Implementation of Department of Health guidelines for hepatitis B vaccination: a regional audit of NHS occupational health policies and procedures

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The objective of this study was to assess the implementation of the UK Health Departments' guidelines on protecting healthcare workers and patients from hepatitis B infection. The survey took place in February 1994 in the form of a postal questionnaire survey of occupational health departments. The study frame was the 18 district-based occupational health departments in the northern region of the NHS. The main outcome measures were compliance with the national guidelines on vaccination and the assessment of the hepatitis B status of employees performing exposure prone procedures. Compliance with the guidelines was variable. There were marked variations in the interpretation of serological data and there was a failure to establish the hepatitis B status of surgeons, in some cases. There is a need to provide training for occupational health practitioners about hepatitis B and to ensure that there is a uniform standard of practice within the NHS.

Key words: Healthcare workers; hepatitis B; NHS; vaccination.

Vaccination of healthcare workers against hepatitis B infection has been advised since the early 1980s. The original vaccine was derived from human plasma and uptake of the vaccine was low, possibly because of concerns about potential transmission of infection, despite reassurances that it was safe. In addition, occupational health services in the NHS were in their infancy at this time, and it is likely that only well-informed, self-motivated employees would have made arrangements to be vaccinated. In 1987 a new genetically-engineered vaccine (Engerix B) was launched in the UK. This was perceived as being safe and the uptake of hepatitis B vaccine subsequently increased.

The new vaccine was also cheaper than the original vaccine, which helped to stimulate demand. The availability of a safe, effective and cheaper vaccine raised the question as to whether Health Authorities should provide the vaccine for their employees. Some Authorities decided to offer some of their clinical staff hepatitis B vaccinations whilst some left it to individuals to obtain vaccinations via their general practitioners. In 1993 the UK Health Departments published guidelines on protecting healthcare workers and patients from hepatitis B. The guidelines were endorsed by the NHS Management Executive who issued their own Health Service Guidelines [HSG(93)40] requiring NHS Trusts to implement a programme of vaccinating and testing staff. The two main purposes of the guidelines were to ensure that healthcare workers who may be at risk of acquiring hepatitis B from a patient were protected by immunization and to protect patients against the risk of acquiring hepatitis B from an infected healthcare

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worker. In particular, the guidelines recommended that carriers of hepatitis B virus who were known to be 'e-antigen positive' must not carry out procedures where there was a risk that injury to themselves would result in their blood contaminating a patient's open tissues. These procedures were termed 'exposure prone procedures'. Exposure prone procedures include those where the worker's gloved hand may be in contact with sharp instruments, needle tips and sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. Annex A of HSG(93)40 provided information and advice about how the guidance should be implemented. The Management Executive required that NHS providers should plan to immunize all appropriate staff by the middle of 1995. In addition, they were required to immunize and check the immunity of all surgeons by the middle of 1994 and of all staff involved in exposure prone procedures by the middle of 1995.

Unless such workers were known to be immune to hepatitis B infection, hepatitis B vaccination was recommended, with the response to vaccination being checked 2–4 months after the completion of the primary course. An antibody level to hepatitis B surface antigen (anti-HBs) of 100 miu/ml was considered to reflect a satisfactory immune response. Anti-HBs levels of less than 10 miu/ml were not considered to be evidence of an acceptable response. Booster doses of vaccine were recommended if the anti-HBs level was less than 100miu/ml, followed by an additional test 2–4 months later. The lack of an acceptable response to vaccination required further investigation where workers carried out exposure prone procedures. Such workers should be referred for specialist advice and counselling about the possible implications of this. Informed consent to test for markers of hepatitis B infection should be obtained, with a view to identifying the worker who was a carrier of HBeAg. Epidemiological evidence suggests that healthcare workers who are HBeAg positive and who carry out exposure prone procedures are most likely to transmit infection. Consequently, such workers are no longer permitted to carry out the parts of their job involving exposure prone procedures.

