Hepatitis B antenatal screening and newborn immunisation programme

Best practice guidance

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Hepatitis B antenatal screening and newborn immunisation programme

Best practice guidance

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Related Documents:

These documents will provide additional information.

Title
'Reducing differences in the uptake of immunisations (including targeted vaccines) among children and young people aged under 19 years' NICE public health guidance 21, September 2009 www.nice.org.uk/PH21
Infectious disease in pregnancy screening programme standards, UK National Screening Committee 2010 http://infectiousdiseases.screening.nhs.uk/standards
Infectious disease in pregnancy screening programme, Handbook for Laboratories, UK National Screening Committee 2010 http://infectiousdiseases.screening.nhs.uk/standards
Equality impact assessment of 'Hepatitis B immunisation programme; Good practice guidance'
Antenatal care: routine care for the healthy pregnant woman. National Collaborating Centre for Women's and Children's Health: Commissioned by the National Institute for Health and Clinical Excellence, March 2008 www.nice.org.uk/guidance/CG62/guidance/pdf
Green book: Immunisation against infectious disease. Department of Health 2006, www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH4097254

Glossary of terms:

Term	Acronym	Definition
Antenatal screening midwife	ANSM	The identified midwife responsible for co-ordinating local antenatal screening
Accountable midwife		The identified midwife responsible for the direct care of the pregnant women
Care Quality Commission	CQC	The CQC is the independent regulator of health and social care in England.
Child Health Informatics System	CHIS	CHIS systems are used primarily to schedule immunisation appointments, and to provide local coverage data, for COVER returns and for use by immunisation leads and others.
Cover of Vaccinations Evaluated Rapidly	COVER	The COVER programme monitors immunisation coverage data for children in the United Kingdom who reach their first, second or fifth birthday during each evaluation quarter.
Deoxyribonucleic acid	DNA	Nucleic acid that contains the genetic instructions used in the development and functioning of all known living organisms
Electronic birth notification	BNeF	BNeF is an electronic version of the Birth Form produced by midwifery services within 24 hrs of delivery
Health Protection Agency	HPA	The HPA is an independent UK organisation that was set up by the government in 2003 to protect the public from threats to their health from infectious diseases and environmental hazards.
Health Protection Unit	HPU	HPUs are responsible for an area roughly corresponding to a county or police boundary. They are staffed by consultants, nurses, and other specialists who work directly with the NHS and civil authorities to deliver health protection at a local level. (See Public Health England)
HPA Centre for infections		The Centre for Infections at Colindale is one of the four main national centres of the HPA and is the base for communicable disease surveillance and specialist microbiology (See Public Health England).
Hepatitis B virus	HBV	HBV is a viral hepatitide that causes a wide range of liver disease in persistently infected individuals.
Infectious diseases in pregnancy screening (Programme)	IDPS	The infectious diseases in pregnancy screening programme sits within the UK National Screening Committee remit and covers the universal screening for pregnant women of certain infectious diseases (currently including HIV, rubella, hepatitis B and syphilis)

Immunise/immunisation		Immunisation refers to a population. Immunise is the process of achieving immunity, either by contracting the disease or being vaccinated against it.
National Institute of Clinical Excellence	NICE	Arm's length body that focuses primarily on establishing national standards and best practice. It provides guidance for healthcare professionals, patients and their carers.
Personal Child Health Record	PCHR	PCHR is a record of a child's health, held by the parent/guardian. This record includes immunisations given. It is often referred to as the 'Red Book' or the 'Yellow Book'.
Movement in/out area		Refers to the situation where a person or family moves into or out of an area.
Provider/commissioning immunisation lead		This is the named individual responsible to oversee the whole immunisation process. Currently they can sit in either a provider or commissioning arm of a PCT. Their key function is to provide governance, assurance and ensure that immunisation programme meets the need of the local population.
Public Health England	PHE	Public Health England is the organisation into which the HPA and it's functions are going to pass. Where comments refer to the HPA/HPU these are, in future, likely to refer to the PHE.
UK National Screening Committee	UK NSC	The UK NSC advises ministers and the NHS in all four UK countries about all aspects of screening policy.
Vaccinate/vaccination		Vaccination is an individual event. To vaccinate refers to the process of inoculation with any vaccine or toxoid to establish resistance to a specific infectious disease, i.e. a vaccination was administered to x.

Foreword

Liver disease is the fifth biggest cause of mortality in England, after heart, cancer, stroke and respiratory disease. Of the 'big five' liver disease is the only major cause of death increasing year on year and it affects people at a younger age than the others.

Each day it is becoming clearer that hepatitis B infection is making an increasing contribution to the burden of liver disease. When not treated, persistent hepatitis B infection can lead to premature death, either due to cirrhosis of the liver or hepatocellular carcinoma (liver cancer). Around a quarter of all liver disease cases in the UK is due to hepatitis infections. Hepatitis B infection transmitted from the mother to child during birth accounts for 21% of all new persistently infected cases. Not only is this an important cause of persistent hepatitis B infection but in most cases it can be prevented.

Improving services for liver disease is key to improving health outcomes and preventing longer term disease. To this end we are currently looking at how to improve clinical services and early identification of people at risk. However, prevention is better than cure and the best approach to reducing the impact of liver disease is to reduce the number of people at risk of liver disease.

This guidance provides a timely reminder of the importance of having robust services. This includes all clinical staff on the patient pathway understanding their role and how it fits with the pathway a whole. It also includes commissioners understanding the pathway and being able to assure themselves that quality services are in place. This guidance will help both groups achieve these aims.

We have an ambitious but necessary goal to reduce the burden of liver disease. This guidance is a useful additional tool to achieve this goal. I would strongly recommend that both commissioners and clinicians involved in this area use this guidance to help reduce the occurrence, of what is, unnecessary persistent infection in babies.

Professor Martin Lombard,

National Clinical Director for Liver Disease

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Purpose of guidance

The purpose of this guidance document is to provide assistance to commissioners in improving the uptake rate of existing infant hepatitis B immunisation programmes for newborns who are at risk of hepatitis B infection. As outlined in the health service circular *Screening of pregnant women for hepatitis B and immunisation of at risk babies* the provision of a targeted infant immunisation programme has been supported by Department of Health policy since 2000[1]. This guidance is not mandatory and it is therefore up to commissioning organisations to decide for themselves how to respond to and use the guidance, within their available resources, to improve services.

To aid commissioners understanding of the patient pathway, this document summarises the elements of the screening and immunisation pathway, including the currently recommended immunisation schedule. This should be considered as advice to help commissioners with the commissioning of existing services.

Following extensive consultation, the guidance also includes a number of the common barriers and problems currently thought to be leading to reduced uptake rates, alongside existing or suggested solutions to these barriers from the field. These barriers have been linked into the relevant elements of the immunisation programme.

The guidance contains various tools for commissioners, including a service pathway checklist. The checklist is designed to help assess the service quality assurance that is in place. Like all resources in the document, its use is voluntary but it is designed to help enable commissioners to take a more structured and therefore more efficient approach to commissioning of services.

Executive summary

An effective hepatitis B antenatal screening and infant immunisation pathway for babies born to women with hepatitis B will:

- identify pregnant women who are infected with hepatitis B virus and whose babies will be born at high risk for hepatitis B infection
- reduce the number of children becoming persistently infected with hepatitis B and reduce their risk of the serious long term consequences
- ensure that referral to appropriate health professionals for assessment and ongoing support and care occurs
- ensure that the agencies responsible for contact tracing are informed
- reduce the costs associated with both short and long term management and treatment of hepatitis B infection
- protect commissioners and providers of services from potential litigation. A member of the public contracting the hepatitis B virus as a result of failing to be vaccinated or receiving an incomplete vaccination schedule could have grounds for litigation. A case potentially could be made if, for example, inefficient management resulted in an individual not receiving the appropriate vaccine doses.

Current data from immunisation programmes regarding babies born to hepatitis B positive mothers suggest there is a need for national guidance to ensure consistent and effective service provision across the country.[2]

Integration of the immunisation programme for hepatitis B with the Infectious diseases in pregnancy screening (IDPS) programme is essential to the development and delivery of an effective pathway. The *UK NSC* have developed guidance on screening and the management of positive test results.[3,4] To complement and support the implementation of their guidance, they have also developed a service framework for commissioners.[5]

Department of Health policy has supported the provision of universal screening of pregnant women for hepatitis B and the immunisation of babies at risk since 2000[1]. This document is intended to assist commissioners of services in improving their newborn hepatitis B immunisation services. It may also be of interest to service providers to help them understand how their role fits into the wider care pathway. The guidance is applicable to the current configuration of services commissioned by PCTs and the future configuration of NHS commissioning organisations and Public Health England.

This guidance should be considered as complementary to UK NSC [3,4] and NICE (National Institute of Clinical Excellence)[1] guidance. In conjunction with the UK NSC commissioning specification[5] this document provides information on:

- the key elements of the screening and immunisation pathway
- examples of currently identified and potential barriers and risks for the immunisation programme
- a checklist for commissioners to help them reach a position of assurance that a good immunisation programme is in place.

This document can also be used to audit existing antenatal hepatitis B immunisation programmes to ensure robust provision of services.

