



Public Health  
England

Protecting and improving the nation's health

# The hepatitis B antenatal screening and selective neonatal immunisation QI project

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# Today's session

- A recap of the aims and objectives of the project
- Opportunity to see resources and discuss their use in clinical practice
- Ensure understanding of importance of increased surveillance of hepatitis B virus
- Q&A session

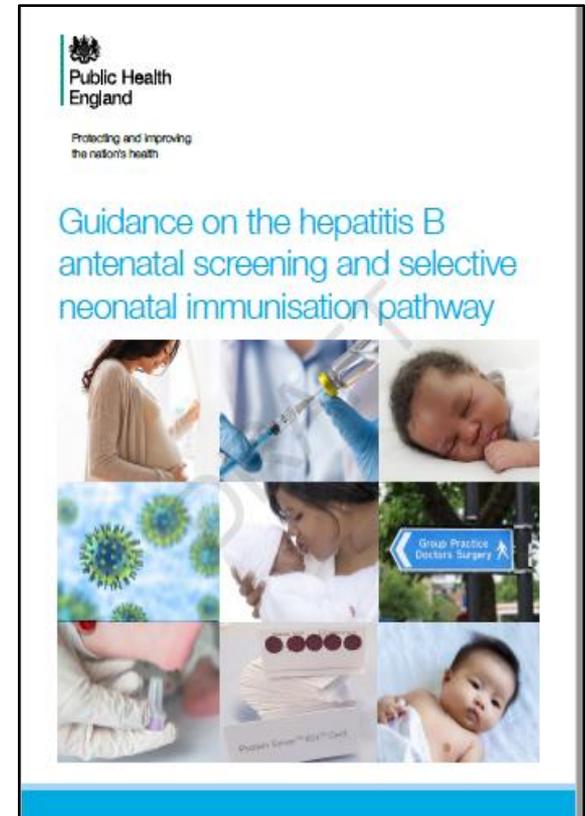
# Global public health problem



Source: Global Burden of Diseases and WHO/UNAIDS estimates <http://ihmeuw.org/3pmt>

# PHE quality improvement project

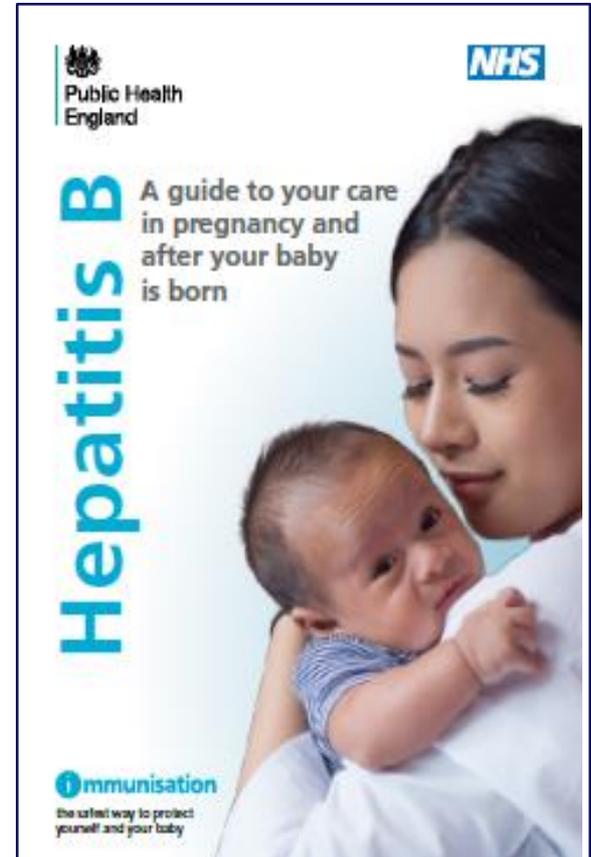
- **Project aims:**
  - enable gold standard care in line with HIV
  - improved multidisciplinary working
  - improved surveillance of virus in mothers and babies
  - increase public awareness and knowledge
  - improve professional knowledge



# PHE quality improvement project

## How ?

- seamless maternal and neonatal pathways
- suite of supporting resources
- robust surveillance & outcome processes- ISOSS and PHE immunisation



# Rationale for quality improvement project

WHY?

