The Epidemiology, Investigation, and Reporting of Hepatitis B, C, and Perinatal Hepatitis B in Kentucky

T.J. Sugg, MPH
Kristy Royalty, RN, BSN
Julie Miracle, RN, BSN, CPAN
Division of Epidemiology and Health Planning
Kentucky Department for Public Health
Viral Hepatitis – Historical Perspective

- “Infectious” → A
- Viral hepatitis
- “Serum” → B, D
- “NANB” → C, E
- Parenterally transmitted
- Enterically transmitted
- Other (non-ABCDE)

Cabinet for Health and Family Services
Acute Hepatitis – Clinical Symptoms

• Asymptomatic infections > Symptomatic diseases > Fulminant Liver Failure > Death
• Symptoms (if present) are similar, regardless of cause (e.g., A, B, C, other viruses, toxins)
  – Fever
  – Nausea, vomiting
  – Loss of appetite
  – Abdominal pain
  – Dark urine
  – Jaundice (yellowing of eyes, skin)
  – Light (clay) colored stools
  – Diarrhea (more common in children with hepatitis A)
Jaundice
General Hepatitis Investigation Process

- Review lab report and/or EPID 200.
- Review specific surveillance case definition.
- Call the health care practitioner who ordered the test.
  - Find out why test was ordered (pt. having s/s, just part of the Hepatitis panel, etc…)
  - Does the provider think this is a case?
- If confirmed case definition is met or suspect, then:
  - Ask the provider if it is okay for you to contact their patient. (They may want to call them first and inform them of the result or to give them a heads up that the HD will be calling.)
• Call the Case
  - Only speak with the Case.
  - Develop rapport
  - Go over CDC’s Viral Hepatitis Case Report Form
• Put all information into NEDSS
• Fax a copy of the lab results to the KY Reportable Disease Section (f:502-696-3803) if we do not have one already.
Hepatitis Investigation Dilemmas

Dilemmas

• PCP not responding to reporting/investigation questions (not calling back).

• Unable to reach hepatitis suspect case by phone.

Suggestions

• Send the request via fax and phone message. Document in the comments section of NEDSS and note each date and time you tried to contact them.

• Document in the comments section of NEDSS attempts to call. Send a certified letter from HD to the case giving them a phone number and times you can be reached. Do not put any information regarding the reason you are contacting them in the letter.
Hepatitis C

T.J. Sugg, MPH
Reportable Disease Section
Division of Epidemiology and Health Planning
Department for Public Health

Kentucky
UNBRIDLED SPIRIT
Hepatitis C Virus (HCV)

- Single-stranded RNA virus belonging to Flaviviridae family (WNV, dengue, yellow fever)
- Does not integrate into human genome
- Replicates preferentially in the hepatocyte, but does not cause direct destruction of hepatic cells
- Chronic HCV infection results from immune response that induces hepatocyte destruction and fibrosis
- 6 HCV genotypes and > 50 subtypes

Cabinet for Health and Family Services
HCV Epidemiology

- WHO estimates that >170 million are infected worldwide
- CDC estimates approximately 4 million infected
  - 2.7 million have chronic infection
  - 10,000 to 12,000 die each year
- Most patients with chronic HCV have not been diagnosed
  - Only an estimated 30% have been diagnosed
- Most morbidity and mortality from HCV is caused by complications of decompensated cirrhosis

Cabinet for Health and Family Services
Figure 4.1. Reported and adjusted* number of acute hepatitis C cases — United States, 1992–2009

* Adjusted for underreporting.
Note: Until 1995, acute hepatitis C was reported as "acute hepatitis, non-A /non-B."
Source: National Notifiable Diseases Surveillance System (NNDSS)
Incidence of Reported Acute HCV in KY

Incidence of Reported Acute Hepatitis C
Kentucky 2005-2011

Rate per 100,000

Year

2005  2006  2007  2008  2009  2010  2011

16*  36*  29*  68*  64*  109*  142*

* = Number of cases
Figure 4.2. Incidence of acute hepatitis C*, by age group — United States, 1992–2009

* Until 1995, acute hepatitis C was reported as “acute hepatitis, non-A /non B.”

