The Shrewsbury and Telford Hospital NHS
NHS Trust

Hepatitis B: Antenatal, Intrapartum and Postnatal Care

Version 6

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For triennial review

VERSION	IMPLEMENTATION DATE	HISTORY	RATIFIED BY	REVIEW DATE
1	December 2006	New Guideline		December 2008
2	14th November 2008	Revised	MG & MGG	November 2011
2.1	1st February 2012	Revised	GC Authorisation	February 2015
2.2	6th October 2015	Full review in progress. Guideline reflects current practice	Extraordinary Approval	April 2016
3	May 2016	Full Review	MGG Maternity Governance	June 2019
4	22nd August 2018	Full Version Review	MGG Maternity Governance	August 2023
4.1	8th March 2019	Addition of 'Missed Screening' section in 5.16	MGG Maternity Governance	August 2023
5	May 2021	Implementation of new National Pathway	MGG Maternity Governance	May 2024
6	21st June 2024	Full Review	Maternity Governance	June 2024

In this guideline we use the terms ‘woman’ or ‘mother’ throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth.

1.0 Introduction

Hepatitis B infection is a risk to public health. Mortality rates from liver disease are rising in the UK. Whilst there are multiple causes of progressive chronic liver disease, around 25% of all liver disease cases in the UK are due to hepatitis infections.

The Department of Health policy has supported the provision of universal screening of pregnant women for hepatitis B and immunisation of babies at risk since 2000, based on The Health Service Circular 1998/127 ‘Screening of pregnant women for Hepatitis B and immunisation of babies at risk’.

2.0 Aims

To ensure that pregnant women at any gestation booking at SATH NHS Trust are recommended screening for Hepatitis B, in order that babies identified at risk of acquiring infection are immunised in a timely and appropriate manner, to reduce the mother to baby transmission risk.

3.0 Objectives

3.1 To offer and recommend screening to all women regardless of gestation as an integral part of antenatal care.
3.2 To provide women with appropriate national screening information in order to facilitate informed decision making.
3.3 To ensure that screening is undertaken in a timely manner
3.4 To report and review screening test results in a timely manner to support appropriate management of care.
3.5 To ensure that women who initially decline screening are formally re-offered screening by 20 weeks
3.6 To ensure that disease specific confirmatory testing is offered to all women with a screen positive result, in line with national standards.
3.7. To provide appropriate information and support to those women with a confirmed diagnosis.
3.8 To ensure appropriate and timely referral to agencies responsible for long term health care management.
3.9 To ensure that all newborn infants of Hepatitis B positive mothers receive a the 1st vaccination as part of the course of vaccinations needed to protect them against acquired infection
3.10 To ensure that care pathways exist with clear lines of responsibility. To ensure that appropriate information is communicated from acute to primary care sectors to ensure full population coverage of vaccination/immunisation programmes for mothers and babies as appropriate.
3.11 To have in place systems for risk assessment and management of adverse incidents occurring during the screening process.
3.12 To participate in routine monitoring of the screening programmes to meet Government recommendations of screening for Hepatitis B and immunising the babies of Hepatitis B positive mothers (DH 2003, 2011)
3.13 To have in place effective and robust audit and monitoring processes in line with clinical governance arrangements to improve quality.

4.0 Definitions

MIS: Maternity Information system
HBV: Hepatitis B virus
HBIG: Hepatitis B Immunoglobulin
SM: Screening Midwife
MDT: Multi-Disciplinary team
PHE: Public Health England
ISOSS: Integrated Screening Outcomes Surveillance Service
SaTH – Shrewsbury and Telford Hospitals

5.0 The Disease

Hepatitis B is an inflammatory illness of the liver caused by the hepatitis B virus (HBV).

Following acquisition, the virus infects human liver cells. Once inside it uses the cell's machinery to replicate, creating copies of itself. The new virus then infects surrounding liver cells and repeats the process of replication. The process of viral replication does not itself damage the liver, instead, it is the individual's own immune system, which detects the virus and mounts an attack which destroys both infected and surrounding non-infected liver cells.

A hepatitis B infection can result in two possible outcomes; an acute (short term) infection, or a chronic (life-long) infection where the body fails to clear the virus.

Acute Hepatitis B refers to newly acquired infections.

In around 90% of healthy adults who acquire HBV their immune response can clear the virus within a few weeks or months. Many do not experience any symptoms, but where they do, it is usually between 1 to 4 months after infection and they are often mild including fever, fatigue, loss of appetite, nausea, vomiting and abdominal pain.

Rarely, a life-threatening condition called 'fulminant hepatitis' can occur with an acute infection. This requires immediate medical attention as it can cause sudden liver failure resulting in the need for a liver transplant and can often be fatal.

Acute hepatitis B may last up to 6 months and individuals can easily pass the virus to others during this time. Those who successfully clear the virus make a full recovery and are then non-infectious to others and immune to reinfection.

Chronic Hepatitis B -refers to infections which fail to clear within 6 months.

Approximately 10% of adults who acquire HBV do not clear the virus spontaneously within 6 months and are diagnosed with chronic hepatitis B. Spontaneous clearance of hepatitis B after this point is very rare and most individuals remain hepatitis B positive for life. The risk of progression to chronic hepatitis B is inversely proportional to the age infection is acquired, with over 90% of infected infants becoming chronically infected.

People with chronic infection have an increased risk of developing liver cirrhosis (permanent scarring of the liver) and liver cancer and management should be by a hepatologist or gastroenterologist. When clinically indicated, antiviral treatment can help to reduce the progression of liver disease and complications.

