August 2012

GPC

General Practitioners Committee

Focus on hepatitis B immunisations

Guidance for GPs

BMA

Focus on hepatitis B immunisations

Introduction

The clinical benefits of hepatitis B immunisation are clear, but there is less clarity in the understanding of the regulations covering hepatitis B immunisation. This is manifested by some practices being pressurised by their Primary Care Organisations (PCOs) into giving hepatitis B immunisation for travel solely as a private service and by some practices charging for occupational hepatitis B.

GPs are often requested to give hepatitis B immunisation covering three broad areas:

- for **travel**
- for **occupational health**
- for **medical reasons** (e.g. IV drug use for renal disease)

This paper aims to deal with the breadth of hepatitis B immunisation; to clarify the circumstances where charges can be made and where active attempts to encourage immunisation ought to be made.

Travel

Hepatitis B immunisation for travel is not remunerated by the NHS as part of additional services. However, the regulations do not impose any circumstances or conditions as to when hepatitis B immunisations should be given on the NHS or as a private service. This causes confusion and the ambiguity stems from the regulations regarding the charging of patients that are registered with the practice. Schedule 5 of *The National Health Service (General Medical Services Contracts) Regulations 2004* of[1] states that:

> *"The contractor may demand or accept a fee or other remuneration…. for treatment consisting of an immunisation for which no remuneration is payable by the Primary Care Trust and which is requested in connection with travel abroad"*

This wording leaves the decision as to whether the practice levies a charge or not to the discretion of the practice, rather than the PCO or commissioning group. **Technically the practice *may* charge any patient a private fee for hepatitis B for travel, as long as it is not combined with hepatitis A, which must be given on the NHS.**

Ultimately it is up to the practice to decide when and if it is clinically appropriate to use the combined immunisation, such as where there is high risk of infection or a barrier to compliance. Practices therefore need to be clear about their policy to avoid falling foul of regulations that prohibit charging NHS registered patients. The service must be provided either entirely as an NHS process or entirely as a private service. For further information how to provide this service, please see Focus on travel immunisations.

[1] http://www.legislation.gov.uk/uksi/2004/291/schedule/5/made

Some confusion may also be caused by the advice given in the 'Green Book' (*Immunisation against infectious disease*[2]) and the former 'Red Book' (*Statement of fees and allowances payable to general medical practitioners in England and Wales*[3]).

In the Green Book, hepatitis B for travel is indicated for:

"*People travelling to or going to reside in areas of high or intermediate prevalence…who place themselves at risk when abroad…..include sexual activity, injecting drug use, undertaking relief aid work and/or participating in contact sports…. Individuals at high risk of requiring medical or dental procedures in such countries should therefore be immunised*". (Full text in appendix 1)

Giving hepatitis B immunisation to patients who are travelling but where it is not indicated in the Green Book is inappropriate and wasteful of resources, however funded.

According to the "Red Book" (paragraph 44.5), 'vaccines [including hepatitis B]..which are supplied and personally administered under the arrangements in Regulation 19(b) a practitioner may claim payment whether or not he or she is a dispensing practitioner'.

Summary

- **As a practice you may choose whether to give single hepatitis B immunisation for travel on the NHS or privately. Combined hepatitis A and B immunisations must always be given on the NHS**.
- the GMS regulations (2004) state that practices **may charge** for hepatitis B immunisations.
- the Green Book advises **what** to give and **when**.
- the former "Red Book" advised what services were **funded by the NHS**.

Please refer to *Focus on travel immunisations*[4] for further information.

Occupational health

This section replaces and updates the former guidance *Hepatitis B vaccination for employees at risk* (2005).

It is GPC's view that **there is no obligation under the GMS regulations for a practice to provide occupational health services for patients**. That responsibility rests with the employer under Health and Safety Legislation, and in occupations where there is a risk to health from any form of work related infection it is the employer's duty to assess that risk and, if present, to protect the workforce. Examples of the groups that are considered at occupational health risk and require hepatitis B immunisation is set out in Chapter 18 of the Green Book (see extract in Appendix 2).

[2] http://immunisation.dh.gov.uk/category/the-green-book/
[3] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007917 (The Red Book is not available to download electronically)
[4] http://bma.org.uk/practical-support-at-work/doctors-as-managers/managing-your-practice/focus-travel-immunisation

The same applies for healthcare students who often request a hepatitis B immunisation prior to, or on entering, a course. **Medical Schools are legally responsible for providing a full occupational health service to their students and applicants.** This should include appropriate training for example in risk reduction and coping with needle stick injuries. By providing a hepatitis B immunisation, a GP could place inexperienced healthcare students at risk by providing a false sense of security and potentially exposing them to clinical risk of other blood borne infections, including HIV and hepatitis C, before they have received appropriate training.

