

2018 Perinatal Hepatitis B Prevention Program Manual

Arizona Immunization Program Office (AIPO) & Office of Infectious Disease Services (OIDS)

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CHAPTER 1

ARIZONA PERINATAL HEPATITIS B PREVENTION PROGRAM DESCRIPTION

Pregnant women who are infected with hepatitis B virus (HBV) have a high likelihood of passing HBV infection to their infant. Children infected with HBV perinatally have up to a 90% chance of developing chronic HBV infection, and a 25% chance of developing cirrhosis or liver cancer. Perinatal HBV infection can be prevented by routine testing of <u>all</u> pregnant women for hepatitis B surface antigen (HBsAg), and intervening in infants born to HBsAg-positive women by giving the infants hepatitis B vaccine (HepBVacc) and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. Only single-antigen HepBVacc should be used for the birth dose.

Subsequently, the infants born to HBsAg-positive mothers will need on-time completion of their HepBVacc series and subsequent serological testing to document if HBV infection was prevented or not. In addition, children whose mothers are HBsAg-negative should also receive their first HepBVacc within 24 hours of birth and complete the HepBVacc series to protect them from postnatal HBV infection.

The Arizona Department of Health Services (ADHS) receives federal funds from the Centers for Disease Control and Prevention (CDC) for implementation of the Arizona Perinatal Hepatitis B Prevention Program. Staff from ADHS' Office of Infectious Disease Services (OIDS) and the Arizona Immunization Program Office (AIPO) work collaboratively with county health departments (CHDs), hospitals, laboratories, and private physicians statewide to coordinate this program. With the assistance of ADHS, the CHDs serve as the case managers for HBsAg-positive mothers, exposed infants, and contacts.

The goals of the Arizona Perinatal Hepatitis B Prevention Program are to:

- Promote policies and procedures to ensure identification of HBsAg-positive pregnant women, and timely interventions and case management for infants and other contacts.
- Identify HBsAg-positive pregnant women and prevent transmission of HBV to their newborn infants.
- Evaluate the household contacts, sexual contacts, and/or needle-sharing contacts of HBsAgpositive pregnant women for HBV and give HepBVacc to susceptible contacts.
- Provide education about perinatal HBV prevention to CHDs, health care providers, hospitals, patients, and the community.
- Promote vaccination of all infants with HepBVacc.

These goals require carefully coordinated communication and activities involving many participants: CHDs, obstetrical health care providers, hospital personnel, pediatric health care providers, laboratories, HBsAg-positive and HBsAg-negative women, and ADHS. Each of these participants needs to know their own specific responsibilities and how to coordinate patient care with the other health care providers. The Arizona Perinatal Hepatitis B Prevention Program

manual is organized to give participant-specific education and guidance for the prevention of perinatal HBV infection.

Additional information about the ADHS Perinatal Hepatitis B Prevention Program can be obtained by contacting the Arizona Department of Health Services, Perinatal Hepatitis B Prevention Program, 150 N. 18th Ave., Suite 140, Phoenix, AZ 85007-3233, (602) 364-3676, FAX (602) 364-3199, <u>vpd@azdhs.gov</u>.

CHAPTER 2

EPIDEMIOLOGY, CLINICAL MANIFESTATIONS, AND PREVENTION OF HEPATITIS B VIRUS INFECTION

Introduction

Hepatitis B virus (HBV) infects the liver and causes both asymptomatic and symptomatic infections. When symptoms of acute disease occur, illness typically begins 2–3 months after HBV exposure, with a range of 6 weeks – 6 months.

Epidemiology

In almost half of the world, over 60% of people have been infected with HBV, and over 8% are chronically infected. HBV infected mothers serve as a reservoir for HBV infection throughout the world since most of their children become HBV infected unless the infants are properly vaccinated starting within 12 hours of birth. In the United States, less than 2% of people are chronically infected. However, given increased global migration, screening for HBV infection in every pregnancy is still essential to prevent perinatal HBV infection.

HBV Infection and Symptoms

Clinical symptoms of HBV infection include nausea, vomiting, jaundice, and fatigue. HBV infection can be self-limited in many people. Infants, children under 5 years of age, and immune suppressed adults with newly acquired HBV infection usually have asymptomatic infections.

About 30–50% of people aged 5 years and older with a new HBV infection will have clinical symptoms. Infected people can have either an acute, self-limited HBV infection that goes away, or a chronic HBV infection that lasts a lifetime. As long as the HBV infected person tests positive for hepatitis B surface antigen (HBsAg), the person is still infectious.

When healthy adults get infected with HBV, approximately 90% recover from their HBV infection within six months. When this happens, their HBsAg test becomes negative, their test for antibodies against HBsAg (anti-HBs) becomes positive, and they develop lifelong immunity. However, approximately 10% of adults who are HBV infected remain HBsAg-positive after six months. These patients are classified as having a chronic HBV infection. Chronic HBV infection means that a person remains infectious and is still able to spread HBV to others. About 15% of those who become chronically infected with HBV after childhood will die prematurely from liver cirrhosis or liver cancer.

HBV Infection in Infancy and Childhood

Infants and children can become infected with HBV by exposure at birth to blood from their HBV infected mother, or by contact with other household members who are HBsAg-positive. Over 90% of new HBV infections in the world occur in infants and young children due to either perinatal or household transmission. In contrast to adults, most infants are not able to get rid of an HBV infection. Over 90% of HBV infected infants develop chronic HBV infection and remain infectious for the rest of their lives. Chronic HBV infection leads to death from liver cirrhosis or liver cancer in approximately 25% of persons who are infected with HBV as infants or young children.

Infants who are born to mothers who are HBsAg-positive have up to a 70–90% chance of becoming chronically infected with HBV unless appropriate action is taken. Fortunately, most of the infants born to HBsAg-positive mothers can be protected from HBV infection if the infants are given hepatitis B vaccine (HepBVacc) and hepatitis B immune globulin (HBIG) within 12 hours after birth, followed by on-time completion of a full series of HepBVacc. When given properly, HBIG and hepatitis B vaccines are 85–95% effective in preventing HBV infection in infants born to HBsAg-positive women.

How HBV Spreads

HBV is a blood borne disease that is spread by exposure to HBsAg-positive body fluids of people who are either acutely or chronically infected with HBV (see Table 2-1 for examples). The exposure occurs when HBsAg-positive body fluids come in contact with breaks in the skin (percutaneous exposure) or when the body fluids come in contact with mucous membranes of the eyes, nose, mouth, or genital area (mucosal exposure).

Infants born to a HBsAg-positive mother are exposed to HBV from their mother's blood during delivery. Sexual or needle-sharing contacts of HBsAg-positive people become infected by exposure to blood and other body fluids of the HBsAg-positive person.

Household contacts of HBsAg-positive people can become infected over time even without a known exposure to the infected person's body fluids. Fifteen percent of people who get HBV infection have no known risk factors for HBV infection.

Table 2-1: Examples of Sources of Exposure to HBV

Percutaneous Exposure	Mucosal Exposure	
Intravenous inoculation (e.g., hemodialysis,	Perinatal transmission from HBsAg-positive	
blood transfusions, injection drug use).	mother to newborn.	
Blood from an HBsAg-positive person	Splashing blood from an HBsAg-positive	
coming in contact with another person's cut	person onto another person's mucous	
or injured skin.	membranes (eyes, nose, or mouth).	

Needle sticks (e.g., tattooing, piercing,	Sexual contact	
acupuncture, IV drug use).	(both heterosexual and/or homosexual).	
Shared household products that may contain	Shared household products that may	
blood (e.g., razors).	contain blood (e.g., toothbrushes).	

Risk Factors Associated with HBV Infection

People who are at higher risk of having HBV infection include the following:

- Persons with multiple sex partners.
- Persons diagnosed with a sexually transmitted disease.
- Men who have sex with men.
- Injection drug users.
- Persons who share needles (e.g., body piercing, tattooing)
- Sexual contacts of an HBV infected person.
- Hemodialysis patients.
- Health care workers.
- Persons who are born in, or whose parent was born in, a country with endemically high levels of chronic HBV infection. These countries and areas include Asia, the Pacific Islands, Africa, the Caribbean, areas of South America, areas of the Middle East, and indigenous populations of Alaska, Australia, and New Zealand.

Elimination of HBV Infection in the US

In order to eliminate the spread of HBV in the United States, the CDC has developed a four part approach:

- I) Universal HepBVacc of infants beginning at birth.
- II) Prevention of perinatal HBV infection through:
 - A) Routine screening of all pregnant women for HBsAg.
 - B) Giving HepBVacc and HBIG to infants born to HBsAg-positive mothers in a timely fashion (the first dose of each within 12 hours of birth).
 - C) Giving HepBVacc (and HBIG if indicated) within 12 hours of birth to infants born to mothers with an unknown HBsAg status.
 - D) Giving HepBVacc to all infants born to women who are HBsAg-negative within 24 hours of birth.
- III) Routine HepBVacc of previously unvaccinated children and adolescents.
- IV) HepBVacc of previously unvaccinated adults at risk for HBV infection.

For more in depth information about HBV and HepBVacc, see the references in <u>chapter 11</u> of this manual.

CHAPTER 3

LABORATORY DIAGNOSIS OF HEPATITIS B VIRUS INFECTION

Serologic Course of Hepatitis B Virus (HBV) Infection

HBV is composed of numerous antigenic components including hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg) and hepatitis B e antigen (HBeAg). Antibodies that are made to these antigens include antibody to HBsAg (anti-HBs), antibody to HBcAg (anti-HBc), and antibody to HBeAg (anti-HBe) respectively. The presence of these antigens and antibodies result in the various blood findings associated with acute HBV infection, recovery from HBV infection, and chronic HBV infection.

The relationship between clinical symptoms, antigen appearance, and antibody responses over time due to HBV infection is illustrated in Figure 1 and Figure 2 (see below). These figures are from a document of the CDC: "Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection." *Morbidity and Mortality Weekly Report* (MMWR), September 19, 2008, pp. 3-4. http://www.cdc.gov/mmwr/PDF/rr/rr5708.pdf

Symptoms HBeAg anti-HBe Total anti-HBc § HBsAg¹ IgM** anti-HBc Titer anti-HBs 0 4 8 12 16 20 24 28 32 36 52 100 Postexposure (wks) Hepatitis B e antigen. [†] Antibody to HBeAg. § Antibody to hepatitis B core antigen. ¹ Hepatitis B surface antigen. ** Immunoglobulin M. ^{††} Antibody to HBsAg.

FIGURE 1. Typical serologic course of acute hepatitis B virus infection with recovery

Figure 1 illustrates the antigens and antibodies involved in the serologic response to an acute HBV infection in the situation where the patient clears the HBV infection. While a person is infected with HBV, HBsAg is found in the blood. As long as the person's blood tests positive for HBsAg, the person is infectious and can spread HBV infection.

People who test positive for HBsAg often will also test positive for HBeAg. Patients who have both HBsAg and HBeAg in their blood are even more infectious than the HBsAg-positive people who have a negative test for HBeAg. However, patients who are HBsAg-positive but HBeAgnegative can still spread HBV infection. Therefore, monitoring for HBeAg is not part of a perinatal hepatitis B prevention program.

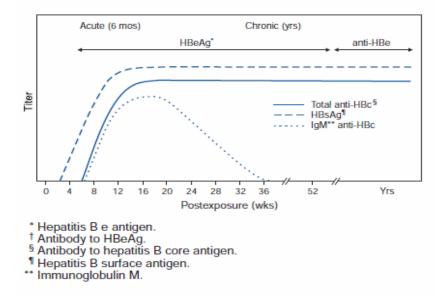
In newly infected people, HBsAg is the only serologic marker in the blood for about 3–5 weeks. HBsAg remains in the blood for less than 6 months in people who clear the HBV infection. Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) soon appears and lasts for less than 6 months, whether or not the HBV infection is cleared. Immunoglobulin G (IgG) antibody to HBcAg (IgG anti-HBc) also appears and will persist for life in most people.

If the patient recovers from HBV infection, HBsAg disappears and protective antibodies to HBsAg (anti-HBs) develop. Therefore, in the typical serologic response to an acute HBV infection that clears is that there will be a time period when only HBsAg is found in the blood, followed by a period with both HBsAg and IgM anti-HBc, followed by a period where there may be only IgM anti-HBc, and finally a time where only anti-HBs is present. Therefore, when a patient is having symptoms of acute hepatitis infection, the clinician will order HBsAg, IgM anti-HBc (or total antibody to HBcAg), and anti-HBs to be able to not miss the time-related changes in HBV blood tests. The presence of IgG anti-HBc or total anti-HBc (which measures both IgM and IgG anti-HBc) does not help in determining the timing of an HBV infection, but it indicates that the patient has been infected with HBV at some point in their life.

Testing for anti-HBc is not part of the perinatal hepatitis B prevention program because the program's purpose is to screen asymptomatic people for HBV infection and prevent perinatal HBV transmission. It does not focus on testing people with symptoms of acute hepatitis. Also, testing for HBeAg or anti-HBe is not done as part of the perinatal hepatitis B prevention program.

A patient's serologic response to hepatitis B vaccine (HepBVacc) is different from the serologic response seen with HBV infection. Since HepBVacc does not contain hepatitis B core antigen (HBcAg), people who receive HepBVacc will only develop antibodies to HBsAg (anti-HBs); they will not develop antibodies to HBcAg (anti-HBc). In contrast, people who have recovered from a HBV infection will have both anti-HBs and anti-HBc in their blood.

FIGURE 2. Typical serologic course of acute hepatitis B virus (HBV) infection with progression to chronic HBV infection



The serologic response of a person with chronic HBV infection is illustrated in Figure 2. When a person becomes infected with HBV and does not clear the infection, HBsAg always remains in the blood. IgM anti-HBc appears and then disappears around 6 months. IgG antibodies to HBcAg (IgG anti-HBc) develop and remain positive for life. In a person with chronic HBV infection, antibodies to HBsAg (anti-HBs) do not develop. Chronic HBV infection is defined as being HBsAg-positive for longer than 6 months.

False Positive and False Negative HBV Serology Results

- No serologic test is 100% accurate. Therefore, there can be false positive and false negative HBV serology tests. The Perinatal Hepatitis B Prevention Program reviews all HBsAg-positive tests results in pregnant women to confirm that the result is a true positive and not a false positive.
- In rare circumstances, a woman could test negative for HBsAg because of a false negative result. By giving all newborns HepBVacc within 24 hours of birth, and completing the HepBVacc series in a timely fashion, infants born to mothers with false negative HBsAg results often develop protection from HBV infection.

Reporting HBV Infections

- <u>Health care providers</u> must report their patients with HBV infection to their local health agency within five working days as per the Arizona Administrative Code (AAC) R9-6-202. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>
 - The report can be made using the Communicable Disease Report form which can be found at http://www.azdhs.gov/cdr, or through the Medical Electronic Disease

Surveillance Intelligence System (MEDSIS), Arizona's electronic reporting and surveillance system. Information about MEDSIS is available at http://www.azdhs.gov/medsis.

- <u>Clinical laboratory</u> directors must report positive HBV results to ADHS within five working days as per AAC R9-6-204. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>
 - The report can be submitted using the ADHS Laboratory Report form at <u>www.azdhs.gov/labreportform</u>, electronic laboratory reporting (ELR), or through <u>MEDSIS</u>.
- <u>Arizona local health agencies</u> must report HBV cases to ADHS as per AAC R9-6-206. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>
 - The ADHS Hepatitis B and D Investigation Form used for case investigation can be obtained at <u>http://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/disease-investigation-resources/hepatitis-B-D-investigation-form.pdf</u>.

ADHS receives HBsAg-positive reports from the local health departments, laboratories, and health care providers by means of <u>MEDSIS</u>, electronic laboratory reporting (ELR), fax, or by mail.

Rationale behind Perinatal Hepatitis B Prevention Program

Serologic testing that is part of a perinatal hepatitis B prevention program has three different aspects:

- I) Testing to see if a pregnant woman is HBsAg-positive.
- II) Testing the HBV exposed infant for HBsAg and for protective antibodies (anti-HBs).
- III) Testing for HBV infection in household, sexual, and needle sharing contacts of HBsAgpositive pregnant women and determining the contacts' need for hepatitis B vaccination.

Ordering and Interpreting HBV Serology for Pregnant Women

- All pregnant women should be tested for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been vaccinated or tested previously. Testing those pregnant women known to be chronically infected with HBV provides documentation of the positive HBsAg test result and helps to ensure that their infants will be identified for timely prophylaxis.
- In a pregnant woman who is not having symptoms of acute hepatitis, it is only necessary to test for HBsAg.
- A copy of the original laboratory report indicating the pregnant woman's HBsAg-positive status or HBsAg-negative status should be provided to the hospital or birthing facility where the delivery is planned and to the health care provider who will care for the newborn infant.
- Pregnant women who are HBsAg-positive are actively infected with HBV and are

contagious. Their infants need to be given single-antigen HepBVacc and HBIG within 12 hours of birth, regardless of any other serologic testing that the mother may have had.

- All women who are HBsAg-positive should be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.
- Women who test HBsAg-positive for the first time will need to be evaluated to determine if they have chronic HBV infection.
- All HBsAg-positive pregnant women should receive information concerning HBV that discusses the potential use of antiviral therapy, the importance of prophylaxis for their infant (HepBVacc and HBIG within 12 hours of birth), completion of the vaccine series, and post-vaccination serologic testing.
- All HBsAg-positive pregnant women should be referred to their <u>county health department</u> for case management to ensure that their infants receive timely prophylaxis and follow-up.
- Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested for HBsAg as soon as possible.
- Even if a woman's initial test is HBsAg-negative, repeat HBsAg any time later in pregnancy if there is evidence of:
 - exposure to HBV
 - symptoms of hepatitis
 - high risk behaviors
 - currently using or recently used injection drugs
 - more than one sex partner in the previous 6 months
 - sex partner is HBsAg-positive
 - evaluated or treated for a sexually transmitted infection
- Test or retest a pregnant woman for HBsAg when admitted for delivery if:
 - She was not screened during the current pregnancy for HBsAg.
 - A copy of her HBsAg test obtained during the current pregnancy is not available in the hospital record at the time of delivery.
 - The electronic medical record says that the woman is HBsAg-negative but she has a history of hepatitis.
- Retest a HBsAg-negative woman for HBsAg when admitted for delivery if she has had:
 - clinical hepatitis since previous HBsAg testing
 - recent exposure to HBV
 - current or recent injection drug use
 - more than one sex partner in the previous 6 months

- sex with a HBsAg-positive partner
- a sexually transmitted infection
- no HBsAg test result available at time of delivery
- Pregnant women who are identified for the first time as HBsAg-positive will need referral for evaluation and further serologic testing to differentiate between acute and chronic HBV infection.
- HBsAg-positive pregnant women are actively infected with HBV and are contagious. Their infants need to be given single-antigen HepBVacc and HBIG within 12 hours of birth, with subsequent on-time completion of the full HepBVacc series.

Ordering and Interpreting HBV Serology for Infants Born to HBsAg-positive Women

- Test HBsAg-exposed infants at ≥9 months old and at least 1–2 months after receiving the final dose of a full HepBVacc series to see if they have developed protective antibodies (anti-HBs) and do not have HBV infection. They should be tested both for HBsAg and antibodies to HBsAg (anti-HBs).
- HBV serology should not be drawn before age 9 months to avoid detection of antibody from hepatitis B immune globulin (HBIG) administered after birth and to maximize the likelihood of detecting late HBV infection. If for some reason the final dose of HepBVacc is delayed, HBsAg and anti-HBs should be drawn 1–2 months after the final dose of HepBVacc.
- Anti-HBs testing should be performed on the infant using a method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).
- Infants should not be tested for antibody to hepatitis B core antigen (anti-HBc). Passively acquired maternal anti-HBc might be detected in infants born to HBV infected mothers up to age 24 months.
- Interpretation of results
 - Immune: Anti-HBs positive (≥10 mIU/mL) & HBsAg negative
 - Infected: Anti-HBs negative (<10 mIU/mL) & HBsAg positive
 - Not immune: Anti-HBs and HBsAg are both negative
- HBsAg-negative infants with anti-HBs levels ≥10 mIU/mL are immune and need no further medical management for HBV.
- Infants who test positive for HBsAg are infected with HBV and should be referred to a pediatric gastroenterologist for further management.
- Infants who are "not Immune" after one full series of hepatitis B vaccine:

- HBsAg-negative infants with anti-HBs <10 mIU/mL should be revaccinated with a single dose of HepBVacc and receive post-vaccination serologic testing 1–2 months later. Infants whose anti-HBs remains <10 mIU/mL following single dose revaccination should receive two additional doses of HepBVacc to complete the second series, followed by post-vaccination serologic testing 1–2 months after the final dose.
- Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs <10 mIU/mL after a full series of hepatitis B vaccine may instead be revaccinated with a second, complete 3-dose series, followed by post-vaccination serologic testing performed 1–2 months after the final dose of vaccine.
- Infants who remain anti-HBs and HBsAg negative after a second full series of HepBVacc are considered to be non-responders and are presumed to be susceptible to HBV infection. However, no further HepBVacc is recommended.

