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NHS Sheffield Clinical Commissioning Group

Business Case for A new Local Enhanced Service for Hepatitis B Screening and vaccination in the Sheffield Roma Slovak Community

Governing Body meeting

5 December 2013

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Sponsor	Tim Furness, Director of Business Planning and Partnerships

Key messages

This paper proposes a local service to screen and vaccinate members of the Sheffield Roma Slovak community against Hepatitis B, which is a population that has a high prevalence of Hepatitis B and poorer health than the general population in Sheffield.

The business case has been developed following discussion at the CCG Governing Body in July 2013, which recognised the urgent health need and requested that a proposal be developed. It is unclear whether NHS England or CCGs have statutory responsibility for local screening and vaccination services and it has been agreed with the NHS England Area Team that the CCG will accept responsibility provisionally, with funding to be reimbursed by NHS England if it is established that the commissioning responsibility is with that body.

Approving this proposal would incur limited costs in 2013/14, but would represent a commitment of £134k (based on the estimates of take up) against resources in 2014/15 and would therefore be establishing this service as a priority in our plans for next year.

Assurance Framework (AF)

How does this paper provide assurance to the Governing Body that the risk is being addressed?
This proposal does not directly address any of the risks identified in the AF, but it does contribute to strategic objective 3, 3. to work with Sheffield City Council to continue to reduce health inequalities in Sheffield.

Is this an existing or additional control:
Additional

Equality/Diversity Impact

Has an equality impact assessment been undertaken? YES - See attached

Which of the 9 Protected Characteristics does it have an impact on?
Race - this programme will improve the health outcomes for a group of the community which experience a number of substantial health inequalities.

Public and Patient Engagement
Local experience reported by Page Hall and Clover Group practices suggests that this proposal would be well received by the Roma Slovak community.
Recommendations
That Governing Body considers the business case and determines whether to approve it, recognising that this will represent a commitment against resources for 2014/15.

Business Case for A new Local Enhanced Service for Hepatitis B Screening and vaccination in the Sheffield Roma Slovak Community

1 CET Portfolio Lead: Tim Furness
Lead Clinician (s): Dr Margaret Ainger
Lead Manager(s): Diane Mason

2 Title of proposed service development/change/de-commissioning:

A new Local Enhanced Service for Hepatitis B Screening and vaccination in the Sheffield Roma Slovak Community

Preventing and treating Hepatitis B is an urgent and pressing issue for primary health services providing care to the Sheffield Roma Slovak Community. Screening and vaccination for this infectious disease would prevent the spread, ill health effects and mortality associated with this condition. The population group already experiences significantly poorer health than the general Sheffield population and so a screening programme tackles health inequalities. This proposal represents a pragmatic response to reaching a population that can be difficult for services to engage with.

This proposal is for a mainstream primary care based service targeted to a section of the population with high prevalence for the new arrivals into Sheffield (estimated at 1,200 per annum). The proposal is to screen and vaccinate both children and adults. Adults are included because the most common routes of transmission of Hepatitis B are from infected mothers to babies or via sexual contact or use of contaminated needles. We are also proposing a catch-up service for the existing population (estimated at 3,000) as a 1 year pilot, this will be evaluated after 9 months of the commencement of the service with appropriate recommendations made for continuation at that time.

This is a priority for funding because it is about an infectious disease in a deprived population already experiencing poor health. Failure to screen and vaccinate will lead in the short term to higher numbers of this population being infected with hepatitis B and/or being undiagnosed and therefore untreated and in the longer term a proportion developing liver disease with its ill health and financial implications. The quicker this proposal can be agreed and implemented the greater the opportunity to reduce the spread and implications of Hepatitis B.

A local enhanced service is required because the prevalence of Hepatitis B in this population is such that it would not be reasonable to expect this to be included in the GMS services offered by Practices and reimbursed through the 'global sum'. The GPC guidance (Focus on hepatitis B immunisations August 2012) states that providing vaccination against Hepatitis B for patients at lifestyle or medical risk is not part of the additional service component of the global sum. It states that it is recommended that practices provide this service and request a LES if appropriate.