Model letters, which can be provided to patients who request a hepatitis B immunisation for occupational health purposes, or to the employers, are available in Appendix 3.

It is worth noting that **a practice can choose to enter into a private contract with an employer or medical school to provide this service,** either to a group of employees or for a single employee. The practice would need to carefully consider the nature of the service required for the employees e.g. whether a full occupational health assessment would be necessary. This will include necessary blood tests (see question 11 of the FAQs at the end of this document).

If a practice decides to enter into a contract to provide such a service, it cannot accept a fee from the registered patients, only from the employer. This is because the exceptions to the ban on charging for GMS set out in Schedule 5 Regulation 24 of the GMS regulations, says:

1. The contractor may demand or accept a fee or other remuneration -

> *(b)'from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take.*'

Based on this legislation, a practice could enter into a contract with an employer for the provision of the hepatitis B immunisation, even if it resulted in treating patients registered with the practice.

One area of difficulty for practices is where there seems to be an occupational health risk but where there is no employer to assess and manage this. An example is in the case of a care worker or health worker who is self employed and works through agencies. Practices may wish to refer such patients to other practices where they can be offered this occupational care as a private service (as the self employed are their own employer and any costs are a legitimate business expense). An alternative is that the practice decides to provide the immunisation as an NHS service for free and claim reimbursement of the vaccine costs. Both routes are acceptable and will depend on the volumes involved and the practice's own agreed policy. Note that practices cannot under any circumstances charge their NHS patients for the occupational service or the hepatitis B vaccine provision.

Lifestyle risk or medical conditions (or 'patients at risk')

Patients whose lifestyle or medical conditions put them at risk of hepatitis B infection, including family members of those who have already contracted hepatitis B, also need immunisation.

Certain lifestyles will put some people at more risk of infection and practices can only act upon patients giving the information. Examples of this may include tattoo parlour workers (difficulty arises from self-employed tattoo parlour owner versus occupational health aspects of employee working), or family members of intravenous drug users and prostitutes.

The judgement as to whether these are lifestyle risks or occupational risks (in the case of the tattoo shop owner or prostitute) is relevant to a strict interpretation of GMS obligations. However, practices are, once again reminded of the primacy of care for the patient and Good Medical Practice.

Giving hepatitis B for those at lifestyle or medical risk is not part of the additional service component of the global sum. Practices are only obliged to offer this service as part of good medical practice and therefore under GMS in clinically appropriate situations, which are determined on an individual basis. However, case-finding and call and recall would be more of a public health issue, and might be better served by a LES. The GPC would encourage PCOs and Clinical Commissioning Groups to develop such LESs.

In short, providing hepatitis B immunisations for patients at risk is not a requirement of the GMS contract, but it is recommended that practices provide this service and request a LES if deemed appropriate.

Further reading

Green Book (*Immunisation against infectious disease*):
http://immunisation.dh.gov.uk/category/the-green-book/

"Red Book" (*Statement of fees and allowances payable to general medical practitioners in England and Wales*) is unavailable online.

Focus on travel immunisations
http://bma.org.uk/practical-support-at-work/doctors-as-managers/managing-your-practice/focus-travel-immunisation

Focus on vaccines and immunisations
http://bma.org.uk/practical-support-at-work/doctors-as-managers/managing-your-practice/focus-vaccinations

Hepatitis B immunisations – Q&A

Hepatitis B immunisation for travel

1. Can I give hepatitis B immunisation for travel on the NHS?

Yes. The GMS regulations do not prohibit NHS provision and it can be given on the NHS *in certain circumstances* and the individual practice can decide how to give their patients hepatitis B immunisation using their clinical judgement. However, it is common practice to give this immunisation privately (for further information see *Focus on travel immunisations*).

2. Can I charge for giving hepatitis B immunisation for travel?

Yes. NHS Regulations (Schedule 5 regulation 24) specifically exempt the giving of immunisations for travel from the 'ban' on charging patients on your registered list for medical services. This ability to charge is limited to immunisations where there is no reimbursement available from the PCO.

As single hepatitis B immunisations do not attract such remuneration you may charge the patient, as long as it is not combined with hepatitis A, which must be given on the NHS.