Source: National Notifiable Diseases Surveillance System (NNDSS)
**Figure 4.3. Incidence of acute hepatitis C*, by sex — United States, 1992–2009**

*Until 1995, acute hepatitis C was reported as “acute hepatitis, non-A /non-B.”*

Source: National Notifiable Diseases Surveillance System (NNDSS)
Figure 4.4. Incidence of acute hepatitis C*, by race/ethnicity — United States, 1992–2009

* Until 1995, acute hepatitis C was reported as “acute hepatitis, non-A/non-B.”

Source: National Notifiable Diseases Surveillance System (NNDSS)
Natural History

- Identification is difficult as most patients are asymptomatic.
- 70%-85% of people infected will develop chronic disease
- Most importance consequence is progressive liver fibrosis, which can lead to:
  - Cirrhosis (20%)
  - Liver failure (6%)
  - Hepatocellular carcinoma (4%)
- Most common indicator for liver transplantation in US and Europe
Vassilopoulos, D. & Calabrese L. H. (2012) Management of rheumatic disease with comorbid HBV or HCV infection

Serologic Pattern of Acute HCV Infection with Recovery

- Symptoms +/-
- HCV RNA
- ALT
- anti-HCV

Titer

Months

Time after Exposure

Years

0 1 2 3 4 5 6 1 2 3 4
Serologic Pattern of Acute HCV Infection with Progression to Chronic Infection

- **anti-HCV**
- **Symptoms +/-**
- **HCV RNA**
- **ALT**

**Time after Exposure**
- Months: 0, 1, 2, 3, 4
- Years: 1, 2, 3, 4

**Titer**
- Normal level
HCV Transmission

- Incubation period is 4-12 weeks (range: 2-24 weeks)
- Transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood, such as:
  - Injection drug use (currently the most common means of HCV transmission in the United States)
  - Receipt of donated blood, blood products, and organs prior to 1992
  - Needlestick injuries in health care settings
  - Birth to an HCV-infected mother
HCV Transmission Cont’

• HCV can also be spread infrequently through
  – Sex with an HCV-infected person (an inefficient means of transmission)
  – Sharing personal items contaminated with infectious blood, such as razors or toothbrushes (also inefficient vectors of transmission)
  – Other health care procedures that involve invasive procedures, such as injections (usually recognized in the context of outbreaks)
  – Intranasal cocaine use, tattooing, and body piercing
HCV Risk Factors

- Injection drug use (IVDU)
- Recipients of clotting factor concentrates made before 1987
- Recipients of blood transfusions or solid organ transplants before July 1992
- Chronic hemodialysis patients
- Persons with known exposures to HCV, such as
  - health care workers after needlesticks
  - recipients of blood or organs from a donor who tested HCV-positive
- Persons with HIV infection
- Children born to HCV-positive mothers
A total of 781 case reports of hepatitis C were received in 2009. More than one risk behavior may be indicated on each case report. Risk data not reported.

A total of 397 hepatitis C cases were reported among males in 2009.

Source: National Notifiable Diseases Surveillance System (NNDSS)

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**Figure 4.6b. Acute hepatitis C reports*, by risk behavior† — United States, 2009**

- **Injection-drug use**: 241 Yes, 191 No, 349 Missing
- **Men who have sex with men**: 1 Yes, 46 No, 347 Missing
- **Sexual contact**: 25 Yes, 128 No, 628 Missing
- **Multiple sex partners**: 94 Yes, 187 No, 500 Missing
- **Household contact**: 5 Yes, 148 No, 628 Missing

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*A total of 781 case reports of hepatitis C were received in 2009.
† More than one risk behavior may be indicated on each case report.
¶ Risk data not reported.
§ A total of 397 hepatitis C cases were reported among males in 2009.
Source: National Notifiable Diseases Surveillance System (NNDSS)
Symptoms of Acute HCV Infection

- Fever
- Fatigue
- Dark urine
- Clay-colored stool
- Abdominal pain
- Loss of appetite
- Nausea
- Vomiting
- Joint pain
- Jaundice

- Newly infected individuals usually asymptomatic or have mild symptoms
HCV Laboratory Testing

- Screening tests for antibody to HCV (anti-HCV)
  - enzyme immunoassay (EIA)
  - enhanced chemiluminescence immunoassay (CIA)
- Recombinant immunoblot assay (RIBA)
- Qualitative tests to detect presence or absence of virus (HCV RNA polymerase chain reaction [PCR])
- Quantitative tests to detect amount (titer) of virus (HCV RNA PCR)
• Clinical description:
  – An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >400IU/L.

