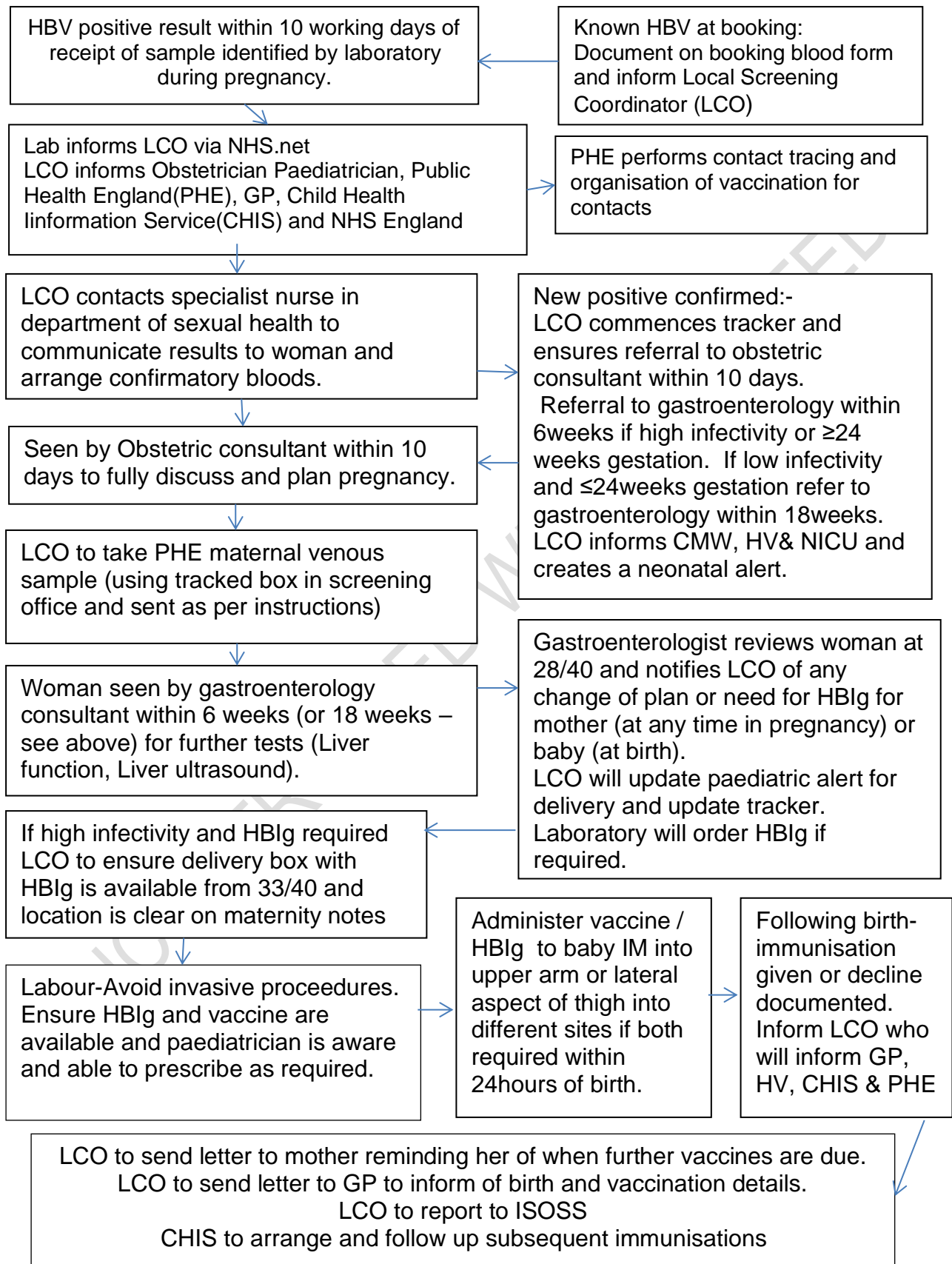




# **Standard Operational Procedure for Management of Pregnant Women with Hepatitis B and the Follow up Of Neonates**

Prepared by: Anya Wright  
Version: 1  
Status: Ratified  
Effective from: 11<sup>th</sup> May 2021  
Review: 11<sup>th</sup> May 2024

