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Editorial

This issue of *Viral Hepatitis* examines the important topic of blood-borne infections in healthcare workers (HCWs), as discussed at the meeting of the Viral Hepatitis Prevention Board (VHPB) held in Rome, Italy, from 17-18 March 2005. The meeting was hosted by the team of experts based at the *Istituto Nazionale per le Malattie Infettive IRCCS 'Lazzaro Spallanzani'*.

The aim was to review the global epidemiology of blood-borne infections in HCWs; to evaluate the transmission of hepatitis B virus (HBV) and hepatitis C virus (HCV) as an occupational risk; to discuss primary and secondary prevention measures against HBV and HCV infections in HCWs; and to review the current recommendations for HBV- and HCV-infected HCWs.

Global epidemiology of blood-borne infections in healthcare workers

Estimated numbers of HCWs vary, with a World Health Organization (WHO) figure of 35 million rising to as many as 100 million if all healthcare-related staff are included, in addition to the doctors, nurses, and midwives in active practice. If we assume that the prevalence rates are at least similar to those in the general population, it is clear that the number of infected healthcare workers is a cause for concern, particularly in under-resourced health systems.

Transmission of hepatitis B and hepatitis C virus as an occupational risk

The risk of transmission of HBV and HCV is most serious between patients, either directly or indirectly. The risk of transmission to HCWs from patients is higher than that of HCWs to patients. It has been shown that some areas of healthcare can represent a higher risk, with surgery, gynaecology, and orthopaedic services heading this unfortunate list. The most common route of transmission is via needlestick injuries, especially those involving hollow needles. Operating in cavities where the tips of the fingers holding sharp surgical instruments are not always visible also poses an important risk for those performing exposure-prone procedures. It is therefore essential that HCWs acknowledge the risk, and exercise caution. When injuries do occur, it is also important that they are reported and the circumstances examined; standardisation of such reporting procedures would help the process of data collection and analysis considerably.

Prevention of hepatitis B and hepatitis C virus infections in healthcare workers

Vaccination is a powerful tool in the prevention of HBV infection. Since this means is not yet available for HCV or human immunodeficiency virus (HIV) infection, adherence to universal standard precautions and the use of often simple and safe techniques to avoid exposure are essential protective measures for all HCWs. Moreover, safer devices should be utilised whenever available. In the case of HBV or HIV, post-exposure prophylaxis (PEP) correctly implemented and followed may literally save the life of the HCW after occupational exposure to these infectious agents. PEP recommendations are now available in most developed countries. However, policies on PEP are by no means standardised, making comparisons between countries and the collection of data problematic. Education in self-protection and the protection of colleagues and patients must be an ongoing process. Regular reviews of universal standard precautions and warnings to staff about complacency must be undertaken by all healthcare facilities to ensure that transmission figures remain as low as possible.

Recommendations for HBV- and HCV-infected healthcare workers

The follow-up of infected HCWs and decisions about their future career options have to be undertaken in a professional and timely manner. New and relatively effective antiviral agents are now available in most Western countries. There are strong arguments for offering medical and nursing students testing for blood-borne viruses as soon as they enter training. It is much more difficult to answer the question of whether all medical professionals including volunteers should be tested at regular intervals. Some countries insist that doctors know their sero-status, others place no restrictions on staff unless they are involved in proven transmission of a viral infection. So many factors come into play here: ethical, legal, economic, moral, and cultural.

The resounding message from the meeting was that these infections are preventable, that healthcare workers need to be constantly alert, and that the scientific community needs more data to work with to fully understand the scale and seriousness of the problem.

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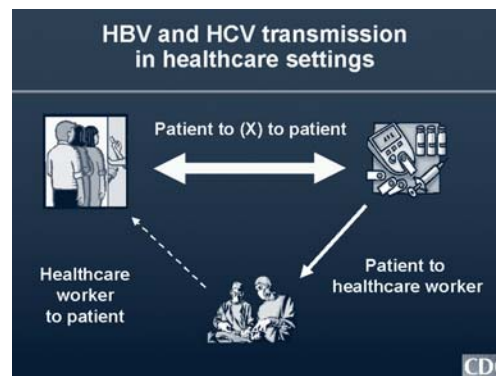
Hepatitis B, hepatitis C, and other blood-borne infections in healthcare workers

- a VHPB Symposium Report -
Rome, Italy, March 17-18, 2005

Transmission of blood-borne viruses in the healthcare setting

The transmission of blood-borne infections within the healthcare setting can occur in three directions: from patient to patient; from healthcare worker (HCW) to patient; and from patient to HCW. Although epidemiological evidence suggests that healthcare-related exposures are not the primary source of hepatitis B virus (HBV) or hepatitis C virus (HCV) transmission, the fact that any transmissions occur within this setting gives rise to concern.

The diagram shows that the most common transmission route is from patient to patient, followed by patient to vulnerable HCW, and more rarely from HCW to vulnerable patient.

**Patient-to-patient transmission**

Patient-to-patient transmission is usually indirect, resulting from contact with HCW's hands, medical equipment and devices, or environmental surfaces and is often a result of failure to adhere to basic principles of aseptic technique for the preparation and administration of parenteral medications in multi-dose vials.

Therapeutic injections are reported as accounting for 21 million new HBV infections and 2 million new HCV infections each year. Many of these injections are performed in less than ideal conditions, often with reuse of needles or multi-dose vials and mainly, but not exclusively, in developing countries. Unsafe injections and reuse of intravenous tubing have been responsible for outbreaks of patient-to-patient transmission of human immunodeficiency virus (HIV) in poorer countries [1].

In recent outbreaks in the United States of America (USA) there are some common themes associated with unsafe use of needles either for injection or for diagnostic procedures. Recently, three nursing homes were involved in incidents with HBV transmission. The sources of transmission were traced back to finger stick tests for diabetes. Although new lancets were usually used for this procedure, a single glucometer was often used for several patients and this device was not cleaned between consecutive tests. The insulin given to patients was also not always labelled and multi-dose vials were shared between patients [2]. These outbreaks could and should have been prevented but were not picked up by current routine surveillance. Fortunately, alert clinicians initiated investigations. The outbreaks occurred in long-term care settings, not hospitals, and it also emerged that the staff responsible for the unsafe practices did not have adequate oversight, were often not adequately trained, and had no idea of the implications of their actions.

It is clear that while hospital environments offer more opportunities for risk of transmission of blood-borne viruses, long-term care homes and other outpatient facilities also need to be aware of the existence of risk and of the often simple measures that need to be implemented to avoid exposure. Adherence to fundamental infection control principles, including safe injection practices and appropriate aseptic techniques, is essential to prevent transmission of blood-borne viruses in healthcare settings. Appropriate oversight of personnel that deliver direct patient care is also critical, particularly in ambulatory care settings, to ensure deficiencies in practice are quickly identified and remedied.

The dialysis setting used to be a high-risk environment for HBV infection. In 1974 the incidence of HBV infections in haemodialysis settings in the USA was 6.2% among patients and 5.2% among staff. After the introduction of a number of measures, including universal precautions, screening of blood for transfusion, and vaccination, this rate fell to 0.1% for patients and 0.03% for staff by 1992 [3].

The dialysis setting is also an environment where patient-to-patient HCV transmission can be clearly demonstrated, with prevalences between 1%-54% in Europe, increasing with the duration of the dialysis. Dialysis using the same machine as a hepatitis C-positive patient or on an adjacent machine increases the risk of HCV infection. One recent study in 58 Italian haemodialysis units showed a cumulative incidence of 9.5 new cases / 1000 patient years. This problem will be even greater in developing countries, where the use of disposable equipment or expensive cleaning techniques is less feasible [4].

Surgery is still a major risk factor for acute hepatitis C: data from the *Sistema Epidemiologico Integrato dell'Epatite Virale Acuta* (SEIEVA) show that the risk ranges from 2.1 for biopsy / endoscopy to 12.1 for gynaecologic surgery, probably due to breaches in infection control procedures between patients. Outbreaks or single cases of HCV infection in other hospital settings were linked to contaminated instruments, multi-dose vials, or anaesthetic circuitry. This is similar to observations made for HBV infection.