*A documented negative HCV antibody laboratory test result followed within 6 months by a positive test (as described in the laboratory criteria for diagnosis) result does not require an acute clinical presentation to meet the surveillance case definition.

Cabinet for Health and Family Services
• **Laboratory criteria:**
  – One or more of the following:
    • Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. ([URL for the signal to cut-off ratios: http://www.cdc.gov/hepatitis/HCV/LabTesting.htm](http://www.cdc.gov/hepatitis/HCV/LabTesting.htm)), OR
    • Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive, OR
    • Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing)
• **Laboratory criteria cont’**:  
  – AND, if done meets the following two criteria:  
    • Absence of IgM antibody to hepatitis A virus (if done) (IgM anti-HAV), AND  
    • Absence of IgM antibody to hepatitis B core antigen (if done) (IgM anti-HBc)

• **Case Classification**  
  – **Confirmed**  
    • A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis C.
• Clinical description:
  – Most hepatitis C virus (HCV)-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.
• Laboratory Criteria for Diagnosis
  – One or more of the following three criteria (except in persons less than 18 months of age, for whom only criteria 3 would meet the case classification criteria):
    • Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/hepatitis/HCV/LabTesting.htm), OR
    • Hepatitis C virus recombinant immunoblot assay (HCV RIBA) positive, OR
    • Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing).
• **Case Classification**
  – **Probable**
    • A case that does not meet the case definition for acute hepatitis C, is anti-HCV positive (repeat reactive) by EIA, and has alanine aminotransferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.
  – **Confirmed**
    • A case that is laboratory confirmed and does not meet the case definition for acute hepatitis C.
HCV Investigations

- **NEDSS ELRs:**
  - All patients (male and female) age 0-18 yrs should be investigated
  - Lab reports other than those described above can remain in your queue for 30 days.
    - If additional lab reports and clinical information are received from a provider, follow up with the provider to determine whether or not it is an acute infection.
    - If no additional information is received from a provider regarding a NEDSS ELR within 30 days, it may be marked as reviewed and removed from your queue.
• **Reports (faxes/mail) from providers:**
  – Educate providers in your jurisdiction regarding reportable diseases and case definitions
  – Follow up with them to see if patient had s/s and/or additional laboratory tests
  – If an acute infection is suspected, contact the patient and interview him/her.
    • Enter the case into NEDSS and submit it to KDPH
  – If an acute infection is not suspected, mark the lab report/EPID 200 as “Appears non-Acute” and file according to your records retention policies

Cabinet for Health and Family Services
HCV Public Health Interventions

- Refer patient to a medical provider to monitor outcome or progress of infection.
- Advise minimizing use of alcohol and other substances known to be toxic to the liver (e.g. Tylenol)
- Educate patient on how to protect others from exposure to HCV infected blood and other body fluids with the practice of good hand washing, and by not sharing personal care items that might have blood on them (e.g. razors, toothbrushes, nail clippers).
- Recommend anti-HCV testing for exposed sexual partners and protecting partners from contact with blood, semen, vaginal secretions, and other body fluids. Use of latex condoms may prevent HCV transmission.
HCV Public Health Interventions

- Testing of household contacts is not necessary unless they have had an identifiable blood exposure to the patient.
- Advise infected mothers of infants to practice good hand washing after contact with blood, to cover skin lesions and to refrain from breast-feeding if their nipples are cracked or bleeding.
- HCV infected persons should be vaccinated against Hepatitis A and B, if not immune.
- HCV infected persons should not donate blood, organs, or tissue.
Questions?

T.J. Sugg, MPH
Epidemiologist
Reportable Diseases
Infectious Disease Branch
Kentucky Department for Public Health
Phone: 502.564.3261 x 3520
Fax: 502.564.0542
Secure Fax: 502.696.3803
Email: Tennis.Sugg@ky.gov
Hepatitis B

Kristy Royalty, RN, BSN
Reportable Disease Section
Division of Epidemiology and Health Planning
Department for Public Health
Hepatitis B (HBV)

- HBV is a small, double-shelled virus in the family Hepadnaviridae
Hepatitis B (HBV)

• Humans are the only known host
• HBV is relatively resilient and may retain infectivity for more than 7 days at room temperature
• Approximately 2 billion persons worldwide have been infected with HBV
  – More than 350 million have chronic infections
• Cause of 80% of hepatocellular carcinomas
Acute Hepatitis B Clinical Features

