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Guidance on Hepatitis B Vaccinations in the Isle of Man

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Next Review Date: January 2016
Background

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). Many new infections with hepatitis B are sub-clinical or may have a flu-like illness. Jaundice only occurs in about 10% of younger children and in 30 to 50% of adults. Acute infection may occasionally lead to fulminant hepatic necrosis, which is often fatal.

- Globally, approximately two billion people have been infected with HBV, of whom 350 million are chronically infected. Overall, an estimated 600,000 persons die each year due to the acute or chronic consequences of hepatitis B infection.

- Areas with the highest prevalence rates of chronic hepatitis B include South East Asia, Africa, the Middle and Far East, and Southern and Eastern Europe.

- In the UK, the prevalence of chronic hepatitis B infection is estimated to be 0.3% (approximately 180,000 people).

- In any given year, the majority (96%) of chronic hepatitis B infections added to the existing numbers of such infections in England and Wales are likely to be in individuals born in countries with an intermediate or high prevalence. This is mirrored in the Isle of Man.

- The hepatitis B virus (HBV) causes hepatitis (inflammation of the liver) and can also cause long-term liver damage. Mortality is rare during the acute phase of infection (less than 1%), but can occur.

- Many people have no symptoms during acute infection, while others can experience:
  - Flu-like illness (sore throat, tiredness, joint pains, loss of appetite)
  - nausea
  - vomiting
  - abdominal discomfort and jaundice with dark urine.

- HBV may be transmitted through contact with infected blood or body fluids by the following routes:
  - Sharing or use of contaminated equipment during injecting drug use
  - vertical transmission (mother to baby)
  - sexual transmission
  - receipt of infectious blood (via transfusion) or infectious blood products (for example, clotting factors)
  - needlestick or other sharps injuries
  - tattooing and body piercing.
- The average incubation period is 40-160 days.
- Most adults infected with HBV fully recover and develop life-long immunity.
- The likelihood that an HBV infection will become chronic depends upon the age at which a person becomes infected. About 90% of infants infected during the first year of life develop chronic infections, compared with 30% to 50% of children infected between one to four years of age, and up to 10% of adults. The risk of chronic infection is increased where immunity is impaired.
- Chronic infection leads to persistent infectivity and can also lead to liver cirrhosis and malignant change in the liver. Approximately 25% of adults who become chronically infected during childhood later die from HBV-related liver cancer or cirrhosis.

The policy for vaccination against hepatitis B recommended in the UK and the Isle of Man is selective vaccination of high-risk groups. In some countries where the carrier rate in the general population is higher a policy of universal vaccinations is recommended.


This document, known as ‘The Green Book’, is subject to regular review and updates and, as such, The Green Book which is now only available electronically should be accessed.

For those patients arriving in the Isle of Man from countries with a high prevalence of hepatitis B where universal vaccination may be implemented, the routine vaccinations can be checked on the World Health Organisation (WHO) website: http://apps.who.int/immunization_monitoring/globalsummary/schedules

The enclosed guidance has been taken from a variety of health documentation and full copies can be easily accessed. The first part is an abstract, more detailed information is in the second part, and the source documents are acknowledged and listed for your convenience.
Hepatitis B 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 needle-stick injuries.

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.

1. **Pre-exposure prophylaxis recommendation**

Pre-exposure immunisation is recommended for the following groups:

- Injecting drug users (IDU)
- Individuals who change sexual partners frequently
- Close family contacts of a case or individual with chronic hepatitis B infection
- Families adopting children from countries with a high or intermediate prevalence of hepatitis B
- Foster carers
- Individuals receiving regular blood or blood products and their carers
- Patients with chronic renal failure
- Patients with chronic liver disease
- Inmates of custodial institutions
- Individuals in residential accommodation for those with learning difficulties
- People travelling to, or going to reside in, areas of high or intermediate prevalence.
• 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)
  - laboratory staff
  - staff of residential and other accommodation for those with learning difficulties
  - other occupational risk groups – for example, risk-assessed tattooists, sewerage workers
  - hepatitis B vaccination may also be considered for other groups such as the police and fire and rescue services.

2. **Primary Immunisation**

   For pre-exposure prophylaxis in most adult and childhood risk groups, an accelerated schedule should be used, with vaccine given at zero, one and two months. For those who are at continued risk, a fourth dose is recommended at 12 months. An alternative schedule at zero, one and six months can be used where rapid protection is not required and there is a high likelihood of compliance.