## Pathway for management of positive Hepatitis B Virus (HBV) in pregnancy



## **1 Purpose/Background:**

- Hepatitis B is an infectious disease caused by the hepatitis B virus (HBV) that affects the liver. The virus causes both acute and chronic infections. Many of those infected with the virus remain asymptomatic and unaware.
- In most individuals, infection will resolve and HBsAg disappears from the serum, but the virus persists in some patients who become chronically infected.
- The virus is transmitted through contact with infected blood and bodily fluids. .
- HBV attacks liver cells; in chronic cases can lead to liver failure, cirrhosis (scarring) or cancer of the liver in later life.
- Vaccination is recommended for anyone living in a household with an infected family member. Hepatitis B-containing vaccines are inactivated.
- Hepatitis B infection can be transmitted from infected mothers to their babies at or around the time of birth. Babies acquiring infection at this time have a high risk of becoming chronic carriers – much higher than if HBV is acquired in adulthood. As well as being infectious to others they will be at increased risk of developing chronic liver disease or hepatocellular carcinoma.
- The development of the carrier state after perinatal transmission can be prevented in around 90-95% of cases by appropriate immunisation, starting at birth, of all infants born to infected mothers.

The purpose of this Standard Operating Procedure (SOP) is to ensure that all pregnant women are offered screening and to ensure that all women identified as having Hepatitis B, their babies and families receive appropriate care and vaccination.

## **2. Scope:**

This document is for use by all obstetricians and midwives and it applies to all women cared for by the Maternity Services at St Mary's Hospital.

### 3. Responsibilities

It is the responsibility of all Midwifery Nursing and medical staff to:

- Access read understand and apply this SOP
- Attend any mandatory training pertaining to the SOP

It is the responsibility of the department to:

- Ensure the SOP is reviewed as required in line with trust and national recommendations
- Ensure the SOP is accessible to all relevant staff

### 4. Procedure:

#### 4.1.1 Antenatal Screening

All pregnant women should be offered screening for Hepatitis B as one of a number of blood tests routinely recommended in early pregnancy. The purpose and potential benefits of such screening should be explained to women and verbal consent obtained.

#### 4.1.2 Positive Results

- Women known to be Hepatitis B positive at the time of booking will require an urgent Consultant appointment to discuss a care pathway and arrange multidisciplinary (MDT) referrals within 10 days of status being reported to the maternity service.
- When the initial screening test for Hepatitis B surface antigen (HBsAg) is reactive, the result will be available and notified to the Local Screening Coordinator (LCO) via nhs.net email within 8 working days. This may be a false positive result.
- The LCO will arrange for the woman to be informed in person and offer support.
- If the woman does not speak English a translator should be arranged.
- Confirmatory testing should be performed for infectivity markers, i.e. Hepatitis B e antigen (HBeAg) and antibody (anti HBe) should be determined on all confirmed Hepatitis B surface antigen (HBsAg) positive samples.
  - **Hepatitis B Surface Antigen (HBsAg)** - is part of the HBV found in the blood of an infected person. When positive HBV is present.

- **Hepatitis B Surface Antibody (HBsAb or Anti-HBs)** – the surface antibody is formed in response to the HBV (vaccination or recovery). If this test is positive the body has developed a protective antibody against the HBV and long term protection.
- **Hepatitis B Core Antibody (HBcAb or anti-HBc)** – This antibody does not provide any protection or immunity against the HBV. A positive test shows exposure to the virus.

