

States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention

Avoid tragic mistakes—vaccinate newborns against HBV in the hospital

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On two annual surveys conducted by the Immunization Action Coalition covering the period from July 1999 to October 2002, state and local hepatitis coordinators reported more than 500 medical errors regarding perinatal hepatitis B prevention. Examples of types of errors included

- not properly prophylaxing infants born to HBsAg-positive mothers with both hepatitis B vaccine and HBIG within 12 hours of birth
- not giving hepatitis B vaccine to infants born to mothers of unknown HBsAg status within 12 hours of birth
- misinterpreting or mistranscribing hepatitis B screening test results, or failing to communicate results to or within the hospital
- ordering the wrong hepatitis B screening test

Because of these types of errors, many children are now chronically infected with hepatitis B virus (HBV) and at least one infant has died. Children infected when less than one year of age have a 90% chance of developing chronic HBV infection with all its serious potential sequelae, such as cirrhosis and liver cancer.

Consider the following examples reported by the nation's hepatitis coordinators where infants were needlessly put at risk for perinatal HBV infection.

Medical Error Type #1: Infants born to HBsAg-positive mothers did not receive both hepatitis B vaccine and HBIG within 12 hours of birth.

Recommendation of the Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG): All infants of HBsAg-positive mothers (including premature infants) should receive hepatitis B vaccine and HBIG within 12 hours of birth.

Case report examples:

- “The mother had been diagnosed with chronic hepatitis B in 1994. In her prenatal record she was documented to be HBsAg and HBeAg positive, and this information appeared in several places on the record that was sent to the hospital. Despite this, her baby did not receive HBIG or the first dose of hepatitis B vaccine in the hospital. In fact, the hepatitis B vaccine order was crossed out in the infant's chart. Follow-up

with the pediatrician on day six indicated that the baby still had not received any prophylaxis. The first dose of vaccine was given when the infant was three weeks of age, the second dose three months after the first, and the third dose six months after the first. The child's current status is unfortunate. Diagnosed HBsAg-positive at 19 months of age, the child is now being followed by a liver specialist for chronic hepatitis B.”

- “We have two cases where infants born to carrier mothers received the first dose of hepatitis B vaccine three weeks after birth and no HBIG. In one of the cases, a resident interviewed the mother who claimed she was not HBsAg positive.”
- “In 2000, we had 25 cases where the babies of positive moms did not receive HBIG at birth. Three of these babies are now infected. In one of the cases, the mother's status was erroneously marked as unknown, another was marked as negative, and in one the status was correctly marked, but the HBIG was still not given.”
- “In 2000, there were eight infants of HBsAg-positive mothers who never received HBIG and six who did not get hepatitis B vaccine within 12 hours of birth. This is despite letters to the hospital and to the OB/GYN prior to the birth.”
- “In one case in a rural hospital, the mother's positive hepatitis B status was documented in her chart and the infant's chart, which were seen by many nurses and three pediatricians, but no prophylaxis was ever initiated.”
- “For 1999 and 2000, of the 771 infants born to HBsAg-positive women in our state, 30 did not receive HBIG at birth, 10 did not receive the first dose of vaccine, and 9 didn't receive either.”

Medical Error Type #2: Infants born to mothers of unknown HBsAg status were not properly prophylaxed.

Recommendation of CDC, AAP, AAFP, and ACOG: If the mother's HBsAg status is unknown, infants must receive hepatitis B vaccine within 12 hours of birth. For premature infants weighing less than 2kg, HBIG is also given. [Authors' note: It's not recommended to wait for the HBsAg lab result to determine your course of action. Order hepatitis B vaccine from the pharmacy and give it immediately—within 12 hours of birth.]

Case report examples:

- “The mother's positive lab result was not re-

ceived before she was discharged, and the hospital did not have a universal hepatitis B birth dose policy. The infant did not receive HBIG or the first dose of vaccine within the recommended time frame.”