HSG(93)40 requires employers to make compliance with the guidance from the expert advisory committee a condition of service for new staff appointed to posts involving exposure prone procedures. The immunity/carryer status should be determined before their employment is confirmed. For staff already in post, immunization and/or checking for the carriage of HBeAg was required, using an accelerated vaccine schedule for surgeons who had not been immunized. This schedule involves giving doses at 0, 1 and 2 months with a booster at 12 months, rather than giving doses at 0, 1 and 6 months in the standard schedule. HSG(93)40 also recommended testing for past or current infection at the time of giving the vaccine to staff who had worked in countries with a high prevalence of hepatitis B.

In light of these developments it was decided to carry out an audit of hepatitis B vaccination practices in the occupational health departments in the Northern Region of England. This topic was chosen as a regional audit project because of its importance to both NHS patients and staff, because of the perceived need to review current practice against the recently set national standards and because occupational health is a small speciality, with only one department per District in most cases. In addition, most occupational health departments in the northern region do not have a consultant occupational physician, nor access to one.

MATERIALS AND METHOD
The starting point for the audit was the observation of practice. A questionnaire was designed to collect information about hepatitis B vaccination and the policies and procedures being implemented by all the occupational health departments in the Northern Region. The questionnaire included questions within the three main categories of audit, i.e. structure, process and outcome. The emphasis was on structure and process. Questions on structure related to the involvement of occupational health departments in carrying out hepatitis B vaccination and the existence of Trust policies to assist in this. The largest section of the questionnaire was on the process of performing hepatitis B vaccinations and the interpretation of the serological results obtained. Questions relating to outcomes were concerned with communicating the results of vaccination to employees, whether the occupational health department played a central role in the Trust's needlestick injury policy and whether there was an identified senior member of the Trust who would be informed in the event of discovering a healthcare worker who was a carrier of HBeAg.

The draft questionnaires were distributed to a small sample of occupational physicians in the Region for comment. The amended questionnaires were then sent by post to all the occupational health departments, addressed to a named doctor or nurse identified either from the Association of NHS Occupational Physicians (ANHOPS) directory or from information held about local occupational health nurses. The questionnaire was accompanied by an explanatory letter which gave a deadline for the return of the questionnaire.

RESULTS
Eighteen questionnaires were distributed and all were returned. However, not all the questions were answered on every questionnaire. The answers to questions on hepatitis B programmes can be seen in Table 1. All departments indicated that hepatitis B vaccinations were offered to healthcare workers, although only 15...
departments had a local policy complying with the Department of Health guidelines. The two departments that arranged for the vaccinations to be performed by general practitioners did so in accordance with their local policy.

Table 2. Audit of hepatitis B vaccination programmes: structure

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is hepatitis B vaccination offered to healthcare workers?</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Are hepatitis B vaccinations carried out by occupational health staff?</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>Established recall system (manual 12, computerized 6)</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Existing record system covering all employees</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Contains information on all surgeons</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>Contains information on staff performing EPPs</td>
<td>12</td>
<td>6</td>
</tr>
</tbody>
</table>

Only 13 departments provided information about their vaccination activity levels which varied considerably across the Region: four departments had given more than 1,000 doses over a 12-month period, whereas four departments had given less than 200 doses. All of the departments asked new employees who would have clinical contact with patients, or pathological specimens, about their hepatitis B vaccination history, including whether a post-vaccination serology (PVS) test of the anti-HBs titre had been carried out (Table 2). This was usually followed up by asking for proof of the PVS result. If staff were unable to provide documentary evidence of the PVS result, most departments carried out the PVS test immediately. In one case staff were asked to go to their GP, but if there were difficulties in obtaining the result the test was carried out in the occupational health department. Another department carried out a PVS test if it was less than 5 years since the primary vaccination course. Yet another variation in practice was to issue staff with a pathology form, presumably with the intention of them arranging for the test themselves. No further action was taken by only one department.

If staff had not completed a full course of vaccinations, 10 departments indicated that they would either give a further full course of vaccinations or give a single extra dose and then measure the anti-HBs level after an appropriate interval. Four departments stated that they would always do the latter. Of the other alternatives, two departments chose the flexible option of giving either a full course or a single dose, but specified additional criteria such as the number of vaccinations already given and the timing of the vaccinations; one department checked the anti-HBs level prior to doing anything else and another simply completed the course of vaccinations.