   Higher completion rates are achieved with the accelerated schedule (at zero, one and two months) in groups where compliance is difficult (for example, in intravenous drug users (IDUs) and genito-urinary medicine clinic attenders). This improved compliance is likely to offset the slightly reduced immunogenicity when compared with the zero-, one- and six-month schedule, and similar response rates can be achieved by opportunistic use of a fourth dose after 12 months.

   Always refer to the vaccine manufacturers’ Summary of Product Characteristics (SPC) and The Green Book for the most up-to-date guidance.

3. **Post-exposure prophylaxis (PEP) is recommended for the following groups:**

   - Babies born to mothers who are chronically infected with HBV, or to mothers who have had acute hepatitis B during pregnancy.
   - Other groups potentially exposed to hepatitis B
   - Sexual partners of those infected
   - Persons who are accidentally inoculated or contaminated.
Generally for post-exposure prophylaxis, an accelerated schedule of monovalent hepatitis B vaccine (or a combined vaccine of equivalent strength) should be used, with vaccine given at zero, one and two months. For those who are at continued risk, a fourth dose is recommended at 12 months. If HBIG is also indicated, it should be given as soon as possible, ideally at the same time as the first dose of vaccine.

Any individual potentially exposed to hepatitis B-infected blood or body fluids should be offered protection against hepatitis B, depending on their prior vaccination status and the status of the source: www.hpa.org.uk/cdr/archives/CDRreview/1992/cdrr0992

Guidance on post-exposure prophylaxis following exposure to hepatitis B has been issued by the former PHLS Hepatitis Subcommittee (PHLS Hepatitis Subcommittee, 1992). A summary of this guidance is given on page 21 - taken from The Green Book.

Always refer to the vaccine manufacturers’ Summary of Product Characteristics (SPC) and The Green Book for the most up-to-date guidance.

4. Reinforcing immunisation

The full duration of protection afforded by hepatitis B vaccine has yet to be established. Levels of vaccine-induced antibody to hepatitis B decline over time, but there is evidence that immune memory can persist in those successfully immunised.

However, recent evidence suggests that not all individuals may respond in this way. It is, therefore, recommended that individuals at continuing risk of infection should be offered a single booster dose of vaccine, once only, around five years after primary immunisation. Measurement of anti-HBs levels is not required either before or after this dose. Boosters are also recommended after exposure to the virus.

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 immunisations, is advised for the children born to hepatitis B-infected mothers. This will also provide the opportunity to check whether the child was properly followed up in infancy.

5. Response to vaccine and the use of additional doses

Except in certain groups, testing for anti-HBs is not recommended; see later section for more detail if required.
6. Contraindications to hepatitis B vaccination

There are very few individuals who cannot receive hepatitis B-containing vaccines. When there is doubt, appropriate advice should be sought – for example, from a consultant paediatrician or Public Health (Health Protection), rather than withholding vaccine.

The vaccine should not be given to those who have had:

- a confirmed anaphylactic reaction to a previous dose of a hepatitis B-containing vaccine
- a confirmed anaphylactic reaction to any component of the vaccine.

Precautions

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

Pregnancy and breast feeding

Hepatitis B infection in pregnant women may result in severe disease for the mother and chronic infection of the new-born. Immunisation should not be withheld from a pregnant woman if she is in a high-risk category. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. Since hepatitis B vaccine is an inactivated vaccine, the risks to the foetus are likely to be negligible, and it should be given where there is a definite risk of infection.

Premature infants

There is evidence that the response to hepatitis B vaccine is lower in pre-term, low-birth weight babies. It is, therefore, important that premature infants receive the full paediatric dose of hepatitis B vaccine on schedule. Babies with a birth weight of 1500g or less, born to mothers infected with hepatitis B, should receive HBIG in addition to the vaccine, regardless of the e-antigen status of the mother.

HIV and immunosuppressed individuals

Hepatitis B vaccine may be given to HIV-infected individuals and should be offered to those at risk, since infection acquired by immunosuppressed, HIV-positive patients can result in higher rates of chronic infection. Response rates are usually lower depending upon the degree of immunosuppression. Increasing the number of doses may improve the anti-HBs response in HIV-infected individuals. Follow specialist advice.
Adverse reactions

Hepatitis B vaccine is generally well-tolerated and the most common adverse reactions are soreness and redness at the injection site. Other reactions that have been reported but may not be causally related include fever, rash, malaise and an influenza-like syndrome, arthritis, arthralgia, myalgia and abnormal liver function tests. As with all suspected adverse reactions these should be reported using the Yellow Card Scheme to the (Medical and Healthcare Products Regulatory Agency (MHRA):
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/index.htm

7. Administering Hepatitis B vaccine

In the Isle of Man not all hepatitis B vaccination is available through the NHS.