Patient-to-healthcare worker transmission

The risk of HBV infection in a HCW after a needle stick injury and in the absence of vaccination or post-exposure prophylaxis is 37%-62% if the source patient is HBeAg positive and 23%-37% if the patient is HBeAg negative [5]. The estimated number of HCWs with HBV infection in the USA has decreased from over 10,000 in 1983 to approximately 400 in 2002 (CDC, unpublished data); this is directly attributable to the introduction of standard precautions, increasing hepatitis B vaccination coverage among HCWs, post-exposure prophylaxis, and more recently the use of safety devices. HBV infection rates have also fallen in the general population in the West, almost certainly due to the introduction of vaccination, but possibly also in part to better socio-economic conditions leading to reduced transmission in family settings.

Since the introduction of hepatitis B vaccination in the USA incidence rates have fallen from a peak of 11.5 per 100,000 in 1985 to 2.6 per 100,000 in 2003 [6]. Similar falls in incidence have also been recorded in other countries after the introduction of hepatitis B vaccination campaigns. For example, in Italy the rate fell from 10.4 per 100,000 in 1987 to 2.9 per 100,000 in 1997 [7].

HCV transmission occurs through occupational exposure to blood, but less efficiently than HBV transmission. The average rate of HCV infection in exposed HCWs is 0.5% (range: 0%-10%) [8,9]. The introduction of universal precaution measures has had an impact on HCV transmission rates. Prevalence rates among healthcare workers remain similar to or lower than those of the general population, even among those in specialties with a high likelihood of percutaneous exposures (e.g., surgeons), suggesting that transmission in healthcare settings has not been a common source of HCV infection for HCWs.

The risk of HCV infection may be effected if the source is co-infected with HIV. In addition, there have been several case reports of delayed seroconversion following exposure to HCV / HIV co-infected source patients. An analysis of risk factors for HCV infection after percutaneous exposure to HCV-infected body fluids showed that the type of device involved, the depth of the injury,

and also gender affected the likelihood of infection, with male HCWs more likely to become infected than female HCWs (3.1 vs 1.0) [10].

HIV transmission in the healthcare setting is more commonly associated with blood contamination, even though HIV is found in all body fluids. The average risk of HIV transmission to an exposed HCW is 0.3%; deep injury, with a device used in a vein or artery and visibly contaminated with blood, increases the risk [11].

Healthcare worker-to-patient transmission

Surgery is a major risk factor for transmission from an HBV-infected HCW, with the level of risk varying by the type of procedure (e.g., exposure-prone invasive procedures are associated with a higher risk of transmission). The number of reports of infected HCWs transmitting HBV to patients has fallen to around ten in the last decade [12]. Most of these cases were associated with HBV-infected surgeons in the United Kingdom (UK) who were carriers of a precore mutant strain of HBV that prevents expression of HBeAg, despite high concentrations of infectious virus, and one technician in Canada who infected 75 patients through procedures involving the implantation of sub-dermal electrodes [13]. For HBV, the risk of transmission from a HCW to one patient during a single procedure is 0.024%-0.24%. The risk of transmission to at least one patient during n procedures is: 11%-70% per 500 interventions and 57%-100% per 3500 interventions [14].

There are few reports of HCV transmission from infected HCWs to patients and most cases have not been associated with the performance of exposure-prone procedures but rather with the use of illicit drugs by the HCW [15]. The transmission of hepatitis C virus from HCW to one patient carries a risk during a single procedure of 0.00036%-0.0036%. The risk of transmission to at least one patient during n procedures is 0.017%-1.7% per 500 interventions and 1%-12% per 3500 interventions [9,14].

Since HBV and HCV share some modes of transmission, HCWs who are at risk may become infected with both viruses. HCWs co-infected with HBV and HCV are more likely to suffer from more severe histological liver disease than those infected with only one of the blood-borne pathogens. The conclusions regarding HBV / HCV co-infection can be summarised as follows: (1) There are scarce data on HBV / HCV co-infection in HCWs; (2) HBV / HCV co-infection by the two viruses is not uncommon; (3) In general, there is decreased replication of one or both viruses in case of combined infection.

The prevalence of HIV in HCWs is similar to or less than that in the general population. The risk of HIV transmission to one patient during a single procedure is 0.00024-0.0024%. The risk of transmission to one patient during n procedures is 0.12-1.2% per 500 interventions and 0.8-8.1% per 3500 interventions. Only one case of transmission has been reported involving an orthopaedic surgeon, and a second case involving a gynaecologist is being investigated.

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Exposure-prone procedures

A healthcare-associated infection is an infection that is not present or incubating at the time of admission and one that can be linked epidemiologically to healthcare procedures.

The risk of healthcare related transmission of HBV and HCV, and to a lesser extent HIV, is increased during the performance of exposure-prone procedures (EPPs). These are defined according to a UK Advisory Panel as: 'invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker. These include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips, or sharp tissues (e.g., 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' [1]. The introduction of standard infection control precautions has some effect on limiting the risks of exposure but does not eliminate them entirely.

Contact and recontact

The estimated risk of percutaneous injury to surgeons varies between 1.3 and 15.4% and the risk of recontact after injury, i.e., the sharp item coming into contact with the patient's tissue again after the injury to the surgeon, was shown by one study to be 2%, rising to 4.2% in general gynaecological procedures, and to 8.5% for vaginal hysterectomy [2]. The same study, conducted in the operating theatres of four major teaching hospitals in the USA showed that of the 88 injuries sustained by surgeons, recontact was as high as 32%.

In a large prospective multicentre survey study by the University of Pisa, Italy (39 hospitals; 15,375 operations), 9.2% of healthcare workers were exposed to blood or body fluids and 2% sustained a parenteral or needle exposure to blood [3].

One technique to reduce glove punctures and blood exposure was studied at the University of Hull, UK, where blunt needles were used to close the abdomen in the studied patients. The puncture rate was 14 out of 39 where cutting needles were used and 3 out of

46 where blunt tipped needles were used. Most of the punctures were through the gloves on the non-dominant hand [4]. In another study of orthopaedic operations during which blunt needles were used in addition to double gloves, there was a 16% rate of penetration of the outer glove and 6% for the inner glove [5].

The problem of recontact could clearly be avoided if the injury was dealt with immediately after it occurred, but this is frequently not feasible simply because it is not noticed at the time. The hand is the most common site of injury and blood contamination in operating theatre personnel, and while gloves are supposed to prevent the transmission of pathogens from patient to surgeon, and from surgeon to patient, there are a number of studies that measure glove leakage rates and skin-blood contacts which suggest that a degree of risk remains.

Working area and risk

Certain hospital departments are considered more likely to be involved in EPPs: accident and emergency units, departments of dentistry, obstetrics and gynaecology, surgery, and orthodontics.

The types of staff likely to carry a high transmitter risk during EPPs include surgeons, operating room nurses, intensive care staff, interventional radiologists and their assistants, and emergency department staff [6].

Risk categories

It is somewhat difficult to precisely define the degree of risk per procedure, but an attempt has been made [7] to divide procedures into groups and categorise them as high, variable, or low risk:

- High risk: Any submucosal invasion with sharp, hand-held instruments or procedures dealing with sharp pathology / bone spicules, usually in poorly visualised or confined spaces (e.g., orthopaedic surgery, trauma surgery, internal cavity surgery).
- Variable risk: Minor dental procedures (excluding examination), routine dental extractions, internal / instrument examinations / biopsy (e.g., endoscopy, vaginal examination, laparoscopy), minor skin surgery.

- Low risk: Interview consultation, dental examination, non-invasive examinations or procedures (aural testing, electrocardiograph, abdominal ultrasound), intact skin palpation (gloves not required), injections / venipuncture (gloves required).

Whilst the type of procedure affects the risk of injury and the accompanying risk of transmission, it should be said that the number of infections resulting from exposure-prone procedures remains low. A literature study by Puro *et al.*, published in 2003, concluded that 50 outbreaks had been reported since 1972 in which 48 infected healthcare workers, 39 of whom were surgeons, had transmitted hepatitis B virus to approximately 500 patients [8]. Six published reports of hepatitis C virus transmission resulted in the infection of 14 patients, with unpublished reports of several more cases in the UK and USA [9]. However, there is no cause for complacency; all measures should be taken to protect patients and healthcare workers and clearly most, if not all of these reported cases could and should have been avoided.

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Are patients a risk to healthcare workers?

The question of whether patients should be tested before undergoing invasive procedures is a valid point for discussion. There are currently no recommendations for patient testing and no public health rationale has been established. If the decision is taken to test patients, we need to examine who has an interest / benefit in testing.