When HBsAg positive, those in whom HBe-antigen (HBeAg) is also detected are the most infectious. Those who are HBsAg positive and HBeAg negative (usually anti HBe Positive) are generally of lower infectivity

### **Flowcharts summarising the Hepatitis B antenatal screening and selective neonatal immunisation pathways**

[Lower infectivity pregnancy pathway: Flowchart](#)

[Higher infectivity pregnancy pathway: Flowchart](#)

On receipt of confirmation the LCO will:

- Contact the woman to offer support and ensure she has information about the disease, and how to prevent vertical transmission to their baby and others in the family.
- Download of NHS leaflet 'Hepatitis B: What does my positive screening result mean' to give to the woman.
- Commence check list (Appendix A)
- Make an urgent consultant appointment within 10 days of the result being available to discuss the results, implications and liaise with MDT to plan an individualised care pathway.
- Refer to Hepatologist/gastroenterologist to be seen within 6 weeks to discuss treatment for the woman and her baby.
- HBsAg positive women will have their results, treatment and ongoing care discussed between the Island Hepatology team and the Southampton team.

The following care will be considered:

- Liver function tests and liver ultrasound

- Tests for hepatitis B e-markers to determine whether babies born to such mothers should be given hepatitis B specific immunoglobulin (HBIG) in addition to the vaccine.
- Women with HBV DNA levels  $> 10^5$  IU/ml should be offered Nucleoside Analogue (NA) Tenofovir in the 3<sup>rd</sup> trimester to reduce vertical transmission risk.
- Treatment with TDF is recommended for women with advanced fibrosis or cirrhosis.
- Inform the following:-
  - Community midwife, Health Visitor
  - CHR D and GP ( Appendix B)
  - NICU
  - NHS England
- Alert in the hand held notes should be sensitive to confidentiality. The CTG envelope may be used to securely store care plan information.
- Consider referral to Department of Sexual Health (DOS H) if appropriate
- Ensure results have been communicated to the GP for screening and possible treatment of partner and other children as soon as possible after diagnosis.
- The LCO will ensure a hepatitis B delivery suite box (along with the HBIG if required) is available in the maternity unit approximately 7 weeks prior to the estimated delivery date.
- The consultant obstetrician will agree and complete a birth plan based on advice from the gastroenterology consultant review.

#### **4.1.3 Notification**

CHR D will report to NHS England-Wessex

**4.1.4** If the mother has high infectivity HBIG should be ordered 6 – 8 weeks prior to the date of delivery, discussed with the parents and consent obtained. (HBIG is obtained from the plasma of immunised and screened individuals).

Mother's Infectivity Markers	Babies should receive	
	Hepatitis b vaccine	Hepatitis B immunoglobulin (single dose)
HBsAg positive & HBeAg positive	Yes	Yes
HBsAg positive, HBeAg negative and anti-HBeAg negative	Yes	Yes
HBsAg positive and e Ag status unknown	Yes	Yes
Acute hepatitis B during this pregnancy	Yes	Yes
HBsAg positive and anti-HBe positive	Yes	No
HBsAg positive and HBV DNA levels > 10 <sup>6</sup> iu/ml	Yes	Yes
Preterm babies weighing 1500g or less	Yes	Yes

#### 4.2. Delivery

- Locate delivery box if mother is on high infectivity pathway.
- Inform NICU/paediatrician of admission and impending birth and the need for vaccination (and immunoglobulin if indicated)
- Invasive procedures such as artificial rupture of membranes, fetal blood sampling and fetal scalp electrodes are not recommended unless absolutely necessary.
- Inform Screening coordinator of delivery.

#### 4.3. Post Natal

There is no contraindication to breast feeding when a baby born to a mother who is HBsAG positive, begins immunisation at birth and completes the full course of immunisation

Women being treated with antiviral prophylaxis started at 24-28weeks should continue for up to 12weeks after delivery.

A dry bloodspot sample (DBS) should be taken on delivery suite from babies born to mothers classified as being at higher infectivity before administration of the vaccine and HBIG.