This business case has been developed following discussion at the CCG Governing Body in July 2013, which recognised the urgent health need and requested that a proposal be developed. It is unclear whether NHS England or CCGs have statutory responsibility for local screening and vaccination services and it has been agreed with the NHS England Area Team that the CCG will accept responsibility provisionally, with funding to be reimbursed by NHS England if it is established that the commissioning responsibility is with that body.

3 Outline of the proposal.

What is the proposal intended to achieve (e.g. savings, health gain, quality improvement – with reference to CCG priorities)

Aim of the proposal:

Hepatitis B is an acute viral infection of the liver. It is a blood borne, transmitted either at birth (from infected mothers to babies) or via sexual contact or use of contaminated needles. The risk of Hepatitis B is exacerbated by people living in deprived circumstances in overcrowded homes. Individuals can carry (and pass on) the infection throughout their lives, especially if they are children when they are infected. Around 20% of people with chronic hepatitis B will go on to develop scarring of the liver (cirrhosis), which can take 20 years to develop, and around 1 in 10 people with cirrhosis will develop liver cancer.

Hepatitis B is preventable through an effective vaccine. Vaccinating those at risk of Hepatitis B is crucial to prevent ill health, to reduce transmission of this infectious disease and to minimise the costs to health services of expensive treatments for cirrhosis and liver cancer.

Prevalence of Hepatitis B in the Sheffield Roma Slovak population has been shown to be high through work done in Page Hall Medical Centre (at around 9.4% compared to 0.3% for the general population[1]). The World Health Organisations advocates that vaccination strategies are cost effective even in *low* prevalence populations. This proposal is for a community with a *high* prevalence of Hepatitis B.

Funding Hepatitis B screening and vaccination for the Sheffield Roma Slovak Community will reduce ill health, address health inequalities and reduce subsequent treatment costs for liver disease.

This proposal intends to address the following CCG priorities (extract from the 4 CCG priorities published on the website)

1. To improve patient experience and access to care *(through providing a mainstream service for a vulnerable population group preventing future ill health)*
2. To improve the quality and equality of healthcare in Sheffield *(for a deprived group with worse than average health outcomes)*
3. To work with Sheffield City Council to continue to reduce health inequalities in Sheffield *(the Roma Slovak community experience poor health and this issue has been highlighted by the Director of Public Health)*
4. To ensure there is a sustainable, affordable healthcare system in Sheffield *(introducing screening will potentially reduce the need for future, more costly treatment for the target group)*

How will this be achieved?

Reducing the spread of Hepatitis B will be achieved through a screening and vaccination programme offered through a Local Enhanced Service with any Sheffield Practices who have a significant number of Roma Slovak patients currently registered with them.

[1] Data from UK antenatal screening programme.

The Local Enhanced Service will include:

- Screening all newly registered Roma Slovak patients for Hepatitis B, (approx. 1,200 per year)
- Catch-up programme to screen the patients previously registered (predicted to achieve about 10% take-up rate- approx. 300)
- Vaccinate patients with no immunity against Hepatitis B (screening and first vaccination will be given together where possible).
- Advice to patients testing positive for Hep B. (information from www.hitsheffield.org.uk is available in Slovak)
- Referral into secondary care for those diagnosed with chronic disease

The attached flow charts illustrate how the service will work.

While the number of new entrants to Sheffield from the Roma Slovak community have been increasing over the last few years it is difficult to predict how many there may be during 2013/14. If the number were the same as during 2012 this would be around 1,200 new arrivals. There will also be a 'catch up' element of the work targeting 10% (approx. 300) of the existing practice population per year, which is estimated at 3,000.

Based on experience to date in Sheffield with this community our estimates are that:

- 9.4% of the population would be diagnosed with chronic disease and be referred (141 patients on a screened population of 1,500)
- Of this 9.4% it is expected that 50% will take up an outpatient first and follow up appointment at Sheffield Teaching Hospital
- 29% (based on figures from Page Hall surgery) will be immune having previously been exposed to Hep B and would be at no further risk of disease or spread to other people.
- The remaining 63% would require Hepatitis B vaccine which is 90% effective.