- Incubation period is 45-160 days with an average of 90 days
- Varied and sometimes vague signs and symptoms may include:
  - Anorexia
  - Nausea
  - Malaise
  - Right upper quadrant abdominal pain
  - Dark urine
  - Jaundice
- Illness is not specific for HBV
- At least 50% of adults with acute HBV infections are asymptomatic
Acute Hepatitis B Clinical Features

• The likelihood of developing symptoms of acute hepatitis is age dependent:
  – <1% of infants younger than 1 year of age
  – 5% to 15% of children ages 1 through 5 years
  – 30% to 50% of people older than 5 years of age are symptomatic

• The risk of developing chronic infection is inversely associated with age
  – >90% of infants infected at birth or in their first year of life
  – 25% to 50% of children ages 1 to 5 years
  – 5% to 10% of older children and adults

2012 Red Book
Hepatitis B

Risk of Chronic HBV Carriage by Age of Infection

Carrier risk (%)

Birth, 1-6 mo, 7-12 mo, 1-4 yrs, 5+ yrs

Age of infection

CDC
Incidence of Reported Acute HBV in KY

Incidence of Reported Acute Hepatitis B
Kentucky 2005-2011

Rate per 100,000

2005  2006  2007  2008  2009  2010  2011

67*  69*  76*  101*  90*  136*  151*

* = Number of cases
HBV Epidemiology

• HBV is transmitted through infected body fluids. Substances capable of transmitting HBV include:
  – Blood and blood products
  – Saliva
  – Cerebrospinal fluid
  – Peritoneal, pericardial, and pleural fluids
  – Synovial, amniotic, seminal, and vaginal fluids
  – Other body fluids containing blood
  – Unfixed tissues and organs

• Persons with chronic HBV infection are the primary reservoirs for infection
Hepatitis B Risk Factors

Transmission is by parenteral or mucosal exposure to HBsAg-positive body fluids from persons who have acute or chronic HBV infection

- Sharing or using nonsterilized needles, syringes or glucose monitoring equipment or devices
- Sexual contact with an infected person
- Perinatal exposure to an infected mother
- Household exposure to a person with chronic HBV infection (especially in areas with a high prevalence of HBV infection)

- Transmission by contaminated blood or blood products is rare in the US due to routine screening

2011 Pink Book and 2012 Red Book
2012 Acute Hepatitis B Case Definition

- **Clinical Description**
  - An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels > 100 IU/L.

  - *a documented negative hepatitis B antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B “e” antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.
2012 Acute Hepatitis B Case Definition

• **Laboratory Criteria for Diagnosis**
  – HBsAg positive, AND
  – Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

• **Case Classification**
  – Confirmed
    • A case that meets the clinical case definition is laboratory confirmed, and is not known to have chronic hepatitis B.
• **Clinical Description**
  • No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

• **Laboratory Criteria for Diagnosis**
  – Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a 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 and genotype testing), OR
  – HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)
2012 Chronic Hepatitis B Case Definition

- **Case Classification**
- **Probable**
  - A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.
- **Confirmed**
  - A person who meets either of the above laboratory criteria for diagnosis.
- **Comment**
  - Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a “hepatitis panel.” Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative AND HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.
• KY DISEASE SURVEILLANCE REQUIRES A REPORT TO THE LHD OR STATE DPH WITHIN ONE BUSINESS DAY OF THE IDENTIFICATION OF A CASE OR SUSPECTED CASE
Acute Hepatitis B Investigation

- **Follow general hepatitis investigation procedure**
- **Identify sexual contacts.** If unimmunized, recommend testing for susceptibility if testing does not delay treatment beyond 14 days of the last sexual exposure. If contact is susceptible, recommend:
  1. HBIG, if it can be given within 14 days of the last sexual exposure, **AND**
  2. Initiate hepatitis B vaccine series
- **Identify household contacts.**
  1. If unimmunized, initiate hepatitis B vaccine series for all household contacts.
  2. Recommend immunoprophylaxis for infants younger than 12 months of age if they have close contact with primary caregivers with acute HBV infection. If the infant has been fully immunized or has received 2 doses of vaccine, the infant should be presumed protected, and HBIG is not required. If only one dose of vaccine has been administered, the 2\textsuperscript{nd} dose should be administered if the interval is appropriate, or HBIG should be administered if immunization is not yet due.