Hepatitis B vaccination is available through the NHS to the following:

- Injecting drug users (IDU)
- Individuals who change sexual partners frequently, e.g. men who have sex with men (MSM) and sex workers
- Close family contacts of a case or individual with chronic hepatitis B infection
- Families adopting children from countries with a high or intermediate prevalence of hepatitis B
- Foster carers
- Individuals receiving regular blood or blood products and their carers
- Patients with chronic renal failure
- Patients with chronic liver disease
- Inmates of custodial institutions
- Individuals in residential accommodation for those with learning difficulties
- Post exposure prophylaxis.

Hepatitis B vaccination is not available through the NHS to the following:

- People travelling to, or going to reside in, areas of high or intermediate prevalence, the traveller will be charged for this.
- Certain occupational groups - Occupational Health is not part of NHS services so the employer will be charged when vaccination is required for occupational health reasons. Employers should make suitable arrangement for hepatitis B vaccination for employment purposes. This may well be a private arrangement with the employee’s GP service.
GP surgeries, sexual health or GUM clinics and Occupational Health Services may provide the hepatitis B vaccination free of charge through the NHS. Other Departments such as Drug and Alcohol teams may discuss the need for vaccination and refer to the GP service for its administration.

GPs will provide in the post-exposure prophylaxis situation whereby a previously not-at-risk patient is inadvertently exposed.

This document used the following references during its compilation:

**Immunisation against infectious diseases**: the Green Book which is regularly reviewed and updated. It is not available in book format but can be readily accessed electronically: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book


**Advisory Committee on Dangerous Pathogens Protection against blood-borne infections in the workplace**: HIV and Hepatitis accessed electronically: http://www.hse.gov.uk/biosafety/diseases/bbv.pdf

**World Health Organisation (WHO) Vaccine preventable diseases, immunisation schedule selection centre**: http://apps.who.int/immunization_monitoring/globalsummary/schedules

**Further information**

8. **Pre-exposure immunisation is recommended for the following groups:**

   a) **Injecting drug users**

   IDUs are a group at particular risk of acquiring hepatitis B infection. The Isle of Man Drug and Alcohol Team do not administer hep B vaccination but do discuss the risks and advise self-referral to the IDUs GP.

   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 injecting users.

b) **Individuals who change sexual partners frequently**

Individuals who change sexual partners frequently are at risk of hepatitis B infection, particularly MSM (men who have sex with men) and male and female commercial sex workers.

c) **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.

d) **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. 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.

e) **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.

f) **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 thalassemia or other chronic anaemia, should be vaccinated against hepatitis B. Carers responsible for the administration of such products should also be vaccinated.

g) **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 immune-competent 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.

Immunisation against hepatitis B is recommended for those 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. The Isle of Man Noble’s Hospital Renal Unit liaises closely with the individual patient’s GP to ensure their vaccination status is up to date and follows evidence-based practice and National Guidelines.

h) **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.
i) **Inmates of custodial institutions**

Immunisation against hepatitis B is recommended for all sentenced prisoners and all new inmates entering prison in the UK. The accelerated course is offered to all prisoners at Jurby prison in the Isle of Man on reception. They are given a record card and advised when to complete the course if released before the full course is completed. GPs are informed of the vaccination and due date.

j) **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 (for example, biting or being bitten) on a regular basis, immunisation should be offered to individuals even in the absence of documented hepatitis B transmission.

k) **People travelling to, or going to reside in, areas of high or intermediate prevalence**

Travellers to areas of high or intermediate prevalence who place themselves at risk when abroad should be offered immunisation. The behaviours that place them at risk will include sexual activity, injecting drug use, undertaking relief aid work and/or participating in contact sports.

Travellers are also at risk of acquiring infection as a result of medical or dental procedures carried out in countries where unsafe therapeutic injections (for example, the re-use of contaminated needles and syringes without sterilisation) are a risk factor for hepatitis B. Individuals at high risk of requiring medical or dental procedures in such countries should therefore be immunised, including:

- those who plan to remain in areas of high or intermediate prevalence for lengthy periods
- children and others who may require medical care while travelling to visit families or relatives in high- or moderate-endemicity countries
- people with chronic medical conditions who may require hospitalisation while overseas
- those travelling for medical care.