**Evidence-** IDPS standards data, COVER data; incidents- missed screening, late or missed vaccinations/HBIG, failure to refer for vaccination schedule, failure to complete schedule

**Vulnerable populations-** language barriers, ethnic minority populations, no strong charitable voice

**Equality issues-** part of PHE strategy

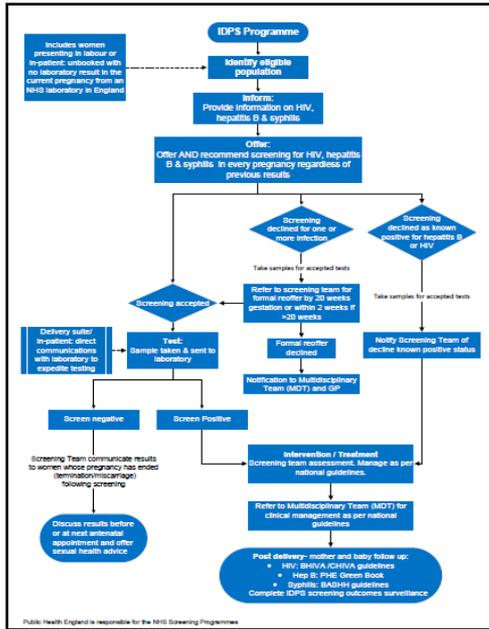
## **Out of date information**

- Need for updated screening and immunisation guidance from PHE (old DH 2011)
- Need for updated clinical guidelines (BHVG 2008)
- No complete database of women with hep B

## **Incomplete evidence of how babies are infected**

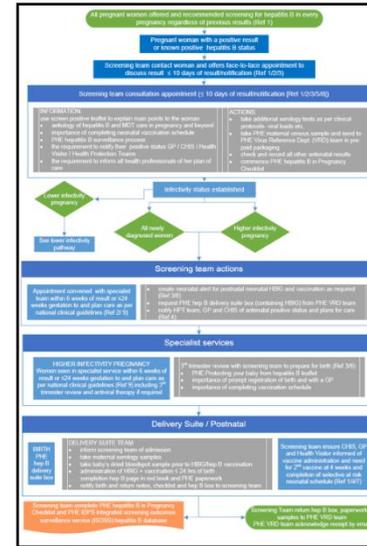
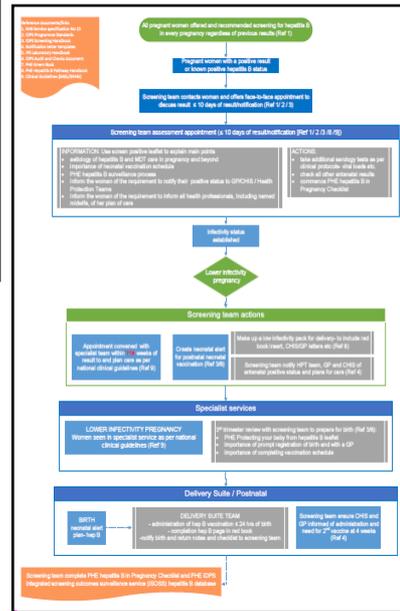
- A recent review by PHE of possible factors associated with HBV infection in 69 infants found all to have received HBIG and vaccine in accordance to national recommendations

# Seamless maternal and neonatal pathways



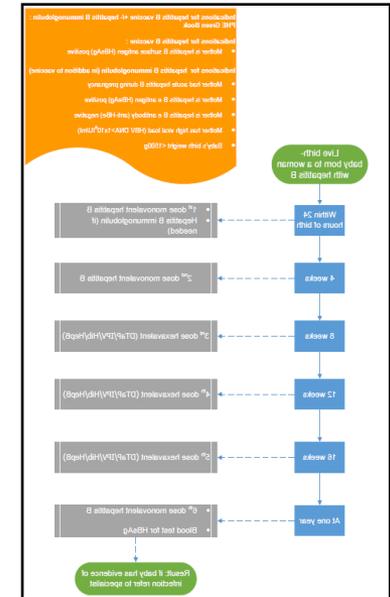
Generic screening

## Lower infectivity



Higher infectivity

## Neonatal schedule



# What do the pathways tell us?



- **WHO-** define roles and responsibilities to ensure seamless handover of care – “passing the baton”
- **WHEN-** establish key timescales for effective care provision
- **WHAT-** the care you need to provide at each stage
- **WHY-** evidence, safety, standards, guidelines, equality and access