2012 Red Book
Acute Hepatitis B Investigation

- Educate case on how to protect others from exposure to the hepatitis B virus
  - Not sharing personal items that may be contaminated with blood or bodily fluid (i.e. razors, toothbrushes, needles, etc…)
  - Using Condoms
  - Disinfect surfaces or equipment contaminated with blood or bodily fluid (household bleach mixed 1:10 with water.)
Hepatitis B Vaccination

• The Advisory Committee on Immunization Practices recommends that the following persons be vaccinated against Hepatitis B:
  • All infants, beginning at birth
  • All children aged <19 years who have not been vaccinated previously
  • Susceptible sex partners of Hepatitis B surface antigen (HBsAg)-positive persons
  • Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
  • Persons seeking evaluation or treatment for a sexually transmitted disease
  • Men who have sex with men
  • Injection drug users
Hepatitis B Vaccination

- Susceptible household contacts of HBsAg-positive persons
- Health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to regions with intermediate or high rates of endemic HBV infection
- Persons with chronic liver disease
- Persons with HIV infection
- Unvaccinated adults with diabetes mellitus who are aged 19 through 59 years (discretion of clinicians for unvaccinated adults with diabetes mellitus who are aged ≥60 years)
- All other persons seeking protection from HBV infection — acknowledgment of a specific risk factor is not a requirement for vaccination

Cabinet for Health and Family Services
• The vaccination schedule most often used for children and adults is
  – 3 intramuscular injections
  – The 2\textsuperscript{nd} and 3\textsuperscript{rd} doses administered 1 and 6 months, respectively, after the first dose.
  – Alternate schedules have been approved for certain vaccines and/or populations.
Questions?

Kristy Royalty, RN, BSN
Nurse Consultant
Reportable Diseases
Infectious Disease Branch
Kentucky Department for Public Health
Phone: 502.564.3261 x 3234
Fax: 502.564.0542
Secure Fax: 502.696.3803
Email: KristenRoyalty@ky.gov
Perinatal Hepatitis B Prevention Program

Julie Miracle, RN, BSN, CPAN
KY Perinatal Hepatitis B Prevention Program Coordinator
• Hepatitis B surface antigen (HBsAg) positivity in any infant aged > 1-24 months who was born in the United States or in U.S. Territories to an HBsAg-positive mother
Risk of Chronic Infection related to age

- 90% Infants will become chronically infected if infected prior to 1 year of life
- 25% to 40% will become chronically infected if infected between 2-5 years of age
- In contrast, ~ 95% adults recover completely from infection and do not become carriers

- From the CDC website: HBV FAQs for Health Professionals
Strategies to Eliminate HBV in US

- Universal immunization of infants beginning at birth
- Prevention of perinatal HBV infections through routine screening of ALL pregnant women and appropriate treatment of infants born to HBsAg-positive mothers
- Routine immunization of adolescent children who previously have not been vaccinated.
- Immunizations of unimmunized adults at-risk for HBV infections.
Hepatitis B Vaccine (HepB)

- Hepatitis B vaccine can prevent hepatitis B virus infection
- It is routinely given as a 3 dose series
- 95% efficacy rate (range 85-100%)
- The **MOST EFFECTIVE** way to prevent HBV infections is pre-exposure immunization.
Hepatitis B Vaccine continued

- Effectiveness of postexposure treatment depends on length of time between exposure and treatment.
- The rate of new HBV infections has declined 82% since 1991.
- Greatest decrease in children and teens. (98% decrease in children under 19.) Vaccine success.
## Hepatitis B Vaccine Schedule for Infants

<table>
<thead>
<tr>
<th>DOSE</th>
<th>USUAL AGE</th>
<th>MINIMUM INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIMARY 1</td>
<td>BIRTH</td>
<td>----------------</td>
</tr>
<tr>
<td>PRIMARY 2</td>
<td>1-2</td>
<td>4 WEEKS</td>
</tr>
<tr>
<td>PRIMARY 3</td>
<td>6-18 MONTHS*</td>
<td>8 WEEKS**</td>
</tr>
</tbody>
</table>

*infants whose mother are HBsAg (+) or whose status is unknown should receive the third dose by 6 months of age