UK NSC[2] and NICE[1] guidance recommends:

- ensuring an integrated antenatal hepatitis B screening and infant immunisation service is commissioned
- identifying named individuals to ensure co-ordination of screening and immunisation services
- ensuring all healthcare professionals in contact with affected mothers reinforce the importance of completion of the vaccination schedule, even if not directly involved in the vaccine administration
- reporting of immunisation data submitted including newborn hepatitis B uptake data for all four doses.

A review of the existing infant hepatitis B immunisation pathways suggests that elements of an effective pathway include:

1. An effective screening programme

The UK NSC has issued guidance[3, 4] defining the objectives of an antenatal infectious diseases screening programme (http://infectiousdiseases.screening.nhs.uk/standards) and a commissioning framework to help with the implementation of their guidance[5].

Issues to consider:

Initial screening:

- the programme should offer screening for hepatitis B, HIV, syphilis and rubella susceptibility to all pregnant women supported by appropriate information
- clarity on the interaction between maternity services and laboratory services is essential, e.g. laboratory turnaround times and reporting requirements

Managing a positive result:

- clarity on the interaction between maternity services and clinical services is essential, e.g. referral of the mother to an appropriate specialist
- the flow of information between services.

Protocols and pathways referenced to the relevant UK NSC guidance should be developed collaboratively.

Hepatitis B immunisation specific issues:

- provision of information to all pregnant women regarding immunisation of her baby should the test be positive, particularly the importance of completion of the immunisation schedule for babies of women with positive results
- communication of the hepatitis B positive result for pregnant women to the appropriate agencies and individuals including local provider/commissioning immunisation lead.

2. Systems to ensure first vaccination/hepatitis B immunoglobulin (HBIG) is administered at birth

Issues to consider:

- clear identification of responsibility for organising timely administration of neonatal (first) vaccine dose and, where appropriate, HBIG (including sourcing the vaccine/HBIG)
- ensure that women who book in labour are managed appropriately
- the flow of clinical information where there are implications for the immunisation schedule
- ensuring the recording and rapid communication of vaccine administration to other relevant health professionals, including child health informatics systems
- issues raised by home delivery or early hospital discharge
- whether plans are in place for mothers who decline vaccination for their babies.

3. Systems to ensure that subsequent vaccinations are given and that the child is tested for hepatitis B infection at 12 months of age

Issues to consider:

- identifying responsibility for organisation of the timely administration of the vaccinations
- ensuring responsibility for the recording and rapid communication of vaccine administration to other relevant health professionals, including child health informatics systems is clear
- follow up protocols for those individuals who do not attend for vaccinations
- policies to address and record movements in and out of an area part way through the immunisation schedule (‘removals’) to ensure continuity of care. This includes identifying responsibility with regard to communicating this information
- implications and specific considerations for children who are fostered/adopted.

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. [6] A major cause of hepatitis is infection with hepatitis B virus (HBV). When not treated, persistent HBV infection leads to premature death due to either cirrhosis or hepatocellular carcinoma in a large proportion of infected individuals.[7] Whilst hospital mortality rates from hepatitis B infection are currently low, these numbers are expected to rise substantially over the next few years.[7] Childhood infection accounts for an estimated 21% of all new persistent infections.[8]

If a pregnant woman has an HBV infection, then:

- there is a 70% to 90% likelihood that this infection will be transferred to the baby in the 10% of women who are highly infectious[10], e.g. those HBeAg seropositive
- there is a 10% likelihood that it will be transferred to the baby if the women is infected but not highly infectious[10]
- around 90% of infected babies will develop persistent HBV infection and be at risk of serious liver disease in later life``
- timely immunisation schedule completion can prevent development of persistent HBV infection in over 90% of these cases.[12]

HBV infection is unevenly distributed throughout the UK with some areas of the country having a higher prevalence of infection than other areas. Hepatitis B service delivery models therefore need to be flexible and responsive according to local need.

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[1]. The aim of the antenatal screening and infant immunisation pathway is to prevent perinatal hepatitis B infection. HBV infection is included within the Infectious diseases in pregnancy screening (IDPS) programme[3]. Screening for this condition is also integrated within the broader antenatal care pathway described in NICE's *Routine antenatal care guideline* (2008).[9] The immunisation programme recommendations are given in the Green Book.[11]

The objectives of the screening programme are to ensure:

- that all pregnant hepatitis B positive women are identified
- all pregnant hepatitis B positive women are referred for assessment and management by an appropriate specialist (e.g. a hepatologist / gastroenterologist

/ infectious diseases specialist) within six weeks of the screening test result being received by maternity services

- that appropriate discussions occur around issues of notification of infection and testing of family members and other closes contacts
- that the infant vaccination schedule is offered for their babies, the first dose is administered within 24 hours of delivery and arrangements for completion of the schedule are initiated.

Any pathway should also include referral for contact tracing of household and sexual partners, testing and immunisation, where appropriate.

The objectives of the immunisation programme are to ensure:

- that the immunisation provision is configured to maximise timely uptake of the full vaccination schedule
- that appropriate handover of mother and baby from maternity services to services completing the immunisation schedule occurs in a timely manner
- that systems are in place to support reporting to COVER[1] at appropriate points
- that 12-month serology testing is undertaken to identify where immunisation has been unsuccessful at preventing transmission.

Integration of the screening and the immunisation services is essential to the development and delivery of an effective infant immunisation service. The UK NSC provides guidance on screening and the management of positive test results (http://infectiousdiseases.screening.nhs.uk/standards). It also advises maternity services on the administration of the first dose of vaccine and the handover steps to services administering the remaining vaccinations in the immunisation schedule.

Evidence suggests that most hepatitis B immunisation programmes fail to provide full protection for all babies at risk. Many factors associated with the organisation of services across the pathway are responsible for this, however, a particular concern is uptake rates of the immunisation doses two to four.[2, 13]

Evaluations by NICE[2] suggest that while investing in services to improve initial uptake rates is important, the greatest gain in health benefits for the population lies in increasing completion rates. Investments in improving uptake rates to completion, if successful, are:

[1] The Cover of Vaccination Evaluated Rapidly (COVER) programme monitors immunisation coverage data for children in the United Kingdom who reach their first, second or fifth birthday during each evaluation quarter. This information is promptly fed back to local level, creating the opportunity to improve coverage and to detect changes in vaccine coverage quickly.

- cost saving when improving uptake of doses 2 to 4 if administration costs remain below £32.50 per dose,
- cost-effective when improving uptake of doses 2 to 4 costs less than £600 per dose.

While timely immunisation is always important, for the hepatitis B immunisation programme it is crucial. A complete course is required for full protection. See the Green Book[11] for further guidance.

Current immunisation schedule

Where a pregnant woman is identified through the screening process as infected with HBV, the Department of Health[11] currently recommends the baby is vaccinated using the accelerated schedule comprising of vaccinations given:

- at birth (dose 1)
- 1 month following dose 1
- 2 months following dose 1
- 12 months following dose 1, plus blood test for serology to check infection and immunity status.

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. However, where administered in line with the Green Book schedule[11], targeted immunisation can prevent persistent hepatitis B infection in around 90% of individuals who would have otherwise developed the infection.

While not part of the primary immunisation course, and therefore not covered in this guidance, it is recommended that a booster dose of the vaccine is given at around five years after the primary immunisation in individuals at continuing risk. Because of the continued presence of infection in other family members, a single booster dose of hepatitis B vaccine, given with the pre-school booster for other childhood illnesses, is advised for children born to hepatitis B infected mothers. See the Green Book[8] for further guidance.

Some newborns will need to receive hepatitis B immunoglobulin (HBIG) within 24 hours of delivery. Figure 1[10] identifies all groups of pregnant women where administration of HBIG would be appropriate.

Ordering hepatitis B immunoglobulin

Currently, in England, HBIG distribution is co-ordinated by the HPA Centre for Infections. See Appendix C for details of how to order HBIG.