**Improve outcomes  
for women, their  
babies and their  
extended family**

# The Pathways – Information & actions

nce documents/links  
Service specifications No 1 and 15  
Programme Standards  
Screening Handbook  
ification letter templates  
Laboratory Handbook  
Audit and Checks document  
Green Book  
Guidance on the hepatitis B antenatal  
ing & selective neonatal immunisation pathway  
cal Guidelines (BASL/BVHG)  
E Healthy Child Programme 0-19: Health Visitor  
specifications

All pregnant women offered and recommended screening for hepatitis B in every pregnancy regardless of previous results (Ref 1)

Pregnant woman with a positive screening result or known positive hepatitis B status

Screening team contacts woman and offers face-to-face appointment to discuss result ≤ 10 days of result/notification (Ref 1/2/3)

Screening team assessment appointment (≤ 10 days of result/notification [Ref 1/2/3/5/8])

**INFORMATION:** use *PHE 'hepatitis B. A guide to your care' leaflet* to explain main points to the woman, including:

- aetiology of hepatitis B and multidisciplinary team care in pregnancy and beyond
- importance of completing neonatal vaccination schedule
- PHE hepatitis B surveillance processes
- the requirement to inform all health professionals of her plan of care and to notify their positive status to GP / CHIS / Health Visitor / Health Protection Teams

**ACTIONS:**

- take additional serology tests as per local clinical protocols- viral loads, LFTs etc. and send to laboratory
- take PHE maternal venous sample and send to PHE Virus Reference Department, Colindale in pre-paid packaging (result will be sent back to you to report to specialist team)
- Check and record all other antenatal results
- commence *PHE Hepatitis B in Pregnancy Checklist*

# Each step explained

## Specialist services

Women seen in specialist service within 6 weeks of result or by 24 weeks gestation to plan care as per national guidelines (Ref 2/8/9)

- higher infectivity: 3<sup>rd</sup> trimester review and antiviral therapy if required
- newly diagnosed/ lower infectivity- go to lower infectivity pathway

3<sup>rd</sup> trimester review with screening team to prepare for birth (Ref 8). Match HBIG with Delivery Suite Box and record location in notes.

Using *PHE Protecting your baby against hepatitis B leaflet* discuss:

- importance of prompt registration with a GP and prompt registration of the baby's birth
- importance of completing vaccination schedule
- PHE hepatitis B surveillance processes post-delivery

## Delivery Suite / Postnatal

Babies with a birthweight of 1500g or less need HBIG plus vaccine regardless of the maternal infectivity status (Ref 7)

### DELIVERY SUITE TEAM

- inform screening team of admission
- locate hep B box and follow instructions:
  - take maternal serology sample after delivery
  - take baby's 'hep B dried bloodspot' sample PRIOR to HBIG/hep B vaccination
  - administration of HBIG + vaccine ≤ 24 hrs of birth
  - completion of hep B page in Red Book and PHE paperwork
  - notify birth and return notes, checklist and hep B box with paperwork and samples to screening team

Screening team ensure GP, CHIS and Health Visitor informed of:

- vaccine administration at birth
- need for 2<sup>nd</sup> vaccine at 4 weeks and completion of selective at risk neonatal immunisation schedule (Ref 1/4/7/8)

Screening team complete *PHE hepatitis B in Pregnancy Checklist* and PHE IDPS Integrated screening outcomes surveillance service (ISOSS) hepatitis B database

Screening Team return paperwork & samples in hep B box to PHE Virus Reference Department, Colindale in pre-paid packaging and acknowledge receipt by email

# Supporting resources

- PHE guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway
- IDPS 'screen positive' leaflet
- PHE hepatitis B safety checklist
- notification letter templates

