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# Reducing Medical Errors: Case Reports

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# States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention

## Avoid tragic mistakes – vaccinate newborns against HBV in the hospital

■ By **Teresa A. Anderson, DDS, MPH,** and **Deborah L. Wexler, MD\***

On two annual surveys conducted by the Immunization Action Coalition covering the period from July 1999 to October 2002 (see first entry in “Related Resources” on page 13), 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 hepatitis B immune globulin (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 for pregnant women

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 of medical errors 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 2 kg (4.4 lb), 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 received 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 mistranscribed 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), antibody 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 12,500 HBsAg-positive women are not reported to their state’s perinatal hepatitis B program and therefore do not benefit from case management. Only about half of the expected infants born to HBsAg-positive mothers are identified for case management. In terms of a “safety net” for these infants, a 2010 CDC survey found that nationwide, only 70% of infants received the first dose of hepatitis B vaccine within three days of birth. 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.”

## Related Resources

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](http://www.immunize.org/birthdose).

*A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States.* Source: *MMWR*, 12/23/05, Vol. 54 (RR16). Online at [www.cdc.gov/mmwr/pdf/rr/rr5416.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5416.pdf)

*Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission.* Source: IAC. Online at [www.immunize.org/protect-newborns/guide/chapter3/guidance-orders.pdf](http://www.immunize.org/protect-newborns/guide/chapter3/guidance-orders.pdf)

*Give the Birth Dose...Hepatitis B Vaccine at Birth Saves Lives!* Source: IAC. Online at [www.immunize.org/protect-newborns/guide/chapter2/give-birth-dose.pdf](http://www.immunize.org/protect-newborns/guide/chapter2/give-birth-dose.pdf)

*Recommended Childhood & Adolescent Immunization Schedule.* Source: CDC. Online at [www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html)

*General Recommendations on Immunization.* Source: *MMWR*, 1/28/11, Vol. 60(RR2). Online at [www.cdc.gov/mmwr/PDF/rr/rr6002.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr6002.pdf)

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\*Teresa A. Anderson, DDS, MPH, has worked in public health for more than 30 years, first as a dentist for low-income children and then as an epidemiologist consultant, specializing in immunization issues. Dr. Anderson coordinated the Immunization Action Coalition’s 2001 and 2002 birth dose surveys and has presented the results at national conferences.

Deborah L. Wexler, MD, a family physician, is the founder and executive director of the Immunization Action Coalition (IAC). The Coalition provides practical immunization education materials to health professionals and patients. IAC promotes the recommendation to give hepatitis B vaccine to every newborn no later than hospital discharge.

# 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

*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.*

**Protect EVERY newborn from hepatitis B virus infection!**

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

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.**

▶ A DISCUSSION FOLLOWS ON THE NEXT PAGE



Hepatitis B:

**What Hospitals Need to Do to Protect Newborns**

www.immunize.org/protect-newborns

## 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.

– NANCY FASANO  
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Department of Community Health*

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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](http://www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm).

# 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.**

# Two More Infants Chronically Infected with Hepatitis B Virus...the Medical Errors Continue

Approximately 24,000 women with chronic hepatitis B virus (HBV) infection give birth in the United States each year. Although 85%–95% of perinatal HBV infections can be prevented by post-exposure prophylaxis (hepatitis B vaccine and hepatitis B immune globulin [HBIG]) given within 12 hours of birth, many high-risk newborns (infants of HBsAg-positive mothers) don't receive this recommended postexposure prophylaxis, or even hepatitis B vaccine alone which will prevent 70%–90% of perinatal HBV infections.

Unfortunately, children who become infected when they are younger than one year of age have a 90% chance of developing chronic hepatitis B virus infection with all its serious potential sequelae, including an up to 25% risk of death from cirrhosis or liver cancer later in life.

*The following two cases from Colorado illustrate how easily unprotected babies can become chronically infected children.*

## Case Report #1

This case occurred in December 1999. The mother was of Hmong ethnicity, born in Thailand. She had been diagnosed with chronic HBV infection in 1994 during her first pregnancy; this pregnancy was her third. 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. As a matter of fact, the hepatitis B vaccine order was crossed out in the newborn's chart. Follow-up with the pediatrician at six days of age 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 three months after the first, and the third six months after the first.