5.1 Prevalence.

Hepatitis B is a major public health problem and became the leading cause of infectious deaths globally in 2013, exceeding HIV, tuberculosis, and malaria. In 2019 The World Health Organization (WHO) estimated 3.8% of the world's population were living with chronic hepatitis B.

The WHO has categorised countries based upon the prevalence of chronic hepatitis B infection (as indicated by HBsAg positivity).

- High-prevalence regions (more than 8%), include sub-Saharan Africa, most of Asia and the Pacific islands.
- Intermediate-prevalence regions (2-8%), include the Amazon, southern parts of Eastern and Central Europe, the Middle East and the Indian sub-continent.
- Low prevalence regions (less than 2%) include most of Western Europe and North America.

In 2021 the UK Health Security Agency (UKHSA) estimated the prevalence of people living with chronic hepatitis B in England to be 0.45% of the population.

Overall, the prevalence rates found in antenatal women in the UK is around 0.4% and varies from 0.05% to 0.08% in some rural areas but rise to 1% or more in certain inner-city areas where populations with origins in endemic countries are higher.

5.2 Transmission

Hepatitis B is very infectious, and the virus may be transmitted by contact with infected blood or body fluids contaminated by blood. Hepatitis B can be passed from person to person through unprotected sexual intercourse, vertically during pregnancy or childbirth and through direct contact with the blood of someone with the virus, including within the household or by sharing needles.

5.3 Symptoms

Exposure to the HBV causes an acute infection.

Many individuals newly infected with HBV may have a sub-clinical or a flu-like illness. The acute illness usually starts insidiously – with tiredness, abdominal pain, nausea, vomiting, joint pains, loss of appetite and jaundice (30-50%), as jaundice develops there is progressive darkening of the urine and lightening of the faeces. Fever, when present, is usually mild. Malaise may be profound.

In people who do not develop symptoms suggestive of hepatitis, the acute illness may only be detected by abnormal liver function tests and/or the presence of serological markers of hepatitis B infection (for example hepatitis B surface antigen (HBsAg) and hepatitis B core IgM antibody (anti-HBc IgM).

The incubation period ranges from 40 to 160 days, HBsAg is most commonly detected by 60 to 90 days.

Current infection can be detected by the presence of HBsAg in the serum. Blood and body fluids from these individuals should be considered to be infectious. In most individuals, infection will resolve and HBsAg disappears from the serum, but the virus persists in some people who become chronically infected with hepatitis B.

5.4 Hepatitis B in Pregnancy

Babies born to mothers with hepatitis B are at high risk of acquiring HBV infection, particularly if the mother has a high level of HBV DNA (viral load) and displays hepatitis B ‘e’ antigen positivity (HBeAg) in her plasma.

The risk of transmission depends on the status of the maternal infection. Without intervention, 70 to 90% of mothers who are ‘e’ antigen positive (HBeAg) will pass the infection to their baby compared to a 10% risk for mothers who are ‘e’ antigen negative.

Perinatal transmission can result in an acute or chronic infection, but babies have a much higher chance of being chronically infected. Whereas most adults who newly acquire Hepatitis B clear the virus, 90% of infants who acquire hepatitis B vertically will develop chronic infection. This chronic infection brings an increased lifetime risk of developing hepatocellular carcinoma. The development of chronic infection after perinatal transmission can be prevented in over 90% of cases by timely vaccination (hepatitis B vaccine +/- hepatitis B immunoglobulin (HBIG)).

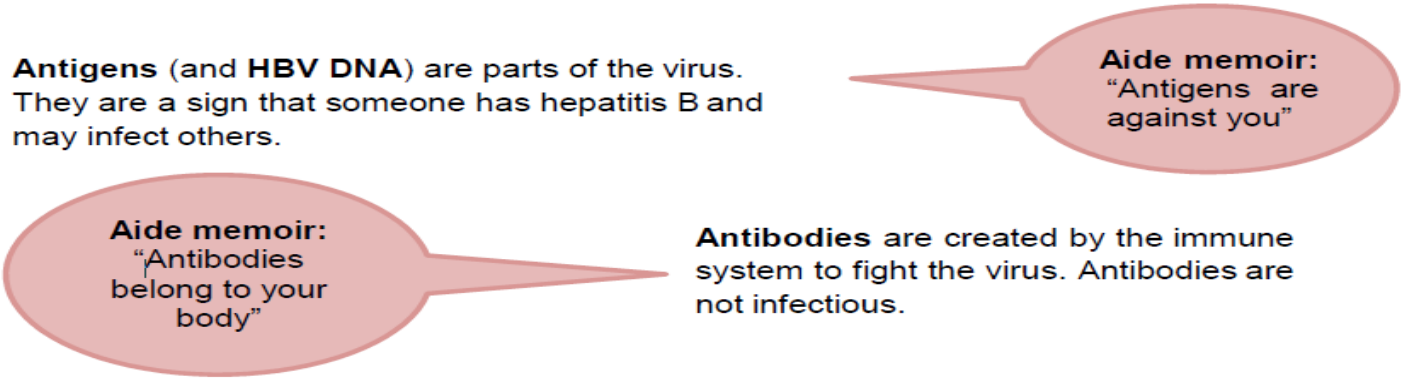
The mode of delivery and breastfeeding does not affect mother to child transmission if the baby receives appropriate management.

5.5 Diagnosis

Screening
The recommended screening test for hepatitis B is an immunoassay to detect hepatitis B surface antigen (HBsAg).

Confirmatory
All specimens that are positive for the HBsAg must be confirmed using a neutralisation assay or an alternative HBsAg test of equivalent analytical sensitivity. Further tests are required to assess infectivity and will identify hepatitis B antigens and antibodies and measure the maternal viral load (HBV DNA).