Table 3. Pre-employment assessment of individuals who have not started hepatitis B vaccination (n = 18)

<table>
<thead>
<tr>
<th>Action</th>
<th>No of depts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinate all employees who will have clinical contact with patients or body fluids</td>
<td>13</td>
</tr>
<tr>
<td>Vaccinate only employees working in high risk jobs</td>
<td>0</td>
</tr>
<tr>
<td>Advise all employees who will have clinical contact with patients or body fluids to ask their GP for vaccinations</td>
<td>2</td>
</tr>
<tr>
<td>Advise only employees working in high risk jobs to ask their GP for vaccinations</td>
<td>0</td>
</tr>
<tr>
<td>Do something else</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3 shows a breakdown of the actions taken by the departments where staff had not started a course of vaccinations. Of the three departments doing something else, one department only vaccinated employees on an 'approved' list, one only vaccinated surgeons and one stated that the action taken depended on circumstances. There was almost a consensus regarding not undertaking pre-vaccination serology testing for markers of infection, although this was not true for employees coming from parts of the world with a high endemicity of hepatitis B. It can be seen in Table 4 that there was inconsistency in the assessment of the overseas staff and only six departments had a policy of testing surgeons and staff performing EPPs who did not have evidence of immunity. Three out of the five departments doing 'something else' stated that, in the absence of documentary evidence that a new member of staff was not a carrier of the virus they would test for the presence of anti-HBcore initially and then test for HBsAg, where appropriate. Thus, 10 departments actually had a system of testing for HBsAg in the absence of documentary evidence of immunity. Of the remaining departments one stated that they had not yet encountered the problem and the other referred staff to their general practitioner.

For existing employees, 16 out of 17 departments answered that they had started a vaccination programme to ensure that all surgeons and all staff
performing EPPs would have been immunized by mid-1994 and mid-1995, respectively. For newly employed surgeons, 12 departments indicated that they were using an accelerated vaccination schedule to meet the deadline. However, for surgeons already in post, only seven departments were using accelerated schedules.

All the departments stated that they carried out PVS tests 1–3 months after the third dose of hepatitis B vaccine. The most common time for testing was after 2 months, with one department testing after 1 month and another after 3 months. In almost every case an anti-HBs titre of > 100 miu/ml was regarded as evidence of successful immunization. One department accepted 50–100 miu/ml as being indicative of this. Where an antibody level of > 100 miu/ml was not achieved, additional doses of vaccine were given. It was usual to give at least one further dose of vaccine (13 departments), but four departments gave two doses and one department gave three doses. Following the primary course of vaccinations all departments gave booster vaccinations to staff who had been immunized. The timing of this depended on the anti-HBs titre achieved initially. Where the post-vaccination serology (PVS) was > 100 miu/ml, 14 departments offered a booster after 5 years. If the PVS was < 100 miu/ml, 11 departments offered a booster after 2 years. This part of the question was answered by 13 departments only. In general, there appeared to be some uncertainty and some confusion about this aspect of practice. Some of the answers linked giving a booster to the extension of the primary vaccination course, where individuals had not been successfully immunized.

Another area of inconsistency was the testing of anti-HBs levels at the time of giving a booster. The practice that was most prevalent was to measure anti-HBs levels after giving the booster for all staff. This was performed by eight departments. Two departments measured anti-HBs before giving the booster for all staff, and two departments tested after giving the booster only in some cases. One department tested for anti-HBs both before and after giving a booster for all staff and another department indicated that their practice was influenced by previous anti-HBs levels without specifying how this translated into the actions taken at the time of giving a booster. Three departments did not measure anti-HBs levels at all arguing that an adequate antibody response had already been documented after the primary course of vaccinations. Failure to seroconvert following hepatitis B vaccination is an indication to test for markers of hepatitis B infection, in certain circumstances. Table 5 shows the numbers of departments not testing for markers of infection. Of the seven departments who answered that they would not test for markers of infection in surgeons or staff performing EPPs, none had answered that they would test all staff in such circumstances. Similarly these departments did not test for markers of infection after three doses of vaccine. One department that did not give an answer to these questions stated that markers of infection had been checked prior to vaccinating.