Upon contacting the hospital where the baby was delivered to determine why HBIG and hepatitis B vaccine were not given within 12 hours of birth, the state health department representative was told that it was unclear how this baby was missed and perhaps it was because the hospital had no hepatitis B vaccine at the time of delivery. They indicated that the infant was to receive the first dose of vaccine at the pediatrician's office. However, this did not happen until the baby was three weeks of age, and only after the office was contacted by the state health department to request that it be done. The child's current status is unfortunate. Diagnosed HBsAg-positive at 19 months of age, the child is being followed by a liver specialist for chronic HBV infection.

## Case Report #2

This case occurred in August 2001, in a different hospital and city. The mother was also of Asian descent (Indonesian) and had tested positive for HBsAg midway through her pregnancy. The HBsAg lab result was recorded on the prenatal record, which was sent to the hospital. The hospital staff also recorded the HBsAg-positive test result on the hospital's obstetrical evaluation sheet. It was not acted upon by either the delivering physician or the labor and delivery staff, nor was the mother's HBsAg-positive test result communicated to or noted by the newborn nursery. The hospital did not have a policy in place to address management of babies born to HBsAg-positive mothers or to mothers of unknown status. The infant received neither HBIG nor hepatitis B vaccine at birth. In fact, the high-risk infant did not receive the first dose of hepatitis B vaccine until two months of age. Unfortunately, this child has also tested HBsAg positive.



In reviewing the case, a staff member at the state health department acknowledges that the baby should have been followed more closely. Part of the problem was that the health department field investigator didn't contact the hospital before the birth to ensure appropriate care would take place. Additionally, after the birth, the hospital sent the state an inaccurate report, stating that the child had received prophylaxis in the hospital. The investigator did not review the hospital record or call the physician to verify that the information was accurate.

**In summary, don't let infants go unprotected against hepatitis B virus infection because of avoidable human errors. Give every infant a dose of hepatitis B vaccine no later than hospital discharge. It's the safety net that will protect all newborns.**

**Such errors are not unique to Colorado.** The Immunization Action Coalition (IAC) surveyed state and local hepatitis B coordinators about perinatal hepatitis B practices in 2001 and again in 2002. The coordinators' responses contain hundreds of examples of children who were unprotected or inadequately protected because health professionals, clinic staff, or hospital staff failed to order or misordered the hepatitis B blood test or misinterpreted, mistranscribed, or miscommunicated the test results of the infants' mothers.\*

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\*To read the survey results, or to view or download related resources and recommendations, visit the Immunization Action Coalition's birth dose web page at [www.immunize.org/birthdose/birthdosesurvey.asp](http://www.immunize.org/birthdose/birthdosesurvey.asp).

# Give the Birth Dose...

## Hepatitis B Vaccine at Birth Saves Lives!

■ By **Deborah L. Wexler, MD**  
Executive Director, Immunization Action Coalition

*In December 2005, CDC issued updated recommendations on hepatitis B vaccination for infants. The recommendations strongly support (1) giving the hepatitis B vaccine birth dose to every newborn prior to hospital discharge and (2) using standardized admission orders for administering the birth dose. In addition, it is recommended that a copy of the **original** maternal hepatitis B lab report be sent to the hospital – **not** a transcribed result. The recommendations also state that the hepatitis B vaccine birth dose may be delayed until after hospital discharge only “in rare circumstances.” When doing so, a physician’s order to withhold the birth dose and a copy of the original lab report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant’s medical record. The most recent CDC estimates indicate only 70% of newborns receive the hepatitis B vaccine birth dose by 3 days of age. Clearly, there is much work left to do to fully protect newborns.*

**Leading health organizations – CDC, AAP, AAFP, and ACOG** – recommend that all hospitals and healthcare professionals protect newborns from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every baby at birth, no later than hospital discharge.

Approximately 24,000 women with chronic HBV infection give birth in the U.S. each year, and many

**State perinatal hepatitis B coordinators provided hundreds of reports of newborns who were unprotected or inadequately protected because of medical errors.**

do not know they are infected. 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 HBV at birth and do not receive appropriate postexposure prophylaxis. Infants infected at birth have a 90% chance of becoming chronically infected with HBV. Chronic HBV infection in infants leads to liver cancer, cirrhosis, and liver failure in up to 25% of these infants when they become adults.

