Unprotected Infant Dies of Fulminant Hepatitis B

The Immunization Action Coalition (IAC) publishes Unprotected People Reports about people who have suffered or died from vaccine-preventable diseases. Nancy Fasano, formerly of the Michigan Department of Community Health, submitted the following case report to IAC. Serious medical errors occurred in this case resulting in the death of a 3-month-old infant. Take measures to make certain that errors such as these do not occur in your practice or hospital. Up to 95% of perinatal infections can be prevented by post-exposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to hepatitis B at birth but do not receive appropriate postexposure prophylaxis. Prevent tragedies like these by administering the first dose of hepatitis B vaccine to all newborns at birth, no later than hospital discharge.

Case Report

On December 13, 1999, a previously healthy 3-month-old infant of Southeast Asian descent was brought to a local Michigan hospital emergency department and was admitted following a 5-day history of fever, diarrhea, and jaundice.

Upon admission to the hospital, hepatitis B serology was obtained along with liver function tests and liver enzymes. Laboratory results revealed that the infant was hepatitis B surface antigen (HBsAg) positive and IgM core antibody (IgM anti-HBc) positive with elevated total bilirubin 16.6, direct bilirubin 4.7, ALT 693, and AST 203. The infant’s test results were reported to the local health department on December 14, 1999. The infant’s mother was tested at the same time and was found to be HBsAg positive and anti-HBc positive.

A diagnosis of hepatic failure due to hepatitis B virus (HBV) infection was made and the infant was transferred to another hospital on December 16 for possible liver transplantation. After transfer, the infant developed seizures and her condition deteriorated rapidly. She died on December 17.

Investigation revealed that the infant’s mother had tested positive for HBsAg during her pregnancy but that the test result was communicated incorrectly as “hepatitis negative” to the hospital where the baby was born. Neither the laboratory nor the prenatal care provider reported the HBsAg-positive test results to the local health department as required by state law. The infant received no hepatitis B vaccine and no hepatitis B immune globulin (HBIG) at the time of birth.

The hospital where the infant was born had suspended administration of hepatitis B vaccine to all newborns during the summer of 1999 due to the concern about the presence of thimerosal used as a preservative in hepatitis B vaccine. The first dose of hepatitis B vaccine wasn’t administered to this infant until two months of age. This tragedy could have been averted.

Protect EVERY newborn from hepatitis B virus infection!

Give the first dose of hepatitis B vaccine before hospital discharge.

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A discussion follows on the next page
Discussion

Serious medical errors occurred in this case resulting in the death of the infant. The following errors occurred:

1. The HBsAg-positive test result was not conveyed to the pregnant woman by her physician.
2. The physician failed to report the HBsAg-positive test result to the local health department as mandated by state law.
3. The laboratory that performed the test did not notify the local health department of the positive result.
4. The HBsAg test result was transcribed incorrectly on the prenatal record which was sent to the hospital. A copy of the original lab report did not accompany the prenatal record.
5. The HBsAg test result was not verified by the perinatal staff; they did not review a copy of the actual lab report.
6. There was no hospital protocol in place to vaccinate infants who live in communities at high risk for early HBV exposure.

Take measures to assure that errors such as these do not occur in your practice or hospital.

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Make sure that a tragedy like this never happens again!

If you provide prenatal care

- Test every pregnant woman during each pregnancy for HBsAg, regardless of her hepatitis B vaccination status.
- Send a copy of the original lab report along with other prenatal records to the hospital where the woman will deliver.
- Notify the local or state health department* of any positive HBsAg test result in a pregnant woman.
- Counsel the pregnant woman about the implications of her positive HBsAg test result (e.g., the need for her to receive ongoing medical evaluation and the need for household and sexual contacts to be tested and vaccinated).
- Communicate the woman’s positive HBsAg status to the clinician who will provide pediatric care to the newborn.

If you work in a hospital labor & delivery unit or newborn nursery

- Know the HBsAg status of every woman giving birth in your facility. A copy of the original lab report should be part of the prenatal record.
- Don’t let any infant slip through the cracks. Administer the first dose of hepatitis B vaccine in the hospital to all newborns.
- Develop hospital policies to assure that all mothers are screened for HBsAg and all newborns are appropriately managed to prevent HBV infection.

If you provide pediatric care to newborns

- Know the HBsAg status of mothers of all infants for whom you provide care.
- Help assure that no babies are infected due to a medical error. Make sure that all newborns under your care receive the first dose of hepatitis B vaccine at birth, before hospital discharge.
- Know the risk groups for HBV infection.

* If you do not know whom to contact at the state/local health department, contact the perinatal hepatitis B coordinator for your state. Contact information can be found at www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm.

Hepatitis B: What Hospitals Need to Do to Protect Newborns

www.immunize.org/protect-newborns