3. Can I charge for a private immunisation despite the Green Book recommending hepatitis B immunisation?

This is an area that is often misunderstood because the Green Book advises what immunisation to give, whereas the former "Red Book" advised what services were funded by the NHS.

Any single hepatitis B immunisation for travel can be given privately (but not in combined vaccine). If there is a lifestyle issue then this is dealt separately in the section below; however if the immunisation is given for travel alone then the practice may charge - whatever the Green Book may say.

4. Can I charge when hepatitis B is in a combination immunisation?

If the other immunisation in that combination is reimbursed then you cannot charge the patient and it has to be given on the NHS. As the only commercially available combination for hepatitis B is with hepatitis A then this immunisation must be given on the NHS.

5. What if there is a lifestyle and travel issue?

If there is a lifestyle risk then you cannot charge. For example, a man who has sex with another man should receive hepatitis B protection as a lifestyle issue. The fact that the patient has, for example, presented at the travel clinic due to their trip to a Gay Pride festival overseas does not negate the fact that they have a lifestyle indication and so must receive the immunisation as an NHS service. You cannot charge a private fee.

6. Can I use a combination immunisation to avoid having to charge the patient?

If a travel risk assessment highlights that both of these immunisations are required, then the practice may decide that the benefits of fewer injections and increased compliance may make this a sensible alternative.

However, it is unacceptable to subjugate responsible clinical behaviour in order to use an inappropriate combination just because that combination has to be given as an NHS service. Patients who have had hepatitis A immunisation in the past should never be given the combined immunisation just because they will not have to pay. After all, charging the patient should not be a barrier to acceptability, as the monovalent hepatitis B can be given on the NHS too (see above).

Hepatitis B immunisation for occupational health

7. Whose responsibility is it to provide hepatitis B immunisation for occupational health?

If the patient is employed then it is the duty of their employer to do a COSSH[5] risk assessment for hepatitis B. If that risk assessment indicates that the employee is at risk then the employer is responsible for arranging immunisation. This might be with their own occupational health service (particularly appropriate for NHS staff) or with a contracted private provider of occupational health services. If a patient is self employed then the responsibility lies with the patient.

8. Is the practice obliged to give hepatitis B immunisation for occupational health?

No. There is no obligation and the patient should be advised that it is the responsibility of their employer to organise hepatitis B immunisation. The employer or medical school can enter into a private contract with the practice to provide this service if they choose, or make alternative arrangements. Registered patients who are self-employed may be referred to an alternate provider as there is no NHS provision or funding.

9. Can the practice charge for hepatitis B immunisation for occupational health?

You cannot charge the patient if they are registered with the practice. If the patient is not registered then the immunisation can be given privately and be charged for. If the patient's employer states that their risk assessment indicates that their employee (your patient) is at risk of hepatitis B and requests that the practice provide such an immunisation, then the practice can choose to do so and charge the employer. It must be clear that this is an arrangement between the practice and the employer and that the patient is not being charged. The vaccine should not be provided on FP10 or FP34 unless it is being given as an NHS service, and would normally be charged to the employer in addition to the cost of the procedure.

[5] http://www.hse.gov.uk/coshh/

10. Can the practice charge the employer?

If the patient's employer states that their risk assessment indicates that their employee (your patient) is at risk of hepatitis B and requests that the practice contracts with them to provide such an immunisation, then the practice can choose to do so. Practices can have agreements, for example with police colleges, where they provide hepatitis B immunisations ONLY at the request of the employer. It must be clear that this is an arrangement between the practice and the employer and that the patient is not being charged.

11. Should the practice provide a service for NHS staff?

The practice is not obliged to do so. In many areas there has been local negotiation between LMCs and PCOs and this has resulted in Locally Enhanced Services (LESs) for the provision, administration and associated testing hepatitis B immunisation of NHS staff and students for occupational health reasons. This solution is advantageous for practice, patients and the PCO.

Hepatitis B immunisation for medical and lifestyle reasons

12. Can I provide hepatitis B immunisation for medical or lifestyle reasons on the NHS?

Maybe. Giving hepatitis B for those at lifestyle or medical risk is not part of the additional service component of the global sum. Practices are only obliged to offer this service as part of good medical practice and therefore under GMS in clinically appropriate situations, which are determined on an individual basis.

13. Who should receive hepatitis B immunisation?

The Green Book[6] details those who should receive hepatitis B immunisations (see Appendix 1). Practices should be alert for patients at risk (which may include family members) and ensure that immunisation is advised for this group.