Ordering and Interpreting HBV Serology for Infants Born to Women whose HBsAg Status is Unknown

- If a woman's HBsAg status is not known at the time of her delivery, a HBsAg test should be obtained on her immediately.
- Infants for whom a maternal HBsAg test is not able to be obtained, should be treated as though their mother had been HBsAg-positive and have post-vaccination serologies drawn in the same way as infants born to HBsAg-exposed infants.

Ordering and Interpreting HBV Serology for Asymptomatic Contacts of HBsAgpositive Women

- Test for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B surface antigen (anti-HBs).
 - Only HBsAg and anti-HBs need to be ordered to screen asymptomatic household, sexual, and needle-sharing contacts of HBsAg-positive pregnant women. Household, sexual, and needle sharing contacts who are both HBsAg-negative and anti-HBs-negative are neither infected nor immune, so they will need a full HepBVacc series.
 - In rare circumstances, contacts of HBsAg-positive mothers may have symptoms of acute hepatitis. In this case, further medical evaluation may need to be done to test not only for HBV but for other causes of hepatitis. In such cases, the person needs to be referred to their health care provider for further evaluation and testing.
- Interpretation of results.
 - <u>Immune</u>: Anti-HBs positive (≥10 mIU/mL) & HBsAg negative.
 - No need for vaccine.
 - <u>Infected</u>: Anti-HBs negative (<10 mIU/mL) & HBsAg positive.
 - Refer for medical management of HBV infection.
 - <u>Not immune</u>: Anti-HBs and HBsAg are both negative.
 - Need to be vaccinated with the HepBVacc series.

- Testing for anti-HBs after vaccination is not routinely indicated in most people who get HepBVacc. However, post-vaccination serology is recommended for persons whose management depends on knowledge of their immune status.
 - Other biological children of HBsAg-positive women who have not been previously tested for immunity.
 - Sexual partners of a HBsAg-positive person.
 - Health care workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids.
 - Chronic hemodialysis patients.
 - HIV-infected and immunocompromised people.
- In the persons listed above, obtain post-vaccination testing 1–2 months after the last dose of the HepBVacc series.

Table for Interpretation of Hepatitis B Virus Serologic Tests

HBsAg and anti-HBs are the serologic tests used in perinatal hepatitis B prevention programs for determining infection with hepatitis B virus and protective antibody against hepatitis B virus. However, sometimes providers may have also ordered other tests such as IgM antibodies to hepatitis B core antigen (IgM anti-HBc) or total antibodies to hepatitis B core antigen (anti-HBc). A CDC document that explains the interpretation of HBV tests that include HBsAg, anti-HBc, anti-HBs, and IgM anti-HBc can be found at

https://www.cdc.gov/hepatitis/hbv/pdfs/SerologicChartv8.pdf.

CHAPTER 4

HEPATITIS B VACCINE SCHEDULES AND HEPATITIS B IMMUNE GLOBULIN USE

Overview of the Arizona Perinatal Hepatitis B Prevention Program

Vaccines for hepatitis B virus (HBV) have been available in the United States since 1981 and are essential for preventing HBV infection. Hepatitis B Immune Globulin (HBIG) is used as an adjunct to hepatitis B vaccine (HepBVacc) in newborns and in some adults.

The CDC strategies for eliminating HBV transmission in the United States include:

- Universal HepBVacc of infants beginning at birth.
- Prevention of perinatal HBV infection through:
 - Routine screening of all pregnant women for hepatitis B surface antigen (HBsAg).
 - Giving HepBVacc and HBIG to infants born to HBsAg-positive women in a timely fashion (first dose of each within 12 hours of birth).
 - Giving HepBVacc (and HBIG if indicated) within 12 hours of birth to infants born to women with an unknown HBsAg status.
 - Giving HepBVacc to all infants born to women who are HBsAg-negative within 24 hours of birth (with the exemption of infants weighing <2,000 g whose mother's HBsAg serology was documented to be HBsAg-negative). Documentation of a mother's HBsAg-negative test from her current pregnancy should be done by means of a copy of the actual HBsAg test included in the hospital record.
- Routine HepBVacc of previously unvaccinated children and adolescents.
- Giving HepBVacc to previously unvaccinated adults at risk for HBV infection.

Vaccine for Children (VFC) HepBVacc for Hospitals

AIPO provides HepBVacc to delivery hospitals through the Vaccine for Children (VFC) program. HepBVacc is given to hospitals for use in any Arizona newborn without charge if the hospital enrolls as VFC providers. For questions about enrolling as VFC providers, or for questions about ordering VFC HepBVacc for newborns, call AIPO at (602) 364-3642 and refer to the VFC website at <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> control/immunization/index.php#vaccines-children-home.

Reporting of Administration of HepBVacc and HBIG to the Arizona State Immunization Information System (ASIIS)

Arizona state law requires that providers administering any vaccine to children (those under 18 years old) must report the vaccine to the state electronic immunization registry (ASIIS). Therefore, hospitals and providers are required to report each dose of HepBVacc to ASIIS. Information on ASIIS can be obtained by calling by calling (602) 364-3899 or toll free at 1-877-

491-5741 or by going to <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> control/immunization/asiis/index.php.

State law does not require reporting of HBIG administration to ASIIS, but the ASIIS form does include the date of HBIG receipt. Entering the HBIG information into ASIIS will assist CHDs as they manage the cases of infants born to HBsAg-positive women.

Schedules and Uses for HepBVacc and HBIG

HepBVacc comes as a single antigen (that only immunizes against HBV) or as a combination HepBVacc (that immunizes against other infections as well as HBV). Only single-antigen HepBVacc should be used in infants less than 6 weeks old.

Recommendations for vaccinating infants born to a HBsAg-positive woman are different from those for household, sexual, and/or needle-sharing contacts of the same HBsAg-positive woman.

HepBVacc recommendations vary based on:

- The HBsAg-status of the mother: whether positive, unknown, or negative.
- The infant's birth weight: "term" is defined as weighing ≥2,000 grams while "preterm" means weighing <2,000 grams.
- Whether only single-antigen HepBVacc (either Recombivax HB[®] or Engerix-B[®]) is used for all doses of vaccine for an infant, or whether combination HepBVacc (Pediarix[®]) is also used as part of the infant series.
- The age of the HepBVacc recipient.
- The type of HepBVacc formulation (pediatric, adult, dialysis, or Twinrix[®]).
- The age group for which a specific HepBVacc is licensed.

Hepatitis B Vaccine (HepBVacc) Schedules and Hepatitis B Immune Globulin (HBIG) Use				
	FOR INFANTS			
Table 4-1	Term Infant HepBVacc and HBIG Schedule Based on Mother's HBsAg Status.			
Table 4-2	Table 4-2Preterm Infant HepBVacc and HBIG Schedule Based on Mother's HBsAg Status.			
Table 4-3	Table 4-3 Routine Infant HepBVacc Schedule.			
Table 4-4	Table 4-4 Infant Schedule for Use of Combination Vaccines Containing HepBVacc Following			
	Single-Antigen Vaccine at Birth.			
FOR CHILDREN, ADOLESCENTS, AND ADULTS				
Table 4-5	HepBVacc Dosing for Children, Adolescents, and Adults, Based on Age, Medical			
	Status, and Vaccine Type.			
Table 4-6	Basic Three Dose HepBVacc Schedule for Previously Unimmunized Children,			
	Adolescents, and Adults.			

The following tables give guidance for HepBVacc schedules and receipt of HBIG.

Table 4-7	Expanded Approved HepBVacc Schedules for Previously Unimmunized Children,		
	Adolescents, and Adults.		

These tables were compiled from CDC recommendations which can be found in documents in chapter 11 listed under <u>"Core Documents for HBV and HepBVacc."</u>

Table 4-1: Term* Infant HepBVacc and HBIG Schedule Based on Mother's HBsAg Status.

Term Infants Born to HBsAg-Positive Women			
Biologic	Age of Infant	IM Dose	
HBIG	Within 12 hours of birth [§]	0.5 mL	
HepBVacc 1 [#]	Within 12 hours of birth [§]	0.5 mL	
HepBVacc 2	1–2 months (6 weeks – 2 months if using a combination	0.5 mL	
	vaccine) [∆]		
HepBVacc 3	6 months [¶]	0.5 mL	
Term Infants Bor	n to Women Whose HBsAg Status is Unknown		
Biologic	Age of Infant	IM Dose	
HepBVacc 1 [#]	Within 12 hours of birth	0.5 mL	
HepBVacc 2	1–2 months (6 weeks – 2 months if using combination	0.5 mL	
	vaccines) [∆]		
HepBVacc 3	6 months [¶]	0.5 mL	
HBIG	Defer giving HBIG pending result of mother's test for HBsAg.	0.5 mL	
	If mother found to be HBsAg-positive, give infant HBIG as		
	soon as possible but within 7 days of birth.		
	rn to HBsAg-Negative Women		
Biologic	Age of Infant	IM Dose	
HepBVacc 1 [#]	Within 24 hours of birth.	0.5 mL	
HepBVacc 2	1–2 months (6 weeks – 2 months if using a combination	0.5 mL	
	vaccine [Pediarix [®]] for the second dose) [△]		
HepBVacc 3	6–18 months¶	0.5 mL	
	th weight of ≥2,000 grams (<u>≥</u> 4.4 pounds).		
[§] Give HBIG and 1 st dose of single-antigen HepBVacc (either Recombivax HB [®] or Engerix-B [®])			
at separate sites in the antero-lateral thigh muscle.			
[#] Infants <6 weeks old may only receive single-antigen HepBVacc. A combination HepBVacc			
(Pediarix [®]) is only approved for ≥6 weeks old.			
^Δ The minimum interval between the 1 st and 2 nd dose of HepBVacc is 4 weeks.			
[¶] Although in older patients the minimum valid interval between the 1 st and 3 rd dose of			
HepBVacc is 4 months, if infants receive the 3 rd dose of HepBVacc before 24 weeks old, the			
3 rd dose is not valid and will need to be repeated.			

Status		
Preterm* Infants Born	to HBsAg-Positive Women	
Biologic	Age of Infant	IM Dose
HepBVacc Birth Dose [#]	Within 12 hours of birth [§]	0.5 mL
HBIG	Within 12 hours of birth [§]	0.5 mL
HepBVacc 1 [#]	1 month	0.5 mL
HepBVacc 2	2 months [∆]	0.5 mL
HepBVacc 3	6 months [¶]	0.5 mL
Preterm* Infants Born	to Women Whose HBsAg Status Is Unknown	
Biologic	Age of Infant	IM Dose
HepBVacc Birth Dose [#]	Within 12 hours of birth [§]	0.5 mL
HBIG	Within 12 hours of birth [§] (unless mother can be shown	0.5 mL
	to be HBsAg-negative within 12 hours of birth)	0.5 m
HepBVacc 1 [#]	1 month	0.5 mL
HepBVacc 2	2 months ^{Δ}	0.5 mL
HepBVacc 3	6 months [¶]	0.5 mL
	omonths	0.5 1112
Preterm* Infants Born	to HBsAg-Negative Women	
Biologic	Age of Infant	IM Dose
HepBVacc 1 [#]	1 month or upon hospital discharge°	0.5 mL
HepBVacc 2	2 months [∆]	0.5 mL
HepBVacc 3	6–18 months [¶]	0.5 mL
*Defined as a birth wei	ght of <2,000 grams (<4.4 pounds).	
[§] Give HBIG and 1 st dose	e of single-antigen HepBVacc (either Recombivax HB $^{\circ}$ or En	gerix-B [®])
at separate sites in the	antero-lateral thigh muscle.	
# Disregard birth dose of	of HepBVacc in a preterm* infant when determining the re	quired
total doses of HepBVac	c. Infants may only receive single-antigen HepBVacc (eithe	er
Recombivax HB [®] or Eng	gerix-B [®]). A combination HepBVacc (Pediarix [®]) is only appro	ved for <u>≥</u> 6
weeks old.		
^Δ The minimum interval	between 1 st and 2 nd dose of HepBVacc is 4 weeks.	
[¶] Although in older pati	ients the minimum valid interval between the 1^{st} and 3^{rd} d	ose of
HepBVacc is 4 months,	if infants receive the 3 rd dose of HepBVacc before 24 weel	<s old<="" td=""></s>
(six months), the 3 rd do	se is not valid and will need to be repeated.	
0.44		

 Table 4-2: Preterm* Infant HepBVacc and HBIG Schedule Based on Mother's HBsAg

 Status

°Whichever is sooner.

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Dose	Usual Age	Minimum Interval
1	Birth	
2	1–2 months	4 weeks
3	6–18 months*	8 weeks [#]

 Table 4-3: Routine Infant Single Antigen HepBVacc Schedule

*Give the 3rd HepBVacc dose at 6 months to infants whose mothers are HBsAg-positive or whose mother's HBsAg status is unknown.

*At least 16 weeks after the first dose. The third dose should not be given before 24 weeks old.

Table 4-4: Infant Schedule for Use of Combination Vaccine* Containing HepBVaccFollowing Single-Antigen** HepBVacc at Birth

Infants can receive all of their HepBVacc as single-antigen vaccines. Alternately, a combination vaccine can be substituted once the infant is at least 6 weeks of age. Use of three doses of Pediarix[®] will result in a fourth HepBVacc dose as shown below.

Infant HepBVacc Schedule if Pediarix	د (DTaP-HBV-IPV) Is Used	
Biologic	Age of Infant	IM Dose
Single antigen— HepBVacc 1	Birth	0.5 mL
Pediarix [®] —HepBVacc 2	2 months	0.5 mL
Pediarix [®] —HepBVacc 3	4 months	0.5 mL
Pediarix [®] —HepBVacc 4	6 months	0.5 mL
Note: Pediarix [®] cannot be used at bir	th, before 6 weeks, or at ≥ 7 y	/ears.
*Pediarix [®] contains vaccines against hepatitis B virus as well as vaccines against diphtheria,		
tetanus, pertussis, and poliomyelitis.		

**Single-antigen HepBVacc are Engerix-B[®] and Recombivax HB[®].

Table 4-5: HepBVacc Dosing for Children, Adolescents, and Adults Based on Age, Medical Status, and Vaccine Type°

Patients	Single-Antigen HepBVacc			Dual Vaccine (HepBVacc and Hepatitis A)		
	Recombivax HB [®] (Merck)		Engerix-B [®] (GSK)		Twinrix [®] (GSK)	
	Dose	Volume	Dose	Volume	Dose	Volume
	(µg)*	(mL)	(µg)*	(mL)	(µg)*	(mL)
Children 1–10 years	5	0.5	10	0.5	N/A**	N/A
Adolescents 11–15 years	10 [§]	1.0 [§]	10	0.5	N/A	N/A
Adolescents 11–19 years	5	0.5	10	0.5	N/A [∆]	N/A
Adolescents (11–19 years) undergoing dialysis or otherwise immunocompromised [#]	5	0.5	10	0.5	N/A [∆]	N/A
Adults (≥ 20 years) undergoing dialysis or otherwise immunocompromised	40¶	1.0	40 ^Ŧ	2.0	N/A	N/A
Adults (<u>≥</u> 20 years) [△]	10	1.0	20	1.0	20	1.0

°Vaccines made by different manufacturers are interchangeable as long as the manufacturers' dosing recommendations are followed (except for a two-dose HepBVacc schedule for adolescents aged 11 through 15 years; only the adult dose of Merck HepBVacc (10µg, 1 mL) is approved for a two-dose schedule in this age group).

*Recombinant hepatitis B surface antigen protein dose.

**N/A=Not applicable.

[§]Adult formulation administered in a 2-dose schedule.

[#]Higher doses might be more immunogenic, but no specific recommendations have been made.

^{Δ}Twinrix[®] (combined hepatitis A & B) may be administered to persons aged \geq 18 years in a three-dose schedule at 0, 1, and 6 months at the same dose as adults \geq 20 years old. Alternatively, a four-dose Twinrix[®] schedule can be used on days 0, 7, and 21-30 followed b

Alternatively, a four-dose Twinrix[®] schedule can be used on days 0, 7, and 21-30 followed by a dose at 12 months.

[¶]Dialysis formulation administered on a 3-dose schedule at 0, 1, and 6 months.

⁺Two 1.0 mL doses or one 2 mL dose given as a 4-dose schedule at 0, 1, 2, and 6 months. Table adapted from *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th edition. <u>http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf</u>

Table 4-6: Basic Three Dose HepBVacc Schedule for Previously Unimmunized Children,Adolescents, and Adults

HepBVacc Dose	Usual Interval	Minimum Interval
	from Previous Dose	from Previous Dose
1		
2	1 month	4 weeks
3	5 months	8 weeks*
*The 3 rd dose mu	st be separated from the 1 st dose b	oy at least 16 weeks.

Table 4-7: Expanded Approved HepBVacc Schedules for Previously Unimmunized Children, Adolescents, and Adults*

Age	HepBVacc Doses	Schedule	Formulations**
Children	3	0, 1, and 6 months	Р
(1–10 years)	3	0, 2, and 4 months	Р
	4	0, 1, 2, and 12 months	P§
Adolescents	3	0, 1, and 6 months	Р
(11–19 years)	3	0, 1, and 4 months	Р
	3	0, 2, and 4 months	Р
	3	0, 12, and 24 months	Р
	2	0 and 4–6 months	A#
	4	0, 1, 2, and 12 months	P§
Adults	3	0, 1, and 6 months	A, T [∆]
(≥20 years)	3	0, 1, and 4 months	A
	3	0, 2, and 4 months	А

4	0, 1, 2, and 12 months	A§
4	0, 7 days, 21-30 days,	T∆
	12 months	

*Children, adolescents, and adults may be vaccinated according to any of the schedules indicated, except as noted. Selection of a schedule should consider the need to optimize compliance with vaccination.

**Formulations: P=Pediatric/adolescent HepBVacc; A=Adult HepBVacc; T=Twinrix[®] (GSK, Combined HepBVacc and Hepatitis A Vaccine). See Table 4-5 for more details about the various formulations.

[§]A 4-dose schedule of Engerix-B[®] (GSK) is licensed for all age groups.

[#]A 2-dose schedule for Recombivax HB^{*} (Merck) is licensed for adolescents ages 11–15 years old, but the adult formulation (10 μ g, 1 mL) must be used. When it is time to receive the second dose, if adolescents are over 15 years old they should be switched to a 3-dose HepBVacc series, with doses 2 and 3 consisting of the pediatric formulation. ^ΔTwinrix^{*} may be administered to persons aged ≥18 years old.

Adapted from *Morbidity and Mortality Weekly Report*, December 23, 2005, p. 10.

http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf

Package Inserts for Hepatitis B Vaccines (HepBVacc)

Note: Hepatitis B vaccines do not contain thimerosal.

- Engerix-B[®]. <u>http://us.gsk.com/products/assets/us_engerixb.pdf</u>
- Recombivax HB[®]
 <u>http://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf</u>
- Pediarix[®]. <u>http://us.gsk.com/products/assets/us_pediarix.pdf</u>
- Twinrix[®]. <u>http://us.gsk.com/products/assets/us_twinrix.pdf</u>

Prescribing information for Hepatitis B Immune Globulin (HBIG)

Note: HBIG does not contain thimerosal.

- HepaGam B[®]. Cangene Corporation. 877-437-2426. <u>http://www.hepagamb.com/pdfs/HepaGam_Pl.pdf</u>
- HyperHEP B[™] S/D. Grifols. 800-520-2807. <u>http://www.grifolsusa.com/documents/10192/60534/ft hepatitis b immune globulin ee</u> uu en/4ae3f29a-9564-48a8-846c-ec469dbdaaf3
- Nabi-HB[®]. Biotest Pharmaceuticals Corporation. 800-327-7106. <u>http://www.biotestpharma.com/clientuploads/pdfs/Nabi-HB_PI_Apr_2008.pdf</u>

(Manufacturers of HBIG obtained from https://www.cdc.gov/hepatitis/ig-hbig_sources.htm.)