- “During a hospital audit, I found one case where the vaccine had been withheld for 25 hours while the staff awaited the results of the ‘stat’ HBsAg blood work on a mother of unknown status.”
- “In one case a mother came in with no prenatal care. The intern did not think she *looked* high risk. She turned out positive. Her child did not receive vaccine.”
- “The mother was known to be HBsAg positive with a previous pregnancy; however, with this pregnancy the woman did not receive prenatal care and reported to a different hospital in active labor. HBIG and hepatitis B vaccine were not given until two days after birth, when the mother was found to be HBsAg positive.”
- “The mother's status was unknown at birth. She left the hospital without the baby being vaccinated. She gave a fictitious address.”
- “This mom had no prenatal care, knew she was a carrier, but gave no indication of her HBsAg status when admitted. The hospital ran tests on mom at delivery, but it wasn't until two days later when the lab results came back positive that the baby was treated with HBIG and hepatitis B vaccine.”
- “My survey found 36 women unscreened in a six-month period. Ten infants did not get vaccine.”

Medical Error Type #3: Screening test results were misordered, misinterpreted, mistranscribed, or miscommunicated.

To avoid these types of errors, CDC recommends that a copy of the mother's original HBsAg lab report be sent to the birthing hospital as part of the prenatal record. Labor and delivery units and nursery units should carefully review this original lab report to determine the appropriate course of action. Do not rely on transcribed results!

Case report examples:

- “We had a mom who was reported to the hospital as HBsAg negative by the prenatal care provider. Unfortunately, this woman was actually HBsAg positive. The baby did not receive HBIG or the birth dose of hepatitis B vaccine, and by three

months of age developed fulminant hepatitis B and died.”

- “In June 2002, a situation occurred where an infant born to an HBsAg-positive mother at a large teaching hospital was not appropriately treated with hepatitis B vaccine and HBIG at birth. A full investigation was launched, and it was found that although the mother’s HBsAg status was clearly marked on the prenatal record as ‘reactive,’ a resident at the hospital mis-transcribed the mother’s HBsAg status onto the hospital chart as ‘negative.’”
- “On an average, we receive ten newborn screening forms each month that indicate a misinterpreted or mistranscribed maternal hepatitis B status.”
- “We find that doctors’ offices sometimes have a positive result in the mother’s chart and neglect to look at it. Or they order labs and neglect to notice that they were never drawn.”
- “Three infants were born to HBsAg-positive mothers where the hospital record erroneously indicated that the mothers were negative for HBsAg. The babies were not prophylaxed within 12 hours with HBIG and hepatitis B vaccine.”
- “In two cases, the mothers were tested prenatally and the mothers’ charts showed positive HBsAg test results. However, the HBsAg test result was documented as negative in the infants’ charts, resulting in neither HBIG nor hepatitis B vaccine being given. In two other cases, the positive results were transcribed incorrectly in the mothers’ charts as negative.”
- “The hospital nursery claimed they had a record of the mother being HBsAg negative. The baby was not immunized at time of birth, although the health department had a copy of the lab slip indicating that mom was HBsAg positive. The OB’s office claimed that they did not have this lab slip in the patient’s chart but later confirmed that mom was HBsAg positive.”
- “We have two cases due to transcription error. The children are now positive.”
- “Concerning an HBsAg-positive mom, I was told by both the doctor and nurse that this meant that the woman had hepatitis B antibodies.”
- “The physician’s interpretation of a mother’s prenatal HBsAg-positive lab was ‘hepatitis B negative.’ This infant was not given HBIG or vaccine prior to hospital discharge. The hospital records recorded the physician’s interpretation of the lab rather than the actual lab results. This child is now HBsAg positive.”

Medical Error Type #4: Pregnant women were screened using the incorrect hepatitis B test

Recommendation of CDC, ACOG, AAP, and AAFP: The hepatitis B screening test to order for each and every pregnancy is HBsAg (hepatitis B surface antigen). [Authors’ note: The standard screening test is NOT antibody to hepatitis B surface antigen (anti-HBs or HBsAb), anti-

body to hepatitis B core antigen (anti-HBc or HBcAb), HBeAg, anti-HBe, or HBV-DNA. These tests are easily confused and often misordered since some differ only by a single letter. Ordering the wrong lab test can be a fatal error.]