This is also within the context that in Slovakia children are vaccinated against Hep B and so families travelling frequently to and from Slovakia may have partly completed vaccination schedules.

There is a need and intention to look at how this issue can be developed further with e.g. employment of linkworker, development of contract tracing service etc. There also may be opportunities to link this work to other developments such as Local Authority bids for 'Roma Slovak community mediators' funding.

4 Clinical, patient, public, stakeholder views

Clinical – this proposal is put forward by Dr Margaret Ainger and is supported by the GPs in practices affected.

The overall implications for secondary care services and wider cost implications have been built into the financial modelling. Infectious disease and hepatology colleagues are supportive of this proposal.

Patient- local experience reported by Page Hall and Clover Group practices suggests that this proposal would be well received by the Roma Slovak community.

Public – Hepatitis B is a highly infectious disease. Vaccinating and treating this condition in the Roma Slovak community will also contribute to preventing Hepatitis B in the wider population in Sheffield.

Stakeholders – Dr Jeremy Wight the Director of Public Health is supportive of this proposal Public Health England Health's Local Health Protection Team are supportive of this proposal This work can be fed into to wider work within Sheffield City Council about the provision of services to the Roma Slovak population.

5 What is the Evidence Base for this proposal?

Data from Page Hall GP practice, where a large number of Roma Slovak adults have been screened shows that 29% are Hepatitis core antibody positive (i.e. they have been infected with Hepatitis B at some point) and 9.4% have chronic Hepatitis B infection.

NICE guidance states that all people from communities of high prevalence (2% or greater) should be offered screening for Hepatitis B and appropriate follow up.[2]

The WHO states that Hepatitis B vaccination saves both money and lives and that universal vaccination strategies are cost-effective even in countries with a low prevalence.[3]

Screening for Hepatitis B would be in keeping with both NICE and WHO recommendations as well as the Foundation for Liver Research[4] and the British Liver Trust, who advocate reaching out to communities of high prevalence to facilitate screening and management[5].

A national antenatal Hepatitis B screening programme has been in place since 2000. The proportion of women who test positive was 0.42% in 2001 (NICE[6]).

The general poor health of this community has been highlighted in a number of documents and work with Roma Slovak communities is made more difficult by communication difficulties and the population being highly mobile[7].

NICE have concluded there is moderate evidence that community based screening and treatment is cost effective.[8]

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[2] Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection. NICE public health guidance 43. December 2012.

[3] http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index4.html#world

[4] Hepatitis B: Out of the shadows. A report into the impact of Hepatitis B on the nation's health. Foundation for Liver Research. October 2004.

[5] www.britishlivertrust.org.uk. Accessed 23.01.13.

[6] Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection. NICE public health guidance 43. December 2012.

[7] G Gill.(2009) The Health Needs of the Roma Slovak Community in Sheffield. Community Practitioner

[8] Jones et al (2012) A systematic review of the effectiveness & cost-effectiveness of interventions aimed at raising awareness and engaging with groups who are at an increased risk of hepatitis B and C infection. Centre for Public Liverpool John Moores University conducted for NICE review on Hepatitis B and C ways to promote and offer testing.

6 Financial Summary

Implementation Date January 2014 at the earliest ……

This service based on the projected activity of 1,500 screens will require a recurrent investment of £134k. There are no savings associated with the project as any savings would be realised in the very long term. The cost per patient is approx. £89 per annum.

Range of activity and costs – whilst the business case is based on 1,500 screens, it is difficult to predict the actual number. The likely activity range is 1000 – 2000 screens which would result in a cost range of £89k - £178k.

Service	Provider	Activity	Cost
			£000
LES costs			
Screen	GP practices	750	6.8
Vaccine	GP practices	3,765	22.9
Advice to positive patients	GP practices	142	8.9
Other Costs			
Interpreter time	SCAIS		11.8
Microbiology testing on screens	STH	1,350	13.7
Vaccine prescribing costs	PPA		37.3
Advice leaflets	CCG		2.0
Referral to Infectious Diseases for positive patients	STH		30.4
Total			**133.8**

Which QIPP line does this relate to? It is not QIPP ……..