Germany recommends hepatitis B vaccination of patients undergoing surgery and is the only country to do this. It could be argued that if all healthcare workers are vaccinated against HBV there should be no need to test or vaccinate patients prior to procedures. The added benefit of testing the serostatus of patients in the presence of full universal precautions may be minimal, except possibly for the diagnostic companies.

According to the evidence derived from a study by Baldo *et al.* [1], post-exposure transmission rates from patients to HCWs are low. In this study involving 245 patients, 11.4% of whom were HBV positive, there were no transmissions over a five-year follow-up period. The study also showed that 27.8% of the 245 source patients were HCV positive and again there were no transmissions over the five year follow-up period.

The risk to HCWs after a percutaneous exposure is 6-30% for HBV and 1.8% for HCV [2]. A French study of HCV status in patients attending for invasive radiology revealed that 9.7% of the 944 patients were HCV positive [3]. This study also commented on the poor adherence to universal precautions, meaning that staff were effectively ignoring the potential risk.

A study in Germany [4] showed that 0.84% of emergency room patients were HBV positive, which is the same prevalence level as in the general population. The same study showed that 2.9% of

patients attending the emergency room were HCV positive, which is higher than the level in the general population.

In answer to the original question of whether to test before invasive procedures, there seem to be only two favourable aspects from the patient's point of view: (a) a patient with positive test result can be referred for proper treatment; and (b) a patient with negative test result can prove nosocomial transmission if this occurs.

From the healthcare point of view, the hospital obtains data for medico-legal purposes if there is a need to prove non-transmission of blood-borne viruses (BBVs) by its services. False-negative results or seroconversions could, however, be a source of problems for both patients and staff.

HCWs may also wish to know a patient's serological status so as to adapt their behaviour, but this is not an acceptable reason for testing. Universal precautions should be just that, applicable at all times and to contacts with all patients. In addition, any question of withholding services in case of positive test results would be extremely unethical.

France now tests patients before blood transfusion for historically based medico-legal reasons. Italian hospitals also test people pre-endoscopy and possibly pre-surgery for a second time, as a requirement of the hospital management, also for medico-legal and not medical reasons.

Prevention strategies should be encouraged in order to eliminate or minimise the transmission risk. Standard precautions for preventing infections in HCWs have already resulted in a dramatic decline in both HBV and HCV infections.

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Sharps injuries in healthcare workers

The World Health Organization (WHO) has recently made an estimation of 25 environmental risk factors [1], which includes the risk from sharps injuries for healthcare workers. The method of assessment involved the quantification of health impacts caused by environmental and other risk factors at population level, using a comparative framework, definitions, and outcome measures. The aim of this study was to raise awareness of the problem and to assess the potential for interventions.

A model was used as there are too little data available on sharps injuries to make a comparative estimate. The basis of the model to give the probability of infection after sharps injury is as follows:

$$P = p_v \cdot p_i \cdot p_s,$$

where:

- P (probability) is based on the assumption that the risk of infection increases in proportion to the number of infectious individuals in the population;
- p_v is the prevalence of active infection in patients – the greater the prevalence, the greater the probability that the injuring sharp will be contaminated with blood-borne pathogens;
- p_i is the probability of infection after percutaneous injury with a sharp that had been used on an infected source patient;
- p_s is the proportion of HCWs susceptible to infection.

The following equation relates the probability of at least one 'success' per year (in this case the infection of a healthcare worker, i.e. the incidence of infection) (I_n) to the number of events needed for an infection to occur (n) and the probability (P) that an event will occur [2]:

$$I_n = 1 - (1 - P)^n$$

The calculated outcome in terms of incidence of HBV, HCV, or HIV infection due to sharps injuries in HCWs is given as the attributable fraction (AF) for occupational incidence.

$$AF (\text{occupational}) = \frac{\text{incidence (occupational)}}{\text{incidence (occupational)} + \text{incidence (other causes)}}$$

The model was made for 14 regions of the world, for four working age groups (15-69 years), and for gender. The difficulties encountered were that

- susceptibility changes with age and differs between the general population and HCWs
- there are poor data on HBV vaccination coverage
- there are poor data on needlestick injuries in certain regions
- the prevalence of active infection is not always the same in the general population and in patients.

The estimated number of deaths was calculated using following figures [3]:

Hepatitis B

- Progression to chronic infection of 6% for adults [4]
- Annual clearance of infection of 1% following chronic infection [5]

- Age-dependant mortality according to African and Asian studies [6]

Hepatitis C

- Rate of progression to chronic infection of 63% before age 40 and 80% after age 40 [7]
- Cumulated incidence rate of cirrhosis of 5% (20% after age 40) at 20 years among patients with chronic infection [7,8]
- Yearly mortality rate associated with hepatocellular carcinoma and chronic liver disease of 2.7% after onset of cirrhosis [7]

A number of uncertainties are reflected in the upper and lower boundaries of the figures and are caused by the lack of data on the annual incidence of sharps injuries, HBV immunisation coverage, and the prevalence among hospital populations, for which the median factors of 3.4 for HCV, 1.9 for HBV and 5.9 for HIV were used.

Input data (with focus on industrialised regions)				
	Amr A	Eur A	World	Sear D
Number of HCWs	7 million	6 million	35 million	1.4 million
Proportion of HCWs in GP	2.5%	1.4%	0.6%	0.11%
Annual number of sharps injuries	0.18	0.64	0.18 - 4.7	2.3
HCWs exposed to contaminated sharp (thousands)	22 HCV 7 HBV 8 HIV	16 HCV 43 HBV 9 HIV	900 HCV 2 100 HBV 327 HIV	57 HCV 109 HBV 23 HIV
Proportion exposed to contaminated sharps	< 0.4%	< 1.1%	< 9%	< 14%

Results for the year 2000			
	Amr A	Eur A	Global
Infections attributable to occupation, HCV	390 (240-1800)	290 (100-2600)	16 400 (5900-86000)
Idem, HBV	40	210	65 000 (2400-240000)
Idem, HIV	5	6	1000 (200-5000)
HBV without PEP	400	2100	
Attributable fraction in HCWs for HCV and HBV	8 and 1%	25 and 8%	39 and 37%

The number of HCWs vaccinated against hepatitis B infection is estimated to be 67% in North America (Amr A), 71% in Europe (Eur A), 77% in the Western Pacific region (Wpr A), and 18% for South-East Asia (Sear D) (see ref. [2] for other regions).

It should be borne in mind that three things are necessary for an infection to be transmitted to a HCW: (1) there must be an injury

with a sharp; (2) the sharp must be infected; and (3) the HCW must be susceptible.

However, since 10% of HCWs worldwide have apparently had a needle stick injury in the past year, this is a real problem and although the burden of disease is globally a relatively small one, the following aspects are worth considering:

- The problem is important in the specific occupational groups of concern
- All of this burden is preventable

This burden concerns those who provide healthcare for others and thus most strongly affects the healthcare system in regions where the problem is greatest, i.e., in developing countries.

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Based on a presentation by Dr Annette Prüss-Üstün, World Health Organization, Geneva, Switzerland.

Management of occupational exposures to blood-borne infections

General measures

It is generally recommended that staff working in risk areas, where the chance of exposure to a blood-borne infection is higher than in general care, such as genito-urinary clinics, emergency departments, or operating theatres, should seriously think about the situation of an actual exposure. In practice, this preparation for the hypothetical event has either not occurred, or the staff member's thought processes are overtaken by the emotion of the moment. It is therefore essential that a structure and an action plan be put in place by the hospital or clinic so that any incidents can be dealt with efficiently and sympathetically.

Most healthcare settings with high HIV or HBV exposure risk have plans in place to offer post-exposure prophylaxis (PEP) to staff. In the case of HIV this will involve a course of antiretrovirals and for HBV, hepatitis B immunoglobulins (HBIG) along with hepatitis B vaccine if indicated; the risk of HBV transmission is obviously vastly reduced if health workers are properly vaccinated. There is currently no PEP for hepatitis C virus exposure as immunoglobulins are not effective, alpha-interferon does not prevent transmission, antiviral agents have not been adequately assessed, and there is no vaccine.

The management of an exposed HCW should follow a written protocol to ensure:

- prompt reporting of occupational exposures
- post-exposure assessment of the exposed HCW
- sources for emergency advice and psychological support
- management options
- comprehensive follow-up
- counselling of the source patient and testing if consent is given
- accessing out-of-hours services
- information and education of HCWs on policy, risks of blood-borne viruses (BBVs), reporting of incidents, and PEP availability and benefits [1].