Detailed travel health advice including official vaccination recommendations by country is available to healthcare professionals and members of the public at National Travel Health Network and Centre – NaTHNaC: http://www.nathnac.org/

I) 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 members 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 (for example, biting), it would be prudent to offer immunisation to staff, even in the absence of documented hepatitis B transmission.
m) **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 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. Such selection is decided locally by the occupational health services or as a result of appropriate medical advice.

Local government and sector-specific risk assessments have also concluded that the following occupational groups may also be at increased risk of exposure to BBV and recommended that they be immunised against HBV. Again, local risk assessment by the employer will determine the level of risk and whether the sector-specific risk assessed apply to Isle of Man workplaces, the cost is then borne by the employer:

- Tattooists
- Ear and body piercers
- Beauticians and hairdressers
- Local authority services for example refuse disposal and street cleaners
- Sewage process workers
- Needle exchange service staff
- Those in professional and semi-professional contact sports.

9. **Post-exposure prophylaxis (PEP)**


Guidance on post-exposure prophylaxis following exposure to hepatitis B has been issued by the former PHLS Hepatitis Subcommittee (PHLS Hepatitis Subcommittee, 1992). A summary of this guidance taken from The Green Book is given on page 19. Always refer to the vaccine manufacturers Summary of Product Characteristics (SPC) and The Green Book for the most up-to-date guidance.
Post-exposure prophylaxis is recommended for the following groups:

a) **Babies born to mothers who are chronically infected with HBV or to mothers who have had acute hepatitis B during pregnancy**

Hepatitis B infection can be transmitted from infected mothers to their babies at or around the time of birth (perinatal transmission). Babies acquiring infection at this time have a high risk of becoming chronically infected with the virus. The development of the chronic infection after perinatal transmission can be prevented in over 90% of cases by appropriate vaccination, starting at birth, of all infants born to infected mothers.

UK guidelines (Department of Health, 1998) recommend that all pregnant women should be offered screening for hepatitis B infection during each pregnancy. Confirmatory testing and testing for hepatitis B e-markers of those mothers shown to be infected should follow. Where an unbooked mother presents in labour, an urgent HBsAg test should be performed to ensure that vaccine can be given to babies born to positive mothers within 24 hours of birth.

Management of the infant should be based on the results of these markers and, if available, HBV viral load testing of the mother. All babies born to these mothers should receive a complete course of vaccine on time. Arrangements should be in place to ensure that information is shared with appropriate local agencies to facilitate follow-up.

Babies born to highly infectious mothers should receive HBIG as well as active immunisation. HBIG should preferably be given within 24 hours of delivery, and should be ordered well in advance of the birth. HBIG may be given simultaneously with vaccine but at a different site. Please see Green Book Hepatitis B chapter for further up-to-date information: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148308/Green-Book-Chapter-18.pdf

b) **Post-exposure prophylaxis vaccination of pre-term babies**

There is evidence that the response to hepatitis B vaccine is lower in pre-term, low-birth weight babies. It is, therefore, important that premature infants receive the full paediatric dose of hepatitis B vaccine on schedule. Babies with a birthweight of 1500g or less, born to mothers infected with hepatitis B, should receive HBIG in addition to the vaccine, regardless of the e-antigen status of the mother.

It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely.
Please see Green Book Hepatitis B chapter for further up-to-date information:

c) **PEP Vaccination schedule and follow-up for babies**

For post-exposure prophylaxis in babies born to mothers infected with hepatitis B, the accelerated immunisation schedule is preferred. For these babies this will mean an initial dose of vaccine at birth, with further doses at one and two months of age and a fourth dose at one year of age.

Testing for HBsAg at one year of age will identify any babies for whom this intervention has not been successful and who have become chronically infected with hepatitis B, and will allow them to be referred for assessment and any further management. This testing can be carried out at the same time as the fourth dose is given.

When immunisation has been delayed beyond the recommended intervals, the vaccine course should be completed, but it is more likely that the child may become infected. In this instance, testing for HBsAg above the age of one year is particularly important.

d) **Other groups potentially exposed to hepatitis B**

Any individual potentially exposed to hepatitis B-infected blood or body fluids should be offered protection against hepatitis B, depending on their prior vaccination status and the status of the source. Guidance on post-exposure prophylaxis following exposure to hepatitis B has been issued by the former PHLS Hepatitis Subcommittee (PHLS Hepatitis Subcommittee, 1992):

e) **Sexual partners**

Any sexual partners of individuals with acute hepatitis B, and who are seen within one week of last contact, should be offered protection with HBIG and vaccine. Sexual contacts of an individual with newly-diagnosed chronic hepatitis B should be offered vaccine; HBIG may be added if unprotected sexual contact occurred in the past week.

f) **Persons who are accidentally inoculated or contaminated**

This includes those who contaminate their eyes or mouth, or fresh cuts or abrasions of the skin, with blood from a known HBsAg-positive person. Individuals who sustain such accidents should wash the affected area well with soap and warm water, and seek medical advice. Advice about prophylaxis after such accidents can be obtained locally from Public Health
Any individual potentially exposed to hepatitis B-infected blood or body fluids should be offered protection against hepatitis B, depending on their prior vaccination status and the status of the source: www.hpa.org.uk/cdr/archives/CDRreview/1992/cdrr0992.pdf.