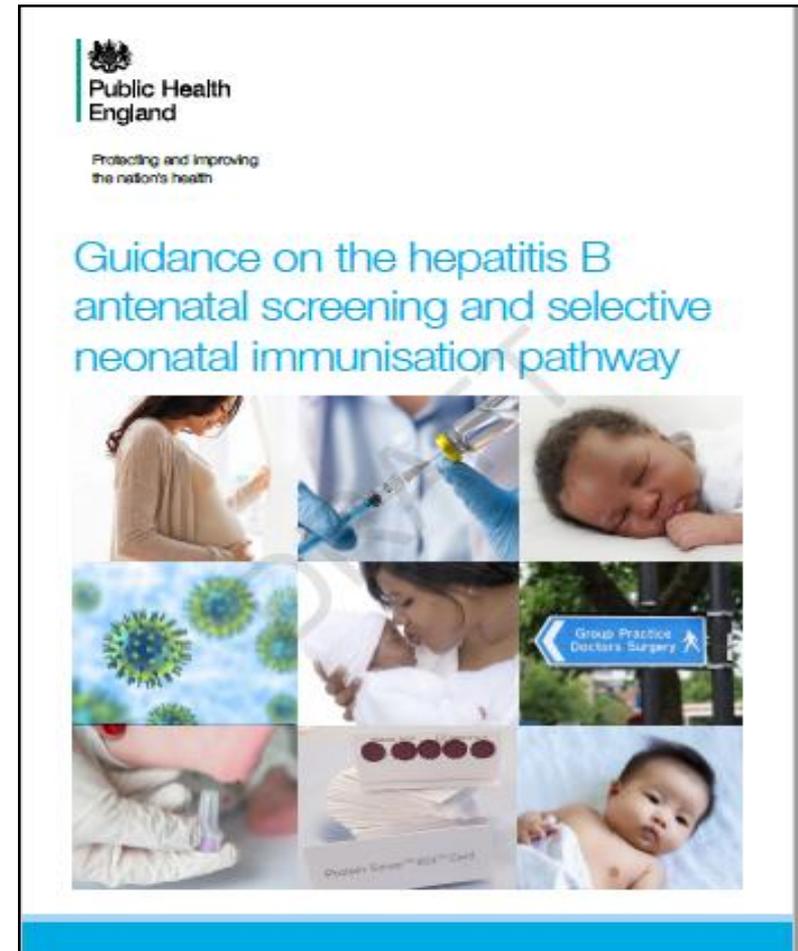


Public Health England HEPATITIS B SCREENING & IMMUNISATION Maternal & Paediatric Checklist		Please complete or Add Patient Label																	
Date of booking ..... Date of hep B screen ..... Date of screening result ..... Date of notification (known positives/decline) ..... Date of screening team assessment ..... Date of specialist appointment .....		Unit No: ..... NHS No: ..... Surname: ..... Forename: ..... Date of birth: .....																	
		<b>Hepatitis B Result / Infectivity Status</b> <table border="1"> <thead> <tr> <th>Test</th> <th>Date of test</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>Viral load</td> <td></td> <td></td> </tr> <tr> <td>HCV</td> <td></td> <td></td> </tr> <tr> <td>LFTs</td> <td></td> <td></td> </tr> <tr> <td>Other test results</td> <td></td> <td></td> </tr> </tbody> </table> Lower infectivity <input type="checkbox"/> Higher infectivity <input type="checkbox"/>			Test	Date of test	Result	Viral load			HCV			LFTs			Other test results		
Test	Date of test	Result																	
Viral load																			
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Screening Team appointment (≤ 10 working days of laboratory result / notification)		Comments	Date	Signature and name in capitals															
All services: Higher or lower infectivity	PHE leaflets discussed Hepatitis B screening result and 'Protecting your baby from Hepatitis B' Additional bloods taken: - per BVHG and local MDT/ hepatology guidelines - PHE maternal venous sample to PHE Viral Reference Department (VRD), Colindale Inform GP, MUM, HPT, CHS & CMAN of positive result and plan of care These process for MDT assessment-appointment details	Download leaflets - screening result - PHE letter BVHG guidelines Prepare packaging order details PHE template letters Insert name of Consultant or CNS referred to, date of referral and appointment																	