Hepatitis B virus exposure

The VHPB recommendations regarding PEP have been described before [2].

As an additional example, the slide in the right column gives an overview of HBV prophylactic measures for reported exposure incidents in the UK.

HBV status of exposed HCW	Significant exposure		
	HBsAg-positive source	Unknown source	HBsAg negative source
< 1 dose hepatitis B vaccine pre-exposure	Accelerated course of hepatitis B vaccine*	Accelerated course of hepatitis B vaccine*	Initiate course of hepatitis B vaccine
> 2 doses hepatitis B vaccine pre-exposure (anti-HBs not known)	One dose of hepatitis B vaccine followed by 2nd dose one month later	One dose of hepatitis B vaccine	Finish course of hepatitis B vaccine
Known responder to hepatitis B vaccine (anti-HBs > 10 mIU/ml)	Consider hepatitis B vaccine booster	Consider hepatitis B vaccine booster	Consider hepatitis B vaccine booster
Known non-responder to hepatitis B vaccine (anti-HBs < 10 mIU/ml 2-4 months post-immunisation)	HBIG x 1 Consider hepatitis B vaccine booster	HBIG x 1 Consider hepatitis B vaccine booster	No HBIG Consider hepatitis B vaccine booster

*An accelerated course of vaccine consists of doses spaced at 0, 1, and 2 months. A booster may be given at 12 months to those at continuing risk of exposure to HBV. Immunisation Against Infectious Disease "The Green Book". London: Department of Health, 1996.

A HCW who is exposed to hepatitis B virus and subsequently experiences seroconversion should receive the following management and care:

- referral to a hepatologist for specialist advice
- counselling on prevention of secondary transmission and management of household contacts
- restriction of performance of exposure-prone procedures to prevent HCW-to-patient transmission
- counselling on future disease management and career options.

Smith [3] looked at the differences between HCWs employed in hospitals and general practice in the UK in relation to their pre- and post-exposure health behaviour. It was shown that general practitioners (GPs) versus hospital consultants were significantly less likely to have received a primary course of HBV vaccination, less likely to have received a booster vaccination and less likely to have had their blood anti-HBs status checked 2-4 months after the last vaccination. Smith also found that GP nurses were less likely to fill in a form reporting community exposure incidents than hospital nurses and that limited access to occupational health services influenced receiving a booster and testing for immunocompetence. It was concluded that occupational health services are pivotal in the protection and follow-up of HCWs [3].

HIV exposure

In the European setting, recommendations have been made for HCWs exposed to HIV infection, according to (a) the type of exposure; (b) the type of material involved; and (c) the source patient [4].

(a) Type of exposure

- In case of percutaneous injury where the injury is deep, the device is visibly contaminated with blood, or the needle has been placed in the source patient's artery or vein, PEP is recommended.
- In case of mucous membrane exposure, non-intact skin or bites, PEP should be considered.
- In case of intact skin exposure, PEP is discouraged.

(b) Type of material

- Blood, body materials containing visible blood, cerebrospinal fluid (CSF), concentrated virus in research laboratories or production facilities: PEP is recommended.
- Semen, vaginal secretions, synovial, pleural, peritoneal, pericardial or amniotic fluid and tissues: PEP should be considered.
- Urine, vomit, saliva, faeces, tears, sweat, or sputum: PEP is discouraged.

(c) Source patient

- Known to be HIV infected: PEP recommended.
- Serostatus unknown but high prevalence rate in general population: PEP should be considered.
- If the source patient is informed about the incident and either refuses to consent to testing, cannot be tested for some reason, or the status is unknown: PEP should be considered.
- If the patient is HIV seronegative: PEP is discouraged.

General guidance on PEP recommends that it should be initiated for all significant exposures. It should ideally be started within one hour of the exposure and the normal recommended cut-off time is 72 hours. In some conditions PEP may also be considered up to two weeks after exposure as the kinetics and early pathogenesis of HIV are not fully understood [1]. PEP should continue for 4 weeks and the affected HCW should be followed-up for at least six months after cessation of PEP.

This follow-up should form part of a package of measures that begin with initial counselling at the time of reporting of the incident and include advice on prevention of secondary transmission, baseline blood sampling after exposure, testing and physical examination at six weeks and three months post-exposure, re-testing at six months, and monitoring of PEP acceptability and drug toxicity [1].

The rapid initiation of PEP often means that the viral status of the source is not immediately available and that the HCW begins taking medication before this information is known. This may lead to the HCW taking toxic drugs for longer than necessary or even unnecessarily if the source proves to be seronegative, and also experiencing prolonged psychological stress as a result of this delay. The cost of anti-retroviral therapy is high and delays in obtaining test results are not cost-effective. One solution to this problem is the introduction of rapid HIV testing. Test results can become available within 45 minutes (for example, the Capillus quantitative HIV1/2 antibody test) facilitating appropriate planning of HCW follow-up and appropriate administration of PEP medication. Rapid testing has also been shown to improve exposure reporting and to decrease the number of source patients remaining untested [5].

HCV exposure

The following measures are recommended in the management of

HCWs exposed to HCV-positive source patients:

- In case of a known HCV-infected source, a baseline serum sample should be obtained from the HCW for storage; serum / EDTA should be collected for genome detection at six and twelve weeks, and for anti-HCV at twelve and twenty-four weeks.
- If the source is known not to be infected with HCV a baseline serum sample should be obtained from the HCW and follow-up serum if symptoms or signs of liver disease develop.
- If the HCV status of the source is unknown, a baseline serum sample should be obtained from the HCW and a designated doctor should perform a risk assessment; *high risk*: manage as for known infected source; *low risk*: obtain serum for anti-HCV at 24 weeks [6].

A number of issues are important when dealing with HCV exposures, including:

- Completeness of follow-up, particularly in cases of exposure to more than one blood-borne infection.
- Appropriate application of virological markers to the management of patients.
- Addressing timing of initiation of treatment for HCWs who have seroconverted and questions about the adequacy of existing evidence in relation to early treatment in the healthcare setting.
- As HCV viral load is high at seroconversion, what are the implications of this in HCW-to-patient transmission of HCV? Should post-exposure management of the HCW include looking for possible cases of transmission from the HCW to patients managed during the seroconversion period?

Summary of main aspects of HCW post-exposure management

- Protocols and continuous access to services including out of hours
- Prompt evaluation and assessment of the exposed HCW
- Source patient testing, bearing in mind the 'serological window' in the source patient
- Rapid source testing to guide the use of PEP
- Viral resistance testing to guide the regimen of PEP
- HCW compliance and dealing with side effects
- Rigorous follow-up for preventing secondary transmission and offering appropriate treatment to the HCW.

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Importance of HBV DNA levels in infected healthcare workers

The policy of excluding healthcare workers from performing exposure-prone procedures varies between countries. The European Consensus on HBV and HCV infection in HCWs [1] recommends

the use of an HBV DNA cut-off level for exclusion of 10^4 genome equivalents (geq)/ml. In the UK all HBeAg-positive staff are excluded, as are HBeAg-negative HCWs with an HBV DNA level

> 10³ geq/ml. In the Netherlands, the HBV DNA cut-off level for exclusion is 10⁵ geq/ml.

A number of factors are associated with the risk of HBV transmission by HCWs [2]:

- the serum HBV DNA level;
- HBeAg positivity;
- the duration of surgery;
- the volume of blood transmitted;
- the route of transmission (percutaneous vs mucosal);
- the skill and medical condition of the HCW involved.

The HBeAg status of HCWs who transmit HBV is important as most cases involve HBeAg-positive HCWs; the first case of HBV transmission by an HBeAg-negative HCW was reported in 1993. All HBeAg-negative surgeons who transmitted HBV to patients had the pre-core mutant with a G-to-A transition at nucleotide 1896, introducing a stop at codon 28. HBeAg was not produced, in spite of continuing viral replication. The HBV DNA levels in the surgeons tested varied from 10⁴-10⁹ geq/ml [3,4].

The use of quantitative detection methods means that more information about the virus is made available, making it easier to:

- follow the course of chronic infections;
- detect disturbances in host-pathogen interactions;
- make soundly based therapeutic decisions; and
- determine levels of infectivity.