These antigens and antibodies are known as viral or 'e markers'. Testing for 'e' markers and measuring the viral load gives an indication of how the infection is progressing and/or if it is responding to treatment. Finding the 'surface' and 'e' antigens (known as HBsAg and HBeAg) and their corresponding antibodies is important in establishing the pattern of disease.



HBs Antigen (HBsAg): surface antigen
The term 'surface' refers to the outer surface of the virus itself. It appears 1 to 2months after infection and disappears from the blood as the infection clears (WHO 2015). A positive result indicates that someone has acute or chronic hepatitis B. A negative result shows that a person has either never been exposed to the virus or that they have recovered from the infection and have rid themselves of the virus. If HBsAg disappears and protective antibodies appear (HBsAg negative, anti-HBs positive), this is considered a "cure".

HBs antibody (anti-HBs)
The immune system creates this antibody to destroy the HBsAg of the virus. Anti-HBs appear if an infected person clears their virus ("cure"), or if a healthy person is successfully vaccinated. The HBs antibody also makes a person immune against hepatitis B, so they cannot be re-infected with hepatitis B.

HBV DNA (viral load)
This test monitors the amount of virus in the blood, known as the 'viral load' (VL) which is an indicator of infectivity. The higher the VL, the more infectious the infected person will be. A high VL is considered as equal to or above 1x106 IUs/ml in an antenatal blood sample. A high VL also increases the risk of cirrhosis and liver cancer. A very low amount or no trace of the virus is a marker of an individual's good immune response to the virus or a good response to antiviral medication in a person who is receiving treatment.

HBc antibody (anti-HBc)
This antibody is created by the immune system against the core of the hepatitis B virus. It always becomes positive in an infection and stays for life, no matter whether the infection is cleared or becomes chronic. Anti-HBc does not appear in healthy vaccinated patients. Its presence shows that a real infection has occurred or is still present.

HBe antigen (HBeAg)
E antigen positivity is a sign that the virus is actively replicating. The viral load (HBV DNA) is usually very high in these patients. Together a high viral load and 'e'antigen positivity indicate that a person is highly infectious and can infect others easily. HBeAg is also a vulnerable part of the virus. The immune system might create anti-HBe antibodies (anti-HBe) which can negate the 'e' antigen. This is called HBeAg seroconversion. This is not a cure, but 'e' antigen negativity means the virus is being controlled by the immune system so it cannot replicate as rapidly.

HBe antibody (anti-HBe)
This is created by the immune system to destroy the HBe antigen. It is present in people recovering from an acute hepatitis B infection. E antibody positivity in chronic hepatitis B infection suggests lower levels of the virus are likely to be present in the blood.

ALT (alanine aminotransferase)
This is a liver enzyme that everyone has in their blood; it is not specific for hepatitis B. ALT levels are raised in conditions where the liver cells (hepatocytes) become damaged. If ALT is higher than normal it can be a sign of liver inflammation. It is important to observe ALT in chronic hepatitis B, along with the viral load (HBVDNA) and other 'liver marker' serology results. ALT levels interpreted in isolation are of no value.

5.6 Screening Pathway

All pregnant women are offered and recommended screening for hepatitis B in every pregnancy regardless of previous results.

Refer to the Antenatal Screening Guideline- The process, review and communication of screening results regarding:

- Screening Information to women
- The offer and uptake of screening
- Women who book after 20 weeks
- Women who transfer from another unit in their pregnancy
- Women who present in labour
- Women who decline screening
- Women who miscarry/TOP

Confidentiality
In order to minimize the adverse effects of screening e.g. anxiety, misunderstanding and unnecessary investigation and follow-up, all health care professionals should be aware of inappropriate disclosure of patient specific information. No information should be recorded on the woman's record without her consent.

5.7 Screen Negative Results for the woman

Results are available on the electronic hospital laboratory reporting system within 3 working days of the test being taken. The woman is informed of her result and the result is documented on the MIS, at her following antenatal visit with the midwife. The woman should be informed that she was negative at the time of testing, if she deems herself at risk or changes her sexual partner, she can request further screening at any stage in her pregnancy.

5.8 The Screening Pathway for a Confirmed Screen positive result

The microbiologist informs the SM by of a screen positive result by telephone within 8 working days of the sample being received by the laboratory. The SM documents the results on the MIS and a face-to-face appointment is generated with the SM for specialist assessment.
If a woman attends her booking appointment and she is a known HBV carrier the midwife should notify the SM to ensure timely care and referral.

The SM will commence a PHE 'Hepatitis B – Maternal and neonatal Checklist' (Appendix 1) and enter the woman on the HBV Screening database.

5.9 Communicating screen positive screening results to the woman – initial consultation

The SM will discuss the screen positive result with the woman ≤10 working days of the positive result being received. For any woman whose first language is not English an interpreter will be used.

Using the PHE leaflet 'Hepatitis B: A guide to your care in pregnancy and after your baby is born', the SM will also discuss:

- Hepatitis B infection and what it means.
- The screening test result and what it means
- The modes of HBV transmission and means of preventing it.
- The benefits of testing and immunising household and /or sexual partners via the GP.
- Referral to a Gastroenterologist for specialist assessment.

- The importance of the MDT in the planning of care and the indication for delivery on the Consultant Unit
- How hepatitis B is usually acquired around the time of birth and that intrauterine infection is rare.
- The importance of completing the vaccination schedule in preventing transmission to the baby
- The PHE surveillance process
- Requirement to notify all health professionals and agencies involved in her and her baby's care

A maternal venous surveillance sample to be taken and sent to PHE Virus Reference Department at Colindale, (Using the Antenatal Surveillance kit' and PHE Microbiology request form).