Which contract(s) does it release money from? No savings…….

How? (e.g. PbR rules, notice on contract) …….

7 How do we know this gives the best possible value for money?

Needs to be a (brief) option appraisal here – i.e. what else has been considered (do nothing, put out to tender as an overall service, ask secondary care etc) i.e. why is this the best solution to this identified problem.

Based on the Page Hall data, it is estimated that around 240 people of the estimated 3,000 current Roma Slovak community could currently have chronic Hepatitis B infection. Of these around 72 are likely to develop liver failure from which 18 will die within 5 years of diagnosis and between 12 and 24, hepatocellular carcinoma which has an extremely poor prognosis (average survival from diagnosis of 6 months)[9].

[9] Stuart, K E et al. Primary Hepatic Carcinoma, Medscape, May 2012

This screening programme will lead to reduced morbidity (particularly over the life course for children with Hepatitis B) and mortality.

This is likely to be cost effective. Screening and early diagnosis will lead to cost savings if it enables treatment to be started that prevents (in at least some patients) deterioration and more expensive treatment being needed later on.

A number of studies have shown that screening is cost effective in populations where prevalence of Hepatitis B is above 2%[10]. Prevalence in the Sheffield Roma Slovak population is estimated at 9.4% based on work in the Page Hall practice.

The service can only be delivered by the practices that register these patients. The Roma Slovak community are fairly difficult to reach, they usually register with the practice in order to claim entitlement to benefits and it is at this first visit that arrangements are made to screen and vaccinate the patients. It is not therefore proposed to put this service out to tender.

The costings have been calculated based on the timed input per patient required at each stage of the pathway. Advice from Dr Margaret Ainger and colleagues has ensured that the pathway is fully and appropriately costed. The LES tariff has been tested with a locality manager.

8 How will we know if the proposal has succeeded?

The following performance measures will be used

- *Numbers screened*
- *Numbers vaccinated*
- *Percentage of target population screened as a proportion of the newly registering Roma Slovak population of a. the practice and b. Sheffield*
- *Proportion of those screened who are diagnosed as having chronic hepatitis B and referred*
- *Vaccination uptake rate in those screened who have been identified as having no immunity to Hepatitis B*
- *Evaluation of the experience of practices and patients in starting and running this service including lessons learnt for a. future work with this population group and b. future establishment of local screening programmes*

[10] Wong et al (2011) Cost effectiveness of screening immigrants for Hepatitis B Liver International , Eckman et al (2011) The cost effectiveness of screening for chronic Hepatitis B infection in the United States Clinical Infectious Diseases.

8 Outline how the proposal will be implemented, including contractual and/or procurement issues, and risks to success.

Operational issues

It is proposed that a LES will be offered to all GP practices. There will be 3 elements to the LES - a tariff per screen for an adult, a tariff per vaccine for children and adults and a tariff per an advice package for patients testing positive. It is anticipated that the practices that will take up the LES seeing significant numbers of Roma Slovak patients are Darnall Health Centre, Upwell Street, Clover Group, Page Hall, Pitsmoor and Burngreave. Operational detail would be for practices to decide based on good knowledge of, and relationships with, their Roma Slovak patients.

As detailed in Section 2 – the service will apply to all new arrivals on a recurrent basis, the service will apply to the existing population on the basis of a 1 year pilot with an evaluation at 9 months

Whilst local experience suggests the Roma Slovak are generally a cooperative community, they are a group with multiple needs both medical and social. It should therefore be borne in mind that there may be individuals within this group who are harder to reach consistently to deliver a full vaccination course or other required input.

Clinical issues

Hepatitis B vaccination is safe, generally well tolerated[11] and effective in 90% of cases. A standard vaccination course involves three doses, each given a minimum of one month apart. The Roma Slovak are a highly mobile community and it should be noted that if vaccination courses are not completed, full immunity may not be incurred. However it is important to note that two or even one dose will give some protection against Hep B and will therefore be worthwhile.