The DBS cards, instructions on collection and pre-paid return envelopes will be provided in the hepatitis B delivery suite box which will be delivered to the maternity unit approximately 7 weeks prior to the estimated delivery date.

**This surveillance blood sample is different to the sample taken on day 5 after the baby's birth. The mother should be informed that the baby will still need to have the newborn blood spot screen sample on day 5.** This DBS is not subject to the standards or requirements of the newborn blood spot screening programme. If the woman declines to have maternal serology and or neonatal DBS taken it should be recorded in her notes and on the completed request forms and returned to PHE Colindale.

#### 4.4.1 Immunisation of babies

- This is a very time sensitive vaccination and delay with any of the first three doses may result in chronic infection. After ensuring parental consent, immunisation of babies should be given within 24 hours of birth (certainly within 72 hours).
- HBIG, if required, should be given within 6 hours of birth (certainly within 12 hours).
- The vaccine is given intramuscularly in the anterolateral surface of the thigh; the buttock is not recommended as absorption from this area is unreliable. If HBIG is also required, this must be given in the opposite thigh.
- Hepatitis B vaccine but not HBIG is recommended for babies born to mothers who are HBsAG positive but known to be anti-HBe positive
- Table 1 shows the appropriate regimens for the use of hepatitis B vaccine and Hepatitis B specific immunoglobulin (HBIG).



#### 4.4.2 Storage

- Vaccines should be stored in the original packaging at + 2° to +8° C and protected from light.
- HBIG should be stored at +2° to +8° C and are tolerant to ambient temperatures for up to one week. They can be distributed in sturdy packaging outside the cold chain if needed

#### 4.4.3 Vaccination schedule follow up

- It is **very important** that the baby receives a full course of vaccinations against Hepatitis B **on time**. This includes Monovalent Hepatitis B vaccination at birth and at 1month, Hexavalent doses at 2, 3 and 4 months with first childhood vaccinations and Monovalent Hepatitis B vaccination at 12 months.
- The Screening coordinator will:
  - Inform the GP by letter and CHRD (see Appendix C)
  - Inform the mother by letter(see Appendix D)
  - Complete Audit
- If correctly administered, this schedule is 90% effective at preventing transmission and therefore the complications of chronic hepatitis B infection
- It is recommended a blood test should be performed at 12 – 14 months of age for Anti-HBs and HbsAg at the same time as the 4<sup>th</sup> dose of the vaccine is given. This is necessary to identify the 5-10% of babies, who in spite of vaccination still become chronic hepatitis carriers. NHS England Wessex will send a dry blood spot testing kit to the patient's GP practice 1 month before the blood test is due.

<b>HBsAg Negative</b>	Child not infected. Requires Booster HepB vaccine with pre-school booster
<b>HBsAg Positive</b>	Child Infected. Refer to paediatric hepatologist

## 5. Implementation/training/awareness

- This is a review of a current document and it formalises current practice.
- Once ratified it will be available in all clinical areas within the Maternity Unit and on the intranet.
- All new, reviewed and ratified documents are notified to staff via the monthly maternity newsletter

## 6. Auditable Standards

The care of every positive case of Hepatitis B occurring in pregnancy is monitored by the local LCO and reported through the Integrated Screening Outcomes Surveillance Service (ISOSS).

Monitoring and audit are undertaken by the LCO as per the Guidelines for management of maternal antenatal screening tests.

The results of monitoring are presented and reported by the local LCO to Public Health England via annual report and the Key Performance Indicator (KPI) submission. Quality reports are also monitored at trust level via Quality Governance Committee, Patient Safety Sub Committee and Quality, Risk and Patient Safety Performance.

Sexual Health (IoW) reports all sexually transmitted infection diagnoses to Public Health England via Genitourinary medicine clinic activity dataset. All cases are discussed locally at the multi-disciplinary screening steering group.

In the event of process failure of any part of this guidance, an investigation will be undertaken using trust investigation procedure and, if appropriate, via the screening incident assessment form (SIAF).