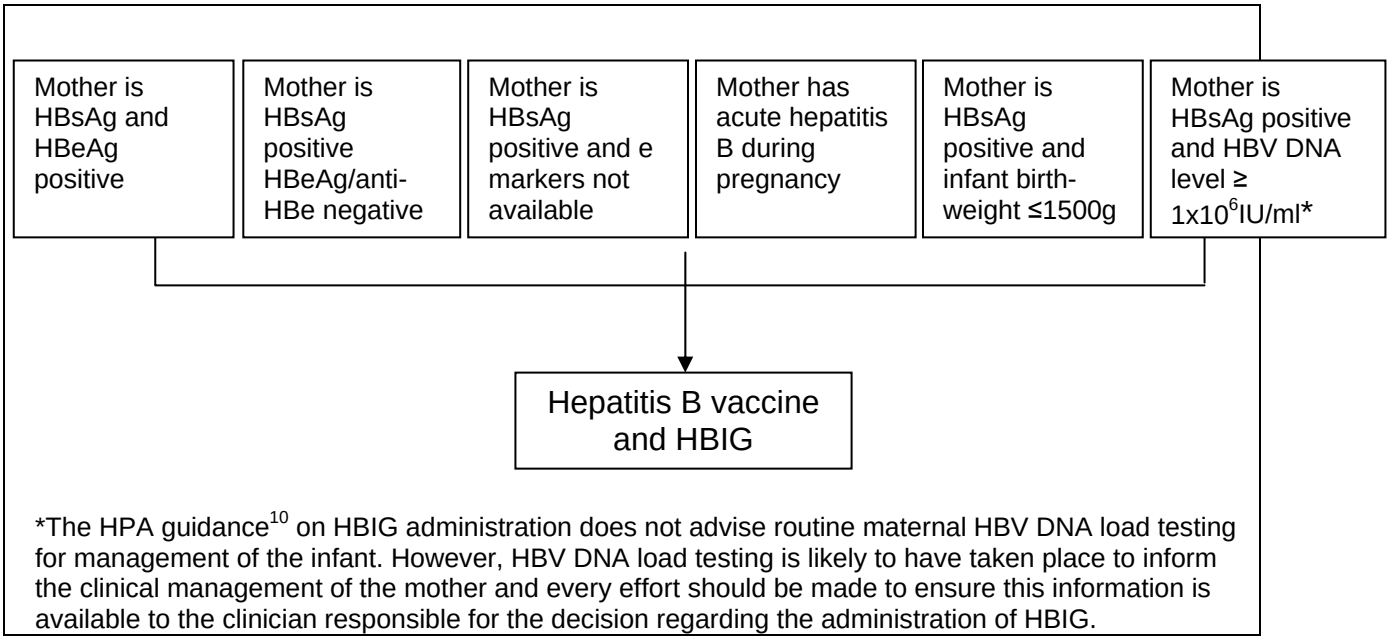

Figure 1: Administering HBIG to term babies according to the hepatitis B status of the mother

Essential elements of the antenatal hepatitis B screening and immunisation programme

Service commissioning considerations

The UK National Screening Committee (NSC) guidance states that the screening programme should be commissioned against a framework which is linked and referenced to their guidance.[3] As part of their role in providing guidance on quality assurance the UKNSC has also developed a commissioning framework (www.screening.nhs.uk/getdata.php?id=9868).[5]

A robust screening programme with systems in place to respond to and manage a positive result (including ensuring appropriate referral, clinical care, contact tracing, and testing and immunisation of contacts) is the first stage in the antenatal hepatitis B screening and immunisation pathway.

As well as best practice, the current document addresses the clinical aspects of the program that need to be commissioned and should be used in conjunction with the UK NSC documents. Systems should be in place to ensure:

- the first vaccination/hepatitis B immunoglobulin is administered within 24 hours of birth (preferably at birth)
- handover of mother and baby to services responsible for subsequent vaccinations is completed appropriately
- subsequent vaccinations are given such that the child receives the full schedule within the recommended timeframe
- that the child is tested for hepatitis B infection at 12 months of age.

The UK NSC guidance recommends 'There should be written protocols and pathways in each trust identifying roles and responsibilities for screening and management of women with positive results'.[3] Similarly, the immunisation programme should be organised against agreed protocols and pathways with key systems for process monitoring and regular auditing. These pathways should ensure vaccination administrations are timely, recorded accurately, and relevant failsafe solutions capture those who miss appointments of move in or out of the area.

It is important for the successful implementation of the programme that one person is identified as having overall responsibility for the commissioning of the pathway and

one person is identified as having overall responsibility for the provision of the pathway.

As part of identifying roles and responsibilities, NICE[2] recommends that there should be a named individual responsible for the hepatitis B immunisation service (e.g. provider immunisation lead). These named individuals should have time protected in order to undertake their duties as a lead clinician. When identifying roles and responsibilities within the commissioning organisation, it is recommended that a named individual (e.g. commissioning immunisation lead) should be responsible for commissioning the service as a single integrated pathway. Specific responsibilities of commissioners are discussed in the following sections. A key commissioning responsibility would be to seek adequate assurance from providers that all aspects of the pathway are functioning smoothly and that different providers are communicating with each other.

When considering the cost implications of improving services, Commissioners can use COVER data for their local area to estimate the additional cost for improving uptake. Commissioners will need to assure themselves of the quality of local COVER data, for example is the denominator (number of babies at risk) considered accurate based on a percentage of the number of women who screened positive for Hep B during pregnancy. COVER data if deemed accurate can be used to identify the current number of infants not completing the full course of immunisation. The detailed NICE economic analysis[20] examining the cost effectiveness of improving hepatitis B uptake can be used to inform any cost calculations. The economic analysis suggests that the cost per vaccine dose (including administration) is £19.67, however commissioners may wish to identify current local costs.

NICE guidance also includes a costing statement[21]. It should be noted that the economic analysis suggests most benefit and saving will occur towards the end of the immunised persons life. This analysis did not include the costs of monitoring and, in a small number of cases, treatment of infants during the current spending review period. Chronic hepatitis B can be treated with drugs, including interferon and anti-viral agents, which can help some patients, but can cost thousands of pounds per annum[21]. However the treatments for children are still under review. The assumptions within the NICE economic analysis, in conjunction with local COVER data, can be used to estimate the likely number of persistently infected children due to failure to complete the immunisation schedule in a local area. In turn this can be used for a more accurate analysis of local costs likely to be incurred during the spending review period while taking into account the more immediate costs of having to provide clinical care when not improving immunisation services.

1) An effective screening programme

As part of antenatal care, UK NSC[3] and NICE[2] currently recommend all pregnant women are offered screening for HBV. The UK NSC has issued guidance [3,4] defining the objectives of an antenatal infectious diseases screening programme and a commissioning framework[5] to support the implementation of their guidance (www.screening.nhs.uk/getdata.php?id=9868).

Issues to consider:

Initial screening:

- the programme should offer screening for hepatitis B, HIV, syphilis and rubella susceptibility to all pregnant women supported by appropriate information
- clarity on the interaction between maternity services and laboratory services is essential, e.g. laboratory turnaround times and reporting requirements.

Managing a positive result:

- clarity on the interaction between maternity services and clinical services is essential, e.g. referral of the mother to an appropriate specialist
- the flow of information between services.

Protocols and pathways, referenced to UK NSC guidance where appropriate, should be developed collaboratively.

Hepatitis B immunisation-specific issues

As part of the broader discussions around hepatitis B with the pregnant woman, at both the screening stage and as part of managing the positive result, it is important that the benefits for the child are emphasised. There is some evidence to suggest that this may improve vaccination understanding, compliance and eventual uptake.[15] Services should be geared to provide this information in such a way as to meet the needs of the pregnant woman, and should take into account that a number of individuals will not have English as a first language. A leaflet *Hepatitis B: how to protect your baby* is available in several languages at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073306.

Multi-disciplinary communication is key to a successful pathway. Appropriate agencies and individuals should be informed of a positive result. Local provider/commissioning immunisation lead should be informed at an early stage, as

this can allow the initiation of processes and failsafe systems. The UK NSC guidance identify the need for clearly defined and agreed roles, including having a named antenatal screening midwife/co-ordinator. This person, as part of a wider role around ensuring multidisciplinary communication, is likely to be best placed to transfer this information to the provider/commissioning immunisation lead. However, direct communication of the results from the laboratories to the immunisation lead could also be considered.

2) Systems to ensure first vaccination/ hepatitis B immunoglobulin is given

Where indicated, the first hepatitis B vaccination with/without HBIG should be given to the newborn baby within 24 hours of birth. UK NSC guidance around the first vaccination, cover the timely administration of the first dose and arrangements for hand over of mother and baby to the immunisation programme. All vaccinations should be given with parental consent and in line with the Green Book.[7]

The pathway should identify clear roles, including who has responsibility for the clinical decision to administer HBIG, for ordering and administering hepatitis B vaccine/HBIG at delivery and for informing the appropriate agencies and individuals, including the provider/commissioning immunisation lead.

Commissioners need to ensure that communication between maternity services and specialised services occurs so that clinical information reaches all relevant parties. This is important for many aspects of care (see UK NSC guidance) but also has particular implications for immunisation decisions around the newborn child. For example, the HBV DNA load levels of the pregnant woman can have implications regarding administration of HBIG. Where mothers HBV DNA level is known to be >= $1x10^6$IU/ml* current guidance advises the use of HBIG (in addition to vaccination), even where not otherwise indicated. Testing is not recommended for the sole purpose of informing decisions around HBIG administration[11], however, this information is usually available as testing is recommended as part of clinical care.[18] Similarly, the UK NSC guidance recommend that known positive hepatitis B pregnant women require a current HBV marker result to be used to determine decisions around HBIG administration. Good communication between specialist services and maternity services is essential to ensure tests are undertaken and information is passed to the relevant health care professionals.

The postnatal midwifery team is best placed to ensure that the neonatal dose is administered and documented and ensure that the maternal infection status is documented and communicated appropriately.