Qualitative analysis of the virus also establishes subtypes, genotypes, variants, mutants, and genotypic resistance, which are increasingly relevant for management of HBV infection.

The amount of virus transmitted during a needlestick injury is important. The following slide shows the estimated quantity of infectious viral particles transmitted when the HBV DNA level is 10⁵ geq/ml.

Estimation of infectious particles transmitted by needlesticks with a HBV DNA level of 10 ⁵ geq/ml		
Event	# μ l serum transmitted ¹	# infectious particles transmitted ²
Suture needle		
• 0.33 mm needle, 5 mm penetration	0.03	< 1
• 1.12 mm needle, 5 mm penetration	0.23	2
Hollow needle		
• 1.07 mm needle, 2 mm penetration	0.14	1
• 1.07 mm needle, 5 mm penetration	0.44	4

¹ Calculation infectious particles: volume of serum in ml x HBV DNA concentration in geq/ml x 0.10 (a)
² a) Number of infectious HBV particles ~ 10% of total number of HBV particles²

¹ Bennett, J Am Coll Surgeons 1994; ² Heermann, J Clin Microbiol 1999

Erasmus MC

There is considerable variation in HBV DNA levels over time, implying inconsistency in the risk of transmission [5]. These significant fluctuations confirm the need for regular repeated testing, particularly in HBeAg-negative carriers [6,7]. Repeated testing, for example every six months, would mean a lower margin for cut-

off is necessary.

When assessing the reliability and reproducibility of HBV DNA tests, the following considerations have to be taken into account:

- there is a need for internationally defined reference standards;
- an internal calibration standard for commercial and non-commercial kits has been mandatory since December 7, 2003;
- a standard has been developed, but only for HBV genotype A;
- qualitative and quantitative assays must yield reproducible results;
- inter- and intra-assay variability is greater for samples with low HBV DNA levels;
- the use of internal controls is essential to monitor the quality of extraction and amplification.

Questions and subjects of discussion

1. Should HBV DNA be measured instead of HBeAg?
 - Active replication of HBV is associated with the presence of HBeAg.
 - Knowledge of HBV DNA levels in HBeAg-negative individuals renders the exclusion of HCWs based solely on HBeAg status alone obsolete.
2. What level of HBV DNA is acceptable to prevent transmission of HBV from HCW to patient during EPPs?
 - The choice of a low level of HBV DNA (10³ geq/ml) must be accompanied by the knowledge that (a) inter- and intra-assay variability is greater in samples with a low HBV DNA level; and (b) repeated testing will lead to a greater proportion of exclusions.
 - Regular monitoring of HBV DNA levels can narrow the safety margin.
 - The introduction of internationally defined reference standards for all genotypes, and participation in international quality control programmes is required.
3. To what extent is the loss of valuable HCWs acceptable?
 - Vaccination against HBV is safe and should be mandatory.
 - Each HCW who is a carrier of HBV should be referred to a hepatologist.
 - Antiviral therapy may reduce the viral load and may thus prevent unnecessary exclusion of valuable medical personnel.

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Look-back studies - medical detective work to trace potential healthcare worker-to-patient transmission of blood-borne viruses

Look-back studies could also be called patient notification exercises or trace-back investigations, which are the more descriptive names for investigations triggered by the identification of a healthcare worker infected with a blood-borne pathogen and may or may not

follow a documented case of transmission from the HCW to a patient.

The main objectives of look-back studies are to:

- Inform patients about the degree of risk

- Detect infections and provide care
- Prevent further transmission
- Collect data to estimate the risk.

The main questions to be asked before embarking on a look-back study are: (1) When should a patient notification exercise be conducted? (2) How far back should this notification go? (3) Which patients should be included?

Look-back studies are extremely time- and resource-consuming activities and currently they are normally only performed for high-risk, category 3 exposures (the fingertips are out of sight for a significant part of the procedure, or during certain critical stages) and when an index case has been identified.

There is a need to:

- define the period involved, which means discovering when the HCW became infected and how far back the possible risk goes;
- define the at-risk population by analysing which procedures were performed and the risk factors involved;
- trace cases via medical records, operating theatre, or other department registers;
- contact cases via GPs, who also need to be fully informed, send letters to patients, establish a contact resource – usually a telephone helpline that should also be manned outside of office hours;
- test consenting patients;
- allocate resources, both in terms of facilities and personnel;
- manage the media whose well-established talent for producing headlines that incite general disquiet may outweigh their usefulness in contacting potentially at-risk patients.

An example of a look-back study that was undertaken in two phases is one involving an obstetrician / gynaecologist working in the UK in 2003 who was infected with HCV. At that time, the 500 most recently treated women were identified; 432 of them could be contacted and were offered a blood test and counselling. None of these HCV test results was positive. Unfortunately, a patient who had also been treated by the healthcare worker but whose surgery had been performed outside of the time limit set for the initial study, presented with hepatitis C that was adjudicated to have been transmitted to her by the HCW. Further advice was taken from the UK Advisory Panel and a second phase look-back exercise was begun in January 2005 to find all of the patients who had been treated by this surgeon. In this phase, 2350 women for whom an address was available were contacted by letter and offered HCV testing. The GPs of these women were also informed about the situation. The whole exercise involved eight UK NHS trusts and one Scottish Health Board, giving some idea of the scale and complexity of some look-back studies.

A total of 50 episodes of HBV transmission to patients, involving 49 healthcare workers, have been described during the period 1972

- 2005. A review of 26 look-back studies prompted by these episodes shows that 29,507 patients were exposed to HBV. Among them, 20,100 were tested and 360 (1.8%) positive cases were identified.

The objective of informing persons who are unaware that they are infected with blood-borne viruses and preventing further transmissions has to be balanced by the feasibility of an exercise such as the one in our hepatitis C example, the availability of suitable treatment, and the availability of preventive measures. The instinctive public reaction would be to inform everyone of any potential risk, but the cost-effectiveness of doing this may be totally unrealistic in terms of quality of life years (QALY) spared or in comparison with other public health interventions. Each case needs to be looked at individually and guidelines such as those issued by the UK Advisory Panel or by health authorities in other countries closely followed [1,2].

It should also not be forgotten that apart from the patient's interests [3], consideration has to be given to the HCW involved. The HCW may not previously have known about his or her infective status. How can he or she best be protected from adverse reactions on the part of patients or even colleagues, and how should future disease follow-up be dealt with to ensure proper and effective care? In many cases a career change of direction will also be necessary – avoidance of exposure-prone procedures until treatment is complete or if this is not possible, advice on re-training or re-orientation.

In conclusion, mandatory / compulsory HBV vaccination should be implemented in medical schools. It is also time to reconsider a wider application of voluntary HCV and HIV screening for HCWs, including post-exposure and regular, scheduled testing.

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Cause and pause for thought - interesting cases

A number of cases discussed during the VHPB meeting in Rome are of interest for healthcare workers; not only because they demonstrate that the chance of infection and the subsequent, possibly unwitting, risk to either themselves or their patients is too real to be ignored, but also because this risk exists in so many areas of professional activity.

Anaesthetists

A recently reported case of HCV transmission during a surgical procedure involved a 44-year-old female patient who presented with acute HCV infection eight weeks after receiving anaesthesia from an HCV-positive anaesthetist [1]. The comparative nucleotide sequence analysis proved that the anaesthetist was the source of the infection

even though no exposure-prone anaesthetic procedures had been performed. This is the first described case of HCV transmission in the UK that could not be attributed to an exposure-prone procedure and the first involving a known HCV-positive anaesthetist.

Cardio-thoracic surgeons

Seven patients treated by an American cardiac surgeon were diagnosed with HCV infection and it was established that the surgeon had definitely infected three of these patients and probably four others [2]. The surgeon was tested once these cases came to light and it was established that he was HCV positive. He had no other risk factors and the probable source of his own infection was an HCV-positive patient.

The name of the surgeon was not released to the general public, but in agreement with his hospital management he now reveals his sero-status to patients before surgery and they undergo baseline testing for hepatitis C and sign a consent form after full discussion of the risks involved. He also takes extra precautions during surgery, such as wearing double gloves and using blunted needles. Since the discovery of the cluster of cases he has continued to operate and no further cases were diagnosed among the two hundred patients he treated in the year following his diagnosis.