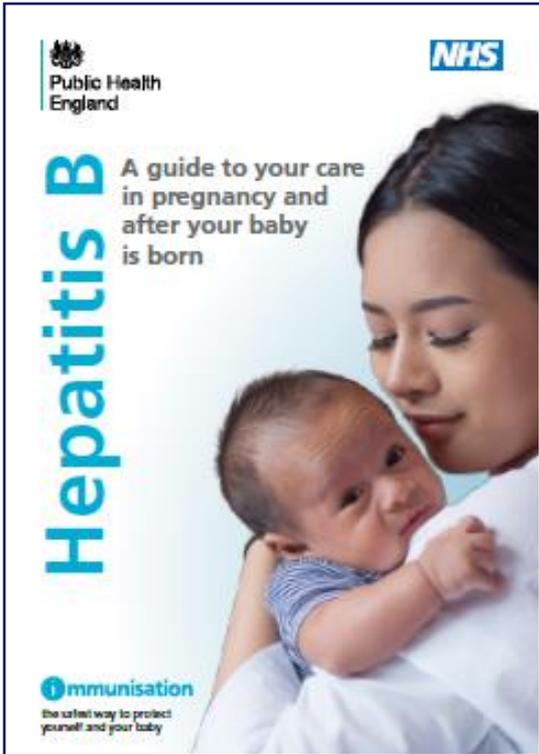
# Comprehensive guidance

antenatal screening and selective neonatal immunisation guidance:

- collaborative work
- covers care pathways from screening to DBS at 12months
- endorsed by NHSE/I



# Leaflets



## Your screening test result and what it means

 You recently had some blood tests taken. One result has shown that you have an infection called hepatitis B.

**This leaflet will explain what hepatitis B is and what it means for you, your baby and your family.**

 This leaflet contains information about the care you will need in your pregnancy to keep you healthy and the care needed for your baby and other family members.

 During your pregnancy you will be cared for by a specialist team who will explain all the information in this leaflet, including details of the care available where you live and answer any questions you or your partner may have.

 The team may include a screening midwife, a specialist nurse, a doctor specialising in liver care, an obstetrician, a pharmacist and your GP, practice nurse and health visitor.

4 Hepatitis B



**Remember to take your red book to all appointments or remind health professionals to fill it in online.**

## When you go home

### Register your baby's birth

All births in England, Wales and Northern Ireland must be registered within 42 days of the child being born. If you are married your husband can do this alone. You will be given a birth certificate.

### Register your baby with your GP

You and your baby need to be registered with a GP to make sure you receive all the care you need.

Register your baby as soon as they are born so you can book in for the baby's 4-week vaccination. It will be easier to do this if you have the birth certificate. Tell your midwife or health visitor if you have any problems with this.

### Future care

It is important to keep all the appointments made for you and your baby including any hospital ones with the specialist team.

You and your baby will need a visit to your GP when the baby is six weeks old to check all is well after the birth.

10 Hepatitis B

# Leaflets

Public Health England

**NHS**

## Protecting your baby against hepatitis B

with the hepatitis B vaccine

**i**mmunisation  
the safest way to protect yourself and your baby

Protecting your baby against hepatitis B 7

**Keep a record of your baby's appointments and vaccination dates below.**

These will also be recorded by your midwife, health visitor, practice nurse and GP in your baby's Red Book (Personal Child Health Record)

Appointment date	Age due	Vaccine	Date vaccine given
	Birth	Single dose of hepatitis B vaccine	
	HBIG (if required)		
	4 weeks	Single dose of hepatitis B vaccine	
	8 weeks	Routine childhood vaccines (contains hepatitis B protection)	
	12 weeks	Routine childhood vaccines (contains hepatitis B protection)	
	16 weeks	Routine childhood vaccines (contains hepatitis B protection)	
	12 months	Single dose of hepatitis B vaccine	
		Blood test to check if your baby has hepatitis B infection	

If you have questions you can speak to your midwife, health visitor

Protecting your baby against hepatitis B

If a young infant is infected, they are more likely to develop long lasting (chronic) infection without any signs or symptoms of infection. **So even if your baby has no signs or symptoms of infection they should still have the blood test.**

Infection can be prevented in 90% of cases if the first dose of vaccine is given at birth and the full course of vaccines is completed on time.

# Checklist – an aide memoire

<b>HEPATITIS B SCREENING AND IMMUNISATION Maternal and neonatal checklist</b>		<i>Please complete or attach patient label</i>		
		Unit number .....	NHS number .....	
		Surname .....		
		Forename(s) .....		
		Date of birth .....		
Date of booking .....		<b>Serology results</b>		
Date of hepatitis B screen .....		<b>Test</b>	<b>Date of test</b>	<b>Result</b>
Date of screening result .....		Viral load		
Date of notification (known positives/decline) .....		HCV		
Date of screening team assessment .....		LFTs		
Date of specialist appointment .....		Other test results		
		Lower infectivity <input type="checkbox"/> Higher infectivity <input type="checkbox"/>		
All women: higher or lower infectivity	<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>
	Using 'Hepatitis B: a guide to your care in pregnancy and after your baby is born' and as per PHE guidance, explain the plan of care and surveillance processes - take antenatal surveillance sample and send to PHE Colindale - additional bloods taken as per local guidelines - check and record all other antenatal results Inform GP, H/V, HPT, CHIS and CMW using PHE letter templates	Record verbal consent for surveillance bloods in notes		
<b>Within 6 weeks of result/notification</b>				
All women with hepatitis 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 to promote timely treatment			
Higher infectivity women only	Submit a HBIG request as per trust practice Use current request form on PHE website			
	7 weeks prior to EDD PHE coordinator will send: • HBIG to your pharmacy • delivery suite box to screening team to match up with HBIG and place in box • box should be stored according to trust practice and the location clearly noted on the maternal record NOTE- if woman's care is transferred notify PHE			