Barrier/risk areas	Solutions
Non consent to HBIG and vaccination.	Maternity services would need to ensure their protocols cover this eventuality. Systems should be in place to ensure that communication to the parent is in an appropriate format (i.e. access to translation services is available if necessary). Policies regarding this area will need to be agreed with all relevant service providers and should state the continued care plan for the mother and child. This may include referral to specialist services for further discussion or referral via 'safeguarding' protocols to child social services, if the child is deemed at significant risk.
Availability and administration of vaccinations.	Pathways must have robust mechanisms for identifying those responsible for ordering and administering the vaccination/HBIG. The midwife is best placed to ensure the vaccine/HBIG ordering and availability. • At 32 weeks gestation the midwife is advised to check the availability of the vaccine/HBIG for delivery. • Where a miscarriage, still birth or multiple pregnancy has occurred, the midwife will need to cancel or adjust the order. Responsibility for vaccine administration needs to be agreed by providers locally prior to delivery.
Timely ordering of HBV vaccine and HBIG.	Communication between relevant healthcare professionals is an area of focus for the UK NSC guidance. Timely communication with the midwife/healthcare professional with responsibility for ordering and organising the vaccine/HBIG administration is a key part of this.

	Commissioners should be assured this is happening and may wish to consider if there is a need to: a. include a requirement for the laboratories to telephone the sample taker with all positive results (the pregnant status of the woman and contact details of the referrer will need to be communicated to the laboratory staff) b. develop arrangements with GP surgeries to ensure all screening laboratory results are directed to the midwife (where screening results are being returned to the GP rather than the midwife).
Lack of communication between specialist services and maternity services/Delay in referral to specialist service.	Specialist services and maternity services should be engaged in the development of the patient pathway. Roles and responsibilities should include clear lines of communication regarding the sharing of clinical information likely to affect immunisation decisions for the newborn. In particular, commissioners need to be assured that the results of testing of viral DNA load are passed onto the appropriate clinician responsible for deciding on the administration of HBIG.
Lack of communication with the delivery team.	Maternity services need to ensure there is good communication with the delivery team. Positive hepatitis B status of the mother has clinical implications for delivery regarding reducing risk of transmission, e.g. the need to avoid both foetal blood sampling and use of a foetal scalp electrode in most circumstances.
Home delivery.	Maternity services need to ensure their protocols cover babies not born in hospital. Where possible, immunisations provided and administered via primary care services is recommended.

Pregnant woman screens negative but there is a known positive close family contact.	The Green Book[11] guidance recommends vaccination should be offered to close household contacts of HBV positive individuals. This would include any newborn child joining the household. Commissioners will need to consider the best approach to ensure this happens and may wish to include it in protocols for hepatitis B antenatal screening and the newborn immunisation pathway.
Existing maternal diagnosis of HBV infection.	Where women have a prior positive HBV diagnosis, referral for evaluation by a specialist is recommended (UK NSC). HBV markers should be checked in every pregnancy, all babies will require vaccination but clinical decisions around the administration of HBIG should be based on the most recent results for the relevant markers.
Lack of communication with the provider/commissioning immunisation lead and passing of information to COVER regarding the administration of the initial vaccine dose/HBIG.	To ensure that robust failsafe systems operate, it is important that the provider/commissioning immunisation lead is informed at an early stage of the pregnant woman's hepatitis B positive status. This is the ideal point at which failsafe and follow-up monitoring can be initiated. For continued monitoring, the initial administration of the vaccine (and HBIG where appropriate) should also be reported in a timely manner to the provider/commissioning immunisation lead and CHIS to ensure that COVER data submitted is reported accurately.

3) Systems to ensure subsequent vaccinations are given and that the child is tested for HBV infection at 12 months of age

A complete course of hepatitis B vaccinations is necessary for full protection to be achieved. The timeliness of administration of hepatitis B vaccine doses is key to ensuring the infant's protection. Currently, the schedule requires the second dose to be administered at one month, the third dose at two months and the fourth dose at 12 months of age. To date, the completion of vaccination schedule has been the area of most concern – a recent London audit[15] found 95% of 'at risk' infants were given the first vaccination but only 49% completed their schedule.

Different models of care provision exist for implementing immunisation programmes. Subsequent vaccinations can be administered in the primary care setting or within local paediatric services.

UK NSC guidance, around ensuring subsequent care, outlines the importance of information transfer, appropriate documentation and maternal understanding of care planned. The transfer of information on immunisation is an area where services have historically failed. Commissioners will need to consider seeking specific assurance around the robustness of information transfer and protocols to ensure all babies within a locality are captured, regardless of movements in and out ('removals'). A key aspect of this will be to ensure that relevant healthcare professionals responsible for administration of the subsequent vaccinations receive this information and are aware of their responsibility to act on this. The assurance commissioners should seek, may include evidence of an audit trail.

On discharge into primary care (health visitor or GP care)/paediatric care, the community midwife is best placed to ensure all relevant information has been sent to child health informatics services (CHIS) and documented in the Personal Child Health Record (PCHR). As recommended by NICE,[2] the PCHR and the child's record on the local CHIS should record the mother's hepatitis B status. CHIS systems are used primarily to schedule immunisation appointments and to provide local coverage data.

The discharging community midwife also needs to ensure that the mother is aware of all subsequent care and the process for further follow-up appointments. It's important that the mother understands the importance of completing the vaccination schedule and the baby being tested for infection status at 12 months of age. It is vitally important that the woman's discharge address is accurate, as follow-up will be compromised if primary care services are unable to contact the woman.

The provider/commissioning immunisation lead will require information regarding the birth to create the denominator for COVER (the national data collection that records the success of the hepatitis B immunisation programme). Ideally, the provider/commissioning immunisation lead should already have been informed of the

pregnant woman's status and the administration of the first vaccine dose (and HBIG if appropriate), however, the discharging community midwife should ensure this information has been transferred.

There is a need for clear protocols to ensure the vaccine doses administered are reported to CHIS/GP systems for COVER. A particular consideration is movement (removal) to or from an area where a paediatric service model is not followed.

In summary, on discharge, the responsible midwife should:

- inform the local Child Health Records Department of the mother's hepatitis B status, that the first dose of vaccine (+ /- HBIG) has been administered and the need for subsequent vaccines
- discuss with the mother/parents the baby's immunisation schedule and importance of completion
- record the mother's hepatitis B status and the baby's vaccination schedule on the postnatal discharge letter as well as the Personal Child Health Record (PCHR)[†]
- confirm that a process is in place for further follow-up appointments
- notify the GP and health visitor of the mother's hepatitis B status and that the infant needs to complete a hepatitis B vaccination course
- inform the provider/commissioning immunisation lead of the administration of the first vaccine dose to allow failsafe monitoring (where other failsafe systems are in place, e.g. within HPUs, the discharging midwife would need to inform the appropriate individual).

Primary care, even if not directly responsible for administering vaccine doses, should reinforce the importance of completing the immunisation schedule and testing the child's infection and immunisations status at 12 months. They should emphasise the importance of informing health providers of any plans to move out of the area so that continuity of care can be organised.

Regardless of the model of service delivery, commissioners will need to ensure that the health professionals providing subsequent vaccinations are aware of their role within the hepatitis B care pathway. This should include mechanisms to ensure that timely administration of the subsequent vaccination dose occurs and that adequate recall systems are in place.

A robust failsafe system is essential to ensure that subsequent vaccinations are administered and that this occurs in a timely manner. This can be built into data reporting systems that will be used to inform COVER. Any failsafe system is likely to

[†] In line with NICE guidance and data protection principles, DH recommends the practice of recording the mother's hepatitis B status within the Personal Child Health Record

be best placed with the either the provider/commissioning immunisation lead, but could sit within local health protection services. This requires rapid reporting of positive maternal hepatitis B and all vaccinations administered. However, this is particularly important after the first vaccination, as subsequent vaccinations and serology testing at 12 months may require more active intervention to ensure they occur within the recommended time frame.

This guidance does not specifically address issues relating to the recommended booster dose of vaccine for those individuals at continuing risk. However, all children born to mothers with hepatitis B infection are likely to be at ongoing risk of exposure to the virus, either directly from the mother, from the source of the infection to the mother or from secondary infections of family members also affected. The Green Book[11] recommends that children at ongoing risk should be given a single booster dose of hepatitis B vaccine with the pre-school booster for other childhood illnesses. Regardless of the model used for immunisations of the primary course, responsibility for the booster vaccination should lie with primary care and those responsible for other pre-school boosters.