CHAPTER 5

OBSTETRICAL HEALTH CARE PROVIDERS' RESPONSIBILITIES FOR MATERNAL HEPATITIS B VIRUS INFECTION SCREENING, REPORTING, AND INTERVENTIONS

Overview of the Arizona Perinatal Hepatitis B Prevention Program

In the United States, an estimated 24,000 women with hepatitis B virus (HBV) infection give birth each year. Pregnant women who are infected with HBV have a high likelihood of passing HBV infection to their infant. Children who are perinatally infected with HBV have a 90% chance of developing chronic HBV infection, and a 25% chance of developing cirrhosis or liver cancer. The CDC has published their recommendations for preventing perinatal HBV infection in "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States." *Morbidity and Mortality Weekly Report* (MMWR), December 23, 2005 <u>http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u> and in "Prevention of Hepatitis B Virus Infection in the United States," MMWR, (RR-1), January 12, 2018 <u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf</u>.

These CDC recommendations state that there should be routine hepatitis B surface antigen (HBsAg) testing of all pregnant women during every pregnancy, followed by timely intervention in infants born to HBsAg-positive women. The HBV exposed infants should be given singleantigen Hepatitis B Vaccine (HepBVacc) and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. Subsequently, these infants born to HBsAg-positive mothers will need on-time completion of their HepBVacc series, and eventual serological testing to document if HBV infection was prevented or not.

The CDC recommends HBsAg screening on <u>all</u> women during <u>every</u> pregnancy because the rate of seroconversion from chronic hepatitis to non-chronic hepatitis is estimated at 0.5% per year. Thus, a few women will convert to HBsAg-negative between past testing and the current pregnancy. In addition, a routine process that tests all pregnant women regardless of their past HBsAg test can minimize misunderstandings of the screening process that might lead to some pregnant women not being screened and hepatitis B exposed infants not getting HepBVacc and HBIG in a timely manner.

Responsibilities of Obstetrical Health Care Providers to Prevent Perinatal Hepatitis B Virus Infection

- Test HBsAg status for all pregnant women during <u>each</u> pregnancy.
- Report HBsAg-positive women to the county health department.

- Provide delivery hospitals with a copy of the actual laboratory test showing the HBsAg status of all pregnant women for each pregnancy, both HBsAg-positive and HBsAg-negative results.
 - A handwritten note or manual entry into an electronic record of the HBsAg result is not acceptable.
- If the delivery hospital does not have the pregnant woman's HBsAg status at the time of delivery, reorder HBsAg testing upon admission.

See CDC's "Testing for Hepatitis B Virus Infection During Pregnancy. Flowchart for Prenatal Providers." <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Prenatal.pdf</u> and "Screening Pregnant Women for Hepatitis B Virus (HBV) Infection." <u>https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf</u>

Health care providers must report their patients with acute or chronic HBV infection to their local health agency within five working days as per the Arizona Administrative Code (AAC) R9-6-202. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>

A provider can report by using the Communicable Disease Report form which is found at <u>http://www.azdhs.gov/cdr</u> or through the Medical Electronic Disease Surveillance Electronic System (MEDSIS), Arizona's electronic reporting system. Information about MEDSIS can be found at <u>http://www.azdhs.gov/medsis</u>.

• Midwives have the same responsibilities as other obstetrical care providers for HBsAg screening of all pregnant women during each pregnancy.

Assistance to Obstetrical Health Care Providers from the County and State Health Departments

Obstetrical health care providers should contact their CHD as needed for assistance with the process to prevent perinatal HBV infections (<u>http://www.azdhs.gov/director/#county-health-departments</u>). In addition, providers can contact the Arizona Department of Health Services' Perinatal Hepatitis B Prevention Program at (602) 364-3676.

ADHS' Arizona Immunization Program Office has developed two checklists (see below) based on the recommendations of the CDC

as found in "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States," *Morbidity and Mortality Weekly Report*, December 23, 2005 <u>http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u> and in "Prevention of Hepatitis B Virus Infection in the United States," MMWR, (RR-1), January 12, 2018 <u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf</u>

Obstetrical Provider Checklists

Obstetrical health care providers may wish to use the following checklists to help them and their staff in carrying out CDC recommendations regarding the prevention of perinatal HBV infection.

Checklist #1: Obstetrical Prenatal HBsAg Screening for All Pregnant Women during Every Pregnancy.

Checklist #2: Management of HBsAg-Positive Pregnant Women.

Checklist #3: Management of HBsAg-Negative Pregnant Women.

CHECKLIST #1	
Obstetrical Prenatal HBsAg Screening for All Pregnant Women during Every Pregnancy	
1. Test hepatitis B surface antigen (HBsAg) on all pregnant women early in each	
pregnancy, even if they have previously been tested.	
2. Send to the hospital where the delivery is planned a copy of the actual laboratory	
report of the mother's most recent HBsAg test.	
 Send to the hospital <u>both</u> HBsAg-positive and HBsAg-negative results. 	
A handwritten note or manual entry into an electronic record of the HBsAg result	
is not acceptable.	
3. Give hepatitis B vaccine (HepBVacc) to unimmunized pregnant women at high risk for	
hepatitis B virus (HBV) infection if their HBsAg test comes back as HBsAg-negative.	
High risk women are defined as:	
 Currently using or recently using injection drugs. 	
 Having had more than one sex partner in the previous 6 months. 	
 Their sex partner is HBsAg-positive. 	
 They have been evaluated or treated for a sexually transmitted disease. 	
 They engage in behaviors that put them at risk for HBV infection. 	
Hepatitis B vaccine is safe to give during pregnancy.	
4. Repeat the HBsAg test on high risk pregnant women at the time of delivery, even if	
they were previously tested for HBsAg during pregnancy and found to be HBsAg-	
negative.	
5. A woman should be tested or retested for HBsAg at delivery when:	
 She was not screened prenatally for HBsAg. 	
 She has had clinical hepatitis since a previous HBsAg testing. 	
• She has had recent exposure to HBV.	
 She engages in behaviors that put her at risk for HBV infection. 	
 She currently uses or recently used injection drugs. 	
 She has had more than one sex partner in the previous 6 months. 	
Her sex partner is HBsAg-positive.	
• She has been evaluated or treated for a sexually transmitted disease.	

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• Her HBsAg test result is not available at time of delivery.

6. If the **copy of the actual laboratory report** of the pregnant woman's most recent HBsAg test is not available at delivery, order an HBsAg test on the woman **as soon as possible** so her infant can receive timely hepatitis B vaccination and hepatitis B immune globulin (HBIG).

	
CHECKLIST #2	
Obstetrical Management of HBsAg-positive Pregnant Women	\checkmark
1. Send to the delivery hospital a copy of the pregnant woman's actual laboratory	
report showing her to be HBsAg-positive. A handwritten note or manual entry into an	
electronic record of the HBsAg result is not acceptable.	
2. All HBsAg-positive women should be tested for HBV DNA to guide maternal antiviral	
during pregnancy to prevent perinatal hepatitis B transmission.	
3. Tell the pregnant woman to inform the delivery staff of her HBsAg-positive status and	
that her infant will need hepatitis B vaccine (HepBVacc) and Hepatitis B Immune	
Globulin (HBIG) within 12 hours of delivery.	
4. Tell the HBsAg-positive pregnant woman that the county health department (CHD)	
will be contacting her to help prevent hepatitis B virus (HBV) infection in the infant and	
household contacts.	
5. HBV education for HBsAg-positive pregnant women should include:	
 HBV is spread by blood and body fluids, including sexual activity. 	
 The need of HepBVacc and HBIG for the newborn. 	
 Infants born to HBsAg-positive mothers may be breast-fed. 	
 The need for serologic testing and giving HepBVacc to household, sexual, and 	
needle-sharing contacts.	
• The need for substance abuse treatment, if appropriate.	
• The need for her to have evaluation for and possible treatment of chronic HBV	
infection.	
6. Refer the HBsAg-positive woman to a physician skilled in treating HBV infections.	
7. Report to the CHD for each pregnancy if the pregnant woman's HBsAg test is HBsAg-	
positive.	
 Use the Communicable Disease Report form at http://www.azdhs.gov/cdr or 	
the Medical Electronic Disease Surveillance Electronic System (MEDSIS).	
Information on MEDSIS is found at <u>http://www.azdhs.gov/medsis.</u>	

CHDs' contact numbers can be found at <u>http://www.azdhs.gov/director/#county-health-departments</u>.

CHECKLIST #3

Obstetrical Management of HBsAg-Negative Pregnant Women

1. Send to the delivery hospital a **copy of the pregnant woman's actual laboratory report** showing her to be HBsAg-negative. A handwritten note or manual entry into an electronic record of the HBsAg result is not acceptable.

CHAPTER 6

HOSPITALS' RESPONSIBILITIES FOR PERINATAL HEPATITIS B VIRUS INFECTION PREVENTION

Overview of the Arizona Perinatal Hepatitis B Prevention Program

In the United States, an estimated 24,000 women with hepatitis B virus (HBV) infection give birth each year. Pregnant women who are infected with HBV have a high likelihood of passing HBV infection to their infant. Children who are perinatally infected with HBV have a 90% chance of developing chronic HBV infection, and a 25% chance of developing cirrhosis or liver cancer. The CDC has published their recommendations for preventing perinatal HBV infection in "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States." *Morbidity and Mortality Weekly Report* (MMWR), December 23, 2005 <u>http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u> and in "Prevention of Hepatitis B Virus Infection in the United States," MMWR, (RR-1), January 12, 2018 https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

These CDC recommendations state that there should be routine hepatitis B surface antigen (HBsAg) testing of all pregnant women during every pregnancy, followed by timely intervention in infants born to HBsAg-positive women. The HBV exposed infants should be given Hepatitis B Vaccine (HepBVacc) and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. Subsequently, these infants born to HBsAg-positive mothers will need on-time completion of their HepBVacc series, and eventual serological testing to document if HBV infection was prevented or not.

The CDC recommends HBsAg screening on <u>all</u> women during <u>every</u> pregnancy because the rate of seroconversion from chronic hepatitis to non-chronic hepatitis is estimated at 0.5% per year. Thus, a few women will convert to HBsAg-negative between past testing and the current pregnancy. In addition, a routine process that tests all pregnant women regardless of their past HBsAg test can minimize misunderstandings of the screening process that might lead to some pregnant women not being screened and hepatitis B virus exposed infants not getting HepBVacc and HBIG in a timely manner.

Hospitals' Responsibilities to Prevent Perinatal Hepatitis B Virus Infection

All birthing hospitals should have written protocols, standing orders, and admission orders to ensure that obstetrical and pediatric health care providers do the following:

- Identify all infants born to pregnant women who are HBsAg-positive, and give these infants both HepBVacc and HBIG within 12 hours of birth.
- Notify the county health department if the hospital HBV serology shows a positive HBsAg test in a pregnant woman.

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- Identify all infants born to women with an unknown HBsAg status and give them HepBVacc within 12 hours of birth, followed by HBIG (as soon as possible but within seven days) if the woman turns out to be HBsAg-positive.
- If the HBsAg status of a mother is unable to be determined within the above guidelines, manage the infant as if the infant were born to a HBsAg-positive mother.
- Administer HepBVacc to <u>all</u> newborns within 24 hours of birth (except to premature infants weighing <2,000 g whose mother's recent HBsAg test has been documented by a copy of the actual laboratory test to be negative).

The strongest predictor of successfully administering HepBVacc to infants born to HBsAgpositive women is having a written hospital policy for newborn hepatitis B vaccination. See *Pediatrics*, April 2010. <u>http://pediatrics.aappublications.org/cgi/reprint/125/4/704</u>

CDC Flowcharts for Providers at Delivery Regarding HepBVacc and HBIG Decisions

- When Maternal Surface Antigen (HBsAg) Test Results are Available. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Available.pdf</u>
- When Maternal Surface Antigen (HBsAg) Test Results are Unavailable at Admission or at Retesting at Delivery. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Unavailable.pdf</u>
- Management of Preterm Infants Weighing <2,000 g by Maternal Hepatitis B Surface Antigen (HBsAg) Status <u>https://www.cdc.gov/hepatitis/hbv/pdfs/CorrectedTable4.pdf</u>

Assistance to Hospitals from the County and State Health Departments

Hospitals should contact their county health department (CHD) as needed for assistance with the process to prevent perinatal HBV infections (<u>http://www.azdhs.gov/director/#county-health-departments</u>). In addition, hospitals may contact the Arizona Department of Health Services' Perinatal Hepatitis B Prevention Program at (602) 364-3676.

ADHS' Arizona Immunization Program Office has developed hospital checklists based on the recommendations of the CDC as found in "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States," MMWR, December 23, 2005, <u>http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u>, in "Prevention of Hepatitis B Virus Infection in the United States," MMWR, January 12, 2018

<u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF</u> and in "Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission" <u>http://www.immunize.org/catg.d/p2130.pdf</u>.

Hospital Checklists

Hospitals may wish to use the following checklists to help carry out CDC recommendations to prevent perinatal HBV infection.

Checklist #1: Hospital Preparations for Delivery to Prevent Perinatal Hepatitis B Virus Infection.

Checklist #2: Admission Orders and Procedures For Birthing Mothers to Prevent Perinatal Hepatitis B Virus Infection.

- Checklist for Pregnant Women Who Have a Prenatal HBsAg Laboratory Report Available at Time of Admission.
- Checklist for Pregnant Women Who Do Not Have a Copy of Their Actual Prenatal HBsAg Laboratory Report From This Pregnancy Available on Admission.

Checklist #3: Hospital Admission Orders and Procedures for Newborns.

- Checklist for Infants Born to HBsAg-Positive Women.
- Checklist for Infants Born to HBsAg-Unknown Women.
- Checklist for Infants Born to HBsAg-Negative Women.

CHECKLIST #1	
Hospital Preparations For Delivery to Prevent Perinatal Hepatitis B Virus Infection	Б
1. Have <u>written</u> hospital policies and procedures that coincide with the most recent CDC	
recommendations: MMWR Dec. 25, 2005	
(http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf) and MMWR Jan. 12, 2018	
(https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF).	
2. Make sure that there is a copy of the pregnant woman's actual HBsAg laboratory	
result (POSITIVE or NEGATIVE) in the hospital record.	
3. Identify the person(s) responsible for checking the pregnant woman's HBsAg test	
status on admission to Labor & Delivery.	
4. Determine the location on the mother's and newborn infant's chart where the	
mother's HBsAg status (POSITIVE, NEGATIVE, or UNKNOWN) will be documented.	
5. Establish a mechanism to notify the nursery staff and the infant's physician when a	
pregnant woman is HBsAg-positive or when her HBsAg status is UNKNOWN.	
6. If the delivering woman's HBsAg test has not been done or if the results are not	
available, determine the process to have her blood tested for HBsAg as soon as possible.	
7. Give both and hepatitis B vaccine* (HepBVacc) and Hepatitis B Immune Globulin	
(HBIG) within 12 hours of birth in the following instances:	
All infants born to HBsAg-positive women.	
• All infants weighing <2,000 g who are born to women of UNKNOWN HBsAg	
status.	
8. All infants weighing ≥2,000 g who are born to women of UNKNOWN HBsAg status	
need HepBVacc within 12 hours of birth.	
9. When both HepBVacc and HBIG are given, they should each be given as soon as	
possible as they are available. They can be given at the same time or at different times,	
but each should be given as soon as possible, and each in a separate site.	
10. Establish a mechanism to notify an infant's physician if a parent refuses to have their	
infant receive HepBVacc and/or HBIG.	

11. Establish a process to notify the county health department of hospital serology showing a HBsAg-positive test in a pregnant woman.

http://www.azdhs.gov/director/#county-health-departments

12. Establish a process so that the hospital reports the dates of every infant's receipt of HepBVacc and HBIG to the Arizona State Immunization Information System (ASIIS). <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/asiis/index.php</u>

13. Have standing orders for all infants to receive HepBVacc within 24 hours of birth.

14. Enroll in Vaccines for Children (VFC) program to get free HepBVacc for newborns. Call (602) 364-3642 or see <u>http://www.azdhs.gov/preparedness/epidemiology-disease-control/immunization/index.php#vaccines-children-home</u>.

15. Contact your hospital pharmacy to make sure that HepBVacc and HBIG are readily available on a routine basis, or that there is a process to obtain them quickly when needed.

CHECKLIST #2

Admission Orders and Procedures For Birthing Mothers to Prevent Perinatal Hepatitis B Virus Infection Checklist for Pregnant Women Who Have a Prenatal HBsAg Laboratory Report

Checklist for Pregnant Women Who Have a Prenatal HBsAg Laboratory Report Available at Time of Admission

- 1. Examine a copy of the pregnant woman's prenatal HBsAg test result.
 - Make sure that the correct test was performed. The correct test is **HBsAg** (hepatitis B surface **antigen**).
 - Make sure to have a copy of the actual HBsAg laboratory report. Do not rely on a handwritten, transcribed, or electronically entered HBsAg test result without having actual documentation of the laboratory report!
 - If the HBsAg test is NEGATIVE, make sure that the testing date was during *this* pregnancy, and not a previous one.

If the HBsAg test is POSITIVE, make sure that the nursery staff and the infant's physician are aware of the test result and that the infant must receive both HepBVacc and HBIG within 12 hours of birth.

2. Make sure that a **copy of the actual HBsAg laboratory report** is part of (1) the pregnant woman's Labor & Delivery record **and** (2) the infant's hospital record.

3. Repeat the pregnant woman's HBsAg blood test on admission if she was HBsAg NEGATIVE during this pregnancy <u>but</u> is at risk for recently acquiring hepatitis B virus (HBV) because she engages in behaviors that put her at high risk for HBV, such as she:

- Is not in a long-term, mutually monogamous relationship.
- Has had an HBsAg-positive sex partner or has had a recent exposure to HBV.
- Has been evaluated or treated for a sexually transmitted disease.
- Currently uses or recently used injection drugs.
- Has had clinical hepatitis since previous HBsAg testing.

Hospital Admission Orders and Procedures for Newborns	
CHECKLIST #3	
receipt status to ensure prophylaxis is administered in a timely manner.	
communicate regarding the mother's HBsAg status and the infant's HepBVacc and HBIG	
level of neonatal care), staff at the transferring and receiving facilities should	
4. For infants transferred to a different facility after birth (e.g., hospital with a higher	
birth.	
B vaccine (HepBVacc) and hepatitis B immune globulin (HBIG) within 12 hours of	
 If the HBsAg test is POSITIVE, make sure that the nursery staff and the infant's physician are aware of the test result so that the infant can receive both hepatitis 	_
Delivery record and (2) the infant's hospital record.	
 Place a copy of the HBsAg laboratory report into (1) the mother's Labor & Delivery record and (2) the infect's beginted record. 	
(hepatitis B surface antigen).	
Make sure that the correct test was performed. The correct test is HBsAg	
3. Once a copy of the pregnant woman's actual HBsAg laboratory report is available:	
delivering pregnant woman's newly obtained HBsAg test result as soon as possible.	
2. Instruct the laboratory to call Labor & Delivery and the nursery staff with the	
delivery.	
staff, and to the infant's physician as soon as possible and optimally before	
her infant's chart and communicated to the woman's physician, to the nursery	
 Make sure that the woman's HBsAg test is done in a timely manner so that the woman's actual HBsAg laboratory result is available in her chart and available in 	
not imminent.	
 Order the woman's HBsAg test to be done as soon as possible, unless delivery is not imminant 	
1. Order an HBsAg blood test on the woman, even if she had been previously tested.	
HBsAg Laboratory Report From This Pregnancy Available on Admission	
Checklist for Pregnant Women Who Do Not Have a Copy of Their Actual Prenatal	
receipt status to ensure prophylaxis is administered in a timely manner.	
communicate regarding the mother's HBsAg status and the infant's HepBVacc and HBIG	
level of neonatal care), staff at the transferring and receiving facilities should	
5. For infants transferred to a different facility after birth (e.g., hospital with a higher	
result as soon as possible.	
and the nursery staff with the delivering pregnant woman's newly obtained HBsAg test	

Checklist for Infants Born to HBsAg-POSITIVE Women

1. Administer hepatitis B vaccine (HepBVacc) [0.5 mL, IM, either Recombivax HB[®] or Engerix-B[®]] **and** Hepatitis B Immune Globulin (HBIG) [0.5 mL, IM] at separate injection sites **as soon as possible within 12 hours of birth.**

• HepBVacc and HBIG can be given at the same time or at different times at separate injection sites. Do not wait for HBIG to be available before giving HepBVacc.