**at least 16 weeks after the first dose. Minimal age of 24 weeks
Hepatitis B Birth Dose

- ACIP recommends all newborns should receive the birth dose of hepatitis B vaccine prior to discharge from the birthing facility.
  - Key element in the elimination of hepatitis B infections
  - Prevents at-risk infants from falling through the cracks
  - Increases likelihood of series completion
  - Healthcare providers need to support the birth dose.
## HepB Schedule for Adults/Adolescent

<table>
<thead>
<tr>
<th>DOSE</th>
<th>USUAL INTERVAL</th>
<th>MINIMAL INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>---------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Primary 2</td>
<td>1 month</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3</td>
<td>5 months</td>
<td>8 weeks*</td>
</tr>
</tbody>
</table>

*Third dose must be separated from first dose by at least 16 weeks*
Hepatitis B Immune Globulin (HBIG)

- Used in postexposure prophylaxis
- Passive Immunity
- Provides short term protection for 3-6 months
- 85-95% effective in preventing perinatal infection if given with HepB vaccine.
The goal of the KY Perinatal Hepatitis B Prevention Program is to reduce the incidence of perinatal hepatitis B infections in Kentucky.
KY law (KRS 214.160) mandates all pregnant women be screened for hepatitis B surface antigen (HBsAg) during each pregnancy.

- Those with positive (+) results must be reported to LHD in the patient’s county of residence or to the State Health Department.

- High risk mothers, previously tested and HBsAg(-), and mothers with unknown HBsAg status must be tested at the time of admission to the hospital for delivery.
Serology Testing

• Serology markers of HBV infection vary depending on whether the infection is acute or chronic

• HBsAg is the most commonly used test for diagnosing HBV infection (both acute and chronic)

• The presence of HBsAg indicates the person is infectious regardless of acute or chronic status

• Anti-HBc (core antibodies) develops in all HBV infections and indicates infections at some undefined past.

• IgM Anti-HBc is a marker for acute infections

From the CDC’s Viral Hepatitis Website
Serology Testing

• IgM anti-HBc(-) with HBsAg(+) indicates chronic infection. Anti-HBc should also be positive.

• HBeAg is a marker associated with the number of infective HBV particle in the serum and high infectivity.

• Anti-HBs (surface antibodies) is a protective neutralizing antibody.

• Presence of Anti-HBs after infection indicates recovery and natural immunity

• Quantitative Anti-HBs Antibody level (Ten mIU/mL or greater) indicates immunity after hepatitis B vaccine series

From the CDC Viral Hepatitis Website.
# Interpretation of HBV Serologic Testing

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Negative</td>
<td>Susceptible</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBsAg</td>
<td>Negative</td>
<td>Immune due to vaccination</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Positive with ≥10mIU/mL</td>
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</tr>
<tr>
<td>HBsAg</td>
<td>Negative</td>
<td>Immune due to natural infection</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Positive</td>
<td></td>
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# Interpretation of HBV Serologic Tests

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<th>Tests</th>
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<tbody>
<tr>
<td>HBsAg</td>
<td>Positive</td>
<td>Acute Infection</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. May be recovering from acute infection.</td>
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<td></td>
<td></td>
<td>2. May be distantly infected and test is not sensitive enough.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. May be susceptible with a false positive anti-HBc</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. May be chronically infected and have a undetectable HBsAg level.</td>
</tr>
</tbody>
</table>

## Table of Results

<table>
<thead>
<tr>
<th>Tests</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>IgM Anti-HBc</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

## Additional Notes
- Positive Anti-HBc with negative HBsAg: may be recovering from acute infection.
- Positive Anti-HBc with negative HBsAg: may be distantly infected and test is not sensitive enough.
- Positive IgM anti-HBc: may be susceptible with a false positive anti-HBc.
- Negative HBsAg with positive Anti-HBc: may be chronically infected and have an undetectable HBsAg level.
Perinatal Risk of Exposure

• Without postexposure prophylaxis to the infant born to HBsAg-positive woman the risk of infection is:
  
  ▶ 70% to 90% for the infant if the mother is both HBsAg and HBeAg positive

• Compare to
  
  ▶ 5% to 20% for the infant if the mother HBsAg positive but HBeAg negative.
Perinatal HBV Management

• All babies born to HBsAg-positive mothers must receive Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) 0.5mL in different sites within 12 hours of birth to protect them from HBV infection.

• When HBsAg status is unknown, HBIG can be held for infant weighing greater than 2,000 if the HBsAg testing can be completed prior to discharge. HBIG must be given to infants weighting less than 2,000 grams if HBsAg is unknown at time of delivery.