14. Can the practice earn money from this provision?

Practices in England and Wales can give the immunisation from stock and claim reimbursement.

[6] http://immunisation.dh.gov.uk/category/the-green-book/

Appendix 1

Lifestyle and medical indications for hepatitis B immunisation (extract from Chapter 18 of the Green Book):

Pre-exposure vaccination
The objective of the immunisation programme is to provide a minimum of three doses of hepatitis B vaccine for individuals at high risk of exposure to the virus or complications of the disease.

Pre-exposure immunisation is used for individuals who are at increased risk of hepatitis B because of their lifestyle, occupation or other factors. Immediate post-exposure vaccination is used to prevent infection, especially in babies born to infected mothers or following needlestick injuries (see below).

Where testing for markers of current or past infection is clinically indicated, this should be done at the same time as the administration of the first dose. Vaccination should not be delayed while waiting for results of the tests. Further doses may not be required in those with clear evidence of past exposure. Pre-exposure immunisation is recommended for the following groups.

Injecting drug users
IDUs are a group at particular risk of acquiring hepatitis B infection. Vaccination is recommended for the following:

- all current IDUs, as a high priority
- those who inject intermittently
- those who are likely to 'progress' to injecting, for example those who are currently smoking heroin and/or crack cocaine, and heavily dependent amphetamine users
- non-injecting users who are living with current injectors
- sexual partners of injecting users
- children of injectors.

Individuals who change sexual partners frequently
Those who change sexual partners frequently, particularly MSM and male and female commercial sex workers.

Close family contacts of a case or individual with chronic hepatitis B infection
Sexual partners are most at risk, and they and close household contacts should be vaccinated. Blood should be taken at the time of the first dose of vaccine to determine if they have already been infected. Contacts shown to be HBsAg, anti-HBs or anti-HBc positive do not require further immunisation. Advice regarding the appropriate use of condoms should be given; a reasonable level of protection can be assumed following the second dose, provided that completion of the schedule can be assured.

Contacts who have had recent unprotected sex with individuals who have acute hepatitis B or who are HBsAg positive require post-exposure prophylaxis, including HBIG (see below).

Families adopting children from countries with a high or intermediate prevalence of hepatitis B
Members of such families may be at risk, as these children could be chronically infected (Christenson, 1986; Rudin et al., 1990). When the status of the child to be adopted is not known, families adopting children from any high or intermediate-prevalence country should be advised as to the risks and hepatitis B vaccination recommended. In due course, testing

such children is advisable because there could be benefits from referring an infected child for further management.

Foster carers
Some children requiring fostering may have been at increased risk of acquiring hepatitis B infection. Emergency placements may be made within a few hours: foster carers who accept children as emergency placements should be made aware of the risks of undiagnosed infection and how they can minimise the risks of transmission of all blood-borne virus infections. All short-term foster carers who receive emergency placements, and their families, should be offered immunisation against hepatitis B. Permanent foster carers (and their families) who accept a child known to be at high risk of hepatitis B should also be offered immunisation.

Individuals receiving regular blood or blood products and their carers
Those individuals receiving regular blood products, such as people with haemophilia, should be vaccinated. Those receiving regular blood transfusions, for example people with thalassaemia or other chronic anaemia, should be vaccinated against hepatitis B. Carers responsible for the administration of such products should also be vaccinated.

Patients with chronic renal failure
Patients with renal failure may need haemodialysis, at which time they may be at increased risk of hepatitis B. The response to hepatitis B vaccine among patients with renal failure is lower than among healthy adults. Between 45 and 66% of patients with chronic renal failure develop anti-HBs responses and, compared with immunocompetent individuals, levels of anti-HBs decline more rapidly. However, increased response rates have been reported in vaccines formulated for use in patients with chronic renal failure (Tong et al., 2005).
Immunisation against hepatitis B is recommended for patients already on haemodialysis or renal transplantation programmes and for other patients with chronic renal failure as soon as it is anticipated that they may require these interventions. The vaccines formulated for use in patients with chronic renal insufficiency should be used.

Patients with chronic liver disease
Individuals with chronic liver disease may be at increased risk of the consequences of hepatitis B infection. Immunisation against hepatitis B is therefore recommended for patients with severe liver disease, such as cirrhosis, of whatever cause. Vaccine should also be offered to individuals with milder liver disease, particularly those who are chronically infected with hepatitis C virus, who may share risk factors that mean that they are at increased risk of acquiring hepatitis B infection. Inmates of custodial institutions

Immunisation against hepatitis B is recommended for all sentenced prisoners and all new inmates entering prison in the UK.