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Obtain verbal consent from the parent prior to the HepBVacc and HBIG administration. Give the HepBVacc Vaccine Information Statement (VIS) to the parent. 3. Document the HepBVacc and HBIG doses in the infant's medical record, including date, **time**, site of administration, manufacturer, and lot number. 4. Give the mother a Lifetime Immunization Record that includes the receipt dates of the HepBVacc and HBIG. Explain the infant's need for the complete HepBVacc series. Remind her to bring the vaccine card with her each time her baby sees a provider. 5. Report the date of the infant's HepBVacc and HBIG to the Arizona State Immunization Information System (ASIIS). http://www.azdhs.gov/preparedness/epidemiologydisease-control/immunization/asiis/index.php 6. Notify the county health department of the birth, and the date and time of receiving HepBVacc and HBIG. http://www.azdhs.gov/director/#county-health-departments 7. Notify the infant's primary care provider of the infant's birth, the date and time of when HepBVacc and HBIG were administered. Inform the provider of the importance of additional timely HepBVacc doses and post-vaccination testing of the infant for HBsAg and for **antibody to HBsAg** after completion of the HepBVacc series. 8. If an infant born to a HBsAg-positive woman weighs <2,000 g, do not count the birth vaccine dose as part of the infant's HepBVacc series. Instead, start the regular HepBVacc series as soon as possible beginning at 4-6 weeks of age. 9. Provide hepatitis B virus (HBV) education to the mother, which includes the following: Infants who receive HepBVacc and HBIG may be breastfed beginning • immediately after birth. • In order to prevent HBV infection, her infant must complete the full HepBVacc series on the recommended schedule. Blood will need to be drawn from her infant after at least 3 doses of the HepBVacc series (at age ≥ 9 months and $\geq 1-2$ months after the last dose) to determine if her infant developed a protective immune response to vaccination or needs additional management. How HBV is spread, that she is contagious, and the need for testing and HepBVacc of susceptible household, sexual, and needle-sharing contacts. The need for substance abuse treatment, if this is a problem. The need for her to have a medical evaluation for her own HBV infection. 10. If the parent is unwilling to give verbal consent to HepBVacc and/or HBIG, notify the infant's physician as soon as possible and prior to 12 hours of age. Checklist for Infants Born to Women with UNKNOWN HBsAg Status \checkmark 1. Administer hepatitis B vaccine (HepBVacc) [0.5 mL, IM, either Recombivax HB[®] or Engerix-B[°]] as soon as possible within 12 hours of birth. 2. An infant weighing <2,000 g whose mother's HBsAg status is UNKNOWN should receive both HepBVacc and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. HepBVacc and HBIG should each be given to the infant as soon as possible as

3. Obtain verbal consent from the parent prior to HepBVacc administration. Give the HepBVacc Vaccine Information Statement (VIS) to the parent.

4. Document the HepBVacc dose (and HBIG, if given) in the infant's medical record, including date, **time**, site of administration, manufacturer, and lot number.

5. Report the date of the infant's HepBVacc (and HBIG if given) to the Arizona State Immunization Information System (ASIIS).

http://www.azdhs.gov/preparedness/epidemiology-disease-

control/immunization/asiis/index.php

6. Give the mother an immunization record card that includes the date of her infant's HepBVacc (and HBIG if given). Explain the infant's need for the complete HepBVacc series. Remind her to bring the card with her each time her baby sees a provider.

7. Confirm that the mother had a HBsAg test ordered on admission.

8. Make sure that the laboratory received the blood for testing the mother's HBsAg status.

9. Verify when the mother's HBsAg result will be available and that it will be reported to Labor & Delivery and the nursery staff **as soon as possible**.

10. If the test indicates that the mother's HBsAg test result is **POSITIVE**, do the following:

- Administer HBIG (0.5 mL, IM) to the infant as soon as possible.
- Follow the checklist "For infants born to HBsAg-positive women."
- Alert the mother's and infant's physician(s) of the POSITIVE HBsAg test result.

11. If the parent is unwilling to give verbal consent to HepBVacc and/or HBIG, notify the infant's physician prior to 12 hours of age.

12. If the infant must be discharged before the mother's HBsAg result is known:

- Ensure that HepBVacc was given as described above.
- Document contact information for the parents (e.g., addresses, telephone numbers, emergency contacts). In case the mother's HBsAg test is POSITIVE, the infant needs to receive HBIG as soon as possible and within 7 days of birth.
- Notify the infant's primary care provider and the county health department that the mother's HBsAg result is pending. <u>http://www.azdhs.gov/director/#county-health-departments</u>
- If the mother's HBsAg result remains UNKNOWN, manage the infant as an HBVexposed infant with serologic testing after the final dose of HepBVacc.

13. Do not count the birth vaccine dose of an infant weighing <2,000 g as part of the	
infant's hepatitis B vaccine series. Instead, start counting the total doses in the	
HepBVacc series starting with the dose at 4–6 weeks of age.	

Checklist for Infants Born to HBsAg-NEGATIVE Women 1. Administer hepatitis B vaccine (HepBVacc) [0.5 mL, IM, either Recombivax HB[®] or

Engerix-B[®]] within 24 hours of birth to all infants weighing \geq 2,000 g at birth.

2. Obtain verbal consent from the parent prior to HepBVacc administration.

Give the HepBVacc Vaccine Information Statement (VIS) to the parent.

3. Document the HepBVacc dose in the infant's medical record, including date, time, site of administration, and lot number.

 \checkmark

4. Report the date of the infant's HepBVacc to the Arizona State Immunization Information System (ASIIS). <u>http://www.azdhs.gov/preparedness/epidemiology-disease-control/immunization/asiis/index.php</u>

5. Give the mother an immunization record card that includes the HepBVacc date. Explain the infant's need for the complete HepBVacc series to protect her baby. Remind her to bring the card with her each time her baby sees a health care provider.

6. If for some reason HepBVacc is not given, make sure that a copy of the actual HBsAgnegative laboratory test of the mother is in the infant's chart.

7. For infants weighing <2,000 g, defer the first dose of HepBVacc until one month after birth or at hospital discharge, whichever comes first.

• However, a copy of the mother's actual HBsAg laboratory test result showing that she is HBsAg-negative should be part of the infant's medical record in order to defer the first dose of HepBVacc.

8. If the parent is unwilling to give verbal consent to HepBVacc, notify the infant's physician.

SAMPLE TEXT for Admission Orders for Routine Newborn Hepatitis B Vaccination

Hepatitis B Vaccine (RECOMBIVAX HB[®] or Engerix-B[®]) IM

Administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, intramuscular (IM), in anterolateral thigh within 24 hours of birth (or sooner if the infant is discharged before 24 hours). Prior to vaccination, give the parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. Give the parent a record of the vaccination. If a parent is unwilling to give consent, notify physician ASAP. Document vaccine administration or vaccine refusal in the hospital record.

 The above sample text was adapted from the Immunization Action Coalition's document "Guidance for Developing Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus (HBV) Transmission" (6/17). <u>http://www.immunize.org/catg.d/p2130.pdf</u>

CHAPTER 7

PEDIATRIC HEALTH CARE PROVIDERS' RESPONSIBILITIES FOR PERINATAL HEPATITIS B VIRUS INFECTION PREVENTION

Overview of the Arizona Perinatal Hepatitis B Prevention Program:

Pregnant women who are infected with hepatitis B virus (HBV) have a high likelihood of passing HBV infection to their infant. Infants infected with HBV perinatally have a 90% chance of developing chronic HBV infection, and a 25% chance of developing cirrhosis or liver cancer. Perinatal HBV infection can be prevented by routine testing of all pregnant women for hepatitis B surface antigen (HBsAg), and intervening in infants born to HBsAg-positive women. These infants are given single-antigen hepatitis B vaccine (HepBVacc) and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. Subsequently, infants born to HBsAg-positive mothers will need on-time completion of their HepBVacc series, and eventual serological testing to document if HBV infection was prevented or not.

Pediatric care providers play an essential role in preventing perinatal HBV infection by intervening at delivery, and by follow up vaccination and serological testing. Pediatricians need to identify infants born to HBsAg-positive pregnant women and ensure that they receive HepBVacc and HBIG within 12 hours of birth.

Hospitals are encouraged to have standing orders to assist pediatricians in taking the necessary steps to prevent perinatal hepatitis B infection. In addition, the pediatrician must administer the remaining doses of HepBVacc in a timely manner.

Finally, at least at nine months of age and at least 1–2 months after the last dose in the HepBVacc series, infants need blood testing for HBsAg and antibody to HBsAg (anti-HBs) to see if HBV infection was prevented or not.

In order to successfully prevent perinatal HBV infection, there needs to be proper communication and coordinated efforts between pediatric care providers, hospital personnel, the CHD, the HBsAg-positive women, obstetrical providers, and the ADHS.

Responsibilities of Pediatric Health Care Providers (In Hospital and Outpatient)

The CDC recommend the following for Pediatric Health Care Providers (as found in *Morbidity and Mortality Weekly Report* (MMWR), December 23, 2005, "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States," <u>https://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u> and MMWR January 12, 2018, "Prevention of Hepatitis B Virus Infection in the United States" <u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF)</u>.

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In Hospital Pediatric Care Responsibilities

- Know the HBsAg test result of the mother for each and every newborn infant.
- Give HepBVacc and HBIG within 12 hours to infants born of HBsAg-positive women.
- Give HepBVacc within 12 hours to full term infants born to women with unknown HBsAg status.
 - Determine the mother's HBsAg status as soon as possible.
 - HBIG should be given as soon as possible to infants born to HBsAg-positive mothers and within seven days.
- Give HepBVacc and HBIG within 12 hours to preterm infants (infants weighing <2,000 grams) born to women with unknown HBsAg status.
- Inform the CHD of the infant's name, contact information and vaccination history of HBIG and HepBVacc prior to discharge.
- Give all other infants HepBVacc within 24 hours of birth (with the exemption of infants weighing <2,000 g where there is a proof that a mother had a recent HBsAg-negative laboratory test as demonstrated by a copy of the actual HBsAg-negative test).

Outpatient Pediatric Care Responsibilities

For infants born to HBsAg-positive mothers:

- Complete the full HepBVacc series as soon as possible. The final dose should not be given before 24 weeks (6 months).
- Obtain post-vaccination serology for HBsAg and antibody to HBsAg (anti-HBs) at least at nine months of age and at least 1–2 months after the last dose in the HepBVacc series.
- Inform the CHD of the dates that the infant received follow-up HepBVacc and the results of the infant's post-vaccination HBV serologies.

For infants whose mother's HBsAg test remains unknown indefinitely:

• Obtain post-vaccination serology on these infants in the same way as is done for infants born to HBsAg-positive mothers.

CDC Flowcharts for Providers at Delivery Regarding HepBVacc and HBIG Decisions

- When Maternal Surface Antigen (HBsAg) Test Results are Available. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Avaliable.pdf</u>
- When Maternal Surface Antigen (HBsAg) Test Results are Unavailable at Admission or at Retesting at Delivery.

https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Unavailable.pdf

 Management of Preterm Infants Weighing <2,000 g by Maternal Hepatitis B Surface Antigen (HBsAg) Status.

https://www.cdc.gov/hepatitis/hbv/pdfs/CorrectedTable4.pdf

Assistance to Pediatric Health Care Providers from the County and State Health Departments

ADHS' Arizona Immunization Program Office has developed checklists that pediatric care providers may wish to use to help them and their staff in carrying out CDC recommendations regarding the prevention of perinatal hepatitis B virus infection. These checklists were developed based on CDC recommendations as found in "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States," MMWR, December 23, 2005, <u>http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u>, "Prevention of Hepatitis B Virus Infection in the United States," January 12, 2018

<u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF</u> and "Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission" <u>http://www.immunize.org/catg.d/p2130.pdf</u>.

CHDs will be reaching out to pediatric health care providers and to parents of HBV-exposed infants to assist with case management. Pediatric health care providers should contact their CHDs as needed for assistance with the process to prevent perinatal HBV infections http://www.azdhs.gov/director/#county-health-departments). Providers may also contact the Arizona Department of Health Services' Perinatal Hepatitis B Prevention Program at (602) 364-3676.

Report HepBVacc and HBIG Administration to the Arizona State Immunization Information System (ASIIS)

Arizona State law requires that health care providers who administer any vaccine to children (birth to 17 years old) must report the vaccine to the Arizona electronic immunization registry (ASIIS). Therefore, hospitals and health care providers are required to report to ASIIS about each dose of HepBVacc given to a child. This can be accomplished by reporting the vaccination online into ASIIS. (See http://www.azdhs.gov/preparedness/epidemiology-disease-control/immunization/asiis/index.php). Online reporting requires ASIIS registration.

ASIIS helpline staff can be reached at (602) 364-3899 or toll free at 1-877-491-5741. Additional information about ASIIS can be obtained at http://www.azdhs.gov/preparedness/epidemiology-disease-control/immunization/asiis/index.php.

State law does not require reporting of HBIG administration to ASIIS, but HBIG reporting is requested and the receipt date can be reported in the same manner as vaccines. Entering HBIG information into ASIIS will assist CHDs as they manage the cases of infants exposed to HBsAgpositive mothers.

Pediatric Health Care Provider Checklist

The checklists for pediatric care providers for in hospital care of the newborns can be found at the end of Chapter 6 (<u>Hospitals' Responsibilities for Perinatal Hepatitis B Virus Infection</u>

<u>Prevention</u>). The checklist for outpatient management of infants born to HBsAg-positive mothers is found below.

Outp	patient Procedures for Infants Born to HBsAg-positive Women	\checkmark
1.	 Instruct office staff to work with the County Health Department (CHD) in order to: Recall the infant for on-time administration of the hepatitis B vaccine (HepBVacc) series. 	
	 Order serological testing for hepatitis B virus (HBV) infection after the final HepBVacc dose (at least at 9 months of age and ≥1–2 months after the last dose). Complete the CHD forms to report dates of the infant's HepBVacc and results of the infant's HBV serological testing. 	
	 Give the family HBV education as needed. HBV educational materials can be obtained from CHDs (<u>http://www.azdhs.gov/director/#county-health-</u> <u>departments</u> and from <u>chapter 11</u> of the ADHS Perinatal Hepatitis B Prevention Program Manual. 	
2.	Schedule the 2 nd HepBVacc dose (the 1 st outpatient dose) as soon as possible. This would be at 4–6 weeks of age depending on which HepBVacc formulation will be used.	
3.	 The total number of HepBVacc doses depends on which vaccine formulations are used and the infant's birth weight. For infants with birth weight ≥2,000 g (≥4.4 lb.), give 3 doses if using all single antigen HepBVacc or 4 doses if Pediarix[®] is used. For infants with birth weight <2,000 g (<4.4 lb.), the birth dose of HepBVacc 	
	dose should be disregarded in calculating the total number of vaccine doses. For more details refer to <u>http://www.cdc.gov/hepatitis/hbv/pdfs/correctedtable4.pdf</u>	
4.	Instruct staff to do a <u>reminder recall</u> for all HepBVacc doses and the final serologic testing. Staff should investigate and follow-up if the infant misses any appointments for HepBVacc.	
5.	Instruct staff to report to the CHD when the HepBVacc are administered and when HBV serologic testing is complete. <u>http://www.azdhs.gov/director/#county-health-</u> departments	
6.	Instruct staff to report each HepBVacc dose in a timely manner to the Arizona State Immunization Information System (ASIIS). <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/asiis/index.php</u>	
7.	When the infant is ≥9 months old and at least 1-2 months after the final HepBVacc dose, order serology for HBsAg (hepatitis B surface antigen) and antibody to HBsAg (anti-HBs).	
8.	 Evaluate the results of the infant's HBsAg and anti-HBs. Infants who test NEGATIVE for HBsAg and test POSITIVE for anti-HBs (≥10 mIU/mL) are <u>not infected</u> and are <u>immune</u>. Infants who test POSITIVE for HBsAg have been <u>infected</u> with HBV and will need pediatric gastroenterology evaluation and management for chronic HBV infection. 	

	• Infants who test NEGATIVE for HBsAg and NEGATIVE for anti-HBs are not infected			
	but they are <i>not immune</i> . Revaccinate the infant with a single dose of HepBVacc			
	and do serologic testing 1–2 months later. An infant whose anti-HBs remains			
	<10mIU/mL after an additional dose of HepBVacc should receive 2 more doses of			
	HepBVacc to complete the 2 nd HepBVacc series, followed by serologic testing 1–2 months after the final dose.			
	• Alternately, HBsAg-negative infants with anti-HBs <10 mIU/mL may instead be			
	given a 2 nd complete 3-dose series, followed by testing 1–2 months after the final			
	HepBVacc dose.			
9.	Report infants who test POSITIVE for HBsAg to the CHD using the Communicable			
	Disease Report form which can be found at <u>http://www.azdhs.gov/cdr</u> , or through			
	MEDSIS at http://www.azdhs.gov/preparedness/epidemiology-disease-			
	<pre>control/infectious-disease-services/index.php#medsis-home</pre>			
Outpatient Procedures for Infants Born to Women whose HBsAg Status Remains				
Unk	nown			
1	Finish the HenDVece series and obtain next vectorization covelegistecting in the			

 Finish the HepBVacc series and obtain post-vaccination serologic testing in the same way as for infants who are born to HBsAG-positive women to assure that the infant is HBsAg-negative and has a protective level of antibody to HBsAg (anti-HBs) of ≥10 mIU/mL.

CHAPTER 8

COUNTY HEALTH DEPARTMENTS' RESPONSIBILITIES FOR PERINATAL HEPATITIS B CASE MANAGEMENT SERVICES

Background

Each County Health Department (CHD) should provide case management for hepatitis B surface antigen (HBsAg)-positive pregnant women, including home visits if necessary, to assure that:

- 1. All infants born to HBsAg-positive mothers are offered hepatitis B vaccine (HepBVacc) and hepatitis B immune globulin (HBIG) within 12 hours of birth;
- All HBsAg-exposed infants receive on-time HepBVacc and post-vaccination serologic testing (PVST);
- 3. The HBsAg-positive mother is educated about hepatitis B virus (HBV) infection;
- 4. The household, sexual, and needle-sharing contacts of the mother are evaluated to see if they are HBV infected, HBV immune, or in need of HepBVacc.

ADHS contracts with all fifteen Arizona counties to provide case management to prevent perinatal HBV transmission. Contract payment for case management for each perinatal HBV case is paid in two increments (one for prenatal services and one for postnatal services).

County Health Departments' Administrative Responsibilities

- 1. Be familiar with the contents of the ADHS Perinatal Hepatitis B Prevention Program Manual and follow the guidance in <u>Appendix A: ADHS MEDSIS User Guide for Perinatal Hepatitis B.</u>
- 2. Have a designated jurisdictional Perinatal Hepatitis B Coordinator (with an identified back-up) as the primary point of contact with ADHS regarding case management. Notify ADHS with any staffing changes as soon as possible to prevent any lapses in service.
- 3. Notify ADHS upon identification of a HBsAg-positive pregnant woman or child ≤24 months of age born to a HBsAg-positive woman through MEDSIS.
- 4. Document any refusals for testing or vaccination on the part of the HBsAg-positive woman or her contacts in MEDSIS.
- 5. Be the primary point of contact for obstetricians, delivery hospitals, and pediatric care providers regarding perinatal hepatitis B cases in their jurisdiction.
- 6. Submit updates about the HBsAg-positive pregnant woman, her infant, and her contacts to ADHS through MEDSIS until completion of case management.
- Submit the line list with each Contractor's Expenditure Report (CER). <u>See Appendix</u> <u>8C: Line Listing for Perinatal Hepatitis B Case Management Billing.</u> Enter and submit electronically using the Excel template which can be downloaded from the <u>link</u>. Electronic or typed line lists are preferred. However, legible handwritten line lists will be accepted.

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County Health Departments' Prenatal Responsibilities

1. Maternal Prenatal Interventions

Provide verbal and written educational materials to the HBsAg-positive pregnant woman to explain that her HBsAg-positive test results means that she has HBV infection and that she can pass the HBV infection to her infant.