Baseline LFT's and Hepatitis B Viral DNA will be taken to assess infectivity levels.

The key serological marker of acute and chronic HBV infection is the detection of hepatitis B surface antigen (HBsAg). The following markers assess the infectivity:

- HBV e antigen (HBeAg) – HBV is replicating at high levels and the patient is highly infectious
- HBV e antibody (anti-HBe)-the body's immune response to the HBeAg and usually indicates lower infectivity.
- HBV DNA (viral load) – gives a direct assessment of infectivity. Higher levels indicate higher infectivity.

Following her initial assessment the woman will be given an Antenatal Obstetric Consultant Clinic appointment where an individual plan of care will be discussed.

5.10 Documentation

The woman's results will be documented on the woman's electronic pregnancy record.

5.11 Antenatal Care

Care is planned as per infectivity.

Higher infectivity

Women with higher infectivity levels; a positive HBeAg, negative anti-HBe status, and/or a high HBV DNA Level, should be seen by specialist hepatitis B services within 6 weeks of the maternity service receiving the positive screening result and the higher infectivity pathway commenced.

Women with an elevated viral load (an HBV DNA level greater than or equal to 2x105 IU/ml) in pregnancy may be offered antiviral medication in the third trimester in order to reduce the amount of virus present in the maternal bloodstream at the time of delivery.

This is lower than the threshold for infants who require HBIG, meaning some women may require treatment in pregnancy but their infants will not require HBIG.

All babies born to women with higher infectivity require hepatitis B immunoglobulin (HBIG) in addition to the hepatitis B vaccine.

Lower infectivity

Women with lower infectivity; a negative HBeAg and positive anti-HBe status, with a viral load below 2x105 IU/ml, should follow the lower infectivity pathway and be seen by specialist hepatology services within 18 weeks of the maternity services receiving the positive result.

Babies born to women with lower infectivity require vaccination only.

However, infants born to women with hepatitis B who have a birthweight of 1500 grams or less, should receive HBIG in addition to the vaccine, regardless of the infectivity status of the mother, as the benefit is high in this group of infants.

Following the woman's initial consultation the SM will:

- Email a referral to the hepatology team.
- Complete the 'PHE Form A: Notification of Hepatitis B positive Antenatal Patient' (Appendix 2) and send to:

- West Midlands Screening and Immunisation Team
- The Child Health Department
- Registered GP
- PHE- Health Protection

- Complete an ISOSS HBV positive antenatal notification.
- For higher infectivity women, submit a HBIG request to the PHE lab in Colindale (Appendix 3). This prompts the lab to send the 'Delivery Suite' box to the SM and HBIG to pharmacy 7 weeks prior to delivery. The SM will link the two together and place in the Drug Fridge on delivery suite and add instructions on the womans electronic record as to its location.
- Complete a Neonatal Alert

The woman's antenatal care will be reviewed as part of a MDT meeting with all specialists represented, (Obstetrician, gastroenterology, neonatology and screening).

Third Trimester Review by the screening team in Antenatal Clinic.

- Discuss preparation for birth.
- Discuss and give the PHE leaflet 'Protecting your baby from Hepatitis B' – in an appropriate language if available.
- Discuss the importance of prompt registration of the baby's birth and with the GP.
- Discuss that the baby will require an accelerated course of HBV Vaccination to protect them from the exposure to the virus at birth and the importance of completing the vaccination programme.

5.12 Intrapartum Care

Infection control procedures must be followed (refer to the Infection Control Manual). The use of fetal scalp electrodes is not indicated. Refer to the individual plan of care which will be documented in the woman's hospital notes. Breastfeeding should not be discouraged. The baby may be breastfed from birth, before immunisation is given.

For High Infectivity women only:

Notify the SM of admission.
Locate the PHE 'Delivery suite box' and follow the instructions.

- Take a maternal serology sample after delivery and complete request form (pack 1)
- Take baby's 'hep B dried bloodspot' sample PRIOR to HBIG/ hep B vaccination. (pack 2)
- Administer HBIG + vaccine ≤ 24 hours of birth
- Complete the Hep B page in the Red Book and the PHE paperwork
- Notify the birth and checklist and Hep B box with the paperwork and samples to the screening team as soon as possible. (If the woman delivers out of hours or at the weekend store in a fridge).

5.13 Immunisation

All babies born to HBV positive women should receive the 1st dose of Hepatitis B vaccine and HBIG (if indicated) within 24 hours of birth and prior to discharge from hospital.

Timely administration of vaccines is always important; however, for hepatitis B vaccinations it is crucial. A complete course is required for full protection. Even the timely administration of the full course of vaccinations will not stop infection in all cases; targeted immunisation can prevent persistent hepatitis B infection in around 90% of individuals who would have otherwise developed the infection.

The PHE leaflet 'Protecting your baby from Hepatitis B', a consent for immunisation sheet (See appendix 6) and a child health insert for the red book will be available when the baby delivers.

There are 2 vaccines that are used for immunisation against Hepatitis B.

- **Hepatitis B Vaccine** which is used to confer active immunity. It is an inactivated vaccine that does not contain live organisms.

- **Hepatitis B Immunoglobulin (HBIG)** which is used to provide passive and temporary immunity while awaiting the body's response to the Hepatitis B vaccine. HBIG is obtained from the plasma of immunised and screened human donors.