Individuals in residential accommodation for those with learning difficulties
A higher prevalence of chronic hepatitis B infection has been found among individuals with learning difficulties in residential accommodation than in the general population. Close, daily living contact and the possibility of behavioural problems may lead to residents being at increased risk of infection. Vaccination is therefore recommended.

Similar considerations may apply to children and adults in day care, schools and centres for those with severe learning disability. Decisions on immunisation should be made on the basis of a local risk assessment. In settings where the individual's behaviour is likely to lead to significant exposure (e.g. biting or being bitten) on a regular basis, immunisation should be offered to individuals even in the absence of documented hepatitis B transmission.

Appendix 2

Examples of the groups that are considered at occupational health risk and require hepatitis B vaccination (extract from Chapter 18 of the Green Book):

Individuals at occupational risk

Hepatitis B vaccination is recommended for the following groups who are considered at increased risk:

- healthcare workers in the UK and overseas (including students and trainees): all healthcare workers who may have direct contact with patients' blood, blood-stained body fluids or tissues, require vaccination. This includes any staff who are at risk of injury from blood- contaminated sharp instruments, or of being deliberately injured or bitten by patients. Advice should be obtained from the appropriate occupational health department.]

- laboratory staff: any laboratory staff who handle material that may contain the virus require vaccination.

- staff of residential and other accommodation for those with learning difficulties: a higher prevalence of hepatitis B carriage has been found among certain groups of patients with learning difficulties in residential accommodation than in the general population. Close contact and the possibility of behavioural problems, including biting and scratching, may lead to staff being at increased risk of infection.

  Similar considerations may apply to staff in day-care settings and special schools for those with severe learning disability. Decisions on immunisation should be made on the basis of a local risk assessment. In settings where the client's behaviour is likely to lead to significant exposures on a regular basis (e.g. biting), it would be prudent to offer immunisation to staff even in the absence of documented hepatitis B transmission.

- other occupational risk groups: in some occupational groups, such as morticians and embalmers, there is an established risk of hepatitis B, and immunisation is recommended. Immunisation is also recommended for all prison service staff who are in regular contact with prisoners.

Hepatitis B vaccination may also be considered for other groups such as the police and fire and rescue services. In these workers an assessment of the frequency of likely exposure should be carried out. For those with frequent exposure, pre-exposure immunisation is recommended. For other groups, post-exposure immunisation at the time of an incident may be more appropriate (see below). Such a selection has to be decided locally by the occupational health services or as a result of appropriate medical advice.

Appendix 3

Model letter to present to patients who request a hepatitis B immunisation for occupational health reasons

Dear Patient,

You have requested hepatitis B immunisation for occupation purposes to be provided by your GP.

GPs do not provide an occupational health service as part of their NHS responsibility nor can they provide this service to you even if it is funded by you.

Under Health and Safety Regulations, your employer has a duty to provide a safe working environment and, therefore, appropriate health advice for those at risk of infection with hepatitis B. We advise you to contact your employer who will be able to make arrangements with an occupational health provider for the provision of any immunisation which you may require following an appropriate assessment of the risk to which you are exposed.

Yours faithfully

XXXXX

Model letter to employers whose employees request a Hepatitis B immunisation for occupational health reasons

Dear Employer

Your employee – [name] –hepatitis B risk assessment

This person presented at my surgery and informed me that they have been advised by you to seek protection against hepatitis B because of the nature of his or her employment.

Under Health and Safety legislation employers have a duty to provide a safe working environment. Employers should undertake a risk assessment and arrange protection for employees, including, where necessary, immunisation against hepatitis B. If an assessment reveals a risk the employer has a duty to act and should make arrangements with a suitably qualified medical service to meet the relevant obligations.

This practice is not aware of the situation and hazards in your employee's workplace and does not have occupational expertise to advise on the risks involved.

It is therefore inappropriate for us to proceed with the immunisation and I have asked your employee to return to you so that you can deal with this appropriately. I should add that the NHS does not fund hepatitis immunisation for employment purposes.

We would be happy to discuss with you the provision of a non-NHS vaccination service once you have arranged the appropriate risk assessment.

Please do not hesitate to contact us if you have any questions about this letter.

Yours faithfully,

Dr X