- A. Provide information concerning HBV that discusses the potential use of antiviral therapy.
 - All HBsAg-positive pregnant women should be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. The American Association for the Study of Liver Diseases (AASLD) suggests maternal antiviral therapy when the maternal HBV DNA is >200,000 IU/mL.
 - 2) Recommend speaking with her provider regarding the need for antiviral therapy during pregnancy.
- B. Provide education regarding infant vaccination and serologic testing.
 - Explain that unless babies are vaccinated soon after birth, most of the babies who are born to HBsAg-positive mothers will develop chronic HBV infection which means that the child will always be infectious to other people for the rest of their lives, and can develop liver damage which leads to liver cancer, liver failure, and death.
 - Describe how giving her infant HepBVacc and HBIG within 12 hours of birth, followed by on-time additional HepBVacc will usually prevent HBV infection in her infant.
 - 3) Explain that even after HepBVacc, follow-up serologic testing will be needed to see if the infant is HBV infected or HBV immune.
 - 4) Stress the importance of her infant receiving the 2nd dose of HepBVacc at 1–2 months of age, and completing the HepBVacc series within six months of age.
 - 5) Explain that her infant may encounter long-term health problems if her infant does not complete the HepBVacc series on time.
 - 6) Tell her to bring the written documentation of HepBVacc when taking her infant for medical care.
- C. Provide education regarding HBV transmission.
 - Explain that since HBV is spread by close contact with blood and body fluids, household contacts, sexual contacts, needle-sharing contacts, and her other biological children will need evaluation, serologic testing, and possibly vaccination.
 - Explain that HBV is not spread by breastfeeding, kissing, hugging, coughing, ingesting food or water, sharing eating utensils, sharing drinking glasses, or casual contact.
 - 3) Explain that, in general, persons should not be excluded from work, school, play, child care, or other settings on the basis of their HBsAg-positive status, unless they are prone to biting or other activities that would expose others to their blood.
- D. Provide education on prevention measures.
 - 1) Notify any sexual partner of her HBsAg-positive status.

- 2) Use condoms (latex or polyurethane) to protect non-immune sex partners from acquiring HBV infection from sexual activity until the sex partners can be vaccinated and their immunity documented.
- 3) Cover cuts and skin lesions to prevent the spread of HBV through body fluids or blood.
- 4) Do not donate blood, plasma, or tissue.
- 5) Refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could become contaminated with blood.
- 6) Inform all medical or dental health care providers of her HBsAg-positive status.
- 7) Avoid or limit alcohol consumption.
- 8) Refrain from taking any new medicines, including over-the-counter and herbal medicines, without consulting with her health-care provider.
- 9) Obtain vaccination against hepatitis A.
- E. Offer the HBsAg-positive pregnant woman information on support groups to help cope with chronic HBV infection. Information about support groups is available at <u>http://www.hepb.org/patients/support_groups.htm</u>.
- F. Instruct her where to call if she changes her address or telephone number.
- 2. Contact Interventions

Provide verbal and written educational materials for household, sexual, and needle-sharing contacts, and other biological children of the HBsAg-positive woman. Educational information can be found in the previous section, <u>"Maternal Prenatal Interventions"</u>.

- A. Recommend pre-vaccination testing (anti-HBc, HBsAg and anti-HBs) to identify infected persons among household, sexual, or needle-sharing contacts.
 - 1) Previously <u>unvaccinated</u> contacts should receive their first dose of HepBVacc immediately after collection of blood for serologic testing to provide protection against HBV in a timely manner.
 - Contacts who are found to be HBV susceptible (negative for both HBsAg and anti-HBs) should complete the full HepBVacc series using an age-appropriate vaccine dose and schedule. This even applies to children who have a history of previous vaccination.
 - 3) Contacts who are found to be HBsAg-positive should be told that they are infected with HBV, and should be educated about HBV infection and transmission in order to prevent spread to others and to maintain their own health. All HBsAgpositive contacts should be referred to a clinician for medical evaluation and management of HBV infection.
- B. Recommend PVST (anti-HBs and HBsAg) after vaccination for all exposed contacts including other biological children of HBsAg-positive women who have not been previously tested for immunity, sexual partners of HBsAg-positive persons, health care workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids, chronic hemodialysis patients, HIV-infected people, and immune-compromised people.
- C. Enter all information into MEDSIS, per the MEDSIS protocol.
- 3. Obstetrical Provider Interventions
 - A. Contact each obstetrical health care provider of a HBsAg-positive pregnant woman

before her expected due date, giving guidance based on the CDC perinatal hepatitis B prevention recommendations. <u>See Appendix 8A for sample letter.</u>

- B. For more information, <u>see Chapter 5: Obstetrical Health Care Providers'</u> <u>Responsibilities for Maternal Hepatitis B Virus Infection Screening, Reporting, and</u> <u>Interventions.</u>
- 4. Delivery Hospital Interventions
 - A. Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg-positive status to the hospital or birthing facility where the delivery is planned.
 - B. Work with delivery hospitals so that each hospital is aware of CDC recommendations regarding perinatal HBV prevention and each has appropriate protocols to carry out the recommendations.
 - C. Work with the delivery hospitals so that there can be HBV educational material available as needed for HBsAg-positive mothers.
 - D. Arrange to have the delivery hospitals notify the CHD when an HBsAg-positive woman delivers, as well as the date and time that her HBsAg-exposed infant was given HBIG and HepBVacc.
 - E. For more information, <u>see Chapter 6: Hospital Responsibilities for Perinatal HBV</u> <u>Infection Prevention.</u>

County Health Departments' Postnatal Responsibilities

- 1. Infant Interventions
 - A. After birth, enter the infant as a perinatal contact of the mother in MEDSIS and complete initial postnatal case management sections <u>as instructed</u>.
 - B. Ensure proper scheduling of HepBVacc and post-vaccination serology for every infant. Document vaccination history and diagnostic test results <u>in MEDSIS</u> as information becomes available.
 - 1) Infants (born to HBsAg-positive women) who completed the full HepBVacc series but subsequently tested negative for both anti-HBs <u>and HBsAg</u> will require revaccination due to non-response.
 - Recommend revaccination with a single dose of HepBVacc and repeat serologic testing one to two months later. Infants whose anti-HBs remain <10 mIU/mL should receive two additional doses of HepBVacc followed by serologic testing one to two months after the last dose. Alternatively, HBsAg-negative infants with anti-HBs <10 mIU/mL may instead be revaccinated with a second complete three dose series followed by serologic testing one to two months after the final dose.
 - C. Notify ADHS if a HBsAg-exposed infant tests positive for HBsAg at PVST. The exposed infant has seroconverted and MEDSIS should be updated to reflect this change from a perinatal contact into a case. <u>See "How to change a perinatal contact into a case"</u>.
 - D. Notify ADHS if a HBsAg-positive pregnant woman, an exposed infant, or a contact has moved to a new jurisdiction so that ADHS can transfer to the new jurisdiction.
- 2. <u>Pediatric Care Provider Interventions</u>

- A. Provide a copy of the original laboratory report indicating the pregnant woman's HBsAgpositive status to the health care provider who will care for the newborn infant.
- B. Contact the infant's health care provider to explain the need for follow up HepBVacc doses and post-vaccination serologic testing and request timely reporting of this information. <u>See Appendix 8B for sample letter.</u>
- C. Send HepBVacc and post-vaccination serologic testing reminders to the pediatric care provider as necessary.
- D. For more information, see <u>Chapter 7: Pediatric Health Care Providers' Responsibilities</u> for Perinatal Hepatitis B Virus Infection Prevention.

APPENDIX 8A

SAMPLE OB LETTER

<<Insert County Letterhead Here>>

«date»

«FirstName» «LastName», M.D. «clinic» «Address» «City», «State» «PostalCode»

RE: «Mom» (DOB:)

Dear Dr. «LastName»:

The Arizona Department of Health Services and the <<County Health Department>> Perinatal Hepatitis B Prevention Program work to facilitate appropriate post exposure protection against the transmission of hepatitis B virus (HBV) to every high risk infant born to a hepatitis B surface antigen (HBsAg) positive mother.

Our records indicate that you are the obstetrical provider for «Mom». She received a positive HBsAg test result on «testdate» and **is due to deliver on «EDC»** at «Hospital». Please send the delivery hospital a copy of the actual laboratory report of <<Mom>>'s most recent positive or negative HBsAg test to ensure that appropriate preparations can be arranged for newborn care, including administration of hepatitis B immune globulin (HBIG) and hepatitis B vaccine at birth.

Please emphasize to the expectant mother that she can play an important role in preventing the transmission of HBV to her newborn by confirming that the <u>1st dose of hepatitis B vaccine</u> and <u>HBIG</u> are administered at birth. Many women with chronic hepatitis B, especially immigrant and refugee women may only see a doctor when they receive prenatal care. Therefore, educating them about this disease would be very helpful for them, their babies, and their families, as well as their respective communities. The following CDC website provides hepatitis B educational material in a variety of languages and may be helpful for those patients with language barriers. <u>https://www.cdc.gov/hepatitis/hbv/patienteduhbv.htm</u>

We hope this letter will assist you in your effort to provide services to this high risk mother. If you or your patient has any questions, please contact us at :<<contact info>>. We will be following up with the mother and infant to provide education and resources.

Sincerely,

<<Your Signature>> <<Your Name>>

APPENDIX 8B

SAMPLE PEDIATRICIAN LETTER

<<Insert County Letterhead Here>>

«Date»

«FirstName» «LastName» «Clinic» «Address» «City», «State» «PostalCode»

RE: «Infant» (DOB:)

Dear Dr. «LastName»:

The <<County Health Department>> Perinatal Hepatitis B Prevention Program is case managing a highrisk infant born to «Mom». Our records indicate that you are the well child provider for «Infant», the exposed infant.

Ms. «Mom» tested positive for hepatitis B surface antigen (HBsAg) during her pregnancy and her infant should have received hepatitis B immune globulin (HBIG) and hepatitis B vaccine at birth in the hospital. Please verify this and ensure that the infant receives the vaccine doses at appropriate intervals. The CDC recommends infants born to HBsAg positive mothers complete post-vaccination serologic tests for **HBsAg and anti-HBs** at age appropriate testing times, usually one to two months following the final dose. Appropriate vaccination and post-vaccination serologic testing intervals can be found in "The Pink Book" (https://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html).

As you are aware, unimmunized infants born to HBsAg positive mothers have up to a 90% chance of becoming chronic hepatitis B carriers resulting in significant disease later in life. Therefore, it is critical that we identify high-risk infants and treat them in an appropriate and timely manner.

We are asking that you provide updates on vaccination and post-vaccination serologic testing of the exposed infant to <<County Health Department>> at <<pre>referred method of contact>>. We hope that you and your staff will continue efforts to prevent perinatal hepatitis B transmission. Thank you for your cooperation with this preventive effort.

Sincerely,

<<Your Signature>> <<Your Name>>

APPENDIX 8C

LINE LISTING FOR PERINATAL HEPATITIS B CASE MANAGEMENT BILLING

Download Excel template here: <u>http://azdhs.gov/preparedness/epidemiology-disease-control/hepatitis/index.php#hepatitis-b</u>

	А	В	С	D
1	Line List	ing for Perina	tal Hepatitis B Case M	lanagement Billing
2				
З	County:			
4	Date:			
5				
6	MEDSIS ID	Last Name	Prenatal Completion Date	Postnatal Completion Date
7	2			
8				
9	-			
10				
11				
12				
13				
14				
15				
16	-			
17	-			
18				
19				
20				
21				
22				
23				
24				
25				

CHAPTER 9

ARIZONA DEPARTMENT OF HEALTH SERVICES' RESPONSIBILITIES FOR THE ARIZONA PERINATAL HEPATITIS B PREVENTION PROGRAM

ADHS is responsible for implementing Arizona's Perinatal Hepatitis B Prevention Program which supports appropriate policies, procedures, laws, regulations, and case management in accordance with the recommendations of the CDC to prevent transmission of maternal hepatitis B virus (HBV) infection to newborn infants. ADHS contracts with all fifteen Arizona counties to provide case management to prevent perinatal HBV transmission.

ADHS' Perinatal Hepatitis B Prevention Program Responsibilities

- 1. Promote the testing of all pregnant women for HBsAg during each pregnancy.
- 2. Require doctors and laboratories to report all positive HBsAg serology results to public health.
- Notify CHDs of HBsAg-positive pregnant women, HBsAg-positive children ≤24 months of age, and children ≤24 months of age born to HBsAg-positive women through MEDSIS (an electronic reporting and surveillance system) for follow-up and case management.
- 4. Contract with CHDs for prenatal and postnatal hepatitis B case managementservices.
- 5. Provide technical assistance to CHDs for case management of HBsAg-positive pregnant women, children born to HBsAg-positive women, and household, sexual, and/or needle-sharing contacts of HBsAg-positive pregnant women.
- 6. Support CHDs in educating obstetrical health care providers, hospitals, and pediatric health care providers about their responsibilities to prevent perinatal HBV infection.
- 7. Provide technical assistance to CHDs regarding discrepant HBsAg test results of pregnant women, children suspected of perinatal HBV exposure, or contacts of HBsAg-positive pregnant women.
- 8. Provide hospitals with a birth dose of HepBVacc for all newborns.
- 9. Ensure that children born to HBsAg-positive women receive HepBVacc and HBIG within 12 hours of delivery and subsequently receive the remaining HepBVacc doses according to the recommended schedule.
- 10. Ensure children born to women of unknown HBsAg status receive HepBVacc within 12 hours of delivery, with rapid testing of the mother for HBsAg so that HBIG can be given to the child within 12 hours of birth, if the mother is HBsAg-positive.
- 11. Promote the implementation of hospital policies that support HepBVacc administration to all newborns within the recommended timeframes (dependent on the HBsAg status of the mother).
- 12. Promote universal hepatitis B vaccination of all children in the community.
- 13. Ensure that children born to HBsAg-positive women are tested for both HBsAg and

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antibody to HBsAg (anti-HBs) by 9–12 months (or 1–2 months after the final dose of the vaccine series, if the series is delayed).

- 14. Compile and evaluate program performance measures, providing the results to the CDC, and sharing the results with the CHDs.
- 15. Consult with CDC on the expected number of HBsAg-positive women in Arizona.
- 16. Maintain an up-to-date Perinatal Hepatitis B Prevention Program Manual.

Perinatal Hepatitis B Prevention Program Components

- 1. Identify cases and notify CHDs for case management
 - A. Laboratories, health care providers, and CHDs report all tests indicative of hepatitis B infection to ADHS by means of MEDSIS, electronic laboratory reporting (ELR), fax, or mail. Maternal HBV status is also documented on birth records.
 - B. The following groups are identified for further investigation:
 - HBsAg-positive, HBV DNA detected, IgM antibody to hepatitis B core antigen (IgM anti-HBc)-positive, and HBeAg-positive women aged 12– 50 years
 - Providers are contacted to verify HBV infection and ascertain pregnancy status
 - 2) HBsAg-positive, HBV DNA detected, IgM anti-HBc-positive, and HBeAgpositive children ≤24 months of age
 - Providers are contacted to determine perinatal HBV exposure
 - Children ≤24 months of age suspected to have been born to a mother with HBV infection
 - Providers are contacted to determine perinatal HBV exposure
 - C. For every HBsAg-positive pregnant woman and HBsAg-positive child ≤24 months of age, a MEDSIS case is created and sent to the appropriate CHD for case management.
- 2. Support CHD case management
 - A. ADHS provides technical assistance to CHDs on perinatal hepatitis B case management and maintains the Arizona Perinatal Hepatitis B Prevention Program manual for guidance.
 - B. ADHS contracts with Arizona CHDs to conduct prenatal and postnatal case management to prevent perinatal HBV infection, and to investigate and offer HepBVacc for contacts of the HBsAg-positive pregnant woman.
 - C. If ADHS becomes aware of discrepant HBsAg test results involving pregnant women, infants, or contacts, the AIPO medical director is consulted for subject matter expertise.
 - D. If ADHS becomes aware of a HBsAg-positive pregnant woman, an exposed infant, or a contact that is moving or has moved to a new jurisdiction, the new jurisdiction is notified.
- 3. Provide HepBVacc and HBIG to delivery hospitals
 - A. AIPO provides HepBVacc to all delivery hospitals who participate in the Vaccines for

Children's Program (VFC) for all infants, free of charge.

- 4. Maintain a Statewide Immunization Reporting System
 - A. AIPO maintains a statewide electronic immunization registry called the Arizona State Immunization Information System (ASIIS) which was authorized by Arizona Revised Statute 36-135 and requires health care providers who give immunizations to children from birth to 17 years old to report the vaccines in ASIIS. <u>http://azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/asiis/index.php</u>
 - B. AIPO links ASIIS with Arizona's program for Electronic Birth Certificates (EBC) to capture immunization-related data submitted on the EBC.
- 5. <u>Analyze Data</u>

The following information is summarized annually, as recommended by the CDC in their Morbidity and Mortality Weekly Report (MMWR), December 23, 2005, p. 16. (<u>https://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf</u>):

- 1) Number of HBsAg-positive pregnant women.
- 2) Proportion of infants born to HBsAg-positive women receiving:
 - HepBVacc and HBIG within 12 hours of birth.
 - 3rd vaccine dose by 6–8 months if monovalent vaccines are given, or 4th vaccine dose by 6–8 months if combination vaccines (DTaP-HBV-IPV) such as Pediarix[®] are given.
- Post-vaccination serologic testing for HBsAg and anti-HBs.
- 6. <u>Complete the CDC Annual Assessment of Progress Reports.</u>
- 7. <u>Report all HBsAg-positive infants to CDC through the National Notifiable Disease</u> <u>Surveillance System.</u>

CHAPTER 10

LEGAL ASPECTS OF ARIZONA PERINATAL HEPATITIS B PREVENTION PROGRAM

ADHS ensures that statutes and rules are carried out regarding control and prevention of hepatitis B virus (HBV). The following list addresses HBV- related statutes and rules as they apply to the Arizona Perinatal Hepatitis B Prevention Program.

HBV-Related Statutes and Rules: Which professionals are allowed to administer vaccines

- ADHS is authorized by Arizona Revised Statute (ARS) 36-104 to conduct epidemiology and disease control activities. <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/00104.</u> <u>htm</u>
- ARS 36-132 describes ADHS' function to collect information, educate, administer programs, and assist local health departments in controlling preventable diseases. <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/00132.</u> <u>htm</u>
- ARS 36-135 established an immunization reporting system (Arizona State Immunization Information System--ASIIS) and required providers giving vaccines to children from birth through 17 years old to report the vaccines to ADHS.
 <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/00135.</u> <u>htm</u>
- Arizona Administrative Code (AAC) R9-6-706 and 707 specify how a health care provider is to report to ASIIS when childhood immunizations are administered and who can have access to the information. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u> Additional information on reporting to ASIIS can be obtained at by calling (602) 364-3899 or toll free at 1-877-491-5741 or at <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/asiis/index.php</u>.
- Arizona Administrative Code (AAC) R9-6-202 requires health care providers to report communicable diseases (including HBV infections) to the local health agency within five working days. The communicable disease reporting form can be obtained at http://www.azdhs.gov/cdr or reporting can be done through the Medical Electronic

Disease Surveillance Electronic System (MEDSIS), Arizona's electronic reporting system at <u>http://www.azdhs.gov/medsis</u>.