This case gives food for thought on a number of issues, including professional ethics, as this doctor had obviously not been tested before the cases came to light; a possible discussion about the ability of patients to fully understand the risks involved; and the problem of patient confidentiality as this surgeon is also a patient who is revealing his sero-status to others each time he operates but may have no control over the further spread of this information. There is also the important fact that if he were to be prevented from operating, a number of seriously ill patients might be deprived of quality of life or even life itself, since his skill as a surgeon has never been disputed and he would normally operate on more than 300 patients per year.

Medical and surgical residents and students

An anonymous survey of 550 medical students and residents in 1989-1990 to look at the incidence of needlesticks and other exposures to patients' blood and body fluids revealed that 71% of respondents reported such exposures in the preceding year [3]. Surgical residents had a six-fold greater rate of occupational exposure than medical residents and were significantly more likely to experience suture needlesticks, cuts, open wound contamination, and mucous membrane exposure. Medical students were at lower risk compared with residents but had higher rates of hollow-needle puncture incidents. There was no trend for level of residency training. Only 9% of these exposures had actually been reported to the health centre. There is a clear need for improvement in reporting of incidents, and also a need for improvement in precautionary measures since a proportion of these accidental exposures were undoubtedly preventable.

Nurse-midwives

Of the nurse-midwives who responded to an anonymous survey, 74% had soiled their hands with blood at least once in the preceding six months, 51% had splashed blood or amniotic fluid in their faces, and 24% had sustained one or more needlestick injuries during this period [4]. In spite of the high level of training and knowledge, only 55% reported routinely practising universal precautions. Several factors apparently affected their use, including perception of risk of transmission of blood-borne

pathogens, knowledge of routes of transmission, and rationale for not using barriers. Clearly there is an important need to develop training strategies to encourage the use of universal precautions.

Orthopaedic surgeons

Tokars *et al.* [5] conducted a survey of surgeons attending an annual meeting of the American Academy of Orthopaedic Surgeons to assess the incidence of occupational blood contact and the prevalence of HIV infection. A total of 3420 surgeons (47.9% of attendees) participated and of these, 87.4% reported a blood-skin contact and 39.2% reported a percutaneous injury in the previous month. These self-reported incidents clearly underline the need for compliance with infection control precautions and the use of techniques and equipment designed to minimise the risk of exposure to blood during surgical procedures.

Pathologists

A retrospective study of injuries and exposures to body fluids while handling tissue published in 1991 revealed that among the team of nine residents and 27 staff pathologists, 20/36 (56%) reported sustaining a cut or needlestick injury in the preceding year [6]. The residents reported five-fold more injuries than staff pathologists and the number of injuries corresponded to a rate of one per 37 autopsies and one per 2,629 specimens handled.

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Universal precautions and the safety of healthcare workers

General precautionary measures protect both healthcare workers and patients whenever there is potential exposure to blood or other body fluids. In the operating theatre, gowns, masks, and gloves are the general standard but no system is foolproof. Of all operating specialists, orthopaedic surgeons most frequently adhere to the recommendations, e.g., donning two pairs of gloves when operating, or application of effective barrier protection. Their main concern, however, is to protect the patient from acquiring osteomyelitis, and much less so to safeguard patients or themselves against transmission of hepatitis viruses.

A number of measures may stop transmission of infection and these may involve the development of alternative techniques and/or

changes in working practices. Utilising laparoscopic surgery to reduce the inherent risks associated with open surgery is an excellent example. The use of stapling devices instead of sutures minimises the risk of glove and skin puncture caused by suture needles. If suturing is essential, blunt needles should be used whenever feasible [1,2]. Double gloving while operating is also helpful, particularly when wearing indicator undergloves since these will change colour if a puncture occurs. Although disliked for the interference with dexterity, two layers of glove will also significantly reduce the transmitted and potentially infective fluid volume; mainly in solid but to a lesser degree also in hollow-bore needles. Needle-protective devices may reduce the incidence of contaminated percutaneous needlestick injury, but the safety device must also be disposed of

with care. Sharps containers are not to be overfilled – unfortunately, something that is all too common – and should be readily accessible. Glass vials are a frequent cause of hand injury or glove damage. Multiple-dose vials, or fluid bags shared amongst cases to draw up drugs, are not safe from the patient's point of view. Some anaesthetic equipment, such as disposable laryngoscopy blades, laryngeal mask airways, or gum elastic bougies, has been redesigned to make contamination and disease transmission unlikely. However, the equipment was often found to be of inferior quality, potentially leading to difficulties in airway management, risking morbidity, or even mortality. Understandably, this can seriously hamper the wider acceptance of an otherwise quite useful development.

It is clear that universal precautions only work if they are applied. It is also a fact of life that familiarity breeds, if not contempt, then at least carelessness. Regular reminders on apparently simple safety measures and discussions of the consequences of mistakes or of deliberately ignoring them should be part of routine training in each hospital department.

Universal precautions also need to be adhered to in non-hospital settings. The problem of re-use of lancets for blood testing has been referred to elsewhere in this issue [see 'Transmission of blood-borne viruses in the healthcare setting']. Sadly, in this example, most of the staff involved in the spread of infection from patient to patient had not received adequate training and had no idea of the dangers they were exposing their elderly residents to. It should also be mentioned that peer comments during the investigation suggested that one reason for not using gloves was to make the environment less 'clinical' [3]. It is surely not impossible to combine homeliness with cleanliness and there should be no question of abandoning the precautions of hand washing and wearing gloves when performing basic care. The increase in the numbers of elderly people needing some kind of residential care means a necessary increase in establishments offering this service. This will as a consequence lead to a much higher number of HCWs in this particular field. Anyone who has contact with patients should be given at least basic training in the practical application of universal precautions and should be encouraged to refresh this knowledge at regular intervals. This rule applies not only to high-powered surgical

or operating room staff but also to low-tech, kindly carers in homes for the elderly, and indeed to all of those working in healthcare.

Universal precautions

The following list is provided by the Health Protection Agency and the National Radiological Protection Board [4]:

- Practice good basic hygiene with regular hand washing, also *before* and *after* donning gloves
- Cover wounds or skin lesions with waterproof dressings
- Avoid contamination of person and clothing with blood / body fluids
- Disposable gloves and aprons should be worn when attending to dressings, performing aseptic techniques, or dealing with blood / body fluids
- Handle and dispose of sharps safely
- Avoid puncture wounds, cuts, and abrasions in the presence of blood
- Avoid using sharps if possible
- Protect eyes, mouth, and nose from blood splashes
- Know what to do if there is a sharps injury or blood splash incident
- Clear up blood spillages promptly and disinfect surfaces
- Dispose of contaminated waste safely
- Know how to deal with soiled linen
- Clean, disinfect, and sterilise equipment as appropriate.

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The European Consensus proposal for handling healthcare workers infected with hepatitis B and C viruses

Current recommendations for infected healthcare personnel

There are unfortunately no universally accepted clear-cut guidelines on how to deal with healthcare workers infected with either HBV or HCV. Some countries restrict staff who are HBeAg positive or HVB DNA positive from performing EPPs, but most countries do not restrict practice for HBsAg-positive / HBeAg-negative healthcare workers.

The European consensus proposal [1] was designed to establish the current state of affairs in the countries surveyed and to make recommendations for change. The considerable problems involved in collating the information were caused by: (a) the lack of standardisation for epidemiological data collection on HCWs in individual countries; (b) the lack of standardisation of viral load assays; (c) variable attitudes regarding the assessment of an acceptable risk when employing an infected HCW; and (d) concern about the effect of opening a debate on the privacy of infected HCWs and the ability to protect them against discrimination.

The countries represented

Sixteen countries were approached with survey questionnaires and

thirteen of them responded: Austria, Belgium, France, Germany, Greece, the Netherlands, Ireland, Israel, Italy, Portugal, Sweden, the UK, and the USA. The work was supported by the European Association for the Study of the Liver (EASL) and the British Liver Trust (BLT).

The expert committee of specialists in blood-borne viruses found that there was full consensus on preventing infection, with agreement on standard precautions and the need for active immunisation against HBV as early as possible in the career of all HCWs, regardless of their involvement in EPPs. The consensus was less strong when it came to identifying infected HCWs and was even lower regarding the management and restriction of infected HCWs performing EPPs. The question of prevention among medical students and trainee health professionals was not covered by the survey.