Information on communicating outcomes showed that 10 departments sent the result by post and five departments gave the result verbally in the occupational health department. Other methods employed by

| Measure hepatitis B surface antigen in all cases | 7 |
| Measure hepatitis B surface antigen only in surgeons | 0 |
| Measure hepatitis B surface antigen in surgeons and staff performing exposure-prone procedures | 6 |
| Do something else | 5 |

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test markers after three doses of vaccine</td>
<td>4</td>
</tr>
<tr>
<td>Test markers after four doses of vaccine in all staff</td>
<td>5</td>
</tr>
<tr>
<td>Test markers after four doses of vaccine only for surgeons or staff performing exposure prone procedures</td>
<td>8</td>
</tr>
</tbody>
</table>

DISCUSSION

Audit is an important clinical activity. It is a systematic enquiry into practises comparing what actually happens against a set of pre-agreed standards. The aim of audit is to raise the overall standard of practice by identifying deviations from the set standards and exploring why this occurs. Many audit projects concentrate on one of three categories: structure, process or outcome. In this audit, assessments were made of all three categories. In part, this reflected the require-
ments of the Department of Health guidelines and HSG(93)40. However, sufficient baseline information was required to be able to recommend both professional and managerial responses to the results of the audit. In particular, additional questions on structure were included because this has resource implications. Compliance with the audit was a high priority and so the questionnaire used had to be easy to understand and quick to complete. That all 18 departments returned the questionnaire suggested that this was achieved.

It was less satisfactory that the returned questionnaires were often incompletely answered. In most cases there was only one missing answer. The question that had least answers asked about offering booster vaccinations. Consequently, this aspect of practice may not have been assessed accurately. Similarly, the question about testing for markers of hepatitis B infection where surgeons or staff performing exposure prone procedures failed to achieve a satisfactory anti-HBs titre after four doses of vaccine was answered by only 15 departments. As the audit revealed that as many as seven departments would not test these healthcare workers for markers of infection, despite this being an explicit requirement of the Department of Health guidelines, the possibility that this question was also unsatisfactory has to be considered. None the less, a review of all the answers to the three questions on this subject suggests that they were reliable. In general, all the questions on the questionnaire appear to have been understood and so the answers obtained probably reflected the practice of the departments, at the time that the audit was carried out.

It was reassuring to find that all the departments were offering hepatitis B vaccinations to healthcare workers, although it was apparent that some departments had been doing this for a short period only. HSG(93)40 was issued in August 1993 and the audit was conducted approximately six months later. In three NHS districts there was still a lack of a local policy for the implementation of the guidelines and, although all departments had established a recall system for contacting employees about vaccinations, many of the departments did not have records that would enable them to readily identify either surgeons or staff performing EPPs. In addition, most departments were not computerized and so their ability to respond to what was likely to be a difficult logistical exercise was limited.

All the departments were complying with the requirement of determining the immunity/carrier status of new employees by obtaining hepatitis B vaccination histories, and documentary evidence for all but one department. Where staff were unable to provide this, a majority of departments measured the anti-HBs titre. Individuals who had not completed their course of vaccinations were offered additional doses of vaccine and then tested. At the time that the audit was conducted this practice complied with the requirement to establish the hepatitis B status of surgeons by mid-1994, as long as they were given an accelerated vaccination course. However, the results of the audit suggest that some departments did not have a vaccination programme that would ensure that this could be achieved.

The results also give rise to concern regarding the employment of locum surgeons, who might be employed by a Trust for short periods. Although the questionnaire did not ask questions specifically about locums it might be inferred that locum surgeons would not have their hepatitis B status determined fully before taking up employment. The lack of consistency in testing new staff coming from parts of the world with a high endemicity of hepatitis B was also worrying. Visiting academic staff or doctors visiting from overseas to supplement their training are at greater risk of being carriers of hepatitis B and so departments should be aware of the importance of establishing the status of this category of staff.