Barrier/risk areas	Solutions
Failure to pass all relevant information in a timely manner from maternity services to health professionals completing schedule.	There should be a clear process for all information transferred in a timely manner. Unlike other schedules, the timing of hepatitis B vaccinations is crucial, and a complete course is required for full protection. Given the importance of this issue, providers should consider auditing this aspect of the pathway. In order to streamline the process of information transfer it may be appropriate for providers to adapt their birth notifications and discharge summaries (paper or electronic) to include hepatitis B status and vaccination information.
Immunisation schedule may not be completed where a baby remains in hospital.	Specialist services caring for the baby must ensure that the completion of all immunisations (specifically hepatitis B) is included within the care plan.
Non-standardised care across a locality.	Where several commissioning groups share a maternity provider it is important that care pathways are developed in collaboration.
Movement (removal) in/out of area.	The care pathway should be designed to capture babies requiring vaccination who move into the locality. These could be identified through existing services in primary care or referred in from other localities. Where a family is known to be moving out of an area liaising with the new service provider is a priority.
Mother/baby does not attend the vaccine appointment.	Protocols should be in place with regard to missed appointments and subsequent follow-up. As schedule completion is crucial to protect the

	baby, active follow-up is recommended. All healthcare workers, even if not directly responsible for administering vaccine, should reinforce the importance of completing the vaccination schedule.
Positive serology result/immunity not achieved at 12 months.	Serology testing at 12 months must be included in all protocols and is particularly important when the immunisation schedule has been delayed. The primary purpose of serology testing is to check whether vertical transmission has been prevented, a secondary benefit is to help determine whether immunisation has been achieved. Therefore, priority should be given to testing markers in the following order: • hepatitis B surface antigen (HBsAg) to check infection status (essential) • hepatitis B surface antibody (anti-HBs) to assess immunity (note: should be interpreted taking into consideration that the sample is taken at the same time as final vaccine dose is given) • anti-hepatitis B core (anti-HBc) to assess immunity if an active infection from which the child has recovered took place and that the child is now naturally immune
Missed serology testing.	Missed serology testing at 12 months should be considered as important as missed vaccination and active follow-up is recommended. All failsafe systems should include serology testing. Protocols should be in place with regard to positive results, including referral to specialist services, and lack of adequate immune response, as outlined in the Green Book[11].
Incomplete serology test results due to difficulty in obtaining	A blood sample allows more complete testing of serology. However, in

sample.	situations where this presents difficulties a blood spot test can be considered. The blood spot test is currently only available as part of research programmes and unlikely to provide full serology information but should determine if the child is infected. Commissioners will need to liaise with local microbiology laboratories to assess if this is feasible.
Failsafe in place	Failsafes within the system should be considered. The information submitted to the provider/commissioning immunisation lead should act as a failsafe, though other systems may be considered. Failsafe systems should be routinely audited to ensure all babies are being identified and captured.
Lack of communication with the provider/commissioning immunisation lead and passing of information to COVER regarding the administration of the subsequent vaccine dose.	To ensure robust failsafe systems can operate it's important that the administration of all subsequent vaccinations and serology testing should be reported in a timely manner to both the provider/commissioning immunisation lead and CHIS to ensure COVER data is submitted and reported accurately.
Need for pre-school booster overlooked.	Practitioners and commissioners need to be aware that a clinical assessment is required to determine if the child is still at risk and hepatitis B booster is required. This booster can be given with the routine pre-school immunisations. Discussions with the mother should cover this potential need and those responsible for administering the vaccine schedule should ensure that primary care is aware of this need.

4) Child Health Informatics Services (CHIS)

CHIS services are locally commissioned and differ across the country. As each system differs, the opportunities and limitations vary with regard to using CHIS systems to provide robust call and recall services for hepatitis B vaccinations. In some areas, CHIS systems are used to provide local coverage data and some are used to schedule immunisation appointments.

It is strongly suggested that both commissioners and providers speak to their local CHIS provider to identify what capacity the systems have. This should include what information can be recorded/ collated, whether scheduling of call/recall can be undertaken through CHIS and whether this is achieved automatically or manually.

Barrier/risk areas	Solutions
Identifying the correct numerator and denominator information for COVER reports.	If good reporting systems are in place (see above barriers in sections 2 and 3) this will address most data quality issues. Regular audit (see appendices) can help to ensure good systems are in place. Where infants move from a country where they have started the vaccination schedule, due to universal or targeted hepatitis B immunisation programmes, the vaccination schedule should be completed. Only those where maternal hepatitis B is positive should be reported to COVER. Recording the reason for the immunisation (i.e. mother's hepatitis B status) in reports to CHIS allows the correct identification of all relevant cases for COVER submission.
Recording of mother's hepatitis B status on Personal Child Health Records (PCHRs) and CHIS.	Roles and responsibilities of health professionals should include the recording of this information. Where concerns exist regarding data protection issues it should be clarified that: • NICE guidance[2] states the mother's hepatitis B status should be recorded in the PCHR **as soon as possible after birth**, before the hand over of care from the midwife to the health visitor and also recorded in the child's record on the local CHIS • Under current data protection and patient confidentiality legislation it is legitimate for information on the mother's health status to be recorded on the local CHIS.
Scheduling call/recall using CHIS.	All systems allow for the scheduling of call and recall for routine immunisation. Providers should engage with CHIS providers to identify what capacities their systems have and how to achieve robust

	call/recall for hepatitis B vaccinations.
Ensuring all immunisation information is promptly and accurately reported to CHIS.	The reporting of hepatitis B vaccinations should follow the normal procedures in place for all childhood immunisations. Care should be taken to ensure that all immunisation information transferred is correct. Special care should be taken to ensure that hepatitis B immunisation information is transferred *promptly* in order to prevent any subsequent delay in call/recall appointments.

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Appendices

The appendices are arranged into six subheadings, these being:

Appendix A: Models of hepatitis B immunisation programme delivery

Appendix B: Checklist for service quality assurance

Appendix C: Ordering hepatitis B immunoglobulin

Appendix D: The Personal Child Health Record (PCHR) insert for the hepatitis B infant immunisation programme

Appendix E: Examples of letters submitted to DH currently in use

Appendix F: UK NSC Guidance; relevant statements mapped to hepatitis B screening and immunisation stages

Appendix A: discusses models of integrated hepatitis B screening and vaccination delivery currently in use within the UK

Highlighted within this area are issues arising from the adoption of a patient pathway that follows a primary care services model for delivery of the second, third and fourth doses of vaccine and the issues arising from the acute care services model for delivery.

The pdf slide set presented alongside this practice guide (on web page) supports models contained within appendix A. This slide set visually presents the complexity of the hepatitis B pathway from antenatal screening to eventual vaccination completion. The care period is lengthy and relies on joined up services throughout the whole process. The slide set outlines actions and possible risks within each pathway stage, and suggests possible roles and responsibilities/ accountabilities for different healthcare professionals. It is hoped this pathway will provide commissioners and providers with areas to consider within their protocols for a seamless hepatitis B service delivery.

Appendix B: checklist for service quality assurance

Hepatitis B services are often historically commissioned services within many NHS organisations. The need to ensure the robustness of service commissioning has never been more urgent. Evidence from workshops held throughout the country highlights that hepatitis B pathways are complicated, and providers within the pathway are frequently unsure of the whole pathway or the importance of their role within this service.

This is not a mandatory checklist. It is designed as a tool for commissioners and providers to assess their current service, to determine its robustness and whether it addresses and encompasses the new UK NSC guidelines. The checklist also indicates possible areas service providers could consider audit and governance requirements. The commissioner should be in a position to feel adequately assured, on an ongoing basis, that the service is functioning appropriately. This could require an initial in-depth service review/audit. It is recommended that ongoing audits on a six monthly basis, at a minimum, are necessary for this assurance to be achieved.

Appendix C: Ordering hepatitis B immunoglobulin

The request form for hepatitis B immunoglobulin is located here. It is also available from www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1205310728612?p=1205310728612).

Appendix D: The Personal Child Health Record (PCHR) insert for the hepatitis B infant immunisation programme

All immunisations should be documented within the PCHR. This insert is an example of the hepatitis B specific inserts that are available and orderable from your PCHR supplier.

Appendix E: Examples of letters submitted to DH currently in use

Information submitted to the Department overwhelmingly highlighted the value of having standardised methods of communication across all multi-agency partners and patients. Within this section are template letters submitted by services for set communications. The template letters contained within this section *are not endorsed* by the Department of Health but may be of use and can be adapted to meet local provider needs.

Appendix F: UK NSC Guidance; relevant statements mapped to hepatitis B screening and immunisation stages

The UK NSC has a specific role in agreeing standards for screening programmes that can be used as a basis for discussion by standard setting bodies in the UK countries (see www.screening.nhs.uk/about for UK NSC terms of reference). For quick reference, relevant statements by the UK NSC for infectious disease in pregnancy screening have been mapped to the different stages identified within this guidance. This should not be considered as an alternative to the UK NSC guidance.

Appendix A: Models of hepatitis B immunisation programme delivery

Model 1 Via GP/ primary care

Delivery method	Benefits	Barriers/Risks
Surgery / clinic centred.	GP services/clinics are accessible and local to their registered patients. Appointments can be flexible to meet the demands of the patients.	The mother/family does not appreciate the importance of the follow-up and so do not attend appointments. GP surgery staff may fail to realise the importance of the timing of immunisations and could delay the schedule to fit with other immunisations schedules.
	GPs have a duty of care to their registered community. Hepatitis B pathways completed within primary care provide the opportunity for ongoing holistic family hepatitis B assessments.	GP practices are likely to have low numbers of infants requiring a hepatitis B vaccination programme and may not feel they have the necessary skills to care for these individuals. An identified hepatitis B co-ordinator could signpost relevant queries. A robust call/recall service is essential for vaccination schedule completion. The care pathway should indicate how to actively follow-up failed appointments.
Out-reach/ home vaccination service *delivered by health visitor*	Patient-centred service. Evidence proves this method of delivery has greater success for delivery/uptake.	Whilst this approach is likely to result in the highest completion rates, it is labour intensive to set up and run. This approach requires: • the support of a firm infrastructure to ensure all information is up to date, stored and inputted in a timely manner • access to multiple systems and firm liaison links to ensure delivery system does not work in a silo. As service frequently relies on one person, gaps in service can occur during times of unplanned leave.
	Use of child health systems for call/recall.	Hepatitis B vaccination lies outside the routine childhood vaccination scheduling process, so often is undertaken manually. If overlooked, this could delay the completion of the vaccination schedule.