Identification of the infected HCWs

There is some degree of controversy as to the wisdom of identifying infected HCWs, unless they are directly involved in a case of HBV or HCV transmission. There is also the problem of the lack of clear guidelines or of legislation on this subject. Nevertheless, there is consensus that screening of HCWs early in their career enables

them to be immunised against HBV. This screening also offers virus carriers the opportunity to make important career choices, and to seek appropriate counselling and treatment.

The importance of viral load

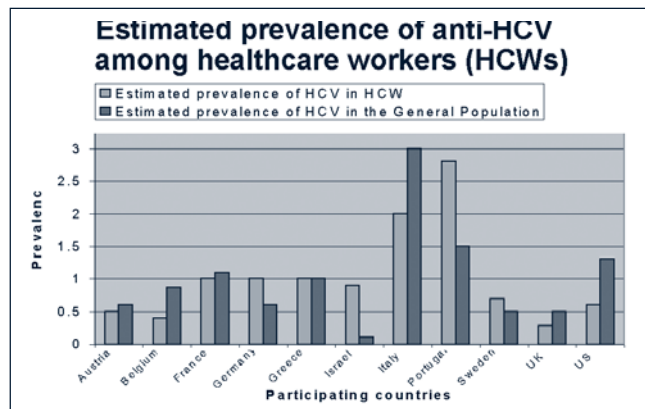
HBV DNA levels in HBeAg-positive carriers are usually above 10^5 copies/ml and HBV DNA levels in HBeAg-negative carriers are usually, but not always, lower than 10^5 copies/ml. Variation in the viral load of HBeAg carriers has been reported as minimal in some studies, with HBV DNA levels remaining unchanged over time [2]. In other studies, however, the HBV DNA levels did fluctuate over time in a number of cases [3]. There are arguments for testing at regular intervals to monitor these fluctuations and the resulting carrier infectivity. The implications of stringent viral load thresholds can be far-reaching. In the UK, for example, cut-off levels of HBV DNA of $\leq 10^3$ copies/ml would result in 58% of infected HCWs being restricted. The same cut-off level in the Netherlands would lead to EPP restrictions for > 94% of all infected HCWs. The Netherlands has therefore adopted a cut-off value of 10^5 copies/ml.

Recommendations of the European Consensus Group

- Each country should define the acceptable risk for HBV transmission from an infected HCW engaged in EPPs to patients.
- The recommended cut-off HBV DNA level in European countries for infected HCWs engaged in EPPs is $\leq 10^4$ copies/ml.
- The $\leq 10^4$ copies/ml level provides a balance between the risk of transmission and the loss of specialised manpower.

HCV-infected healthcare workers

The following slide shows the estimated prevalence of HCV in HCWs and that of the general population.



The risk of transmission

Published data on HCV transmission from HCW to patient is scarce but there would appear to be a low risk of transmission. However, since the infection is frequently asymptomatic, the true incidence is difficult to estimate. It is clear from the responses to the questionnaire that (1) comprehensive information is often not readily available; and (2) most countries do not have national policies for practice restriction of HCV-infected HCWs unless they are involved in a case of HCV transmission. European countries with established guidelines are Belgium, Germany, Italy, and the UK, while Austria, France, Greece, the Netherlands, Ireland, Israel, Portugal, and Sweden do not have national guidelines. The USA, Canada, and Australia all have procedures in place for managing infected HCWs.

The advantage of awareness

The benefits to HCWs of knowing their HCV status are somewhat limited, especially as screening for HCV and restricting infected HCWs is not justified based on published data. However, HCWs whose work includes EPPs should know their HCV status at the earliest possible stage of their training and certainly before they

engage in EPPs. Similar to the case of HBV, such a policy would enable HCWs to make informed career choices and enable them to receive counselling and treatment.

Summary of European Consensus recommendations

- All HCWs should apply standard precautions to every patient.
- All HCWs in contact with body fluids should be vaccinated against HBV and checked for quantitative anti-HBs response within 1-3 months after the final vaccine dose.
- All HCWs who intend to practice EPPs must provide proof of anti-HBs response prior to starting a post (and preferably before starting training).
- Non-responders to hepatitis B vaccination should be given up to an additional three doses with a conventional hepatitis B vaccine or a third generation PreS/S vaccine where available.
- Non-responders to hepatitis B vaccination engaged in EPPs must undergo an individual risk assessment with annual testing of anti-HBc and HBsAg.
- HCWs who refused to be vaccinated against hepatitis B should confirm that they understand the implications of such refusal.
- All HBV-infected HCWs being HBeAg positive should not perform EPPs.
- HBsAg-positive HCWs (HBeAg-positive or HBeAg-negative) who wish to practice EPPs must be referred to an expert panel and present results of quantitative HBV DNA testing.
- Each country should determine the HBV DNA cut-off level above which restriction of EPPs is mandatory.
- The recommendation of the panel is an HBV DNA cut-off level of 10^4 genome equivalents/ml.
- All HCWs performing EPPs should know their HBV and HCV status.
- All HCWs shown to be a source of viral hepatitis transmission to patients should not perform EPPs.
- No consensus was reached regarding restriction of HCV-infected HCWs from EPPs.
- All infected HBV- or HCV-infected HCWs should be referred to a hepatologist or gastroenterologist for counselling and potential treatment with anti-viral agents.
- All efforts must be made to respect the privacy of infected HCWs.

Ethical considerations

The complex interactions between personal, community, religious, ethnic, and cultural values vary widely between countries, making ethical discussions difficult. There are also enormous problems as regards acceptance of risk, as society tends to view even a minor threat from HCWs with zero tolerance. It has been suggested that infected HCWs who disclose their status with a view to continuing to practise EPPs should obtain informed consent from their patients. However, it is extremely difficult for the average layman to fully understand the risks and weigh them against the potential benefit of care from that particular HCW. In an age of increasing medico-legal activity, ethical considerations may also be swayed by the prospect of high-profile and potentially costly court cases.

Conclusion

The aim of the European Consensus is to offer guidance on policy. Some countries have already introduced recommendations and others have semi-official guidelines. It is hoped that all national health authorities examine the proposals carefully and look at ways to introduce and implement them in their own countries.

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Based on a presentation by Dr Daniel Shouval, Hadassah-Hebrew University Hospital, Liver Unit, Jerusalem, Israel.

Differing guidelines toward the infected healthcare worker

A number of countries have guidelines for identifying and managing HBV-, HCV-, or HIV-infected healthcare workers.

Identifying infected healthcare workers

Recommendations for identifying infected HCWs vary with respect to who should be tested (all HCWs or just those performing EPPs), how they should be tested (voluntary or mandatory testing), and when they should be tested (before studying or before taking up a new post that involves performing EPPs).

Most countries do not support routine testing of existing HCWs. Instead, they encourage HCWs who have sustained a significant occupational (and in some countries non-occupational) exposure to blood or biological fluids, to seek advice and testing where appropriate. Australia requires all HCWs to know their sero-status and recommends testing for staff performing EPPs if they have been untested for 12 months [1]. Canada stipulates that all HCWs who perform EPPs have an ethical obligation to know their HIV and HCV serological status, and encourages HCWs who perform or will perform EPPs, and those who have not responded to HBV vaccination to be tested for HBV infection annually. Canada also recommends HBsAg and HBeAg testing should be undertaken on renewal of privileges, which they indicate as being annually [2,3].