Case report examples:

- “We have examples of approximately 25 such cases: we ask for copies of the labs and we find that anti-HBs has been frequently ordered.”
- “We get reports of the wrong screening test ordered, including HBcAb and HBV-DNA.”
- “Two maternal records were found to have anti-HBc documented instead of HBsAg. In one hospital, cord blood was used to test mother’s HBsAg status.”
- “We see anti-HBs erroneously ordered in clinics and hospitals for unscreened women. We also see HBsAg ordered correctly in the hospitals but sent to the labs requesting an anti-HBs test. These appear to be errors and lack of knowledge on the part of the physicians and other hospital staff. Most disturbing is that it has never been noticed by the physicians, lab staff, or nursing staff until it is brought to their attention by health department staff. We also see physicians who only order HBsAg screening for the first pregnancy and none of the following pregnancies, and also those who order only anti-HBs when their patient has had the vaccine series.”

Conclusion

As these examples demonstrate, medical errors in perinatal hepatitis B prevention can occur at any time—beginning with the woman’s first prenatal visit and extending beyond the mother’s and infant’s hospital discharge. The errors described in this article are only the “tip of the iceberg.” Most errors remain undiscovered. CDC estimates that annually about 12,000 HBsAg-positive women are not reported to their state’s perinatal hepatitis B program and therefore do not benefit from case management. Less than half (48%) of the expected infants born to HBsAg-positive mothers are identified for case management. In terms of a “safety net” for these infants, a 2007 CDC survey found that nationwide, only 51% of infants received the first dose of hepatitis B vaccine within two days. Putting these numbers together, one can conclude that many high-risk infants are not being identified and protected against HBV infection.

Errors are made by a broad range of perinatal healthcare workers including obstetricians, family physicians, pediatricians, nurses, lab technicians, and clerical staff, and these errors occur in hospitals as well as in primary care settings. While you may be following the national recommendations for the patients under your care, you can’t be certain about everyone else. Human error will never be eliminated.

Only a universal hepatitis B vaccine birth dose policy in every hospital will optimize the protection of all infants from human error and chronic

HBV infection. If your hospital isn’t vaccinating every infant against hepatitis B virus infection prior to discharge, IAC urges you to work together with your hospital, your medical staff, and your local and/or state health departments to institute this lifesaving policy in your hospital. The words of one hepatitis coordinator (whose state experienced an infant death from fulminant hepatitis B) make the case for this policy: “Life is messy, and giving the birth dose is the best way to avoid worst-case scenarios.”

For resources and ideas to help you, including all responses to IAC’s 2001 and 2002 birth dose surveys, related journal articles, and more, visit the Immunization Action Coalition’s birth dose web pages at www.immunize.org/birthdose.

Other Related Resources

“A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States.” Source: *MMWR*, 2005, Vol. 54(RR16). www.cdc.gov/mmwr/pdf/rr/rr5416.pdf

“Hospitals and Doctors Sued for Failure to Protect Newborns from Hepatitis B Virus Transmission.” Source: Immunization Action Coalition (IAC). www.immunize.org/catg.d/p2061.pdf

“Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent HBV Transmission to Newborns.” Source: IAC. www.immunize.org/catg.d/p2130.pdf

“Give the Birth Dose... Hepatitis B Vaccine at Birth Saves Lives!” Source: IAC. www.immunize.org/catg.d/p2125.htm

“Recommended Childhood Immunization Schedule.” Source: ACIP, AAP, AAFP. www.cdc.gov/vaccines/recs/schedules/child-schedule.htm

“General Recommendations on Immunization” Source: *MMWR*, 12/1/06, Vol. 55(RR15):1-48. www.cdc.gov/mmwr/PDF/rr/rr5515.pdf

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