<b>What aspects of compliance with the document will be monitored</b>	<b>What will be reviewed to evidence this</b>	<b>How and how often will this be done</b>	<b>Detail sample size (if applicable)</b>	<b>Who will coordinate findings</b>	<b>Which group or report will receive findings</b>
Referral into care within 10 days	Evidence of consultant appointment	This will be checked for every woman with a positive result	N/A	LCO	Screening steering group
Outcome for baby born to Hepatitis B positive woman	Evidence of vaccine (and HBiG) at delivery and vaccinations up to one year.	This will be checked for every baby born to a woman with a positive	N/A	LCO	Screening steering group

## 7. Related Documents:

### Guidelines/SOP's:-

- Guidelines for the Management of Maternal Antenatal Screening Tests

### Policies:-

- Infection Prevention and Control Standard Precautions: Use of Personal Protective Equipment (PPE)
- Sharps Injury – Management of Blood Borne Viruses
- Safe Handling and Disposal of Sharps.
- Prevention of Occupational Exposure to Blood Borne Viruses (BBV)

### Patient Information:

Test result and protecting your baby leaflets:

There are [leaflets](#) available to help midwives explain the screening result and the care pathway to parents. They should be given to parents as a guide to help them understand about hepatitis B, their care in pregnancy and the baby's immunisation schedule.

## 8. References:


- The Green Book: Immunisation against Infectious diseases  
[www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18](http://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18)
- NHS Infectious diseases screening in pregnancy guidance  
[www.infectiousdiseases.screening.nhs.uk/standards](http://www.infectiousdiseases.screening.nhs.uk/standards)
- Hepatitis B Foundation  
[www.hepb.org/pdf/pregnancy.pdf](http://www.hepb.org/pdf/pregnancy.pdf)
- [www.rcog.uk](http://www.rcog.uk) Query bank
- EASL – European clinical guidance 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection

## 9 DISCLAIMER

It is the responsibility of staff to check the Trust intranet to ensure that the most recent version/issue of this document is being referenced

<b>DOCUMENT HISTORY</b>					
<b>Date of Issue</b>	<b>Version No.</b>	<b>Next Review Date</b>	<b>Date Approved</b>	<b>Director Responsible for Change</b>	<b>Nature of Change</b>
May 2016	1.0	03/05/2019	03/05/2016	Clinical Director of SWCH	<b>Approved at Maternity CSG</b>
March 2018	2.0	06/03/2021	06/03/2018	Clinical Director of SWCH	<b>Approved at Maternity CSG</b>
May 2021	SOPv1	May 2024	11 <sup>th</sup> May 2021	MCSG	Converted to SOP, Reviewed and Ratified

**Appendix A**

 <p><b>Public Health England</b></p> <p><b>HEPATITIS B (HEP B) SCREENING AND IMMUNISATION</b></p> <p><b>MATERNAL AND PAEDIATRIC CHECKLIST</b></p>	<p align="center">Please complete or attach patient label</p> <p>Unit number: .....</p> <p>NHS number: .....</p> <p>Surname .....</p> <p>Forename(s) .....</p> <p>Date of birth ...../...../.....</p>																		
<p>Date of booking...../...../.....</p> <p>Date of hep B screen...../...../.....</p> <p>Date of screening result...../...../.....</p> <p>Date of notification...../...../..... (known positives/decline)</p> <p>Date of screening...../...../..... team assessment</p> <p>Date of specialist...../...../..... appointment</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">Serology results</th> </tr> <tr> <th style="width: 30%;">Test</th> <th style="width: 30%;">Date of test</th> <th style="width: 40%;">Result</th> </tr> </thead> <tbody> <tr> <td><b>Viral load</b></td> <td></td> <td></td> </tr> <tr> <td><b>HCV</b></td> <td></td> <td></td> </tr> <tr> <td><b>LFTs</b></td> <td></td> <td></td> </tr> <tr> <td><b>Other test results</b></td> <td colspan="2"></td> </tr> </tbody> </table> <p align="center">Lower infectivity <input type="checkbox"/> Higher infectivity <input type="checkbox"/></p>	Serology results			Test	Date of test	Result	<b>Viral load</b>			<b>HCV</b>			<b>LFTs</b>			<b>Other test results</b>		
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<b>LFTs</b>																			
<b>Other test results</b>																			
<b>All women: higher or lower infectivity</b>	<b>Screening team appointment (≤ 10 working days of laboratory result/notification)</b>	<b>Status/comments</b>	<b>Date</b>	<b>Signature and name in capitals</b>															
	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.																		
<b>Within 6 weeks of result/notification</b>																			
<b>All women with hepatitis B</b>	Specialist MDT appointment.																		
	<b>High infectivity and all newly diagnosed women:</b> within 6 weeks or by 24 weeks gestation.																		
	<b>Low infectivity known status:</b> 18-week OPD target or within 6 weeks if ≥ 24 weeks																		
	Create neonatal alert																		