Managing infected healthcare workers

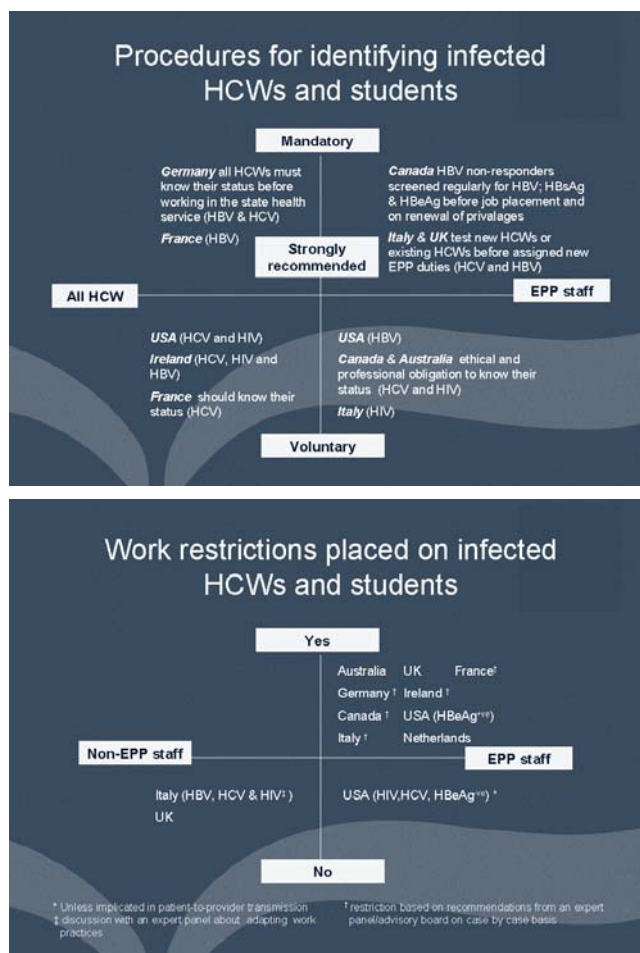
All guidelines agree that the risk of transmission of a blood-borne virus from a HCW to a patient is low; the guidelines, however, disagree about whether a HCW should have their working practice restricted, how this is decided, and what procedures they are restricted from performing.

In many countries there is some form of restriction regarding the work practices of HIV- or HCV-infected HCWs. USA guidelines recommend that unless a practitioner is implicated in provider-to-patient HIV or HCV transmission they should not be prohibited from participating in patient-care activities, including invasive procedures, solely on the basis of the infection [4].

With regard to HBV infection, there is general agreement to restrict or exclude HCWs testing HBeAg positive or HBV DNA positive above a certain cut-off level from performing EPPs. There appears, however, to be some disagreement over the need to establish the presence of HBV DNA and the level at which work practices should be restricted [5]. The cut-off level chosen by a country is most likely based on the risk the country is prepared to take and the proportion of their HBV-infected HCWs that are likely to be affected.

A number of countries make use of expert panels to consider, on a case-by-case basis, whether the HCW is safe to continue practising EPPs, or whether there is a need for practice modifications – these panels take into consideration the specific procedures performed as well as the skill and experience of the HCWs, their technique, and their compliance with standard infection control procedures. Although most guidelines advise who should be included in such a panel there may be variations in their composition and multiple standards, even within countries.

The first of the following slides shows the gradations from mandatory to voluntary testing and from all HCWs to those performing EPPs. The second one shows the work restrictions placed on infected HCWs and students in the countries for which information is available.



In summary, few countries have national guidelines for managing infected healthcare workers and where guidelines exist, there are variations, particularly in relation to how infected HCWs should be identified, how they should be managed, and criteria for restricting work practices where appropriate.

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Based on presentations by Dr Kirsty Roy, Scottish Centre for Infection and Environmental Health, Glasgow, UK; and Dr Daniel Shouval, Liver Unit, Hadassah-Hebrew University Hospital, Jerusalem, Israel.

Conclusions of the meeting

The subject of hospital- or healthcare-related infections is a topical one. However, although the spread of methicillin-resistant *Staphylococcus aureus* (MRSA) in the hospital environment is rarely out of the headlines, the ongoing problem discussed at this meeting in Rome is one that rarely receives public attention, but is of major concern to public health professionals and epidemiologists.

Blood-borne infections such as HBV, HCV, and HIV infections vary in prevalence between countries in both the developed and developing world. The risk of parenteral transmission of each of these viruses also varies, with HBV being ten times more likely to be transmitted than HCV, and HIV much less likely to be transmitted than either of these. Much is known about the role of viral load in the transmission of HBV and HIV, but there is little information available on the role of viral load, genotype, or other virological factors in the spread of HCV.

Epidemiology and risk

Blood-borne viruses are most commonly spread within the healthcare environment by needlestick or sharps injuries during medical procedures, or through mucocutaneous exposure. With estimates of the number of healthcare workers worldwide varying between 35 and 100 million, the potential number of people at risk is extremely high. Fortunately, numbers of actual infections attributed to occupational exposure are relatively low with 65,000 HBV infections, 16,400 HCV and 1000 HIV infections in 2000. However, most, if not all of these infections could have been prevented, usually by the health professional him- or herself.

Transmission

Transmission of blood-borne infections occurs most frequently between patients, is less common from patient to healthcare worker, and even less common from healthcare worker to patient. The introduction of immunisation against HBV and the equally important promotion and observation of universal precautions, including hand washing and safe needle disposal, have made major contributions to the reduction in numbers of infections passed from patients to HCWs. However, some areas still carry a high risk of transmission, particularly for staff working in cardiac or orthopaedic surgery, obstetrics, or gynaecology.

The number of transmissions from HCWs to patients is extremely low, but these are the infections that reach the public's attention. A serious topic for discussion here is the HCW and the performance of exposure-prone procedures. The main problems are defining the risk according to the type of procedure, for example whether blind suturing may lead to unobserved injury and HCW-patient blood contact, the compliance with universal precautions, the skill of the HCW, the availability of special equipment such as blunt needles etc.

Patient-to-patient transmission through haemodialysis equipment, via multi-dose vials, or from re-used needles sadly still occurs and is often a result of inadequate training in

infection control procedures or of staff simply ignoring the rules. Some outpatient settings have also been involved in outbreaks, raising questions about access to essential basic training for workers.

Risk evaluation

Information about the way different individual establishments and also central authorities deal with the training in procedures and of maintaining standards is lacking. The way the staff themselves view the problem of blood-borne infections is also difficult to assess, although the fact that many sharps incidents are apparently not reported at the time they occur implies that the problem is not being taken seriously enough.

In case of infection, prompt evaluation and subsequent follow-up of the involved HCW is essential, especially with regard to post-exposure prophylaxis for HBV and HIV infection, and written protocols on this are strongly recommended.

Prevention

Although it is generally accepted that hepatitis B vaccination is an essential tool in reducing the number of HBV infections, coverage remains variable and frequently inadequate. Policies on vaccination need to be more fully discussed and guidelines established.

A recurring theme is clearly the preventability of transmission and this depends to a large extent on compliance with universal precautions. These need to be instilled into staff in such a way that they are used automatically and not in a haphazard manner. Regular reminders in the form of practical training sessions and not just written instructions may produce a more concrete response from HCWs. They need to be convinced that the cost of ignoring or forgetting to comply with a comparatively simple procedure may have devastating consequences.

Policies and guidelines

Policies on the employment of infected HCWs also vary, with some countries adhering to established guidelines and others lacking any formal structural guidance. The European Consensus Group [1] drew up guidelines recommending that HCWs with HBV DNA levels of 10^4 genome equivalents/ml should be restricted from performing exposure-prone procedures, a cut-off level that attempted to balance the risk of infection against the withdrawal of essential specialist staff. These guidelines also recommended that all healthcare workers be vaccinated against hepatitis B, apply standard precautions, and also know their hepatitis B and C status. No consensus was established on the restriction of HCWs with hepatitis C virus infection.

Nomenclature

The discussions consistently refer to healthcare workers, but this term may be inadequate if all those involved in healthcare, from doctors and nurses to maintenance and janitorial staff are to be considered. Healthcare personnel or health personnel may be more adequate terms for the broad group of workers potentially at risk from blood-borne infections.

Consensus of the meeting

The participants in the VHPB meeting reached the following consensus in addition to those points discussed by the European Consensus Group:

- Universal infection control precautions must be applied and there must be regular review of practice to ensure compliance with guidelines and recommendations.
- Counselling must be made available for infected healthcare workers and patients.
- Immunisation of students and healthcare workers against hepatitis B should take place early on in their careers and immunologically bad responders need to be identified and given appropriate advice.
- Criteria for the restriction of practice for infected healthcare workers involved in exposure-prone procedures need to be defined. HBV-infected healthcare workers should be screened for HBeAg and monitored for viral load. The management of HCV-infected healthcare workers remains a problem requiring further discussion.
- Further consideration needs to be given to ethical and legal

issues, including safeguarding privacy and confidentiality.

- There is a need for the assessment of risk and costs before decisions are taken with regard to establishing threshold values to determine immunity, or to grant or withdraw permission to work.
- Countries need to manage their own epidemiological situation, but the general consensus is that there should be universal immunisation against hepatitis B for specific age cohorts.
- The VHPB urges countries that do not yet have policies or guidelines on the restriction of working practices for blood-borne virus-infected healthcare personnel to review this situation as a matter of priority.

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