15. Review the [EpiTrax User Guide, Case Routing](#) for further guidance.

ADDITIONAL INFORMATION / REFERENCES

A. Perinatal Hepatitis B Prevention Educational Materials:

www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm,
<http://liver.stanford.edu/Public/brochures.html>

B. Treatment / Differential Diagnosis: Red Book: 2015 Report of the Committee on Infectious Diseases. 30th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015:564-568.

C. Epidemiology, Investigation and Control: Heymann, D., ed., Control of Communicable Diseases Manual, Washington, DC, American Public Health Association, 2015.

D. Case Definitions: www.cdc.gov/nndss/

E. Kansas Regulations/Statutes Related to Infectious Disease:

www.kdheks.gov/epi/regulations.htm

F. Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases.

www.cdc.gov/vaccines/pubs/pinkbook/index.html

G. Manual for the Surveillance of Vaccine-Preventable Diseases:

www.cdc.gov/vaccines/pubs/surv-manual/index.html

H. CDC Hepatitis MMWR Resource Center:

www.cdc.gov/hepatitis/Resources/Professionals/MMWRs.htm

I. CDC Hepatitis page: www.cdc.gov/hepatitis/

ATTACHMENTS

To view attachments in the electronic version:

1. Go to <View>; <Navigation Pane>; <Attachments> – OR – Click on the “Paper Clip”  icon at the left.
2. Double click on the document to open.

- **Fact Sheet**
- **Hospital Letter**
- **OB/GYN Letter**
- **Pediatrician Letter**
- **Hospital Report Form**
- **Patient Information Brochure**