<b>women Higher infectivity only</b>	<p>Submit a HBIG request as per trust practice.</p> <p>7 weeks before EDD PHE coordinator will send:</p> <ul style="list-style-type: none"> <li>• HBIG to your pharmacy</li> <li>• delivery suite box to screening team to match up with HBIG and place in box</li> <li>• box which should be stored according to trust practice and the location clearly noted on the maternal record.</li> </ul> <p>Notify the PHE co-ordinator if the woman's care is transferred.</p>			
<b>34-week pre-birth consultation/screening team review</b>		<b>Status/comments</b>	<b>Date</b>	<b>Signature and name in capitals</b>
<b>All women</b>	<p><b>Preparation for birth</b> Discuss care and adherence to schedule using PHE 'Protecting your baby from hep B' leaflet. Check neonatal alert is in place.</p>			
<b>Higher infectivity</b>	<p>Confirm where <b>PHE hep B delivery suite box</b> containing HBIG is stored and that the location is recorded in notes/birth plan/maternity information system.</p>			
<b>Delivery suite team</b>				
<b>Higher infectivity mother and baby</b>	<p><b>On admission:</b></p> <ul style="list-style-type: none"> <li>• inform screening team of admission</li> <li>• locate PHE hep B delivery suite box</li> </ul>			
	<p><b>Using the hep B delivery suite box</b> - take maternal serology sample after delivery and complete form (pack 1)</p>	Date/time of blood test		
	<p>- 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</p>	Card number/time of blood test. Date/time given/batch number.		
	<p>- 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)</p>			

Lower infectivity mother and baby	<ul style="list-style-type: none"> <li>- vaccination administered ≤24 hours of birth</li> <li>- complete PCHR red book hep B page and given to mother</li> </ul>	Prescription in notes/batch number.		
<b>Post-natal</b>				
Pre-discharge checks	<ul style="list-style-type: none"> <li>- PCHR book has completed hep B page</li> <li>- mother has a copy of the vaccination leaflet</li> <li>- mother informed of the importance of early registration of the birth with a GP</li> <li>- ensure notes go back to screening team</li> </ul>			
Screening team	<ul style="list-style-type: none"> <li>- check request form for maternal sample and PHE notification forms are completed</li> <li>- DBS and bloods and forms despatched to PHE Virus Reference Department, Colindale in pre-paid packaging</li> <li>- inform CHIS, H/V GP, and CMW of vaccination using PHE letter templates</li> <li>- complete ISOSS database</li> </ul>			

[Add GP address and date of letter]

Dear Dr [*insert name*]

### Notification of maternal positive hepatitis B antenatal result form

- **Child Health Information System (CHIS):** see section A
- **Actions for primary care:** see section B

Maternal demographics and pregnancy details		
Name of pregnant woman	Date of birth	NHS number
Address		
Estimated due date	Additional information	

#### Section A: action for CHIS

This woman is hepatitis B positive so can you please create a record for her?