**Healthcare professionals: Urge your patients to protect their newborns with hepatitis B vaccine before hospital discharge.**

**Your recommendation to vaccinate is a strong patient motivator!**

**The birth dose saves lives!**

**To obtain CDC’s recommendations for hepatitis B immunization of infants, children, and adolescents, see pages 41–74.**

### Why is a universal birth dose policy necessary in hospitals?

Following are some of the ways newborns can be infected if they do not receive a dose of hepatitis B vaccine, ideally within 12 hours of birth:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her “infected” status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor hepatitis B immune globulin (HBIG) protection at birth.
- A chronically infected pregnant woman receives the wrong test. For example, antibody to hepatitis B surface antigen (antiHBs) is ordered in error, instead of HBsAg. This can happen because some labs use the confusing abbreviation HBsAb instead of anti-HBs. This misordering of a test is relatively common since the two abbreviations (HBsAg and HBsAb) differ by only one letter. However, when her incorrectly ordered test comes back “negative,” the woman may actually be HBsAg positive and her infant would not receive appropriate postexposure prophylaxis.



Hepatitis B:  
**What Hospitals Need to Do to Protect Newborns**

- The pregnant woman is HBsAg positive, but her test results are misinterpreted or mistranscribed into her prenatal record or her infant's chart. As a result, her infant does not receive HBIG or hepatitis B vaccine.
- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. In one study, women who didn't receive prenatal care were eight times more likely to be HBsAg positive than women who received prenatal care. When a woman does not receive prenatal care and is not tested at the time of delivery, her infant is in danger of being infected with HBV at birth – unless he or she is born in a hospital that adheres to a policy of administering hepatitis B vaccine within 12–24 hours of birth to every newborn **without fail**. This provides the greatest effectiveness in preventing HBV infection.
- She develops HBV infection later in pregnancy, but it is not clinically detected. Because her initial HBsAg test result is negative, she is not retested later in pregnancy as CDC recommends for high-risk women, and her infant does not receive hepatitis B vaccine or HBIG at birth.
- The mother is HBsAg negative, but the infant is exposed to HBV postnatally from another family member or caregiver. This occurs in two-thirds of the cases of childhood transmission.

In 2001, 2002, and 2008, the Immunization Action Coalition surveyed perinatal hepatitis B coordinators at every state health department, as well as at city and county CDC projects to assess their

**State perinatal hepatitis B coordinators surveyed overwhelmingly endorsed providing the birth dose.** views about providing hepatitis B

vaccine in the hospital. Their responses contained hundreds of reports of newborns who were unprotected or inadequately protected because healthcare professionals failed to order or misordered hepatitis B blood tests or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers. (See *States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention*, pages 10–13.)

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing in screening all pregnant women for HBsAg, mistakes continue to occur. Newborns are unnecessarily being exposed without the benefit of postexposure prophylaxis. At least one baby has died of fulminant hepatitis B; hundreds have become chronically infected and are doomed to preventable hepatocellular carcinoma or cirrhosis later in life. To overcome these failures, perinatal hepatitis B vaccine coordinators overwhelmingly endorse providing a hepatitis B vaccine birth dose as the first step in developing a safety net to protect all infants from HBV infection, regardless of the circumstances.

To maximally protect every newborn, CDC, AAP, AAFP, and ACOG recommend all infants be vaccinated with a hepatitis B vaccine birth dose prior to hospital discharge. Delaying hepatitis B vaccination until a follow-up office visit will be too late to prevent perinatal HBV transmission.\*

Hepatitis B vaccine is a highly effective vaccine. Studies have shown that infants of the most highly infectious mothers (women who are both HBsAg and HBeAg positive) who receive postexposure prophylaxis with hepatitis B vaccine alone (without HBIG) at birth are protected in 70%–95% of cases. Please read the hepatitis coordinators' survey results ([www.immunize.org/birthdose/birthdose\\_survey.asp](http://www.immunize.org/birthdose/birthdose_survey.asp)), including descriptions of their experiences with failures of the system – failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital, ideally within 12 hours of birth.

Your support for providing a birth dose to newborns while they are still in the hospital will protect and save lives that are now being put at risk.

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*\*For subsequent doses of hepatitis B vaccine in infants, use monovalent hepatitis B vaccine or hepatitis B-containing combination vaccines. If using a hepatitis B-containing combination vaccine, you will be giving 3 more doses of hepatitis B vaccine. Giving a total of 4 doses of hepatitis B vaccine to infants is acceptable practice according to CDC, AAP, and AAFP. These vaccine doses are covered under the Vaccines For Children (VFC) program for VFC-eligible children.*