Timescales

It is proposed that this service commences as soon as possible – likely date of January 2014.

9 Equality Impact Assessment

See attached EIA

10 Sustainability Impact

Please describe any impact on carbon management

Management of chronic Hepatitis B and its complications is more intensive than prevention through vaccination in terms of travel required by patients, hospital visits and stay and medication usage and prevention of more serious complications through early treatment. It is therefore likely that this proposal will be carbon and financial cost saving in the long term.

[11] The Green Book. Department of Health. www.immunisation.dh.gov.uk/category/the-green-book. Accessed 23.01.13.

11	Any other relevant information

Please attach any supporting information, keeping the main form (i.e. the above) to a maximum of five sides of A4

Hepatitis B screening and vaccination for Slovak Roma population in Sheffield.

1/Start standard schedule of hepatitis B vaccination if history of incomplete vaccination (DOH Green Book) and
2/ Screen for hepatitis B.

Age < 16

Send blood sample as for >16 Child to attend Sheffield Children's Hospital. This would be age appropriate, suitability for venous access should be individually assessed by the clinician. Dry Blood Spot sampling is also an option.*

Age >16

Send 1 clotted venous blood sample to Virology.
Request 'high risk baseline prevaccination screen'-this requests
1.Hepatitis B surface antigen (HBsAg)
2.Hepatits B surface antibody (HBsAb)

Is the patient hepatitis B surface antigen positive ?

Yes

Contact patient and arrange appointment to inform of likely hepatitis B diagnosis.

Repeat bloods to confirm diagnosis add LFT and check for hepatitis A immunity.

Refer patient to Infectious Diseases Unit or Hepatology.
Ensure Health Protection England are notified.

Give lifestyle advice, including safe sex and alcohol recommendations.

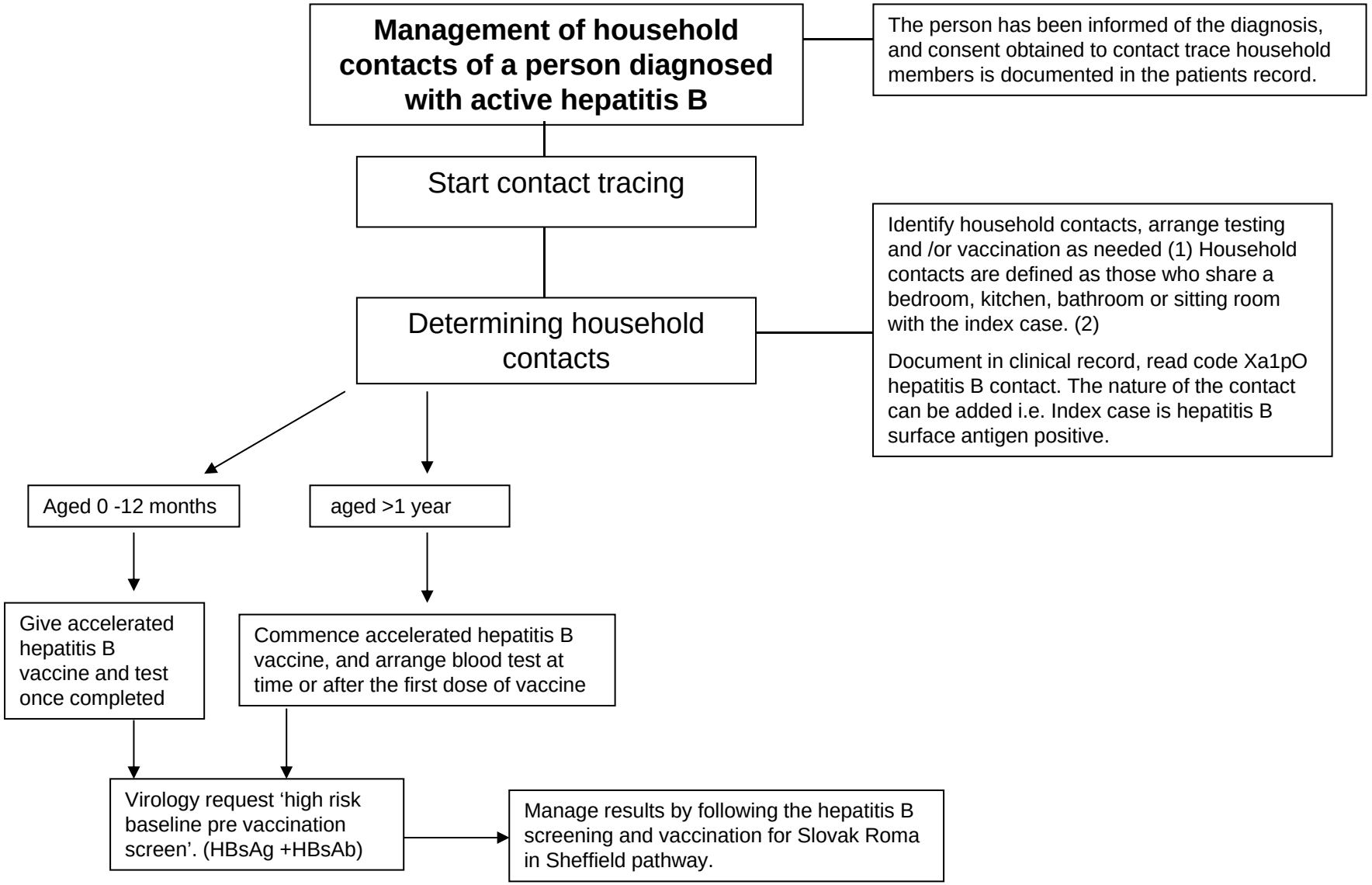
Give hepatitis B information leaflet in English and Slovakian.