- AAC 9-6-204 requires clinical laboratory directors to report communicable diseases (including a positive serology result for hepatitis B surface antigen [HBsAg]) within five working days to ADHS. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u> The ADHS Laboratory Reporting Form can be found at <u>http://www.azdhs.gov/labreportform</u>
- AAC R9-6-206 describes local health agencies' responsibilities for reporting communicable diseases (including HBV) to ADHS and to conduct an epidemiologic investigation. http://apps.azsos.gov/public_services/Title_09/9-06.pdf The ADHS forms for HBV reporting and case investigation (Hepatitis B & D Investigation Form) can be obtained at http://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/disease-investigation-resources/hepatitis-B-D-investigation-form.pdf, or reporting can be done through MEDSIS (Medical Electronic Disease Surveillance Intelligence System). http://www.azdhs.gov/medsis
- AAC R9-6-338 describes control measures for HBV including epidemiologic investigations of cases, education and vaccination of contacts, and reporting of perinatal HBV infections. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>
- AAC R9-6-702 lists hepatitis B vaccine as a required vaccine for child care or school entry. <u>http://apps.azsos.gov/public_services/Title_09/9-06.pdf</u>
- Arizona law does not specify that all pregnant women must be screened for HBsAg; however many states do. <u>https://www2a.cdc.gov/vaccines/statevaccsApp/HepatitisScreenandReport.asp</u> Screening all pregnant women for HBsAg represents the appropriate standard of care in the community. <u>https://www.hhs.gov/hepatitis/blog/2015/05/12/eliminating-hepatitisb-in-the-united-states-mothers-matter.html.</u> All positive serology results for HBsAg should be reported to ADHS.
- The Code of Federal Regulations (CFR) Title 45, § 164.512(b)(i) allows medical information disclosures for public health activities under the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. This permits health care providers, hospitals, and laboratories to provide patient information to state and local health departments for public health purposes. https://www.ecfr.gov/cgi-bin/text-idx?SID=e3ae08bd95117b322a7df8056a49295b&mc=true&node=se45.1.164 1512&rgn =div8
- The National Childhood Vaccine Injury Act of 1986 requires that Vaccine Information Statements (VISs) be given to a child's parent or legal representative each time vaccine

is given. Hepatitis B vaccine is one of the vaccinations that require a VIS. http://www.cdc.gov/vaccinesafety/Vaccine Monitoring/history.html#NCVIA

- In 2009, ARS 32-1974 was amended to authorize pharmacies to give most vaccines to adults without a prescription (including hepatitis B vaccine) but pharmacists must report the vaccination to the Arizona State Immunization Information system (ASIIS). <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/32/01974.</u> <u>htm</u>
- In 2011, ARS 32-1974 was amended to allow pharmacists to give most vaccines to children 6 years and older with a prescription (including hepatitis B vaccine). <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/32/01974.</u> <u>htm</u>
- In 2011, ARS 32-1401 was amended to allow physicians to administer immunizations to a household member of a patient. See ARS 32-1401 (27) (ss) (vi) at <u>http://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/32/01401.</u> <u>htm</u>

Additional Legal Information Links

- CDC. Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rules as relating to public health activities. *Morbidity and Mortality Weekly Report* (MMWR). May 2, 2003. <u>http://www.cdc.gov/mmwr/pdf/wk/mmSU5201.pdf</u>
- CDC. HIPAA and Perinatal Hepatitis B Prevention. <u>https://www.cdc.gov/vaccines/imz-</u> <u>managers/laws/hipaa/qa-patient-recs-perinatal-hepb.html</u>
- CDC. Legal requirements for providing Vaccine Information Statements (VISs) to patients. <u>https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html</u>

CHAPTER 11

MISCELLANEOUS EDUCATIONAL DOCUMENTS FOR HEPATITIS B VIRUS (HBV) INFECTION PREVENTION

Core Documents for Hepatitis B Virus (HBV) and Hepatitis B Vaccine (HepBVacc)

- Centers for Disease Control and Prevention (CDC). A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Part 1: Immunization of Infants, Children, and Adolescents. *Morbidity and Mortality Weekly Report* (MMWR), December 23, 2005; Vol. 54, No. RR-16. http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
- CDC. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Part 2: Immunization of Adults. MMWR, December 8, 2006; Vol. 55, No. RR-16. <u>http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf</u>
- CDC. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR, September 19, 2008; Vol. 57, No. RR-8. <u>http://www.cdc.gov/mmwr/PDF/rr/rr5708.pdf</u>
- CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th edition, Chapter 10: Hepatitis B. <u>http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf</u>
- CDC. Immunization Schedules for Children, Adolescents, and Adults. <u>https://www.cdc.gov/vaccines/schedules/index.html</u>
- Willis BC, Wortley P, Wang SA, et al. Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus. *Pediatrics*. April 2010. Vol. 125, No. 4: 704-711. <u>http://pediatrics.aappublications.org/cgi/reprint/peds.2009-1831v1</u>
- CDC. Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers. MMWR, October 9, 2015. <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w</u>
- CDC. Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017. <u>https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html</u>

 CDC. Prevention of Hepatitis B Virus Infection in the United States. Recommendations of the Advisory Committee on Immunization Practices. MMWR, (RR-1), January 12, 2018. <u>https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf</u>

Education for Health Care Professionals about HBV and HepBVacc

- CDC. Testing for Hepatitis B Virus Infection During Pregnancy. Flowchart for Prenatal Providers. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Prenatal.pdf</u>
- CDC. Procedures to Prevent Perinatal Hepatitis B Virus Transmission at Delivery when Maternal Surface Antigen (HBsAg) Test Results are AVAILABLE. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Avaliable.pdf</u>
- CDC. Procedures to Prevent Perinatal Hepatitis B Virus Transmission at Delivery when Maternal Surface Antigen (HBsAg) Test Results are UNAVAILABLE at Admission or at Retesting at Delivery. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/PerinatalAlgorithm-Unavailable.pdf</u>
- CDC. Hepatitis B Immunization Management of Preterm Infants Weighing <2,000 g by Maternal Hepatitis B Surface Antigen (HBsAg) Status. <u>https://www.cdc.gov/hepatitis/hbv/pdfs/CorrectedTable4.pdf</u>
- CDC. Interpretation of Hepatitis B Serologic Tests. <u>https://www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf</u>
- IAC. Hepatitis B FAQs for Health Professionals. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm
- IAC. Give the Birth Dose...Hepatitis B Vaccine at Birth Saves Lives. <u>http://www.immunize.org/catg.d/p2125.pdf</u>
- IAC. Hepatitis A & B Vaccines. Make Sure Your Patient Get the Correct Dose! http://www.immunize.org/catg.d/p2081.pdf
- IAC. Hepatitis B Facts: Testing and Vaccination. http://www.immunize.org/catg.d/p2110.pdf

Standing Orders for HBV Prevention

 Immunization Action Coalition (IAC). Guidance for Developing Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus (HBV) Transmission. (6/17). http://www.immunize.org/catg.d/p2130.pdf

- IAC. Labor & Delivery HBsAg Admission Checklist for Birthing Mother (4/16). http://www.immunize.org/catg.d/p2225.pdf
- IAC. Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose (6/17). <u>http://www.immunize.org/catg.d/p2131.pdf</u>
- IAC. Standing Orders for Administering Hepatitis B Vaccine to Children & Teens (10/17). <u>http://www.immunize.org/catg.d/p3076a.pdf</u>
- IAC. Standing Orders for Administering Hepatitis B Vaccine to Adults (10/15). <u>http://www.immunize.org/catg.d/p3076.pdf</u>
- IAC. Using Standing Orders for Administering Vaccines (8/15). http://www.immunize.org/catg.d/p3066.pdf
- IAC. 10 Steps to Implementing Standing Orders for Immunization in Your Practice Setting. <u>http://www.immunize.org/catg.d/p3067.pdf</u>

Package Inserts for Hepatitis B Vaccines

- Engerix-B[®] <u>http://us.gsk.com/products/assets/us_engerixb.pdf</u>
- Recombivax HB[®]
 <u>http://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf</u>
- Pediarix[®] <u>http://us.gsk.com/products/assets/us_pediarix.pdf</u>
- Twinrix[®] <u>http://us.gsk.com/products/assets/us_twinrix.pdf</u>

Prescribing Information for Hepatitis B Immune Globulin (HBIG)

- HepaGam B[®]. Cangene Corporation. 877-437-2426. http://www.hepagamb.com/pdfs/HepaGam_PI.pdf
- HyperHEP B[®] S/D. Grifols. 800-520-2807. <u>http://www.grifolsusa.com/documents/10192/60534/ft_hepatitis_b_immune_globulin_ee_uu_en/4ae3f29a-9564-48a8-846c-ec469dbdaaf3</u>
- Nabi-HB[®]. Biotest Pharmaceuticals Corporation. 800-327-7106. <u>http://www.biotestpharma.com/clientuploads/pdfs/Nabi-HB_PI_Apr_2008.pdf</u>

Vaccine Information Statement (VIS) for HepBVacc in English and Other Languages.

- CDC site for VIS for hepatitis B vaccine (single antigen and combination). <u>https://www.cdc.gov/vaccines/hcp/vis/index.html</u>
- IAC site for hepatitis B vaccine VIS. <u>http://www.immunize.org/vis/vis_hepatitis_b.asp</u>

CDC HBV and HepBVacc Patient Education Brochures

 Various handouts available in Amharic, Arabic, Burmese, Chinese, French, Hmong, Khmer, Korean, Lao, Russian, Somali, Spanish, Swahili, Tagalog, and Vietnamese. <u>https://www.cdc.gov/hepatitis/hbv/patienteduhbv.htm</u>

Immunization Action Coalition (IAC) Resources for HBV and HepBVacc

• IAC hepatitis B website. <u>http://www.immunize.org/hepatitis-b</u>

IAC Patient Education about HBV and HepBVacc

- Hepatitis B: Questions and Answers. Information about the disease and vaccines for patients and parents. <u>http://www.immunize.org/catg.d/p4205.pdf</u>
- Questions Frequently Asked about Hepatitis B. http://www.immunize.org/catg.d/p4090.pdf
- Preguntas frecuentes acerca de la hepatitis B (Spanish for "Questions Frequently Asked about Hepatitis B"). <u>http://www.immunize.org/catg.d/p4090-01.pdf</u>
- If You Have Chronic Hepatitis B Virus (HBV) Infection.... http://www.immunize.org/catg.d/p4120.pdf
- Hepatitis B Shots Are Recommended for All New Babies.
 - English <u>http://www.immunize.org/catg.d/p4110.pdf</u>
 - Spanish http://www.immunize.org/catg.d/p4110-01.pdf
- Hepatitis B and Moms-to-Be
 - English http://med.stanford.edu/yucorps/files/hepbmoms.pdf
 - Hmong <u>https://issuu.com/asianlivercenter/docs/hepatitis b moms to be hmong 8 25</u> <u>10</u>
 - Lao <u>https://issuu.com/asianlivercenter/docs/pregbrochure--lao--09.09.2010-web</u>
 - Spanish <u>https://issuu.com/asianlivercenter/docs/pregnant-brochure--spanish--</u>08.25.2010-web
 - Vietnamese <u>https://issuu.com/asianlivercenter/docs/pregbrochure--vietnamese--09.09.2010-web</u>

CHAPTER 12

PUBLIC HEALTH CONTACT NUMBERS AND LINKS

- County Health Departments in Arizona. <u>http://www.azdhs.gov/director/#county-health-departments</u>.
- Arizona Department of Health Services, Arizona Perinatal Hepatitis B Prevention Program. Office of Infectious Disease Services. (602) 364-3676, FAX (602) 364-3199.
- Arizona Department of Health Services, Immunization Program Office. (602) 364-3630, FAX (602) 364-3285.
- Arizona Vaccine for Children (VFC) program enrollment. Call (602) 364-3642 or go to <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/index.php#vaccines-children-home</u>.
- Arizona State Immunization Information System (ASIIS). <u>http://www.azdhs.gov/preparedness/epidemiology-disease-</u> <u>control/immunization/asiis/index.php</u>. (602) 364-3899 or 1-(877) 491-5741.
- Centers for Disease Control and Prevention (CDC) Perinatal Hepatitis B Prevention Coordinators website. <u>http://www.cdc.gov/hepatitis/Partners/PeriHepBCoord.htm</u>.

APPENDIX A

ADHS MEDSIS USER GUIDE FOR PERINATAL HEPATITIS B

(Refer to ADHS Perinatal Hepatitis B MEDSIS Data Entry Videos)

I) Prenatal case management

Notification will be received of a confirmed hepatitis B surface antigen positive pregnant woman through an email from the ADHS perinatal hepatitis B coordinator. This email will contain the MEDSIS ID of the confirmed pregnant woman.

A) Prenatal management table

The prenatal management table is where you can keep track of current and past pregnancies. Each row in the table represents one pregnancy. You can add multiple pregnancies, link the pregnancy to infant(s) born from that pregnancy, and keep track of information that is submitted to ADHS for receiving payment for services.

1) To easily get to the table, click on **Case Management** in the right hand sidebar and then **Prenatal Management**.



2) A pregnancy should already be added, but if not, click Add to create a new pregnancy. You can enter the estimated delivery date, up to two planned delivery hospitals, the final disposition. Selecting a final disposition pops up two additional boxes regarding submitting information for payment. You can also add notes about the pregnancy.

. . .

Estimated Delivery Date	Delivery Hospital(s)	Date Cor Prenatal /
Estimated Delivery Date		
Planned Delivery Hospital 1		
Planned Delivery Hospital 2	T	
Final Disposition		
For ADHS Use Only		
Date Approved for Payment		
Nill postnatal case management be performed in .	Arizona (i.e. perinatal contacts created in MEDSIS)?	
Notes	-	

Note: the case must have a female gender selected in order to add a birth event to the prenatal management table. If female is not selected, the following error will appear:

medsisstage.health.azdhs.gov says:	×	
This section is only available for female patients.		
	ОК	

3) The perinatal hepatitis B coordinator at ADHS will most likely enter the **estimated delivery date** and the **planned delivery hospital** or hospitals, but if they are blank, collect the information and fill it out.

Up to two planned delivery hospitals can be selected. If the delivery hospital is not listed, you can select **Other** and type in the delivery hospital.

Estimated Delivery Date 5/10/2017		
Planned Delivery Hospital 1 Honor Health Deer Valley Medical Center	¥	
Planned Delivery Hospital 2 Other	Specify: A delivery hospital not liste	ď

Note: Estimated delivery date must be filled out in order to save the birth event. If it is not filled out, an error will appear upon saving.



- 4) Select the final disposition from the drop down menu once it has been reached. Options include:
 - Completed Education: this is selected if education is provided, regardless if the woman moves to another jurisdiction within Arizona or out of state, dies, or has a miscarriage. If education is provided and the woman says she will be moving afterwards (whether in the initial conversation where education is provided or another conversation later), then keep this as the final disposition. Do not change it to another status, since education was provided and the jurisdiction who did so will still receive payment.
 - Death: ensure that in the demographics, the **date of death** is indicated and that **patient outcome** is marked as died.
 - Education provided in another jurisdiction
 - Lost to follow up
 - Miscarriage
 - Refused services
 - Ruled out (HBsAg Negative)
 - Transferred out of state: this should only be selected if you call the woman and she has moved/is moving out of state and no education is provided.
- 5) After selecting a disposition, **Prenatal Activities Complete Date** and **County Completed** fields will appear.

Final Disposition Completed education	¥
Prenatal Activities Complete Date	County Completed

Select a date that activities were completed and fill out your county name (i.e. the county that is requesting payment for services). This must be filled out because an expectant mother could move to another county after receiving education from the previous county and the case would be transferred to the new jurisdiction. This keeps track of what county provided the services. Regardless if the pregnant woman moves, the county who provided education will receive payment.

Note: All three of these fields must be filled out in order to save the birth event. If one of these three is not filled out, an error will appear:

medsisstage.health.azdhs.gov says:		×
County Completed is required		
	ОК	

- 6) Select if postnatal case management will need to be performed in AZ (Will postnatal case management be performed in Arizona (i.e. perinatal contacts created in MEDSIS)?). It has options of Yes or No. The intention of this question is to let you know if you need to link the infants to the pregnancy. No can be selected for various reasons, including moving out of state, death, miscarriage, etc. Yes indicates that infant(s) will need to be linked after they are born. Once the infant(s) are born and linked to the pregnancy, the Yes option will need to stay selected. Changing the option to No will cause all linked contacts/infants to become un-linked.
- 7) The perinatal hepatitis B coordinator at ADHS will monitor the data, and once you are requesting payment for services, the coordinator will fill out the **For ADHS Use Only** section with the date that the services were approved for payment.

For ADHS Use Only	
Date Approved for Payment	

Note: filling this out ensures that you have received payment for the prenatal management activities associated with the pregnancy. Do not fill this section out as it can prevent you from receiving payment.

8) Fill out the **Notes** section if there is any additional information regarding the mother or pregnancy that you would like to add.

Notes	
Notes can go here.	
Save Cancel	

9) Make sure you hit Save after filling out any aspect of the table.

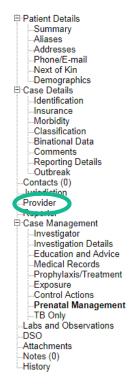
Note: Each pregnancy in the prenatal management table can be edited or deleted by selecting the pencil or the red deletion circle. Multiple pregnancies can be added.

Prenatal Management							
		Estimated Delivery Date	Delivery Hospital(s)	Date Completed Prenatal Activities	Date Approved for Payment	Contacts	Notes
Ċ		/10/2017	1: Honor Health Deer Valley Medical Center	Completed education — 3/9/2017 by Maricopa County		Postnatal Management in Arizona: Yes	Notes can go here.
			2: A delivery hospital not listed				

B) Add provider(s) to the case

The OBGYN can be added to the case under the provider section. This will allow you to keep track of any sort of provider, including OBGYN, that you might be in contact with.

1) To easily get to the provider section, click on **Provider** in the right hand sidebar.



2) Click on Add to add a new provider.

Provider Search Result

Search Criteria: Last Name = 'Creen'

Pro

viders				
	Name	Organization	Phone	Report Date

3) Enter in the available information (last name, first name, organization, country, and state) and hit search.

Last Name	First Name	Organization	Outside Jurisdiction	Country
Search Dancel				State

4) If the provider is already listed, select it by hitting the green plus sign. If the provider is not listed, hit new provider.

<u></u>	Healthcare Provider	Healthcare Facility	Phone
Green	, Kristen	BANNER GOOD SAMARITAN MEDICAL CENTER 1111 EAST MCDOWELL RD, PHOENIX, AZ 85006	(602) 239-420
Green	L.	CMC North-Ruthrauff 2005 W Ruthrauff Rd, Tucson, AZ 85705	
GREE	N,	CMC NORTH-RUTHRAUFF RD. 2005 W. RUTHRAUFF RD., TUCSON, AZ 85705	
Green	, David	GREEN, DAVID Dr. 1003 Division St, Prescott, AZ 86301	
Green	, Cary	MERCY GILBERT MEDICAL CENTER 3555 SOUTH VAL VISTA ROAD, GILBERT, AZ 85296	480-503-5440
0 0	land d	Manakana Manifa Carata	

5) If you select **new provider** you will be able to enter in additional information.

Provider		
*Last Name	*First Name	Phone
E-mail		
Assigning Authority		
*Provider Organization	Street	Unit
City	State Arizona	ZIP Code
Country		
United States	•	

6) Save the information.

62

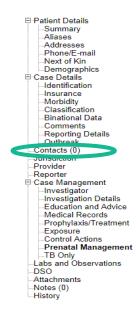
II) Postnatal case management

A) Create a perinatal contact

After the infant is born, create a contact to the mother. This must be done within 15 days of birth.

Note: *DO NOT* create a contact prior to birth as this will prevent the date of birth from being entered correctly for the contact/infant.

1) Go into the mother's case and in the right hand sidebar, select **Contacts**.



	Contacts (0)
tacts	
Patient was exposed to:	
is person was not exposed to any known contact or case.	
s Patient exposed: is person di not expose any known contact or case.	
is person du not expose any known contact of case.	

2) Click **Add** to add new contact(s) (the infant(s) born) and type in the First Name, Last Name, DOB, Gender, and hit **search**.

This person was n This Patient exposed	Contacts This Patient was exposed to: This person was not exposed to any known contact or case. This Patient exposed: This person did not expose any known contact or case.							
First Name Matthew Search	Last Name Jones	DOB 5/12/2017	Gender Male • Show More Fields Save					

3) Click on **New Person** and enter in the information that is available. Make sure you select **Perinatal** from the exposure category and **save** the contact.

First Name Matthew	Last Name	DOB 5/12/2017	Gender	Show Fewer I	
	Jones	5/12/2017	Male	 Snow Fewer I 	Fields Save
Search Contact Information Home Address Same as index c	ase				Home Phone
Street	Unit	City	State	ZIP Code	
143 Yellow St		Phoenix	Arizona	▼ 12345	
County Maricopa County ▼ Patient		rvation	T		
Maricopa County Patient		rvation	T		
Maricopa County V atient spe at Event Is the patient ase Management Exposure Exposure Category Perinatal	t immunocompromised?		۲		
Maricopa County ▼ Patient Age at Event Is the patient Case Management Exposure Exposure Category	t immunocompromised?		·		

4) The contact/infant will then show up as a contact:

Со	ontacts							
	This Patient was exposed to:							
	This person was not exposed to any known contact or case. This Patient exposed:							
	17-2799491	1 Contact Jones, Matthew						
	Status	ADHS Classification	Local Classification	Event Date 10/20/2017	Gender Male	Exposure Category Perinatal	Date/Time of First Exposure N/A	Date/Time of Last Exposure N/A

5) By selecting **Perinatal** from the exposure category, the **Hepatitis B Type** in the DSO for the contact will automatically update to say **Perinatal**.

DSO	
Hepatitis B Type 😮	Perinatal v

B) Link the contact to the mother's pregnancy

 In the Prenatal Management table, click the pencil to edit the pregnancy you want to add the contact/infant to ensure that Yes is selected for Will postnatal case management be performed in Arizona (i.e. perinatal contacts created in MEDSIS)? You will be able to select the contact/infant. After doing so, save the updated information.

Note: the Hepatitis B Type must say Perinatal in order to link a contact to the prenatal management table. Click <u>HERE</u> if you did not select perinatal for the exposure category when creating the contact.