• HBIG must be given within 7 days.

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Perinatal HBV Management

• The infant must complete a valid hepatitis B vaccine series with the second dose at 1-2 months of age and third dose at 6 months of age.

• Serology testing for HBsAg and Quantitative Anti-HBs is recommended at 9-15 months of age.
# Post Vaccination Serology Results

<table>
<thead>
<tr>
<th>Serology Test</th>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg…………………..</td>
<td>Negative</td>
<td>Immunity to HBV. Case Closed</td>
</tr>
<tr>
<td>Quantitative Anti-HBs…</td>
<td>Ten mIU/mL or greater</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg…………………..</td>
<td>Positive</td>
<td>Report to NEDSS as perinatal hepatitis B infection</td>
</tr>
<tr>
<td>Quantitative Anti-HBs…</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg…………………..</td>
<td>Negative</td>
<td>Not immune. Some people repeat vaccination with a 3 dose series of a different brand of monovalent vaccine. Repeat serology testing 2 months after last dose of vaccine.</td>
</tr>
<tr>
<td>Quantitative Anti-HBs…</td>
<td>Less than ten mIU/mL</td>
<td></td>
</tr>
</tbody>
</table>
Preterm Infants Born to HBsAg (+) Moms

- Infants born to HBsAg (+) or unknown status mothers and who weigh less than 2000 grams must be given HBIG and hepatitis B vaccine within 12 hours of birth.
- This birth dose will not be counted in the three dose series.
- The 3 dose series should start at 1 month of age.
Preterm Infants Born to HBsAg (+) Moms

- Dose one of the three dose series should be started at one month of age or at least 4 weeks from the birth dose.
- Dose two should be administered 1-2 months later.
- Third dose of the series should be given at 6 months of age.
- Check Quantitative Anti-HBS and HBsAg at 9-18 months of age.
Challenges to the PHBPP

- CDC indicates approximately only 50% of expected births to HBsAg(+) mothers are identified.
- 1-2% of all deliveries will be born to HBsAg(+) mothers.
- In KY that will be about 95-160 infants born to HBsAg(+) mothers (From The PHBPP Birth Table 2008)
- Our program identified 49 cases in 2009, 80 cases in 2010, and 58 cases in 2011
- Case management can follow mother and child for over a two-three year period until serology is completed on infant.
Challenges to the PHPP

• The following are the reasons babies may not being reported:
  ❖ Healthcare providers awareness of reporting requirements
  ❖ Communication errors
  ❖ Documentation errors
  ❖ Testing errors
Who Can Identify a Case

- Private Providers (EPID-394)
- Laboratory Facility Reports (NEDSS)
- DPH Reportable Disease Section (NEDSS)
- Perinatal Hepatitis B Coordinator
- Birthing Hospitals at time of delivery (EPID-399)
- LHD personnel (EPID-394 & initiate the EPID 395)
Roles of the LHD & LHD Nurse in PHBPP

- Each LHD must have nurse delegated to manage Perinatal Hepatitis B Prevention Cases for their agency. *(Perinatal Hepatitis B Prevention Nurse Case Manager)*
Roles Cont.

• Determine pregnancy status on all HBsAg(+) women between 11-46.

• Contact, counsel and offer vaccination to all pregnant women and postpartum women who are at high risk and susceptible.

• Pregnancy and Lactation are not a contraindication for vaccination
• Initiate Case Management/Follow-up which includes:
  ❖ Review all EPID-394 forms or cases reported in NEDSS—research and complete missing information
  ❖ May use an EPID-395 form for case management
  ❖ Counsel the pregnant woman concerning HBV infection, Transmission, vaccination, and prevention of perinatal hepatitis B infection in her newborn
Roles Cont.

• Identify, counsel, test, and if susceptible vaccinate all sexual and household contacts

• Track
  ❖ Infant delivery
  ❖ Administration of Hepatitis B vaccine series & HBIG
  ❖ Serology testing of the infant

• Send all updates to the State Perinatal Hepatitis B Coordinator, Julie Miracle, RN, BSN, CPAN
EPID 394, 395, and 399 Forms

• These forms are used to report Perinatal Hepatitis B Infection in a Pregnant Woman or Child.

• The provider, hospital or lab facility completes the forms and forwards them to the LHD or DPH when a case is identified. Some providers will use an EPID 200.