Explain that all household contacts should be tested and vaccinated if not immune, they should attend their own GP for this. (See pathway for management of household contacts)
Household contacts should receive the accelerated Hepatitis B schedule if non-immune.

** See additional notes for babies born to hep b su ag positive mothers

No

Follow Interpretation of hepatitis B results pathway.
If Immune inform patient and stop vaccination schedule.
If non – immune continue vaccination schedule.


Management of household contacts of a person diagnosed with active hepatitis B
The person has been informed of the diagnosis, and consent obtained to contact trace household members is documented in the patients record.
Start contact tracing
Determining household contacts
Identify household contacts, arrange testing and /or vaccination as needed (1) Household contacts are defined as those who share a bedroom, kitchen, bathroom or sitting room with the index case. (2)
Document in clinical record, read code Xa1pO hepatitis B contact. The nature of the contact can be added i.e. Index case is hepatitis B surface antigen positive.
Aged 0 -12 months
aged >1 year
Give accelerated hepatitis B vaccine and test once completed
Commence accelerated hepatitis B vaccine, and arrange blood test at time or after the first dose of vaccine
Virology request 'high risk baseline pre vaccination screen'. (HBsAg +HBsAb)
Manage results by following the hepatitis B screening and vaccination for Slovak Roma in Sheffield pathway.

Interpretation of hepatitis B results

Hepatitis B surface antigen positive Hepatitis B core antibody positive Hepatitis B surface antibody <10	Chronic Infection	Refer patient to Infectious diseases unit or Hepatology. Test / vaccinate contacts
Hepatitis B Surface antigen positive Hepatitis B core antibody negative Hepatitis B surface antibody < 10	Unclear	Unusual. Refer to the clinical comment on virology report for interpretation and discuss with medical virologist if required (0114 2266477).
Hepatitis B surface antigen positive Hepatitis B core antibody positive Hepatitis B surface antibody <10 Hepatitis B core IgM positive	Acute Infection	Flag to GP/PN – assess need for referral. Telephone public health (notifiable infection) Test and vaccinate contacts
Hepatitis B surface antigen negative Hepatitis B core antibody positive Hepatitis B surface antibody >10	Past Infection	Inform patient of past history of infection, no other action needed. Household and sexual contacts will need testing.
Hepatitis B surface antigen negative Hepatitis B core antibody positive Hepatitis B surface antibody <10	Unclear	Refer to clinical comment on virology report and discuss with medical virologist if required
Hepatitis B surface antigen negative Hepatitis B core antibody negative Hepatitis B surface antibody10-100iu	Partial response to vaccination	Boost Hepatitis B vaccine
Hepatitis B surface antigen negative Hepatitis B core antibody negative Hepatitis B surface antibody >100 iu	Full response to vaccination	No action required. Single booster required 5 years after primary vaccination course.