#### Section B: actions for primary care

The baby will need **6 vaccinations** to protect him or her from acquiring chronic hepatitis B virus (HBV) in line with the Public Health England (PHE) Green Book. The first vaccination +/- human immunoglobulin (HBIG) will be given within 24 hours of birth. Please ensure you schedule appointments for:

- 2 extra hepatitis B vaccinations – at **4 weeks** and **12 months**
- routine childhood immunisation schedule (containing the hexavalent vaccine) at **8, 12** and **16 weeks**
- a blood test to check infectivity status at **12 months** (ideally using the dried blood spot card available at [www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants](http://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants))

#### Additional information on management of mother and baby

We have referred the woman to hepatology/gastroenterology for specialist management and multidisciplinary care. The sexual and household contacts of an



adult with HBV will benefit from hepatitis B testing and vaccination in primary care. We will notify your practice again when the baby has been born to support prompt registration of the baby with your practice and timely scheduling of extra appointments.

Timeliness of vaccinations is important to prevent viral transmission.

Yours sincerely

[Add details of health professional, including name, contact number and email].

[Insert GP address]

[Insert date of letter]

Dear Dr [insert name]

**Notification of birth: baby of mother with hepatitis B form**

Maternal details			
Name	Date of birth	NHS number	Address

Neonatal details			
Name	Date of birth	NHS number	Address (if different)

Hepatitis B vaccination/HBIG details			
Date/time vaccine administered		Vaccine batch number	
Date/time immunoglobulin given if required		Human immunoglobulin (HBIG) batch number	
Vaccinator name (print and sign)			

**Section A: actions for CHIS**

You must:

- mark this woman as hepatitis B positive on the system
- mark this baby as an infant of a woman who is hepatitis B positive on the system (as a failsafe to ensure follow up of the baby's vaccinations)

### **Section B: actions for primary care**

The baby will need **6 vaccinations** to protect him/her from acquiring chronic hepatitis B virus (HBV) in line with the Public Health England (PHE) Green Book [www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18](http://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18). The first vaccination +/- Human Immunoglobulin (HBIG) has been administered within the first 24 hours after the birth (see above).

The baby will now need **5 more vaccinations**. Please ensure you schedule appointments for:

- 2 extra hepatitis B vaccinations at **4 weeks** and **12 months**
- routine childhood immunisation schedule (containing the hexavalent vaccine) at **8, 12** and **16 weeks**
- a blood test to check infectivity status at **12 months** (ideally using the PHE dried bloodspot available at [www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants](http://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants))

### **Additional information on management of the mother and her baby**

Please support prompt registration of the baby with your practice and timely scheduling of the extra appointments.

Timeliness of vaccinations is important to prevent viral transmission.

The sexual and household contacts of an adult with HBV will benefit from hepatitis B testing and vaccination in primary care.

Yours sincerely

[Name of and contact telephone number/email of health professional]

## Appendix D

Screening team  
Screening office  
Antenatal clinic  
St Mary's Hospital  
Newport  
Isle of Wight  
PO30 5TG

Tel: 01983 534332  
Mon – Fri between 08:30 – 16:30

Date

**Private and confidential**

Address

Dear

Congratulations on the birth of your baby. This letter is to remind you that your baby will require further Hepatitis B vaccinations at 1 month, then as part of the routine vaccination schedule at 2, 3 and 4 months and finally at 1 year.

These vaccinations will be given at your GP surgery and you should receive an appointment from the child health records department team giving a date and time for these.

Your baby should also have a heel prick blood test at the GP surgery at 1 year old at the time of the final booster.

**If you do not receive an appointment or have any concerns please contact your GP surgery or the screening team on the number above.**

**Yours sincerely**

**Anya Wright**  
**Antenatal and Newborn Screening Coordinator**