	Estimated Delivery Date	Delivery Hospital(s)	
	5/10/2017	1: Honor Health Deer Valley Medical Center	Complete
		2: A delivery hospital not listed	
5/10/2 Planned Honor Planned Other Prenatal 3/9/20 Final Dis	Delivery Hospital 1 Health Deer Valle Delivery Hospital 2 Activities Complete I	y Medical Center Specify: A delivery hospital not listed Date County Completed Maricopa County	
Date	ADHS Use Only Approved for Payme	nt ent be performed in Arizona (i.e. perinatal contacts created in MED	SIS)?
(100			
Perinata	I Contacts		
Sele	ct perinatal contac	t record(s)	
	17-2799491: Matth	ew Jones	
Notes			
noces	can go nere.		
Save	Cancel		

Date Completed Prenatal Activities	Date Approved for Payment	Contacts	
Completed education — 3/9/2017 by Maricopa County		Postnatal Management in Arizona: Yes 17-2799491: Matthew Jones	Notes ca

After linking the contact to the prenatal management table, the **Hepatitis B Type** in the contact's DSO will be grayed out and you will not be able to change it unless the contact is unlinked from the table.

DSO	
Hepatitis B Type 🔮	Perinatal 🔻

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Note: You can select multiple infants for each pregnancy and you can only link an infant to a pregnancy once. The hepatitis B type in the contact/infant's DSO must be selected to **Perinatal** in order for the contact to show up. Once the contact/infant is linked, you will not be able to change the hepatitis type of the contact (it will be grayed out). If the contact becomes a case, the morbidity needs to be changed from **Contact** to **Hepatitis B**. Sometimes, the morbidity will be grayed out and you will not be able to change it. If this happens, the contact must be unlinked from the prenatal management table first. After going back into the contact and changing the morbidity, go back to the prenatal table of the mother's case and relink the contact to the appropriate pregnancy (more on this <u>HERE</u>). Once the contact has become a case, you will not be able to go back and make it a contact.

C) Fill out the DSO for the perinatal contact

All applicable information in the perinatal DSO must be filled out for payment to be received.

Note: DO NOT change the *Hepatitis B Type* from *Perinatal* as this will cause you to lose any information that you have entered into the DSO.

1) Perinatal questions

All questions in the **Perinatal Questions** section need to be filled out.

Perinatal Questions		
Time the infant was born?	-	
What hospital was the infant born in?	1	•
What was the birthweight of the infant in grams?		
		Birthweight less than 2000 grams?
What was the date and time the infant received HBIG?	-	
Did the infant die prior to receiving post-exposure prophylaxis and hospital discharge?		

(a) Fill out the **time of birth**.

Note: The time of birth is a time field that will automatically convert what you enter into 12-hour time. For example, entering in 2:23, 223, 2:23AM, 0223, or 223 AM will change the time to 2:23 AM. You can also enter in 24 hour time. 1443 or 14:43 will change the time to 2:23 PM. Likewise, entering in 2:23pm, 223pm, or 223 PM will change the time to 2:23 PM. If you enter in anything else, the box will turn red and not accept what you are entering. *Note*: If entering 24 hour time, do not include the AM or PM, it will not be accepted.

- (b) Enter the **birth hospital** for the infant. If the birth hospital is not listed, you can select **Other** and type in the delivery hospital.
- (c) Enter the **birthweight** (in grams) of the infant without using any commas or units.
 - If the infant weighed less than 2000 grams, then check the box.
- (d) Fill out the **date** and **time** that the infant received HBIG.
- (e) Indicate if the infant died prior to receiving post-exposure prophylaxis and hospital discharge.
 - If the infant died, ensure that in the demographics, the **date of death** is indicated and that **patient outcome** is marked as died.

Classification													Cancel Save
State Classification	Local Classificatio	n State Reviewe	d Disease Imported	Binational 🕜	Detection Method	Is the pat	ent immunocompromised	Investigation Status	s Date Completed	P	atient Outcome	Date of Death	
•	•	•	· · · · · ·	Unknown	•	•	•	•			Died 🔹		
Death Certificate Nu	Death Certificate Number Contributed												
Dealer Communication Communica													

2) Vaccination History

Most questions in the vaccination history need to be filled out. Fill out all applicable information as it becomes available.

What was the date and time the infant received the first dose of hepatitis B vaccine?	
Vaccine type?	
What date was the second dose of hepatitis B vaccine given?	
Vaccine type?	
What date was the third dose of hepatitis B vaccine given?	
Vaccine type?	
[If needed] What date was the fourth dose hepatitis B vaccine given?	
Vaccine type?	
[If needed] What date was the fifth dose hepatitis B vaccine given?	
Vaccine type?	
After post vaccination serology, did the infant require evaccination due to non-response?	•

Some data that may not be filled out includes:

- Information regarding the fourth and fifth dose of the hepatitis B vaccine. The fourth dose will always be filled out if the infant weighed less than 2000 grams at birth and might be filled out if the provider vaccinated the infant with DTaP-Hep B-IPV (Pediarix).
- (a) Fill out the vaccination history. The **date** and **time** for the first dose is required; all subsequent doses only require a date. All vaccinations require a **type**.
- (b) Indicate if the infant was a non-responder. Marking yes will cause a non-response vaccination history. Fill out the **dates** and **types** of the vaccinations received.

Non-response Vaccination History		
What date was the first revaccination dose administered?		
Vaccine type?		•
What date was the second revaccination dose administered?	-	
Vaccine type?		•
What date was the third revaccination dose administered?		
Vaccine type?		•

3) Diagnostic tests

PVST 1 will always be filled out, PVST 2 and PVST 3 may not be applicable.

Diagnostic Tests	
Post vaccination serological testing (PVST) 1	
What was the date of the first HBsAb post vaccine serological test?	
Result?	T
What was the date of the first HBsAg post vaccine serological test?	
Result?	T
[If needed] PVST 2	
What was the date of the second HBsAb post vaccine serological test?	
Result?	•
What was the date of the second HBsAg post vaccine serological test?	
Result?	•
[If needed] PVST 3	
What was the date of the third HBsAb post vaccine serological test?	
Result?	▼
What was the date of the third HBsAg post vaccine serological test?	
Result?	T

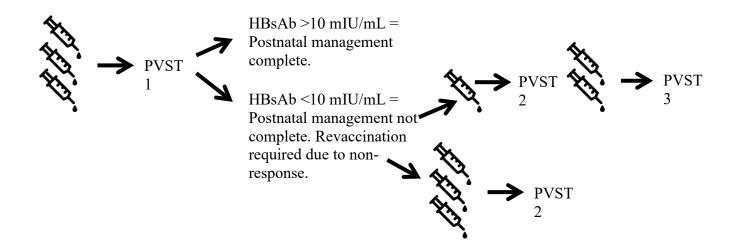
(a) Fill out the **date** and **results** of **HBsAb** (anti-HBs).

Antibody testing (anti-HBs or HBsAb) has three options:

- Negative: this will often be resulted from the lab as <10 mIU/mL, negative, undetected, not considered immune, etc. Some labs will result as <5 mIU/mL or <8 mIU/mL. CDC considers <10 mIU/mL as not considered immune and the infant should be revaccinated and retested.
- Indeterminate: some labs might result >5 mIU/mL (or >8 mIU/mL) but <12 mIU/mL. These are considered indeterminate, gray zone, equivocal, etc. The infant should be considered not immune, but it is the provider's decision if they wish to retest the infant in a few months or if they want to revaccinate the infant.
- Positive: CDC considers >10 mIU/mL as immune and a result that falls into this category should be considered positive. The exception is labs that consider 10–12 mIU/mL as indeterminate.

(b) Fill out the date and results of HBsAg.

PVST 2 should be filled out if the infant is a non-responder. A non-responder is indicated if the HBsAb of PVST 1 is negative (<10 mIU/mL) and the HBsAg is negative. PVST 2 could also be filled out if the provider ordered PVST 1 at an inappropriate time (e.g., in the middle of the initial three dose series). The following shows *possible* scenarios of when PVST 2 and PVST 3 would be required (one syringe represents one vaccination dose).



(c) Enter all test results for the post vaccination serological testing into the <u>labs and</u> <u>observation table</u>. Add the laboratory into the notes section for test.

4) Postnatal management (complete for each infant contact/case)

This section is how you receive payment for postnatal management.

Postnatal Management (complete for each infant contact/case)								
Was the infant transferred into the program from another state for case management?		•						
Postnatal Complete Date								
County Completed	ł	T						
Final disposition?	ł	T						
Date approved for payment (ADHS Only)								

- (a) Enter if the infant was **transferred** into the program from another state.
- (b) Indicate the **date** that postnatal management was completed.
- (c) Select the **county** that completed the management.
- (d) Select the **final disposition**. Options include:
 - Immune: HBsAb >10 mIU/mL and HBsAg negative
 - Death: ensure that in the demographics, the date of death is indicated and that patient outcome is marked as died
 - HBsAg positive: ensure that the contact is turned into a case
 - Lost to follow up
 - Nonresponder (after two series): HBsAb <10 mIU/mL after successfully completing two vaccination series
 - Refused PVST
 - Refused vaccine
 - Transferred to another county within state: ensure that the contact is transferred to the new jurisdiction
 - Transferred out of state
 - Transferred out of country

If the infant is transferred to another county within Arizona, fill out the final disposition, date that you were informed the infant was moved to another county, and your county. You will be paid for the postnatal management services completed. Be sure to <u>transfer the case to the new jurisdiction</u>.

Was the infant transferred into the program from another state for case management?		T
Postnatal Complete Date		10/12/2017
County Completed		Crooplos -
Final disposition?		Transferred to another jurisdiction within state 🔻
Date approved for payment (ADHS Only)	ł	
Postnatal Complete Date (2)		
County Completed (2)	-	▼
Final disposition? (2)		T

After you select this final disposition, a second set of postnatal management questions will appear. This will be completed by the new jurisdiction.

If the infant was transferred out of state before postnatal management care was complete, let the perinatal hepatitis B coordinator at ADHS know. The coordinator will inform the new state so that they can complete postnatal management.

Note: Do not fill out the **Date approved for payment (ADHS Only)** question. This question ensures that you receive payment for completing postnatal management care and if it is filled out without the perinatal hepatitis B coordinator knowing, then payment may be overlooked.

D) Add provider(s) to the case

Add the pediatrician or any other providers to the contact's case. See <u>Add provider(s) to the case</u>.

E) Unique situations

1) If the infant is transferred into the state

If you receive notification of an infant who was born in another state and is being transferred into the state without having postnatal management care completed, then add all available information that is known. If the mother is not in MEDSIS, put her into MEDSIS with a **probable** hepatitis B case classification and add the infant as the contact to the mother.

2) If the infant is adopted

If the birth mother is known, search for the birth mother in MEDSIS and add the infant as a contact. Add the adoptive mother as <u>next of kin</u>. If the birth mother is not in MEDSIS, add her as a **probable** case of hepatitis B. If the birth mother is not known, add the infant

as a hepatitis B case without completing the case classification and add the adoptive mother as <u>next of kin</u>.

3) If the infant will be born in a different state, but care will be managed in AZ

If the mother receives prenatal management care in AZ, but you learn that the infant will be born in another state, let the perinatal hepatitis B coordinator at ADHS know. They will let the other jurisdiction know that a hepatitis B positive pregnant woman is expected to give birth in their jurisdiction.

III) Household Contacts

Household contacts should be added to the mother's case at any part during pre- or postnatal management activities. The process will be different for each household contact depending on the information collected and the status of the contact. If you have any questions not covered here, please reach out the perinatal hepatitis B coordinator at ADHS.

A) Create a contact

1) Go into the mother's case and in the right hand sidebar, select Contacts.





2) Click **Add** to add new contact(s) and type in the First Name, Last Name, DOB, Gender, and hit **search**.

cts (0)

Contacts											
This Patient was exp											
	This person was not exposed to any known contact or case.										
This Patient expose											
This person did n	ot expose any known contac	t or case.									
First Name	Last Name	DOB	Gender								
Matthew	Jones	5/12/2017	Male Show More Fields Save								
Search											

3) If the contact is not in MEDSIS, click on New Person.

	First Name Benjamin	Last Name Jones	DOB 5/14/1983	Gender Male ▼	Show More Fields Save
	Search No results found.				
<	New Person				

4) Select **Household** from the exposure category. Add the address if different from the index, and save the contact.

First Name	Last Name	DOB	Gender			
Benjamin	Jones	5/14/1983	Male	Show Fewer Field	s Save	
Search Contact Information						
Home Address					Home Phone	
Same as index ca	ise					
Street	Unit	City	State	ZIP Code		
			Arizona	T		
County	Country Reserva	ation				
T			٧			
Patient					1	
Age at Event Is the patien	t immunocompromised?					
34						
Case Management						
Exposure Category Household	-					
Date/Time of First Expos	Date/Time of Last E					
Prophylaxis			•			
Was prophylaxis provided	d? Prophylaxis date	Provided by	Type of Prophylaxis			
	•		· · · ·			
Type of medication	Dose	Duration				

5) If the contact **is** in MEDSIS for a morbidity other than hepatitis B, click on the green add button to add the contact.

First Nan Mary Search		Last Name Jones	DOB 11/19/2008	Gender Female ▼		Show More Fields Save
	First Name	Middle Name	Last Name	Date of Birth Gender	Address	
	Mary		Jones	11/19/2008 Female AZ US		
New P	erson					

6) Select **Household** from the exposure category and **Save** the contact.

Mary Contac	t Information Address S			how Fewer F	Fields	Save		
9 Case M Expos	Event Is the part	tient immunoc	ompromised?	Is the patient	pregnan	12		
Date, Proph		eadre	Date/Time of	Last Exposure	F	ollow-up need	led ▼	
Was p	rophylaxis prov	ided? Proph	nylaxis date		Provide	ed by	•	Type of Prophylaxis
Туре	of medication		Dose			uration		

7) If the contact **is** in MEDSIS for hepatitis B, then click on the green add button to add the hepatitis B case as a contact to the mother. You will not be able to specify that the contact is a household contact.

First Name Alex Search		Last Name Jones	DOB 8/19/1982	Gender Male T		Show More Fields Save
	First Name	Middle Name	Last Name	Date of Birth Gender	Address	
	8-5081309 He	patitis B Event Date: 3/13/20	Jones 18 12:00 AM	8/19/1982 Male AZ US		
New Person						I

The household contact(s) will all be listed:

	was exposed to: n was not exposed to any	v known contact or case.					
is Patient							
Status	ADHS Classification	Local Classification	Event Date 3/21/2018	Gender Male	Exposure Category Perinatal	Date/Time of First Exposure	Date/Time of Last Exposure N/A
18-508130	8 Contact Jones, Benjamin	Jones					
Status	ADHS Classification	Local Classification	Event Date 3/21/2018	Gender Male	Exposure Category Household	Date/Time of First Exposure N/A	Date/Time of Last Exposure
18-508130	9 Hepatitis B Jones, Alex						
Status new	ADHS Classification	Local Classification	Event Date 3/13/2018	Gender Male	Exposure Category	Date/Time of First Exposure N/A	Date/Time of Last Exposure
18-508131	1 Contact Jones, Mary						
Status	ADHS Classification	Local Classification	Event Date 3/21/2018	Gender Female	Exposure Category Household	Date/Time of First Exposure N/A	Date/Time of Last Exposure

Note: Alex is listed as a hepatitis B contact with a hepatitis B morbidity, not as a contact with a contact morbidity because the hepatitis B case was selected to be linked to the mother.

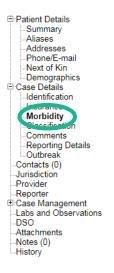
B) Changing the morbidity from contact to hepatitis B

This if for contacts that were not already in MEDSIS and you need to change the morbidity from **contact** to **hepatitis B**.

1) Click on the linked contact's MEDSIS ID to go into the case.

This persor This Patient e	exposed:	y known contact or case.						
18-5081307 Status	7 Contact Jones, Matthew ADHS Classification	Local Classification	Event Date 3/21/2018	Gender Male	Exposure Category Perinatal	Date/Time of First Exposure	Date/Time of Last Exposure N/A	
18-5081308	18-5081308 Contact Jones, Benjamin Jones							
Status	ADHS Classification	Local Classification	Event Date 3/21/2018	Gender Male	Exposure Category Household	Date/Time of First Exposure N/A	Date/Time of Last Exposure N/A	

2) On the right hand sidebar in the contact, select Morbidity.



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3) Change the morbidity from **Contact** to **Hepatitis B** and hit save.

	Morbidity Morbidity CONTACT		Onset Date	Diagnosis Date	Event Date 3/21/2018	
Morbidity Morbidity Hepatitis B	• Date	Diagnosis Date	Event Dete 3/21/2018			Canc Save

Note: Most likely, the following error will pop up. Add one of the following dates into the case after clicking ok.

From medsisstage.health.azdhs.gov	
At least one of the four following dates is required: Onset Date, Diagnosis Date, Date(s) Collected, or Test Result Date(s)	
ОК	

For information on adding lab results, click <u>HERE</u>. To add onset date or diagnosis date, fill in one of the dates next to the morbidity field:



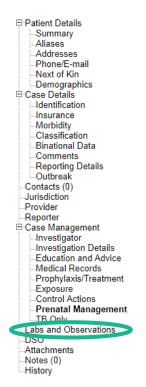
C) Adding additional information to the contact

Add any information collected on the contact to the case. If the contact has hepatitis B, be sure to include lab information and fill out the DSO. If you have any questions on how to fill out any aspects, please reach out to the perinatal hepatitis B coordinator at ADHS.

Supplemental Notes

A) Entering a lab result into the labs and observations table

1) To quickly jump to the labs and observations section, click on Labs and Observations in the right hand sidebar.



2) Click Add will allow you to add a new observation/lab result.

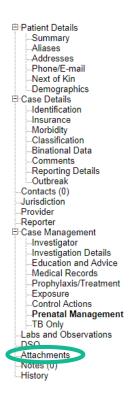
Labs and Observations										Add	D	
	♦ ELR Report	Date Collected	Test Result Date	Specimen Number		Specimen Type		Test Performed	Test Results	Notes		

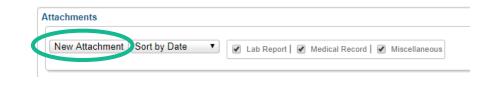
3) Enter in all information. The fields with an asterisk are required to be filled out, but enter in as much information as possible.

Labs and Observ	ations								
÷	ELR Report	Date Collected	♦ Test Result Date	Specimen Number	¢	Specimen Type	\$	Test Performed	¢
Add/Edit Observatio	n								
Specimen Number	Spec	imen Type							
*Test Performed			*Test Results				Date Collected	Test Result Date	
Notes									

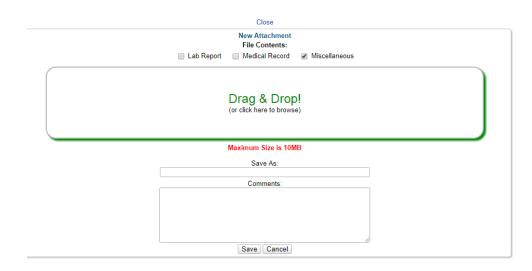
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- Specimen number
- Specimen type
- Test performed: this is whether it is the HBsAg or the HBsAb (anti-HBs)
- Test results: negative, positive, indeterminate, or the actual value obtained from the laboratory
- Date collected
- Test result date
- Notes: the testing laboratory can be recorded here
- 4) Hit save after entering in information. More than one lab result can be entered and each one can be edited or deleted.
- 5) If you receive a copy of the lab result from the provider, attach it to the case. To do this, click on **attachments** from the right hand sidebar to jump to the attachments section.





6) Click on New Attachment to add a new file.



A pop-up window will appear. You can either select a file from your computer by browsing or you can click and drag the file from your computer to the box.

- 7) Select **Lab Report** to identify if it is a lab report, give the file a name, and add any comments (if you wish).
- 8) Hit save to attach the file.

Note: Any attachment can be added to the contact, it does not need to be a lab report.

B) How to change a perinatal contact into a case

If the HBsAg is positive at PVST testing, then the infant should now be considered a case and the morbidity needs to be changed from **contact** to **hepatitis B**.

- 1) Add the positive lab test to the labs and observation table.
- 2) Change the **onset date** to the date of birth.
- 3) Change the morbidity to hepatitis **B** and hit save.

If the morbidity is grayed out and you cannot change it:

(a) Go into the **mother's case** and go to the **prenatal management table** within case management.

Prenatal	Management

Propetal Management

	Estimated Delivery Date	Delivery	Hospital(s)	Date Compl Prenatal Acti	eted	Date Approved for Payment	Contacts
/)	5/10/2017	1: Honor Health Deer Valley 2: A delivery hospital not lis		Completed education — 3/9/2017 by M	ricopa County	,	Postnatal Management in Arizona: Yes 17-2799491: Matthew Jones
5/10/2 Planned Honor Planned Other Prenatal 3/9/20 Final Dis	Delivery Hospital 1 Health Deer Valle Delivery Hospital 2 Activities Complete [17	y Medical Center V	ecify: delivery hospital not listed	1			1
	DHS Use Only Approved for Payme	nt					
Yes		ent be performed in Arizona (i.e.	perinatal contacts created in MED	SIS)? ▼			
	il Contacts ct perinatal contact 7-2799491: Matth	··· /	Uncheck to un from the pregr	nlink the contact			

(b) Go back into the contact's case and change the morbidity to **hepatitis B** and hit **save**.