For babies whose birth weight is 1500kgs or less, HBIG is indicated regardless of the mother's HBVe antigen status this will need to be ordered from Collingdale urgently to ensure it is given within 24 hours.

For the management of the baby and details of how to request HBIG refer to the Neonatal Guideline 'Management of Babies born to women with Hepatitis B and C infection' and Appendix 3

Hepatitis B Status of Mother	Baby Should Recieve	
	Hepatitis B Vaccine	HBIG
HBsAg pos and HBeAg pos	+	+
HBsAg pos and HBeAg neg/anti-HBeAb neg	+	+
HBsAg positive, e-markers undetermined	+	+
Acute Hepatitis B during Pregnancy	+	+
HbsAg pos, anti-HbeAg pos	+	-
HbsAg pos and known HBV DNA level equal to or above 1x106 IUs/ml in an antenatal sample (even if anti-HBe pos)* * where viral load testing has been performed to inform the management of the mother.	+	+
HBsAg positive and infant born ≤ 1500g, regardless of e antigen status	+	+

To ensure the timeliness of subsequent hepatitis B vaccine doses on discharge, the midwife should:

- Discuss with the mother/parents the baby's immunisation schedule and importance of completion.
- Record the mother's HBV status and the baby's vaccination schedule on the postnatal discharge summary as well as the Personal Child Health Record (PCHR).
- Send a copy of the discharge summary to the GP informing them that the 1st vaccine has been given.
- Notify the Screening team

Following Delivery the SM will:
Complete PHE Form B: 'Notification of Birth to a HBV Positive patient' (Appendix 4) and send to:

- The West Midlands Screening and Immunisation Team
- The Child Health Information Department
- The Registered GP

Complete the ISOSS hepatitis B outcome form
Complete the maternal and neonatal checklist and update the screening database

For high infectivity women the SM will:

- Check the request form for the maternal sample and ensure the sample has been taken.
- Check the neonatal sample has been taken and the form is complete.
- Send both maternal and neonatal samples to the PHE virus reference dept., Colindale in the pre-paid packaging.

5.15 Other resources
This guideline is to be used in conjunction with:

- Management of Babies born to Women with Hepatitis B and Hepatitis C infection.
- Antenatal Screening Guideline- The process, review and communication of screening results
- SaTH Infection Control Policy

5.16 Screening Failsafes for Infectious Diseases Screening

Each week the SM runs a report to identify all women booked from the MIS.
The microbiology lab sends the SM a weekly report of all the antenatal samples received. The SM cross checks both list to ensure that all women who booked during that week have had screening tests performed and a complete set of results.

The list also identifies:

- All the screen positives
- If any tests have been omitted/declined in order to ensure timely repeat screening is re-offered
- If any samples have been rejected and a repeat required.

All women with positive screening results are put onto individual databases, which enable an audit of the screening programme and outcome data for each of the conditions.

5.17 Missed Screening

In the event of a missed screen refer to PHE Guidance 'Managing Safety Incidents in the NHS Screening Programmes' published 2017.

- Report the incident on 'Datix' , the Trust incident reporting system
- Inform the Screening Midwife
- The SM will complete a Screening Incident Assessment Form (SIAF) to collect information on the suspected incident to determine its severity.
- The SIAF will be sent to the PHE Screening Quality Assurance Service (SQAS) and the Screening and Immunisation Team for Shropshire and Staffordshire.
- The incident will be reviewed at the 'Maternity Risk Meeting'
- The incident investigation will follow the Trust Risk Management Policy and PHE Guidance.

6.0 Training

Training and updating will be delivered in accordance with the SATH Maternity Services Training Needs Analysis. The current programme of the training that is being provided can be found on the programme details which are kept by the Lead Midwife for Education.

7.0 Monitoring and audit

The SM collates data required to monitor and provide the assurance of the delivery of the local screening programmes in line with National Standards and recommendations.

All the Screening Programme Standards are audited annually. An annual Screening Report is submitted to the Regional Screening Team, local commissioners and the Trust. Actions are developed and monitored through the Programme Board.

Data that is submitted by the SM includes:

Quarterly National Screening Key Performance Indicators (KPI's) for the Infectious Disease Screening Programme to PHE.

- **ID3 –Hepatitis B coverage**
  The number of eligible women tested for Hepatitis B
  Acceptable level ≥ 95.0%
  Achievable level ≥ 99.0%

Data for the National Hepatitis in Pregnancy Audit

The Local Screening programmes are Quality Assured through an external QA Assessment from PHE. The SM coordinates the data collection and submission in preparation for the assessments.

8.0 References

- PHE (2016) NHS Infectious Diseases in Pregnancy Screening Programme Standards 2016 to 2017 (Updated February 2023)
- PHE (2016-2017) NHS Infectious Diseases in Pregnancy Screening Programme Handbook – updated October 2023
- PHE Guidance on Infectious disease in pregnancy screening pathway requirements specification. June 2021
- Hepatitis B: the green book, chapter 18
- NICE (2014) Hepatitis B Quality Standard 65
- PHE Guidance 'Managing Safety Incidents in the NHS Screening Programmes. (2017) updated March 2024.

Appendix 1 – HBV Checklist

Public Health England

MATERNAL AND NEONATAL HEPATITIS B CHECKLIST

Unit number: ……
NHS number: ……
Surname ……
Forename(s) ……..
Date of birth ……/……/……
Ethnicity ……..Language spoken……..
GP…….. CMW ……

EDD

Date of booking……/……/……

Date of HBV screen..…/……/…..
Gest …….