Model 2 Via paediatric/acute care

Delivery method	Benefits	Barrier/risk areas
Paediatric clinic based	The paediatric services tend to be closely linked to delivery units, therefore information transfer is not as challenging. Clear protocols with defined roles for information sharing should be followed, with clear processes being identified to document information within the PCHR.	The risk of mother and babies missing appointments is greater due to location. Paediatric clinics are frequently held within hospital settings and are often less accessible to mothers with newborn babies who sometimes are not able to travel long distances. Access needs to be considered especially where women have had caesarian sections and may not be as readily mobile.
.	Within paediatric services an administrator is responsible for call/recall and following up missed appointments, often via primary care.	Risk of loss to follow-up in primary care. Primary care professionals not understanding the importance of timely completion.
	The administrator liaises with CHIS.	Vaccinations given within paediatric services may not be registered on CHIS/GP systems and COVER statistics. Protocols need to capture babies who move into/out of the area mid-schedule, where transferring areas do not deliver through a paediatric model.
Paediatric outreach team – home visiting	Person-centred service. Evidence proves this method of home vaccination delivery has greater success for delivery/ uptake.	Whilst this approach is likely to result in the highest completion rates, it is labour intensive to set up and run. This approach requires: • the support of a firm infrastructure to ensure all information is up to date, stored and inputted in a timely manner. • access to multiple systems and firm liaison links to ensure delivery system does not work in a silo.

Hepatitis B Pathway slide set.

The pdf slide set presented alongside this practice guide (on web page) supports models contained within appendix A. It illustrates the complexity of the hepatitis B pathway from antenatal screening to eventual vaccination completion. The care period is lengthy and relies on joined up services throughout the whole process.

The slide set outlines each stage, highlighting actions, possible risks, and suggests possible roles and responsibilities for different healthcare professionals.

Appendix B: Checklist for service quality assurance

(This is not a mandatory checklist, it is a commissioning tool to assist Commissioners)

		Yes/no unsure	Evidence	Responsible provider
				Comments
	Are there failsafe systems in place and is the hepatitis B pathway regularly audited?			
1.	**Essential elements of the antenatal hepatitis B screening and immunisation programme: service commissioning considerations**			
	Are you aware of your disease prevalence? Do you have a high or low need for services due to hepatitis B infectivity within your commissioned population?			
	Do you have a clear and agreed pathway in line with the UK NSC guidance and the Department of Health Green Book?			
	Is there a responsible commissioning board level representative who owns, oversees and manages the pathway?			
	Is there a named individual who is responsible to oversee the hepatitis B service from screening to completion of the immunisation schedule at 12 months?			
	How robust is the pathway – does each section of the pathway have a clearly designated responsible person?			
	Are there systems in place to report and investigate screens missed in line with Managing Serious Incidents guidance?[18]			
	Are all interfacing services within the pathway aware of their roles and responsibilities?			
2.	**An effective screening programme:**[3]			
	Are all women offered universal screening (including late bookers)? Is this offer supported by appropriate information and protocols for when a test is declined?			
	Are laboratory turnaround times and reporting in line with UK NSC guidance?			
	Are there clear agreed pathways for receiving and acting on positive results? This includes appropriate referral systems, agreed areas of responsibility for ongoing care and the flow of information between services			

[3] Note: The UK NSC is currently in the process of developing an audit checklist for the hepatitis B screening aspects of the screening and immunisation pathway. When developed, we strongly recommend the UK NSC checklist is used for auditing the screening sections of the pathway.

		Yes/no unsure	Evidence	Responsible provider
	Are the results being documented and communicated appropriately, including reporting of positive results to the local provider provider/commissioning immunisation lead and HPU?			
	Are there systems in place to ensure appropriate referral to services for contact tracing and whole family follow-up?			
3.	**Systems to ensure first vaccination/HBIG is given**			
	Are there clear responsibilities for ordering and adjusting vaccinations/HBIG?			
	Are there failsafes in place to ensure that vaccination/HBIG are available at delivery?			
	Are vaccinations/HBIG given within 24 hours of birth?			
	At delivery, where no booking visit blood test results are apparent, are protocols in place to assess maternal hepatitis B risk to inform immunisation decisions?			
	Are there appropriate systems in place for recording and communicating vaccination information to relevant health professionals (inc. immunisation co-ordinator)?			
	Are there protocols in place for those who refuse vaccination?			
	Are protocols/guidance in place to vaccinate those who choose to deliver at home?			
	Does the system identify all babies for their first vaccination (COVER denominator)?			
4.	**Systems to ensure subsequent vaccinations are given and that the child is tested for HBV infection at 12 months of age**			
	Is there a clear process to communicate subsequent vaccination and serology requirements?			
	Is there a robust call/ recall process, and how timely is this?			
	Are failsafe systems evident for call/recall?			
	Are there clear lines of responsibility for subsequent vaccination schedule completion and serology testing?			
	Are there protocols/ systems in place to capture those who move into/out of the area to ensure timely schedule completion?			
	Are there protocols and systems to capture children who are fostered/adopted?			
	Are there systems in place to follow up and actively trace			

		Yes/no unsure	Evidence	Responsible provider
	those who do not present/attend for vaccination?			
	Do the hepatitis B status/vaccinations accurately feed into data describing coverage?			
5.	**Audit**			
	Is there evidence of :			
	• universal antenatal screening being offered to all pregnant women ?			
	• clear systems/protocols in place for late bookers?			
	• all screening results being received by midwives within ten working days of sample being sent?			
	• *all positive* results being reported to the local HPU?			
	• failsafes in place to ensure that vaccination/HBIG is available at delivery?			
	• appropriate systems in place for recording and communicating vaccination information to those highlighted by the UK NSC guidance?			
	• protocols in place for those who refuse vaccination?			
	• protocols/guidance to vaccinate those who choose to deliver at home?			
	• a robust call/ recall process, and is this timely?			
	• protocols/ systems in place to capture those who move into/out of the area mid schedule? • How timely is the vaccination and serology testing completion?			
	• systems in place to follow up and actively trace those who do not present/attend for vaccination?			
	• systems identifying all babies for their first vaccination (COVER denominator)?			
	• hepatitis B status and vaccinations given accurately feeding into coverage data (COVER numerator)?			
6.	**Future developments**			
	Tools to aid communication and enhanced data capture may include: • the use of birth notification/discharge summaries to communicate information • local IT solutions to ensure all professionals gain relevant information in a timely manner.			

Appendix C: Ordering hepatitis B immunoglobulin

Currently, in England, HBIG distribution is co-ordinated by the HPA Centre for Infections.

Where HBIG is indicated:

- for “NAMED” babies and late booked babies (if practical), a request form (WDD004 – See Appendix C, also available at www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1205310728612?p=1205310728612) should be completed by the responsible healthcare professional, usually the delivery midwife. Currently this is sent to:

  Hepatitis B Infant Study Co-ordinator, Immunisation Dept

  Health Protection Agency Centre for Infections

  61 Colindale Avenue, London, NW9 5EQ

  Tel: 0208 327 6439 Fax: 0208 327 7404

The HBIG is dispatched approximately eight weeks prior to estimated due date by Royal Mail Special Delivery (to arrive by 1pm next working day).

- for emergency situations, i.e. very late booking or premature babies with a birth weight of less than 1500g, requests should be phoned through, both in and out of hours, to 020 8327 6439 or 0208 8327 7471.

  For these babies, you should also complete the request form WDD004 and fax to the Hepatitis B Infant Study Co-ordinator (020 8327 7404).

  In most cases, HBIG can still be dispatched via Royal Mail Special Delivery and be administered within 24hrs, however; if necessary, it can be couriered from the Centre for Infections or local holding points at the expense of the requesting hospital. (Note the Green Book[8] (P165) states ‘Ideally, HBIG should be given within 48 hours, although it should still be considered up to a week after exposure’).

  At certain locations throughout England and Wales, a small stock supply of 200iu and/or 500iu hepatitis B immunoglobulin is held. Details of local stocks can also be accessed by contacting 0208 327 7471.