Note: do not change any aspect of the DSO, the type will stay **perinatal**. Changing the type carries the risk of losing all filled out information within the DSO.

Morbidity	
Morbidity	Onset Date
Hepatitis B	▼ 10/20/201

(c) Go back into the mother's case and relink the infant to the pregnancy in the prenatal management table.

Estimated Delivery Date	Delivery Hospital(s)	Date Completed Prenatal Activities	Date Approve for Payment
5/10/2017	1: Honor Health Deer Valley Medical C	Center Completed education	— 3/9/2017 by Maricopa County	
	2: A delivery hospital not listed			
timated Delivery Date				
10/2017				
anned Delivery Hospital 1	Madianal October			
Ionor Health Deer Valle				
anned Delivery Hospital 2 Other	Specify: A delivery ho	spital not listed		
enatal Activities Complete				
/9/2017	Maricopa County			
nal Disposition				
Completed education	▼			
For ADHS Use Only				
Date Approved for Payme	nt			
ill nostnatal case manager	nent be performed in Arizona (i.e. perinatal co	ntacts created in MEDSIS)?		
es	ion be performed in Anzona (i.e. permutar co			
erinatal Contacts				
Select perinatal contact	t record(e)			
7-2799491: Mattl	👘 🕒 📕 Ke-ch	eck to re-link the		
7-2799491: Matti	case/i	nfant to the pregnancy		
	Cuber 1			
	Raci	k to Table of Contents		

Note: If you try to change the morbidity from *contact* to *hepatitis B* without doing one of the above first, then MEDSIS will tell you what needs to be changed before being able to change the morbidity.

C) How to search for active prenatal management cases

MEDSIS has a capability for you to easily search for mothers in which a pregnancy has been added to the prenatal management table, but where prenatal management has not been completed. The qualification for a mother to show up on this page is if the pregnancy in the prenatal management table does not have **Final Disposition**, **Prenatal Activities Complete Date**, or **County Completed** filled out. Once all of these are filled out, the mother will not show up on the cases tab.

1) Go to the cases tab in MEDSIS and search for Hep B Cases with Prenatal Record Without Activities Completed.

Enter New Case

Home Cases Search Merge Records	Reports and Extracts OB Management	-All Current Cases -All Current Cases - Year to Date -All Current Cases - 6 Months -My Current Cases & Contacts B Shared Cases & Contacts -Archived Cases
		Current Cases by Investigator Current Cases by Morbidity
Current Cases And Contacts		Loron Cases by Worbidity Loron Conces Hep B Cases with Prenatal Record Without Activities Completed Hep B Cases with Posmatal Record Without Activities Completed Saved Searches
	Estimated Delivery Date	
	2/9/2018	
	Planned Delivery Hospital 1 Banner Del E Webb Medical Center	
	Planned Delivery Hospital 2 Scottsdale Osborn wedical Center	
	Final Disposition	
(Completed education •	
	Prenatal Activities Complete Date County Completed 10/19/2017 La Paz County	2

D) How to search for cases that require postnatal follow up

This search is for you to find the mothers for which you have completed prenatal management, but do not have their infants contacts added to the case yet (e.g., infant hasn't

been born yet, recently born, etc.). ADHS is working on simplifying this process. a process to provide this data regularly to counties.

- 1) Pull a line list of all pregnancies (See <u>Pulling a line list of all pregnancies</u>).
- 2) Save the extract pulled from step 1 to your computer.
- 3) Open the text file in excel.
 - (a) In excel, go to File \rightarrow Open \rightarrow and select the file location
 - (b) Make sure you select All Files instead of All Excel Files (the default).

File name:	✓ All Excel Files
Tools	▼ Open ▼ Cancel
File name:	All Files
Tool	s 🔻 Open 🔻 Cancel

- (c) Select **Next** in the list of questions that excel asks you and hit **Finish** when **Next** can no longer be selected.
- 4) Select all cases in excel and filter.
 - (a) Select the arrow to select the file.

	A	В	С	D	E	F	G
4	MEDSISIE	MORBC 🔻	MORBID 🔻	MORBSI -	INFTEDD 🔻	PLNDHOSP1	PLNDHOSPO1
2	17-4726097	HBV	Hepatitis B	Chronic	6/14/2017	Chandler Regional Medical Center	
3	17-4742016	HBV	Hepatitis B	Chronic	7/12/2017	Banner University Medical Center Phoenix	

(b) Apply the filter to the file. Select **Sort & Filter** from the home tab and hit **Filter** from the drop down list. This will cause arrows to appear next to your variables.

Insert Delete F	ormat	Σ AutoSum Fill ▼	Sort & Filter * See	nd & lect •
Cells		E	diting	

	А	В	С	D	E	F	G	Н
1	MET SIS -	MC RBI	MORBS 🔻	BRTHLC 🔻	BRTHLC -	BRTHLC 🔻	PTSXIC 🔻	SXONS -
2	17-275775	пвV	Acute	USA		ESTONIA	No	########
3	17-279815	HBV	Perinatal					

5) To expand all the cells to their correct size, highlight the entire document (See 6a) and double click on the line separating one of the variable cells.

	Α	В	С	D	E	F	G	Н	
1	MEDSIS 🔻	N DPBI	MORBS 🔻	BRTHLC 🔻	BRTHLC 🔻	BRTHLC 🔻	PTSXIC 🔻	SXONS ⁻ -	٤
2	17-279775	HBV	Acute	USA		ESTONIA	No	****	ľ
3	17-279815	HRV	Perinatal						

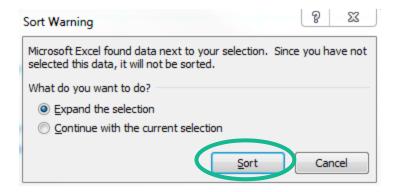
- 6) Highlight the INFTEDD (column E) and filter by newest to oldest.
 - (a) Click on the column letter (E) above the variable name. This will cause the entire column to be selected.

D	E	
DRBSI 🔻	INFTEDD 💌	PLNDHOSP
ronic	6/14/2017	Chandler R
ronic	7/12/2017	Banner Uni
ronic	7/23/2017	Abrazo Cer
ronic	5/9/2017	Yavapai Re
ronic	10/13/2017	Scottsdale
ronic	4/9/2018	Scottsdale
ronic	7/2/2017	Abrazo Arro
ronic	7/28/2017	Tucson Me
	8/28/2017	Canyon Vis
	7/27/2018	St. Joseph'
ronic	11/1/2017	Abrazo Arro
ronic	10/13/2017	Banner Thu
	10/10/2017	Abrazo Arro
ronic	10/8/2017	Banner Des
ronic	10/5/2017	Tucson Me
ronic	10/24/2017	Abrazo Arro
ronic	8/8/2017	Banner Uni
ronic	7/11/2017	Abrazo Arro
ronic	7/10/2017	Banner Uni
ronic	1/27/2010	Chandler P

(b) Select **Sort & Filter** from the home tab and hit **Sort Newest to Oldest** from the drop down list.



(c) A warning box will appear on the screen. Ensure the default setting **Expand the selection** is marked and hit **Sort**. This will cause the more recent delivery dates to be on the top of your file.

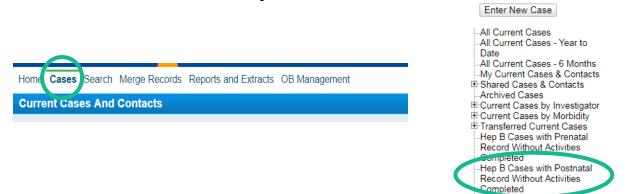


7) You can look through all of your pregnancies and based on the delivery date and the final disposition (PREFINDISP) you can determine if an infant should be born soon or if you need to enter in an infant. The PRELINKINFT variable contains the MEDSIS IDs of the linked infants. If it is blank, that means you have not linked the infant yet.

E) How to search for active postnatal management cases

MEDSIS has a capability for you to easily search for infants where the date approved for payment for postnatal services has not been filled out. Cases will continue to show up on your list, even if you have filled out final disposition, your county, and postnatal complete date variables until the **date approved for payment** (filled out by ADHS) is completed. This allows you to ensure that you have been paid for postnatal management. Once this variable is filled out, the case will no longer show up on your list of active postnatal management cases.

1) Go to the cases tab in MEDSIS and search for Hep B Cases with Postnatal Record Without Activities Completed.



If the final disposition is transferred to another jurisdiction within the state, the case will continue to show up on your search until payment has been approved. For the receiving county, the case will continue to show up on your list until the second payment has been approved.

Saved Searches

Example: This case would no longer show up on Apache's search, but it will show up on the receiving county's search until **Date approved for payment (2)** is filled out.

Was the infant transferred into the program from another state for case management?	T
Postnatal Complete Date	3/1/2018
County Completed	Apache •
Final disposition?	Transferred to another jurisdiction within state
Date approved for payment (ADHS Only)	3/2/2018
Postnatal Complete Date (2)	
County Completed (2)	▼
Final disposition? (2)	T
Date approved for payment (2)	

F) How to pull extracts

1) Pulling a line list of all pregnancies

This allows you to pull a line list of the prenatal management table. It is structured with one pregnancy per line. If a mother has multiple pregnancies, each pregnancy from the table will be on one line of the extract.

(a) Go to the **Reports and Extracts** section.



(b) Underneath Extracts, select Perinatal Hep B Extract.

Extracts	
Extract Name	Description
All Reporters Extract	All Reporters Extract
DSO Extract MORBSPC	DSO Extract MORBSPC
DSO Extracts	DSO Extracts
H1N1 Extract AZDHS	H1N1 Extract AZDHS
Lab Observations Extract	Lab Observations Extract
MEDSIS Extract	Extract of cases in your Jurisdiction
NETSS Extract	NETSS Extract
Perinatal Hep B Extract	Perinatal Hep B Extract

(c) Select the time period for the extract you wish to pull and hit Run Extract.

	Close
	Perinatal Hep B Extract
Case Entry From 1/1/2017	
Case Entry To 11/13/2017	
	Run Extract

Note: the case entry from will always be the start of the current MMWR year.

2) Pulling a line list of open contacts

This allows you to pull a line list of all the open contacts that you have in your jurisdiction.

Note: the extract that is pulled by this method includes all hepatitis B cases that have some part of the DSO filled out.

(a) Go to the **Reports and Extracts** section.

Home Cases Search Merge Record	Reports and Extracts OB Management
Current Cases And Contacts	

(b) Underneath Extracts, select DSO Extracts.

Ext	Extracts					
	Extract Name	Description				
	All Reporters Extract	All Reporters Extract				
a	DSO Extract MORBSPC	DSO Extract MORBSPC				
	DSO Extracts	DSO Extracts				
d	H1N1 Extract AZDHS	H1N1 Extract AZDHS				
	Lab Observations Extract	Lab Observations Extract				
	MEDSIS Extract	Extract of cases in your Jurisdiction				
	NETSS Extract	NETSS Extract				
	Perinatal Hep B Extract	Perinatal Hep B Extract				

(c) Select **Hepatitis B** as the morbidity and select the time period that you wish to pull.

			Close
			DSO Extracts
Morbio Hepat			
Enter 1 1/1/20	Date From 17		
Enter 1 12/22/	Date To 2017		
			Run Extract

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Note: the enter date from will always be the start of the current MMWR year.

(d) Select **Run extract.** The file will download as a text file.

• Save the file to your computer.

(e) Open the text file in excel.

- In excel, go to File \rightarrow Open \rightarrow and select the file location
- Make sure you select All Files instead of All Excel Files (the default).

File name:		
	Tools	▼ Open ▼ Cancel
File name:		All Files
	Tools	▼ Open ▼ Cancel

• Select Next in the list of questions that excel asks you and hit Finish when Next can no longer be selected.

(f) Select all cases in excel and filter.

• Select the arrow to select the file.

	Α	В	С	D	E	F	G	Н	
1	MEDSISID	MORBIDC	MORBSPC	BRTHLC	BRTHLCSP	BRTHLCM	PTSXIC	SXONSTD	SX
2	17-279775	HBV	Acute	USA		ESTONIA	No	****	Nc
3	17-279815	HBV	Perinatal						
4	17-279947	HBV	Perinatal					****	

• Apply the filter to the file. Select **Sort & Filter** from the home tab and hit **Filter** from the drop down list. This will causes arrows to appear next to your variables.



	А		В	С	D	E	F	G	Н
1	MET SIS -	MC F	RBI	MORBS 🔻	BRTHLC 🔻	BRTHLC -	BRTHLC 🔻	PTSXIC 🔻	SXONS' 🔻
2	17-279775	πв٧		Acute	USA		ESTONIA	No	#########
3	17-279815	HRV		Perinatal					

(g) To expand all the cells to their correct size, highlight the entire document (See 6a) and double click on the line separating one of the variable cells.

	А	В	С	D	E	F	G	Н
1	MEDSIS 🔻	MORBII 🔻	MORBS 🔻	BRTHLC	BRTHLC	BRTHLC	PTSXIC 🔻	SXONS 💌 S
2	17-279775	HBV	Acute	USA		ESTONIA	No	******
3	17-279815	HRV	Perinatal					

- (h) In the **MORBSPC** column (Column C), filter by **Perinatal**. This will cause only perinatal cases to appear in the excel file.
 - Select on the drop down arrow and make sure **Perinatal** is the only option selected.
- (i) To see only open perinatal cases in the line list, scroll over to **POSTFINDISP** (Column **EA**) and filter to show only (**blanks**). This will cause only cases that do not have a final disposition to be appear.

Note: if you are handling a contact that was transferred into your jurisdiction from another county, scroll over to **POSTFINDISP2** (*Column* **EF**) *and filter to show only* (*blanks*).

(j) If you would like to only see variables associated with the perinatal DSO, select columns between BIRTHLC (column D) and INCAREVSP (Column CM).
 Right click over one of the variable column headers and select Hide. These are all variables associated with acute and chronic hepatitis B cases.

Note: to see what the variable names correspond to, you can access the **data dictionary** in the **Health Services Portal**. From the portal, click on **Epi & Disease Control** \rightarrow **MEDSIS Documentation** \rightarrow **Extracts** \rightarrow **DSO Extracts** \rightarrow **Hepatitis B and D Data Dictionary**.

G) How to add next of kin

This allows you to keep track of family members that you will have contact with.

1) On the right hand sidebar, click on **next of kin**.



2) Click on **add** to add a family member.

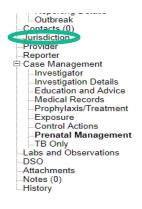


3) Add known information and hit save.

Primary		Name	Relationship
Prefix *First	Middle	*Last	Suffix
Relationship	Primary next of kin?		
Same as patient primary address			
Organization Name			
Street	Unit		
City	State ZIP Code	Country	County
Home Phone	Work Phone	Cell Phone	Other Phone
E-mail address			
Comments			
Save Cancel			//

H) How to transfer to a new jurisdiction

1) In the left hand side bar, click on **Jurisdiction**.



Jurisdictio	Jurisdictions Shar Tran									
	Start	Stop	Action	Jurisdiction Name	User					
	10/18/2017		Primary	ARIZONA DEPARTMENT OF HEALTH SERVICES	Rachel Perry					

- 2) Click on the **Transfer** button.
- 3) From the drop down menu, click on the jurisdiction that you wish to transfer the case to.

Sta	rt Stop	Action	Jurisdiction Name
10/18/20)17	Primary	ARIZONA DEPARTMENT OF HEALTH SERVICES

4) Click on **Transfer** after selecting the county.

I) What to do if perinatal was not selected as the exposure when creating a contact

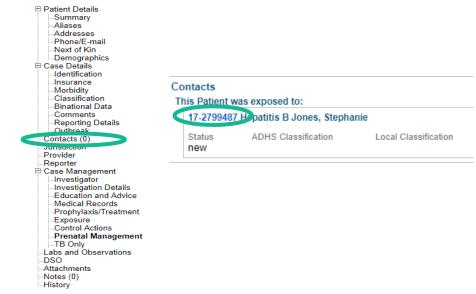
1) Go into the new contact and for the **Hepatitis B Type** in the DSO, select **Perinatal**. This will cause perinatal hepatitis B DSO specific questions to appear.

DSO	
Hepatitis B Type 📀	Perinatal 🔻

Note: Once perinatal is selected, DO NOT change the *Hepatitis B Type* as this will cause you to lose any information that you have entered into the DSO.

2) After saving the type as **Perinatal**, you will be able to link the infant to the pregnancy in the perinatal management table on the mother's MEDSIS case.

Tip: To easily go back to the mother's case, click on contacts from the side bar and the mother's case will be listed as a contact in the infant. Clicking on the MEDSIS ID of the mother will allow you to go back to her case.



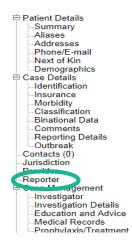
3) Edit the pregnancy in the table that you wish to add the contact/infant to and ensure that Yes is selected for Will postnatal case management be performed in Arizona (i.e. perinatal contacts created in MEDSIS)? You will be able to select the contact/infant. After doing so, save the updated information.

	Estimated Delivery Date	Delivery Hospital(s)	
	5/10/2017	1: Honor Health Deer Valley Medical Center	Complet
7		2: A delivery hospital not listed	
5/10/2 Planne Hono Planne Other Prenata 3/9/20	d Delivery Hospital 1 r Health Deer Valle d Delivery Hospital 2 al Activities Complete	ey Medical Center Specify: A delivery hospital not liste Date County Completed Maricopa County	d
Com	eleted education	¥	
For Date	Neted education ADHS Use Only Approved for Payme		
For Date Will por Yes	ADHS Use Only ADHS Use Only Approved for Payme	ant	MEDSIS)?
For Date Will por Yes	Neted education ADHS Use Only Approved for Payme	ant	
For Date Will por Yes Perinat	ADHS Use Only ADHS Use Only Approved for Payme	ent	
For Date Will pos Yes Perinat Sele	ADHS Use Only ADHS Use Only Approved for Payme Innatal case managen al Contacts	ent	
Vill por Yes Perinat	Noted education ADHS Use Only ADHS Use Only Approved for Payme stratal case managen al Contacts act perinatal contact	ent	
Vill por Yes Perinat Selu	ADHS Use Only ADHS Use Only & Approved for Payme Intralal case managen al Contacts act perinatal contact 17-2799491: Matth	ent	
Vill por Yes Perinat Selu	Noted education ADHS Use Only ADHS Use Only Approved for Payme stratal case managen al Contacts act perinatal contact	ent	

Date Completed Prenatal Activities	Date Approved for Payment	Contacts	
Completed education — 3/9/2017 by Maricopa County		Postnatal Management in Arizona: Yes 17-2799491: Matthew Jones	Notes ca

J) How to add a reporter

1) Click on **Reporter** from the right hand sidebar to jump to the reporter section



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2) Click on Add to add a new reporter



3) In the organization section, search for "ADHS*" (make sure to include the asterisk) and hit Search

Last Name	First Name	Organization ADHS*	 Outside Jurisdiction 	Country
				State
Search Cancel				

4) Click on the green add button to add the **ADHS Perinatal Hepatitis B Program** as the reporter

Search Criteria: Organizati	ion Name = 'ADHS*'		
C-lost	Reporter	Reporting Organization	Phone
Reporter, Unknown		ADHS Perinatal Hepatitis B Program , , AZ	

5) The reporter will then show up for the case

Reporters										
		Name	Reporting Organization	Phone	Report Date					
6	/	Reporter, Unknown	MIHS - MARICOPA INTEGRATED HEALTH SYSTEM PHOENIX, AZ 85008	(602) 344-5011	1/7/2018					
6	/	Reporter, Unknown	ADHS Perinatal Hepatitis B Program , AZ		3/22/2018					

Additional resources

Videos demonstrating entry into MEDSIS can be found <u>here</u>.

Release Notes

Version 1.2: Released 3/2019

Updates:

• Additional Link to YouTube videos added

Version 1.1: Released 4/2018

Updates:

- How to search for active postnatal management cases section added
- Update on how to link infants to the prenatal management table
- Links to YouTube videos added
- Added transferred out of country to final disposition options for postnatal management
- Household contacts section added
- How to add a reporter section added
- Added how to search for closed prenatal cases that need postnatal management

Version 1.0: Released 1/2018