Date of screening result……/……/……

Date of notification……/……/……
Known / New

Date of screening……/……/……
team assessment

Date of specialist…/……/……
Hepatology appointment

Serology results

Test	Date of test	Result
Viral load		
HCV		
LFTs		
Other test results		

Lower infectivity ☐ Higher infectivity ☐

	Screening team appointment (≤ 10 working days of laboratory result/notification)	Status/comments	Date	Signature and name in capitals
All women: high/low infectivity	Discuss care using 'Hep B: a guide to your care in pregnancy and after your baby is born'			
	Additional bloods taken as per local guidelines. Maternal venous sample sent to PHE Colindale. Check and record all other antenatal results.			
	Inform GP, H/V, HPT, CHIS and CMW.(Form A)			
Within 6 weeks of result/notification				
All women with hepatitis B	Specialist MDT appointment. **High infectivity and all newly diagnosed women:** within 6 weeks or by 24 weeks gestation. **Low infectivity known status:** 18-week OPD target or within 6 weeks if ≥ 24 weeks			
	Create neonatal alert			

Higher infectivity women only	Submit a HBIG request as per trust practice. 7 weeks before EDD PHE coordinator will send: • HBIG to your pharmacy • delivery suite box to screening team to match up with HBIG and place in box • box which should be stored according to trust practice and the location clearly noted on the maternal record. Notify the PHE co-ordinator if the woman's care is transferred.			
34-week pre-birth consultation/screening team review		**Status/comments**	**Date**	**Signature and name in capitals**
All women	**Preparation for birth** Discuss care and adherence to schedule using PHE 'Protecting your baby from hep B' leaflet. Check neonatal alert is in place.			
Higher infectivity	Confirm where **PHE hep B delivery suite box** containing HBIG is stored and that the location is recorded in notes/birth plan/maternity information system.			
Delivery suite team				
Higher infectivity mother and baby	**On admission:** • inform screening team of admission • locate PHE hep B delivery suite box			
	Using the hep B delivery suite box - take maternal serology sample after delivery and complete form (pack 1)	Date/time of blood test		
	- take neonatal 'hep B dried blood spot' prior to vaccination (pack 2) - give HBIG + hep B vaccination (pack 3) - complete PCHR red book hep B page and give to mother	Card number/time of blood test. Date/time given/batch number.		
	- complete paperwork and store with samples in hep B delivery suite box and return to screening team as soon as possible (if weekend/BH: recommend store in fridge at 4°C or room temperature if not available)			
Lower infectivity mother and baby	- vaccination administered ≤24 hours of birth - complete PCHR red book hep B page and given to mother	Prescription in notes/batch number.		
Post-natal				
Pre-discharge checks	- PCHR book has completed hep B page - mother has a copy of the vaccination leaflet - mother informed of the importance of early registration of the birth with a GP - ensure notes go back to screening team			

Screening team	- check request form for maternal sample and PHE notification forms are completed - DBS and bloods and forms despatched to PHE Virus Reference Department, Colindale in pre-paid packaging - inform CHIS, H/V GP, and CMW of vaccination using PHE letter templates (Form B) - complete ISOSS database			

Appendix 2 – HBV Notification Form

Public Health England

NHS England

Form A. Notification of Hepatitis B Positive Antenatal Patient

Staffordshire and Shropshire

Maternity Unit			
Lead Professional		EDD	Click or tap to enter a date.

Mother Details			
NHS Number		Unit Number	
First Name		Surname	
Date of Birth	Click or tap to enter a date.	Ethnic Origin	
Preferred Language		Is an interpreter required?	Choose an item.
Address			
Telephone Number		Mobile Number	
GP Name			
GP Address			

Was this woman previously known to be Hepatitis B Positive?			Choose an item.
Latest Hepatitis B Blood Results			
Sample Date	Click or tap to enter a date.	Sample Number	
HbsAg	Choose an item.	AntiHbc (total)	
AntiHbc (IGM)	Choose an item.	HbeAg	Choose an item.
AntiHbe	Choose an item.		
Is Neonatal Immunoglobulin required? (See table below)			Choose an item.

Interpretation of Serology Results		
Status of Mother	Hep B Vaccine	Hep B Immunoglobulin
HBsAg positive + HBeAg Positive	Yes	Yes
HBsAg positive + negative for BOTH HBeAg and AntiHBe	Yes	Yes
HBsAg positive + e markers not known	Yes	Yes
HBsAg positive + AntiHBe negative	Yes	Yes
HBsAg positive + AntiHBe positive	Yes	No
Acute Hepatitis B in Pregnancy	Yes	Yes

Reported by		Date	Click or tap to enter a date.

The completed Neonatal Hepatitis B Notification form must be sent to;

1) West Midlands Screening and Immunisation Team
2) The responsible Child Health Information Department
3) Registered GP Practice
4) Public Health England – Health Protection

Appendix 3 - HBIG Request Form

Hepatitis B Immunoglobulin request form

Public Health England

Hepatitis B Immunoglobulin request form

For infants at high risk of perinatal hepatitis B infection

Please write clearly in dark ink **IMPORTANT: Please complete all fields below to avoid delays in processing.**

ANTENATAL PATIENT DETAILS

Mother's surname:

First name:

Date of birth:

NHS Number:

Booking blood sample number:

Requesting hospital:

Home address:

GP name and address:

Ethnic Group

☐ White ☐ Indian ☐ Chinese ☐ Other Asian
☐ Black African ☐ Black British or Caribbean ☐ Mixed
☐ Other

Country of birth

Has the mother been referred to specialist care for her hepatitis B?