Guidance on post-exposure prophylaxis following exposure to hepatitis B has been issued by the former PHLS Hepatitis Subcommittee (PHLS Hepatitis Subcommittee, 1992). A summary of this guidance from The Green Book is given on page 21 taken.

10. **Response to vaccine and the use of additional doses**

Except in certain groups, testing for anti-HBs is not recommended.

a) **Those at risk of occupational exposure**

In those at risk of occupational exposure, particularly healthcare and laboratory workers, antibody titres should be checked one to four months after the completion of a primary course of vaccine. Under the Control of Substances Hazardous to Health (COSHH) Regulations, individual workers have the right to know whether or not they have been protected. Such information allows appropriate decisions to be made concerning post-exposure prophylaxis following known or suspected exposure to the virus (see above).

Antibody responses to hepatitis B vaccine vary widely between individuals. It is preferable to achieve anti-HBs levels above 100mIU/ml, although levels of 10mIU/ml or more are generally accepted as enough to protect against infection. Some anti-HBs assays are not particularly specific at the lower levels, and anti-HBs levels of 100mIU/ml provide greater confidence that a specific response has been established.

Responders with anti-HBs levels greater than or equal to 100mIU/ml do not require any further primary doses. In immune-competent individuals, once a response has been established further assessment of antibody levels is not indicated. They should receive the reinforcing dose at five years as recommended in the Green Book.

Responders with anti-HBs levels of 10 to 100mIU/ml should receive one additional dose of vaccine at that time. In immune-competent individuals, further assessment of antibody levels is not indicated. They should receive the reinforcing dose at five years as currently recommended in the Green Book.
An antibody level below 10mIU/ml is classified as a non-response to vaccine, and testing for markers of current or past infection is good clinical practice. In non-responders, a repeat course of vaccine is recommended, followed by re-testing one to four months after the second course. Those who still have anti-HBs levels below 10mIU/ml, and who have no markers of current or past infection, will require HBIG for protection if exposed to the virus.

b) Patients with renal failure

The role of immunological memory in patients with chronic renal failure on renal dialysis does not appear to have been studied, and protection may persist only as long as anti-HBs levels remain above 10mIU/ml. Antibody levels should, therefore, be monitored annually and if they fall below 10mIU/ml, a booster dose of vaccine should be given to patients who have previously responded to the vaccine.

Booster doses should also be offered to any haemodialysis patients who are intending to visit countries with a high endemicity of hepatitis B and who have previously responded to the vaccine, particularly if they are to receive haemodialysis and have not received a booster in the last 12 months.

11. HBV prophylaxis for reported exposure incidents – taken from the Green Book

<table>
<thead>
<tr>
<th>HBV status of person exposed</th>
<th>Significant exposure</th>
<th>Non-significant exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBsAg positive source</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 1 dose HB vaccine pre-exposure</td>
<td>Accelerated course of HB vaccine*</td>
<td>Initiate course of HB vaccine</td>
</tr>
<tr>
<td>≥ 2 doses HB vaccine pre-exposure (anti-HBs not known)</td>
<td>One dose of HB vaccine followed by second dose one month later</td>
<td>Finish course of HB vaccine</td>
</tr>
</tbody>
</table>

| **HBsAg negative source**    |                     |                         |
| Known responder to HB vaccine (anti-HBs > 10mIU/ml) | Consider booster dose of HB vaccine | Consider booster dose of HB vaccine |
| Known non-responder to HB vaccine (anti-HBs < 10mIU/ml 2-4 months post-immunisation) | HBIG × 1 Consider booster dose of HB vaccine A second dose of HBIG should be given at one month | No HBIG Consider booster dose of HB vaccine |

*An accelerated course of vaccine consists of doses spaced at zero, one and two months. A booster dose may be given at 12 months to those at continuing risk of exposure to HBV.

The information in this booklet can be provided in large print or in audio format on request.