Another area of practice where there was a divergence from the guidelines was in the interpretation of anti-HBs titres and subsequent actions. Most departments took 100 miu/ml to be evidence of successful immunization. Previously, the manufacturers of the vaccine have equated an antibody response of 10 miu/ml with immunity to hepatitis B, which might have been a possible source of confusion. This titre is now used as indicating a response that makes the carriage of hepatitis B virus unlikely. The Department of Health guidelines recommend that non-responders who are not carriers should be given a repeat course of vaccinations, but only one department gave three additional doses of vaccine to this group of staff. This is consistent with advice given by the Public Health Laboratory Service (PHLS) in Newcastle that, in the event of obtaining an anti-HBs titre of <10 miu/ml after three doses of vaccine, a fourth dose only is required in most cases. PHLS also advise that a booster dose after 5 years should be given for individuals achieving >100 miu/ml and after 2 years for 10-100 miu/ml. There was considerable variation with regard to testing anti-HBs either before or after giving a booster and this probably reflected the lack of any recommendations about the need to do this. Perhaps the most important action that must be taken, based on the PVS result, is the testing for markers of infection in non-seroconverters. The PHLS advise testing of non-seroconverters after four doses of vaccine but the Departmental guidelines state that this should be done after the primary course. Only four departments stated that they would test for markers after three doses. The guidelines state clearly that a non-responder is defined by an antibody titre of <10 miu/ml, yet one department indicated that they would test for markers if the anti-HBs titre was <100 miu/ml and another would do so if the titre was 50-100 miu/ml. It appears that poor responders, defined by an antibody response of 10-100 miu/ml, have been confused with non-responders and, as a result, have been tested for markers of infection unnecessarily.
The need to have documentary evidence of hepatitis B status means that it is desirable for doctors and other healthcare workers who carry out EPPs, such as midwives, to carry the results of their vaccinations with them. It is helpful, therefore, if occupational health departments provide written evidence of the PVS result or of the results of testing for markers of infection. Although 11 departments said that they provided results in writing, it is likely that this number will have increased since the audit was carried out. The number of departments giving advice about needlestick injuries at the same time as giving the results was encouraging, although not high enough given the importance of this type of accident in the NHS. Important variations in the management of needlestick injuries have been highlighted by a recent audit in two other NHS regions and the results of this study emphasized the contribution that effective hepatitis vaccination programmes play in achieving successful outcomes. However, it was reassuring that almost all the departments had an identified senior physician within the Trust who they would contact in the event of a healthcare worker performing EPPs being diagnosed as having HBeAg. This should facilitate the further management of the case taking into account the organizational implications of the diagnosis, as well as protecting the confidentiality of the individual concerned.

The results of the audit clearly demonstrate that there were significant variations in practice within the region. Some of the variation was due to non-compliance with the national guidelines, whilst some reflected an apparent inability to interpret hepatitis B serology correctly and take appropriate action. As a consequence of this a regional workshop was held in association with PHLS to remedy this. A further audit is planned for 1995/96. This was a regional study and so care must be taken in extrapolating the results to the rest of the country. Nonetheless, anecdotal evidence obtained at national ANHOPS meetings and the results of this study emphasized the contribution that effective hepatitis vaccination programmes play in achieving successful outcomes. However, it was reassuring that almost all the departments had an identified senior physician within the Trust who they would contact in the event of a healthcare worker performing EPPs being diagnosed as having HBeAg. This should facilitate the further management of the case taking into account the organizational implications of the diagnosis, as well as protecting the confidentiality of the individual concerned.

The following observations were made:

- All departments were offering hepatitis B vaccinations to healthcare workers.
- Not all departments had policies for the implementation of national guidelines.
- Many departments did not have records that were sufficiently detailed to enable them to identify employees carrying out exposure prone procedures.
- Almost all departments obtained a history of hepatitis B vaccination status and documentary evidence of this at pre-employment assessments.
- Many departments did not use the accelerated course of vaccinations.
- Seven departments would not test surgeons for markers of hepatitis B infection following a failure to respond to hepatitis B vaccinations.
- There was a lack of consistency in establishing the hepatitis B status of staff coming from areas of the world with a high hepatitis B endemicity.
- Only 11 departments provided written evidence of hepatitis B status, post-vaccination.
- Most departments gave advice about action to be taken in the event of a needlestick injury.
- Almost all departments had an identified senior physician within their Trust who would be contacted in the event of discovering a member of staff who was hepatitis B e-antigen positive.
- There is a need for further training of occupational health staff in devising and implementing hepatitis B preventative programmes. The recently published code of practice for the implementation of the UK hepatitis B immunization guidelines should be of assistance in standardizing practice in the future.

REFERENCES