34-week pre-birth consultation/screening team review		Status/comments	Date	Signature and name in capitals
All women	<b>Preparation for birth</b> Discuss care and adherence to vaccination schedule using PHE 'Protecting your baby from Hepatitis B' leaflet Check neonatal alert is in place			
Higher infectivity	Confirm where PHE Hep B delivery suite box containing HBIG is stored and that the location is recorded in notes /birth plan / maternity information system			
	Explain the surveillance bloods required at the birth from the baby and clarify these are different from the NBS sample at Day 5	Record verbal consent for surveillance bloods in notes		
<b>Delivery Suite Team</b>				
Higher infectivity mother and baby	<b>On admission:</b> • inform screening team of admission • locate PHE hepatitis B delivery suite box and HBIG			
	<b>Using the hepatitis B delivery suite box</b> - take maternal serology sample with verbal consent recorded after delivery and complete form (Pack1)		Date/time of blood test	
	take neonatal 'hep B dried blood spot' prior to vaccination (Pack 2) - give HBIG + hep B vaccination (Pack 3) - complete PCHR red book and hep B page and give to mother	Card number/time of blood test Date/time given/batch number. Record verbal consent for maternal and neonatal surveillance bloods in notes		
	- 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 temp. if not available)			
Lower infectivity mother and baby	-vaccination administered ≤24 hours of birth - complete PCHR red book and hep B page and give to mother	Prescription in notes / Batch number		
<b>Post-natal</b>				
Pre-discharge checks	- PCHR book has completed hep B page - mother has a copy of the vaccination leaflet - mother informed of the importance of early registration of the birth and registering baby with a GP to book vaccinations at 4 weeks etc - ensure notes go back to screening team			
Screening team	- check request forms for maternal sample and PHE notification forms are fully completed - despatch DBS, bloods and forms to PHE Virus Reference Department, Colindale in pre-paid packaging - inform CHIS, H/V, GP, & CMW of vaccination using PHE letter templates - complete ISOSS database			

# Surveillance

**In spite of vaccine/HBIG intervention, babies who are infected with hepatitis B infected are still seen, possibly due to:**

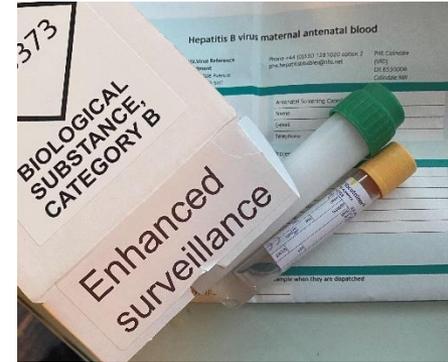
- inter-uterine transfer of infection
- perinatal transmission
- vaccine/HBIG failure possibly due to mutant hepatitis B viruses that “escape” the vaccine
- **Currently no way of knowing which one**

# Surveillance- mother

## Maternal

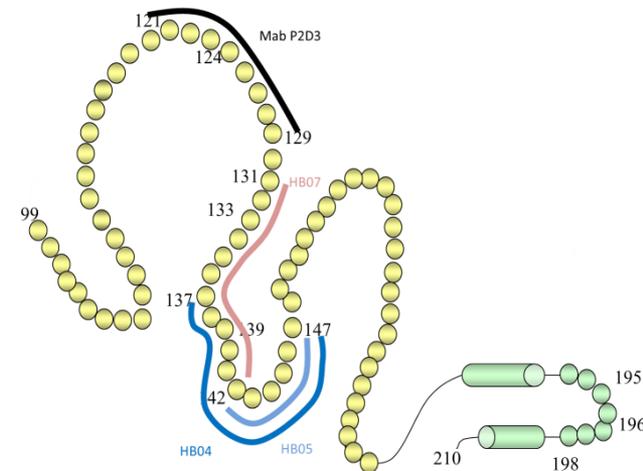
HBV DNA levels at 2 time points

- antenatal surveillance sample –**all** women
- Taken at result visit
- antenatal surveillance sampling kits – stock provided/prepaid envelope posted **directly** to PHE Colindale
- delivery - **higher infectivity women only**
- hep B HBIG delivery suite boxes contain kits for maternal sample, DBS and HBIG