Issues of hepatitis B immunoglobulin for infants at risk of hepatitis B

ANTENATAL PATIENT DETAILS

Mother's surname: _____ **First name:**_____ **DOB:** _____

Hospital number: _____ **NHS number:** _____

Home address: _____

Ethnic group: □ **Chinese** □ **Other Asian (Indian sub continent)** □ **Black** □ **White**

□ **Other** **If other, please give details:** _____

Country of birth: _____ **PCT/GP Consortia name:** _____

GP name and address:_____

Immunoglobulin is indicated for infants of mother with acute hepatitis or those who are HBsAg positive and anti-HBe negative or unknown

Acute hepatitis **Yes** ☐ **Please give details of other risk factor for HBV infection:**_____

	Positive	Negative	Not tested
HBsAg	☐	☐	☐
HBeAg	☐	☐	☐
Anti-HBe	☐	☐	☐

Viral Load testing

For labs where Viral Load is taken, please note that HBIg will only be issued to women with viral loads which are greater than **1 x 10^6 iu/ml**

Viral load: ..... iu/ml

200iu HBIG will be posted to the designated person approximately eight weeks prior to EDD

Delivered ☐ **In Labour** ☐ **Expected** ☐ **If expected, please give expected delivery date:** __/__/____

N.B. If baby has already been delivered please also COMPLETE the back of the form

Please name the person authorised to receive/store HBIG at your location

Sister in charge □ **Midwife in charge** □ **Pharmacist** □ **Other** □ Please specify:_____

Authorised person: _____
Deliver to:
Ward/Dept/Unit: _____ **Hospital Name:** _____

_____ **Tel no:** _____

Completed by: _____ Contact no: _____ Date: _____

During working hours: In an **emergency, HBIG** will be issued in response to a telephone call on **020 8327 6439 followed** by a faxed request to **020 8327 7404. Out of hours:** please telephone 020 8200 6868 and speak to a duty doctor. **Please send completed request form to: Hepatitis B Infant Study Coordinator, Health Protection Agency, Immunisation Dept, Centre for Infections, 61 Colindale Avenue, London, NW9 5EQ**

Customer Verified □

PLEASE COMPLETE AFTER BIRTH (CONTINUED FROM OVERLEAF)

DETAILS OF DELIVERY

Infant's surname: _____ **First name:** _____

Hospital number: _____ **NHS Number:** _____

Sex: Male □ **Female** □ **Date of Birth:** _____ **Time:** _____

Type of delivery: _____ **Birthweight:** _____

If multiple birth please specify: _____ **(Please complete a separate form for each sibling)**

DETAILS OF ADMINISTRATION

The infant should receive **200iu** of **HBIG intra-muscular injection** and **0.5ml** of **Hepatitis B vaccine** shortly after birth

HBIG
Date given: _____ **Time given:** _____ **Dose given:** _____ **Batch No:** _____

VACCINE
Date given: _____ **Dose given:** _____ **Make of vaccine:** _____**Batch No:** _____

DOCTOR RESPONSIBLE FOR FUTURE CARE OF THE INFANT

Who will be responsible for future vaccination of the infant?:

Paediatrician ☐ **GP** ☐

Consultant paediatrician: _____

Trust name: _____

Trust address: _____

_____

(only complete this section if GP details are not stated on page 1)

Name of GP: _____

GP address: _____

_____

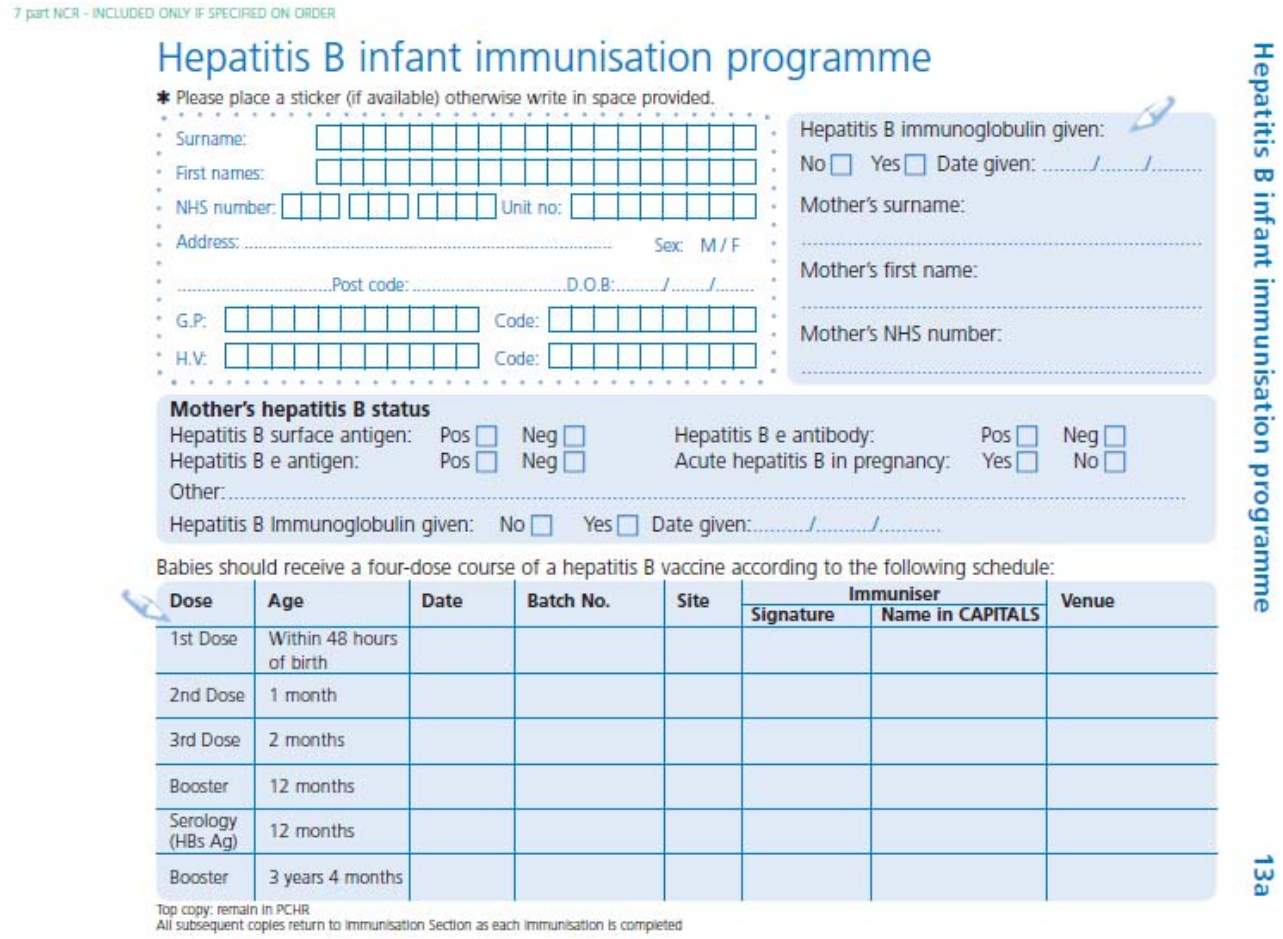
Completed by:_____ **Contact no**: _____ **Date**: _____

Please arrange for an appointment for the infant to be given the **second dose of vaccine ONE-month** after the first.

Please send completed form to:
Hepatitis B Infant Study Co-ordinator, Immunisation Dept
Health Protection Agency Centre for Infections
61 Colindale Avenue, London, NW9 5EQ

Appendix D: The Personal Child Health Record (PCHR) insert for the hepatitis B infant immunisation programme

All immunisations should be documented within the PCHR. This insert is an example of the hepatitis B specific inserts that are available and orderable from your PCHR supplier. This form is often known as form 13a to health professionals working in microbiology laboratories.



7 part NCR - INCLUDED ONLY IF SPECIFIED ON ORDER

Hepatitis B infant immunisation programme

✱ 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:

Hepatitis B immunoglobulin given:
No ☐ Yes ☐ Date given: ...../...../.....

Mother's surname:

Mother's first name:

Mother's NHS number:

Mother's hepatitis B status

Hepatitis B surface antigen: Pos ☐ Neg ☐
Hepatitis B e antigen: Pos ☐ Neg ☐
Hepatitis B e antibody: Pos ☐ Neg ☐
Acute hepatitis B in pregnancy: Yes ☐ No ☐
Other:
Hepatitis B Immunoglobulin given: No ☐ Yes ☐ Date given: ...../...../.....

Babies should receive a four-dose course of a hepatitis B vaccine according to the following schedule:

Dose	Age	Date	Batch No.	Site	Immuniser		Venue
					Signature	Name in CAPITALS	
1st Dose	Within 48 hours of birth						
2nd Dose	1 month						
3rd Dose	2 months						
Booster	12 months						
Serology (HBs Ag)	12 months						
Booster	3 years 4 months						

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

Hepatitis B infant immunisation programme 13a

Appendix E: Examples of letters submitted to DH currently in use

Hepatitis B screening test result: GP notification letter

XXX Maternity Department

Date

ATTENTION GENERAL PRACTIONER

Dear Doctor,

Re:

Patient's name:	Date of birth:
Address:	Home postcode:
Hospital number:	Hospital:
E.D.D. of child Parity:	Country of birth:
GP name and address:	Ethnicity:

The above patient has been found to be HBsAg positive (**Acutely/Persistently** (delete as appropriate) **infected with hepatitis B**) on testing of serum dated / / .

The results of the hepatitis B tests are as follows:
HBsAg _____

anti-HBc, IgM _____

HBeAb _____

HBeAg _____

HBV DNA_____IU/ml

☐ **Her baby will require the initiation of a course of hepatitis B vaccine immediately after birth**, with a second dose at one month, third dose at two months and fourth dose at 12 months. Administration of the first dose will be organised by maternity services. Subsequent vaccine doses and serology testing at 12 months of age are the responsibility of ……(*local protocol)*

☐ In addition, if the mother is HBeAg positive (or has other markers of high infectivity, see the Green Book), the baby will also require immunoglobulin (HBIG). This should be administered within 24 hours of birth. Administration of HBIG will be organised by maternity services.