Ann Gregory 8/13 and HIT Sheffield.Org (3)

References and notes.

- 1/ Hepatitis B**:** the green book, chapter 18, Updated 19 April 2013. Public Health England.
- 2/ Hepatitis B and C - ways to promote and offer testing. Nice 12 December 2012.
- 3/ http://hitsheffield.org

* Dry Blood Spot kits are available for local testing.

** Babies born to mothers of hepatitis B su ag positive patients are screened and vaccinated in accordance with DOH Green Book and local procedures.

Thanks to Dr Helena Ellam and Dr Raza from Virology at Northern General Hospital Sheffield.

Ann Gregory. Practice Nurse, Page Hall Medical Centre. anngregory@nhs.net

NHS
Sheffield Clinical Commissioning Group

NHS Sheffield CCG Equality Impact Assessment 2013

Title of policy or service	Business case for Hepatitis B screening in the Sheffield Roma Slovak Community	
Name and role of officers completing the assessment	Ruth Granger Health Protection Manager Public Health Sheffield City Council	
Date assessment started/completed	October 8th 2013	

1. Outline	
Give a brief summary of your policy or service • Aims • Objectives • Links to other policies, including partners, national or regional	This proposal is to fund a new service within primary care to screen newly registering patients for Hepatitis B. The need for this service has been identified through work in one practice which has identified that levels of Hepatitis B exceed WHO criteria for screening programmes (level of Hepatitis B is 8% compared to 0.3% in the general population source: antenatal data) The objective is to identify those members of the Slovak Roma community who do not have immunity to Hepatitis B and to vaccinate them. This specifically tackles health inequalities in Sheffield.

2. Gathering of Information This is the core of the analysis; what information do you have that indicates the policy or service might *impact on protected groups, with consideration of the General Equality Duty*.					
	What key impact have you identified?			**What action do you need to take to address these issues?**	**What difference will this make?**
	Positive Impact	**Neutral impact**	**Negative impact**		
Human rights	√				
Age	√				If this programme is targeted initially at children it will have a positive impact on the life course implications of Hepatitis B infection
Carers		√			
Disability		√			
Sex		√			
Race	√				This programme will improve the health outcomes for a group of the community which experience a number of substantial health inequalities.
Religion or belief		√			
Sexual orientation		√			
Gender reassignment		√			
Pregnancy and maternity		√			
Marriage and civil partnership (only eliminating discrimination)		√			
Other relevant group		√			

Please provide details on the actions you need to take below.

3. Action plan			
Issues identified	**Actions required**	**How will you measure impact/progress**	**Timescale**	**Officer responsible**
Positive impact for Roma Slovak Community	Implement the screening programme and subsequent vaccination/referral secondary care in order to reduce the prevalence of Hepatitis B infection in the Roma Slovak Community	By looking at data on vaccination rates across the whole Roma Slovak population. Ultimately we will be looking at reducing the rates of Hepatitis B in the Roma Slovak population. This could be measured through antenatal data.	Implement programme following agreement from CCG, collect data throughout the programme and present evaluation report December 2014	
Potential positive impact first on children	Need to identify whether we will target children first if this is the case it will have an earlier impact on children	By looking at data on vaccination rates in children compared to other ages in the Roma Slovak population	As above	

4. Monitoring, Review and Publication			
When will the proposal be reviewed and by whom?			
Lead Officer	**Margaret Ainger**	**Review date:**	**December 2014**