# Virus mutation???

- Hepatitis B surface antigen (HbsAg) formed of many loops
- antibody generated following immunisation recognises these loops and binds to it
- But the virus can introduce an amino acid change within these loops, resulting in shape changes
- the antibody generated will not recognise the shape and possibly will allow virus to escape the vaccine
- 'vaccine escape mutants' can result in infections
- the antenatal surveillance sample will check if these amino acid changes are present
- giving antiviral treatment may protect baby



# Baby

assessing markers of HBV infection in baby at 2 time points

- at birth – HBV DNA via Dried Blood spot (DBS) higher infectivity only



- NB – Not subject to NBS standards and women must be told of importance of having NBS
- 12 month DBS

# Key messages- generic pathway



- check all results at every contact
- management of women who decline in a timely manner
- care of women who miscarry after screening
  - trust process in place
- triage into clinical care and multidisciplinary working
- work as a team- involve members of MDT
- support improvement of screening and follow up on delivery suites

# Key messages- antenatal



- screening team co-ordinate care package from start to finish
- all women screening positive including known must be seen
- antenatal surveillance sample sent to PHE Colindale- result will come back to screening team for forwarding to specialist team
- never presume known positive women understand their condition and the care they will need to protect their babies
- information given and consent recorded on data collection and national surveillance
- Notify H/V
- third trimester review- Empowering parents -
  - important to individualise care for each woman
  - check understanding of care at delivery and beyond
  - repeat info about schedule, registration of birth and with GP

# Key messages- delivery and postnatal

- Inform screening team of admission
- check every woman's results on admission
- offer and recommend screening if no reliable laboratory results in labour
  - expedite lab testing and reporting
  - notify screening team to follow up
- HBIG box and paperwork back to screening team to complete the notifications to primary care H/V ,CHIS and ISOSS

**THERE IS NOTHING ROUTINE ABOUT NEONATAL IMMUNISATION:  
IT IS URGENT POST EXPOSURE TREATMENT**

# HBIG – ordering update

- Ordering as before – trust process-but if you don't order – find out who does
- HBIG now delivered via cold chain to pharmacy (national process )
- Info with HBIG states pharmacy should inform screening team
- As the HBIG sent out – Screening Team will receive HBIG box
- Screening team match HBIG to the box and store as trust process
- Record on maternal record/checklist where this is !



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Integrated Screening Outcomes Surveillance Service

# Integrated Screening Outcomes Surveillance Service

Hepatitis B data collection for women who book or screen positive from the 1<sup>st</sup> April 2021 onwards

All women who screen positive or who are known to be living with hepatitis B to be reported to ISOSS

The green card will have all 3 infections on and will limit duplication for women with coinfections

# Integrated Screening Outcomes Surveillance Service



- Notification form very similar to existing forms
  - Maternal demographics
  - Social circumstances
  - Obstetric history
  - Pregnancy details
  - Screening info
  - Screening assessment visit (in line with pathway)
  - Blood results
  - Clinical management
- 2 different outcome forms (automatically generated depending on info submitted on notification form)
  - Minimal info for lower infectivity
  - More detail for higher infectivity (following the pathway)
- Forms will be available on the UCL ISOSS website to look at from Feb/March

# Next steps

- Resources now available
- <https://www.gov.uk/government/collections/infectious-diseases-in-pregnancy-screening-clinical-guidance#hepatitis-b:-information-on-antenatal-screening-and-neonatal-immunisation>
- Jan- March – Trusts review pathways and processes – be aware this is commissioned and will be embedded in QA assessments
- Antenatal surveillance kits sent to trusts ( stock based on prevalence)
- April 1<sup>st</sup> 21– all women screening positive for hep B commence improved pathway with notification to ISOSS