☐ Yes ☐ No ☐ Unknown

If yes: Specialist name

Hospital

Title/position Contact number

INDICATION FOR HBIG: WOMEN WITH HIGHER INFECTIVITY

Acute hepatitis B in pregnancy ☐ Yes ☐ No

HBsAG ☐ Positive ☐ Negative ☐ Unknown

HBeAG ☐ Positive ☐ Negative ☐ Unknown

Anti-HBe ☐ Positive ☐ Negative ☐ Unknown

Viral load iu/ml

Immunoglobulin is indicated for INFANTS of women with higher infectivity risk, i.e:
Pregnant women with acute hepatitis B OR:
Pregnant women who are HBsAg positive AND:
- HBeAg positive OR
- Anti-HBe negative OR
- E-markers unknown OR
- HBV DNA ≥ 1 x 10^6 IU/mL OR
- Birth weight of their newborn is ≤1500g

CURRENT STATUS OF PREGNANCY

☐ Expected ☐ Delivered | Est. delivery date ☐ Multiple birth (please complete a separate form for each sibling)

HBIG ISSUE
For routine issues, this HBIG request will prompt the dispatch of the HepB delivery suite box to the antenatal screening team and a vial of HBIG for the named baby to your pharmacy 6-8 weeks prior to the EDD (during normal office hours). The HBIG vial will have instructions for the pharmacist to contact the Antenatal Screening Team on receipt of the vial in order to link the vial and the box.

Please provide name of the ASC or equivalent person responsible for storing HBIG (if not at pharmacy)

Antenatal Screening Coordinator:

Telephone number:

Email address:

Form completed by

Contact number

Date

Coordinator address for HepB delivery suite box:

Signature of GMC registered medical practitioner (required by HMRA)

Name of GMC doctor

GMC no. Date

Please send completed form via email to: **phe.hepatitisbbabies@nhs.net** from @nhs.net email address only

EMERGENCY HBIG ISSUE
During office hours: call 0330 1281020 option 2 and email request to: **phe.hepatitisbbabies@nhs.net.**
Out of hours: call **020 8327 7471** and speak to the duty doctor.
Emergency HBIG will be sent to the location specified by the requestor OR collected by courier from a local stockholder

Ward/Unit | Hospital | FAO

All requests are subject to PHE standard terms and conditions IMM113 – Infant Hepatitis B Immunoglobulin Issue Request Form Version 6

Hepatitis B Immunoglobulin request form

Public Health England

If baby has already delivered, please also complete this birth notification form

MATERNAL ANTIVIRAL TREATMENT (during last trimester of pregnancy)

Mother's Hepatologist or equivalent	Name	Telephone number
Antiviral treatment in pregnancy	☐ Yes (if yes, please fill in details below)	☐ No

Drug name	Dose	Start date	End date

DELIVERY

Infant surname

First name

NHS Number:

Hospital number:

Sex ☐ Male ☐ Female

Date of birth

Time of birth

Type of delivery

Birth weight

Gestation

If multiple birth please specify number of babies (please complete a separate form for each sibling)

VACCINE AND HBIG ADMINISTRATION

NOTE

The infant should **receive 250IU of HBIg intra-muscular injection and paediatric hepatitis B vaccine** immediately after birth. Vials of HBIG are approx. 500IU so the whole vial should not be given

Vaccine	**HBIG**
Date given	Date given
Dose given	Dose given
Make of vaccine	Time given:
Batch no.	Batch no.

*If baby is very low birth weight and clinical decision made to give divided doses, please record when 2nd part of dose was given (should be given ASAP)

HBIG (2nd part of dose*)	Date given	Dose given	Time given	Batch n

DOCTOR RESPONSIBLE FOR FUTURE CARE OF THE INFANT (IF NOT GP)

Name

Title/Position

Contact no.

Address

Form completed by

Contact no.

Date

Please send completed form via email to:

phe.hepatitisbbabies@nhs.net from **@nhs.net** email address only. Please communicate to the GP or responsible clinician for care of the baby that the infant should be given the second dose of HepB vaccine at 4 weeks old and follow the immunisation schedule in PHE's Green Book.

Appendix 4

Public Health England

NHS England

Form B: Notification of Birth to a Hepatitis B Positive Patient

Staffordshire and Shropshire

Paediatrician/Neonatologist	

Mother's Details	
NHS Number	
Full Name	

Baby's Details			
NHS Number		Unit Number	
First Name		Surname	
Date of Birth	Click or tap to enter a date.	Sex	Choose an item.
Address (if different from mothers)			
GP Name and Address (if different from mother's			

Immunisation Details				
Immunoglobulin (HBIG) Within in 24 hours of birth if applicable	Date	Click or tap to enter a date.	Time	
	Batch Number			
1st Hepatitis B Vaccine Within 24 hours of birth	Date	Click or tap to enter a date.	Time	
	Batch Number			
Reason vaccine or HBIG was not given or given within the appropriate timeframe (if applicable)				