• EPID 395 is used for case management of these at-risk infants.

• Copy of all the forms are in your handouts.
EPID 399 Form

PERINATAL HEPATITIS B PREVENTION FORM FOR INFANTS

<table>
<thead>
<tr>
<th>Full name of patient</th>
<th>Date of birth</th>
<th>Time of birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name(s) of parent(s)</td>
<td>County of residence</td>
<td>Weight at vaccination</td>
</tr>
<tr>
<td>Patient’s address</td>
<td>Obstetrician’s name</td>
<td>Pediatrician’s name</td>
</tr>
<tr>
<td>City</td>
<td>State</td>
<td>Zip</td>
</tr>
</tbody>
</table>

**Phone Number**

<table>
<thead>
<tr>
<th>Biological Administered</th>
<th>Date</th>
<th>Time</th>
<th>Dosage</th>
<th>Manufacturer &amp; Lot No.</th>
<th>BN Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B Vaccine</td>
<td></td>
<td></td>
<td>0.5cc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBIG</td>
<td></td>
<td></td>
<td>0.5cc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If vaccine not given, please specify reason: __________________________________________

**HBsAg testing**

<table>
<thead>
<tr>
<th>Yes</th>
<th>Pending</th>
<th>*see below</th>
</tr>
</thead>
</table>

**Mother’s HBsAg Status**

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
<th>Date of Mother’s lab work</th>
</tr>
</thead>
</table>

***Notify the Infection Control nurse in your facility if the mother is HBsAg positive***

*Pending ( ) A pending HBsAg is acceptable only if blood has been drawn and sent to a laboratory. Attempt to obtain a verbal report of result from laboratory before the infant is discharged. If HBsAg is pending (name) at (phone number) is responsible for confirming the laboratory results and telephoning the health department if the mother is HBsAg positive. If mother did not have HBsAg testing during prenatal care or if results are not available please collect at the time of delivery and review results prior to discharge.

**Telephone positive results to the local health department immediately. Infants born to HBsAg positive mothers must receive 0.5cc Hepatitis B vaccine and 0.5cc HBIG.**

<table>
<thead>
<tr>
<th>Name of Hospital or Other Institution</th>
<th>Telephone Number</th>
</tr>
</thead>
</table>

Appropriate screening of pregnant women is an important step in the strategy to prevent perinatal hepatitis B infection. To decrease the perinatal transmission of hepatitis B, all pregnant women in Kentucky must be screened for hepatitis B surface antigen (HBsAg). State legislation mandating the testing became effective July 13, 1998. Administrative regulation 902 KAR 2-020 requires all licensed health professionals and facilities to report hepatitis B in a pregnant woman to the local or state health department. This form is required to be completed on all infants born to HBsAg positive mothers and those whose HBsAg status is pending or unknown to ensure adequate follow-up of reportable disease. It is suggested that the form be completed on all births to confirm every pregnant woman’s status has been verified and the infant has been treated appropriately.

White copy to LHD, Canary copy to parent, Pink copy to hospital, Goldenrod copy to physician

EPID-399
What to do with a EPID 399

- Review form for completion and accuracy
- Review lab reports/ results
- Screen the form for infant vaccination history
  - Hepatitis B vaccine received
  - HBIG given to infants of HBsAg-positive mother and mother of HBsAg-unknown status.
What to do with EPID 399 Forms

• **ALL HBsAg-POSITIVES** must be forwarded to the LHD Perinatal Hep. B Nurse Case Manager and/or to Julie Miracle, KY Perinatal Hepatitis B Prevention Program Coordinator
Important Reminders

- A complete and accurate EPID 399 form is imperative for timely completion of case management for at risk infants.
- Communication is essential to a successful Perinatal Hepatitis B Prevention Program.
- You provide one of the most important steps of management and prevention of hepatitis B infections in at risk infants.
Resources

- Immunization Action Coalition at http://www.immunize.org/
- CDC Information on Perinatal Hepatitis B Prevention at http://www.cdc.gov/hepatitis/HBV/PerinatalXmtn.htm
- Educational materials at http://www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm
Questions? Call or Email DPH

Julie Miracle, RN, BSN, CPAN
502-564-4478 ext. 4038
Fax 502-564-4760
Julie.Miracle@ky.gov

Margaret Jones, RN, BSN, BSEd
502-564-4478 ext. 3514
Margaret.Jones@ky.gov