

Medical Errors Put Infants at Risk for Chronic Hepatitis B Virus Infection – Six Case Reports

Since 1990, New York state has had a law mandating hepatitis B surface antigen (HBsAg) testing of all pregnant women, reporting of positive HBsAg results, and treatment of infants born to HBsAg-positive women. Compliance with these mandates and current Centers for Disease Control and Prevention recommendations for perinatal hepatitis B prevention is closely monitored through routine visits to birthing hospitals to conduct record reviews and provide education for hospital staff. Despite these efforts, medical errors continue to be made that put infants at risk for chronic hepatitis B virus (HBV) infection. These errors underscore the importance of administering the first dose of hepatitis B vaccine at birth, before discharge from the hospital.

Although 85%–95% percent of perinatal hepatitis B virus infections can be prevented by appropriate prophylactic treatment, many newborns don't receive such prophylaxis. Approximately 90% of infants who become infected will develop chronic HBV infection with all its serious potential sequelae, including possible cirrhosis and liver cancer later in life. To better protect newborns against chronic HBV infection, the New York State Department of Health Immunization Program provides state-funded hepatitis B vaccine, free of charge, to any birthing hospital that institutes a universal hepatitis B birth dose policy.

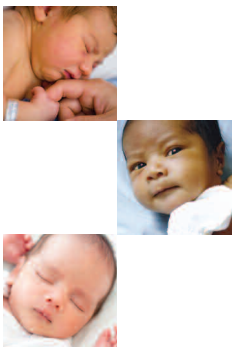
The following six cases from New York were reported in April 2005 by Elizabeth J. Herlihy, RN, BSN, MS, who was the New York State Department of Health's hepatitis B coordinator at that time. The cases illustrate a variety of medical errors that led to high-risk newborns not receiving the recommended hepatitis B prophylaxis (0.5 mL hepatitis B vaccine and 0.5 mL hepatitis B immune globulin [HBIG] within 12 hours of birth).

Case Report #1

A woman known to be chronically infected with HBV delivered her third infant a month early at a birthing hospital. Unfortunately, her HBsAg status was incorrectly recorded in her hospital record as negative. The hospital did not have a universal birth dose policy, so the infant received no hepatitis B vaccine at birth. The mother assumed that the baby was vaccinated because her other two infants had been treated appropriately. A few weeks later (at the time of the mother's original due date), the public health department contacted her to make sure the infant had been vaccinated. They discovered the mother had not been given a shot record for her newborn upon discharge, nor had vaccines ever been discussed with her at the hospital. The hospital was contacted, and it was discovered that the infant had not received any prophylaxis. The first dose of vaccine was immediately administered, but by then the infant was already one month old.

Case Report #2

A woman in labor presented to a suburban birthing hospital. The hospital staff found that she had not been tested for HBsAg this pregnancy because her family practice physician said she was negative two years ago so "not to worry about it." The hospital correctly ordered a test, but did not ask the test to be done as quickly as possible and did not give the infant hepatitis B vaccine dose #1 within 12 hours of birth as recommended. The infant was discharged two days after birth; the mother's HBsAg test came back positive three days after birth. That same day, public health representatives tracked down the family and made sure the infant immediately received vaccine dose #1 and HBIG. Hepatitis vaccine doses #2 and #3 were given according to the recommended schedule.



Case Report #3

An infant born to an HBsAg-positive mother at a birthing hospital received HBIG at birth but not hepatitis B vaccine. Upon investigation, it was learned that the physician forgot to write an order for the vaccine. The hospital did not have standing orders in effect for the universal hepatitis B birth dose, so the infant did not routinely receive hepatitis B vaccine. Public health staff uncovered the error when the infant was two weeks of age, and the infant was immediately vaccinated.

Case Report #4

Staff from the New York State Department of Health conducted a perinatal hepatitis B record review at a birthing hospital. The hospital had failed a record review the prior year, and one of the corrective actions recommended was to include a hard copy of the maternal HBsAg test result in the record. Upon review, it was discovered that the wrong hepatitis test (hepatitis B surface antibody [HBsAb], rather than hepatitis B surface antigen [HBsAg]) had been ordered in three out of the 35 records reviewed. Furthermore, this same error had been made by three different ob-gyn physicians. The obstetrics department head was very surprised to learn of this error and immediately issued a memorandum of clarification to the physicians that HBsAg must be ordered for all pregnant women.

Case Report #5

A woman known to be chronically infected with HBV delivered her second infant five weeks prematurely. Her first infant had received appropriate prophylaxis, and postvaccination serology revealed that child to be immune. The woman was tested during her current pregnancy and again found to be HBsAg positive. She was referred to a gastroenterologist who ordered further serology including hepatitis B e antigen and viral load tests. The e antigen was non-reactive and the viral load was low (which is often the case in persons chronically infected with HBV). The infant was born five weeks early and transferred to the neonatal intensive care unit (NICU). The neonatologist at the NICU consulted the mother's gastroenterologist. The two decided that the infant did not need to

receive hepatitis B prophylaxis, even though it was clearly documented on the hospital record that the mother was HBsAg positive. Neither HBIG nor hepatitis B vaccine was given to the infant. The hospital did not have a universal birth dose policy, so vaccine was not routinely administered. The county health department, assuming the appropriate treatment had been given at birth, discovered this error when following up to make sure the infant was scheduled to receive a second dose of vaccine. The infant's pediatrician was not aware that the mother was chronically infected with HBV and was very disturbed to learn that the infant had not received prophylaxis at birth. The infant was immediately seen in the pediatric office and given the first dose of vaccine at two months of age.

Case Report #6

A multipara woman sought late prenatal care for her current pregnancy. She had been HBsAg positive during all prior pregnancies, but her current HBsAg test result was negative. Suspecting this could be a false negative HBsAg result, the provider ordered another specimen to be drawn and sent to the state laboratory. Before the results were known, the woman delivered at a birthing hospital that had been sent the prenatal file, which included negative HBsAg results. Since the mother was incorrectly thought to be HBsAg negative, no HBIG was administered to the infant. Fortunately, the hospital recently had adopted a universal hepatitis B birth dose policy, so the infant was administered a routine birth dose of hepatitis B vaccine.

The medical errors described in cases 1–5 would have been circumvented had these hospitals had policies in place to administer hepatitis B vaccine to all newborns. Hepatitis B vaccine is the safety net that protects newborns from HBV infection and its complications.