A referral to …….. has been made for follow-up.

It is important that the household contacts and sexual partners of this hepatitis B positive mother are screened for hepatitis B and vaccinated as necessary. Sexual partners require immediate vaccination while serology testing is being undertaken, please refer to the Green Book and your local health protection unit for guidance. For eligible patients registered with you please organise this.

Thank you.
Yours sincerely

Specialist midwife

Copy to: - - CCDC - at the Health Protection unit
-Provider Immunisation Lead
- Specialist service *(Local protocol)*

Child born and first vaccination given: notification to health care professional (where primary care delivers subsequent vaccine doses)

HEPATITIS B NOTIFICATION
for GPs / health visitors / practice nurses

L2

GP copy

Dear Doctor,

RE: **BABY: sticky label if available**
name
date of birth
hosp. Number
address
tel. no.

Mother: Name:
Hosp. No:

Date: / /

GP: Name:
Address:

This infant needs to complete a course of **hepatitis B** vaccinations. The first dose has been given in _____ hospital

Date_____ Batch number _____ Site_____ Name immuniser_____

Please could you as their **GP, health visitor or practice nurse**:

1. Complete the second, third, and fourth doses of hepatitis B vaccine as indicated (it is of vital importance for full protection to be achieved that the second and third immunisation are given exactly one month and two months after the initial immunisation).
2. Check the child's serology on the same day as the fourth dose. Where a blood sample cannot be taken a blood spot test can be used, orderable from… *(local protocol/local CCDC)*. Serology testing will identify infants who are infected with hepatitis B and need referral for further assessment.
3. Ensure arrangements have been made to refer the mother to a liver-specialist for follow-up, and that her partner and other children are screened for hepatitis B.
4. Ensure that after each immunisation and the serology testing the child's PCHR is completed and a copy is returned to the local provider immunisation lead and ……
5. Please record that hepatitis B vaccine has been given in the "additional field" of the CIS computer system

If you have any queries please contact your… *(local protocol)*

CHECK LIST FOR PAEDIATRIC SHO

☐ 1.Give hep B vaccine +/- HBIG

☐ 2.Sign this form (L2) & pass to midwife

If you have any problems please contact Paediatric specialist; Dr. X (Y Hospital),

CHECK LIST FOR MIDWIFE

☐ 1.Document hep b status on discharge summary

☐ 2. Complete L2 and send to GP

☐ 3. Send copy of L2 to health visitor

☐ 4. Send copy of L2 to CCDC at HA

☐ 5 Leave copy of L2 in baby's hospital notes

☐ 6. Give mother info sheet & L2 for red book

Appendix F: UK NSC Guidance; relevant statements mapped to hepatitis B screening and immunisation stages

1) Essential elements of the antenatal hepatitis B screening and immunisation programme: Service commissioning considerations	
	PCTs should commission the screening service against a framework which is linked and referenced to national standards.
	Primary Care Trusts are responsible for commissioning screening services and ensuring that the screening pathway is robust.
	There should be written protocols and pathways in each trust (identifying roles and responsibilities for screening and management of women with positive results, local contact details etc.) to support these standards. These should be developed collaboratively and should cross refer to laboratory protocols and standard operating procedures where appropriate.
	There should be named individuals at PCT level responsible for ensuring that the screening and immunisation programmes are integrated, for coordinating the delivery of the full immunisation schedule, for monitoring and receiving audits of the programme and other data.
2) An effective screening programme	
	The hepatitis B screening and management pathway is both complex and evolving. The development of robust multidisciplinary working relationships is essential to ensure it functions appropriately.
	All pregnant women should be offered screening in each pregnancy regardless of immunisation history, unless they are already known to be hepatitis B positive.
	Women with positive screening test results should be contacted and advised about the results, at an appointment made for that purpose, within ten working days of the results being made available to maternity services.
	Negative screening test results should be reported back to women before or at the next antenatal visit, according to local protocol.

	All Hepatitis B positive women are referred for assessment and management by an appropriate specialist (e.g. a hepatologist, gastroenterologist or infectious disease specialist) within six weeks of the screening test result being received by maternity services.
	Processes should be in place to identify and follow up results that have not been received within ten working days.
	A significant change is the recommendation that a second specimen need not be taken by maternity services to repeat the initial screen positive tests as these have already been confirmed by the laboratory. At appointments to discuss screening test results the emphasis should be placed on the arrangements for specialist assessment where the second sample should be taken as part of a more comprehensive assessment.
	The time between initial contact with the woman and the appointment should be as short as possible to minimise the duration of anxiety she is likely to experience.
	The purpose of this appointment is to discuss the screening test result and arrange for referral to a relevant specialist service for clinical assessment.
	The following should be discussed with the woman: • the significance of the hepatitis B infection for her own health, the pregnancy and the baby's health • the need for further tests for confirmation of identity and evaluation of maternal management requirements • the potential benefits of specialist management for the pregnancy, the woman's health and that of the baby • practical arrangements for further assessment e.g. date options for appointments with specialist services.
	Efforts must be made to ensure that women whose first language is not English understand the significance of the screening test result and the need for specialist assessment. The use of interpreters is recommended where appropriate.
	Positive screening results should be made available to the healthcare professionals responsible for the care of the woman and her baby without compromising the woman's right to confidentiality.

	The following should be informed of all confirmed positive screening results: • the specialist responsible for clinical assessment and management of the woman • the health professional responsible for arranging testing of sibling, partner and other household contacts • the GP, health visitor and/or practice nurse • health protection unit (HPU). This is to notify the HPA of the screening result and the details of the clinician responsible for requesting diagnostic laboratory testing • the PCT immunisation lead should be informed at an early stage.
	Assessment by an appropriate specialist provides a comprehensive evaluation of maternal infection, determines whether treatment in late pregnancy is indicated and further assesses risk of transmission and whether HBIG should be administered with the first dose of the infant vaccination schedule.
	Local protocols should be in place to ensure multidisciplinary links and close working relationships between maternity services and specialist services.
	For women booking 24 weeks gestation or later blood samples should be marked as urgent.
	Test results should be received within 24 hours of receipt of the specimen by the laboratory. If positive, the woman should be referred immediately to the relevant specialist services for further assessment.
	Where a prior positive diagnosis of HIV or hepatitis B is documented and known to the healthcare professional this should be recorded and arrangements for prompt clinical evaluation made.
	It is essential that the current status of the infection is promptly assessed by an appropriate specialist to evaluate its implications for the care of the woman, the onward management of the pregnancy and care of the baby.
3) Systems to ensure first vaccination/ hepatitis B immunoglobulin is given	
	Maternal consent for the baby to be vaccinated in accordance with the Green Book schedule should be sought and action taken to facilitate this.

	It is essential that the relevant information is available to the delivery team. This should include: • maternal disease status • confirmation of the neonatal vaccination requirements • the need to avoid both foetal blood sampling and use of a foetal scalp electrode in most circumstances.
	The first dose of vaccination (+/- HBIG) should be administered within 24 hours birth.
4) Systems to ensure the subsequent vaccinations are given and that the child is tested for Hepatitis B infection at 12 months of age	
	The subsequent doses of the vaccination schedule are administered over a lengthy period, usually within primary care.
	It is important that processes are in place to ensure the mother is aware of the immunisation schedule.
	It is of vital importance that the woman's discharge address is accurate as follow up will be compromised if a health visitor is not able to contact the woman.
	Making arrangements for completion of the vaccination schedule is a critical point in the pathway. It is important that the midwife responsible for this action undertakes the following prior to discharge: • inform CHIS of the mother's hepatitis B status, that the first dose of vaccine (+/- HBIG) has been administered and the need for subsequent vaccines • discussion with the mother regarding the baby's immunisation schedule and importance of completion • complete all relevant vaccination forms • record woman's Hepatitis B status and the baby's vaccination schedule on the postnatal discharge letter as well as the Personal Child Health Record (PCHR). • confirm that a process is in place for arranging further follow-up appointments • notification to the GP and health visitor of the mother's hepatitis B status and that the infant needs to complete a hepatitis B vaccination course

	• informing the health protection unit (HPU) hepatitis lead or PCT equivalent regarding the follow up with GP.
	The subsequent doses of the vaccination schedule are administered over a lengthy period, usually within primary care.
	It is important that processes are in place to ensure the mother is aware of the immunisation schedule
	It is of vital importance that the woman's discharge address is accurate as follow-up will be compromised if a health visitor is not able to contact the woman
5) CHIS	
	A process to arrange appointments, issue prompts and identify missed appointments at each stage should take place to facilitate completion of the schedule. This may require an IT process through Child Health Records Department.
	Systems must be in place to ensure data is submitted to the appropriate reporting bodies, for example the COVER data system[4] collects data on infant hepatitis B vaccination.

Infectious disease in pregnancy screening programme standards, UK National Screening Committee 2010 http://infectiousdiseases.screening.nhs.uk/standards

[4] This is a mandatory data collection reference ROCR/OR/0105/004 MAND and the licence continues pending the outcome of the informatics review.


DH
Department
of Health