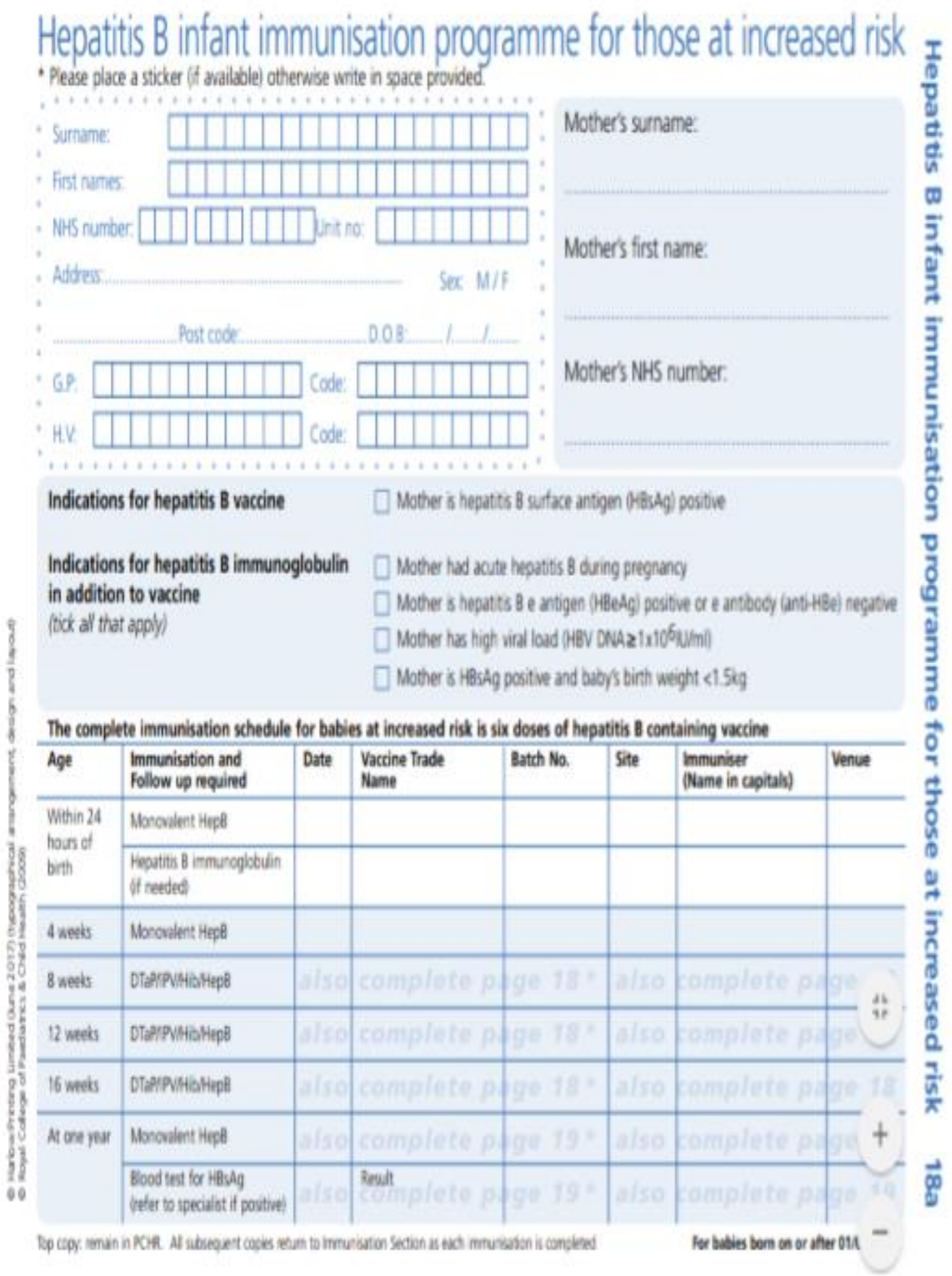
Reported by		Date	Click or tap to enter a date.

The completed Neonatal Hepatitis B Notification form must be sent to;

1) West Midlands Screening and Immunisation Team
2) The responsible Child Health Information Department
3) Registered GP Practice

Appendix 5

The Personal Child Health Record (PCHR) insert for the Hepatitis B infant immunisation programme



Hepatitis B infant immunisation programme for those at increased risk

* Please place a sticker (if available) otherwise write in space provided.

Surname:

First names:

NHS number: Unit no:

Address: Sex: M / F

Post code: D.O.B: / /

G.P: Code:

H.V: Code:

Mother's surname:

Mother's first name:

Mother's NHS number:

Indications for hepatitis B vaccine

☐ Mother is hepatitis B surface antigen (HBsAg) positive

Indications for hepatitis B immunoglobulin in addition to vaccine
(tick all that apply)

☐ Mother had acute hepatitis B during pregnancy
☐ Mother is hepatitis B e antigen (HBeAg) positive or e antibody (anti-HBe) negative
☐ Mother has high viral load (HBV DNA ≥ 1×10^6 IU/ml)
☐ Mother is HBsAg positive and baby's birth weight <1.5kg

The complete immunisation schedule for babies at increased risk is six doses of hepatitis B containing vaccine

Age	Immunisation and Follow up required	Date	Vaccine Trade Name	Batch No.	Site	Immuniser (Name in capitals)	Venue
Within 24 hours of birth	Monovalent HepB						
	Hepatitis B immunoglobulin (if needed)						
4 weeks	Monovalent HepB						
8 weeks	DTaP/IPV/Hib/HepB						
12 weeks	DTaP/IPV/Hib/HepB						
16 weeks	DTaP/IPV/Hib/HepB						
At one year	Monovalent HepB						
	Blood test for HBsAg (refer to specialist if positive)		Result				

Top copy: remain in PCHR. All subsequent copies return to Immunisation Section as each immunisation is completed

For babies born on or after 01/

Hepatitis B infant immunisation programme for those at increased risk 18a

Appendix 6.

Parental consent form for immunisation

TO BE KEPT IN PATIENT NOTES

CONSENT FORM

I…..……..
give consent for my baby……
to receive HBVax/and Hepatitis B specific Immunoglobulin (HBIG)*. The reason for this being given has been explained to me by Dr……..

Signed……...

Dated……

Witnessed……

delete if not applicable